



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, and 1306

[Docket No. DEA-499]

RIN 1117-AB55

Implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the SUPPORT Act),” which became law on October 24, 2018, amended the Controlled Substances Act to expand the conditions a practitioner must meet to provide medication-assisted treatment for opioid use disorder and expand the options available for a physician to be considered a qualifying physician. The SUPPORT Act also allowed a pharmacy to deliver prescribed controlled substances to a practitioner’s registered location for the purpose of maintenance or detoxification treatment to be administered under certain conditions by a practitioner. The Drug Enforcement Administration promulgated an interim final rule with request for comments in November 2020 to amend its regulations to make them consistent with the SUPPORT Act and implement its requirements. On December 29, 2022, the Restoring Hope for Mental Health and Well-Being Act of 2022 removed many of the statutory provisions of the SUPPORT Act. This final rule adopts the provisions of the interim final rule that are still applicable as final, with minor changes. In addition, this

final rule implements the related provisions of the Restoring Hope for Mental Health and Well-Being Act of 2022.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Legal Authority

Pertinent Provisions of the SUPPORT Act

The Controlled Substances Act (CSA), in 21 U.S.C 823(h),¹ has long mandated that practitioners who dispense narcotic drugs for maintenance or detoxification treatment must obtain an annual separate registration for that purpose² and has also provided exceptions to that requirement in a previous iteration. Congress has revised, and then removed, the exceptions over time. Previously, 21 U.S.C. 823(h)(2) set forth the conditions under which a practitioner could, without being separately registered as a Narcotic Treatment Program (NTP), dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment³ or detoxification treatment.⁴ On October 24, 2018, the President signed the SUPPORT Act into law as Public Law 115-271. Sections

¹ The language being discussed originally was codified at 21 U.S.C. 823(g). It was redesignated as 21 U.S.C. 823(h) by the Medical Marijuana and Cannabidiol Research Expansion Act, 117 P.L. 215 § 103 (2022).

² This requirement was incorporated into the CSA by the Narcotic Treatment Act of 1974 (NATA), 93 P.L. 281 §3 (1974).

³ 21 U.S.C. 802(29) defines *maintenance treatment* as the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

⁴ 21 U.S.C. 802(30) defines *detoxification treatment* as the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

3201 and 3202 of the SUPPORT Act amended certain provisions of 21 U.S.C. 823(g)(2) [now 823(h)(2)].⁵ Section 3204 of the SUPPORT Act amended the Controlled Substances Act (CSA) by adding section 309A (21 U.S.C. 829a), which sets forth the conditions under which a pharmacy may deliver certain controlled substances to the prescribing practitioner or the practitioner administering the controlled substance (administering practitioner) for the purpose of maintenance or detoxification treatment. All of the changes to the CSA, from these sections of the SUPPORT Act, will be fully described below.

Restoring Hope for Mental Health and Well-Being Act of 2022

On December 29, 2022, the President signed the Restoring Hope for Mental Health and Well-Being Act of 2022 into law by way of the Consolidated Appropriations Act, 2023 (hereinafter Omnibus), as title I of Division FF of Public Law 117-328.

Section 1262 of the Omnibus amended the CSA by striking section 303(h)(2) (21 U.S.C. 823(h)(2)) in its entirety and striking parts of 303(h)(1) (21 U.S.C. 823(h)(1)), eliminating the DATA-waiver program.⁶ Additionally, Section 1263 of the Omnibus added paragraph (m) to section 303 (21 U.S.C. 823), implementing a one-time training requirement for prescribers of controlled substances.⁷ Section 1264 amended section 309A(a)(5) (21 U.S.C. 829a(a)(5)) by increasing the number of days within which certain

⁵ DEA notes that the SUPPORT for Patients and Communities Reauthorization Act of 2025 (Pub. L. 119-44) became law on December 1, 2025, which includes an additional flexibility to allow delivery of a controlled substance by a pharmacy to a practitioner. This provision will be implemented in a future rulemaking.

⁶ On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000 (DATA), amending the CSA to establish “waiver authority for physicians who dispense or prescribe certain narcotic drugs for maintenance treatment or detoxification treatment.” Pub. L. 106-310, title XXXV; 114 Stat. 1222. Prior to DATA, the CSA and DEA regulations required practitioners who wanted to conduct maintenance or detoxification treatment using any narcotic controlled drugs to be registered as a Narcotic Treatment Program (NTP) in addition to the practitioner's personal registration. Hence, the term “DATA-waiver program” is used to describe the process by which individual practitioners (physicians, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) would receive an identification number from DEA, and be exempt from the requirement for separate registration to dispense or prescribe schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

⁷ In the Omnibus, this provision was designated as subsection (l). In the Halt All Lethal Trafficking of Fentanyl Act, Pub. L. 119-26 § 3(a) (2025), Congress redesignated this provision as subsection (m) because 21 U.S.C. 823 already contained a subsection (l).

controlled substances must be administered. All of the changes to the CSA from these sections of the Omnibus will be fully described below.

Background

Opioid Use Disorder and Treatment Need

Opioid use disorder in the United States continue to impact disparate communities and populations. According to the report “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health” released by the Substance Abuse and Mental Health Services Administration (SAMHSA), an estimated 1.6 million people (0.6 percent of this population) aged 12 or older had an opioid use disorder (OUD) in 2019.⁸ The share of the population 12 and older estimated to have had an OUD in 2015, 2016, 2017, and 2018 was 0.9 percent, 0.8 percent, 0.8 percent, and 0.7 percent respectively. Among people aged 12 or older with an OUD in 2019, about 294,000 received medication-assisted treatment (MAT) for OUD at a specialty facility⁹ in the past year, or 18.1 percent of all those with an OUD. The percentage of those with an OUD that received treatment at a specialty facility in 2015, 2016, 2017, and 2018 was estimated to be 21.7 percent, 21.1 percent, 28.6 percent, and 19.7 percent respectively.

Interim Final Rule

DEA published an Interim Final Rule (IFR) with request for comments in the *Federal Register* on November 2, 2020. 85 FR 69153. The regulations went into effect on October 30, 2020; however, comments could be submitted through January 4, 2021.

⁸ U.S. Department of Health and Human Services. SAMHSA. Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health. 2020. In this final rule, the Drug Enforcement Administration (DEA) used results from the 2019 National Survey on Drug Use and Health, the most recent data available at the time of the initial drafting of this final rule. In its November 2, 2020, interim final rule, the DEA used results from the 2018 National Survey on Drug Use and Health, the most recent data available at that time. See 85 FR 69153, 69154.

⁹ According to the 2019 National Survey on Drug Use and Health, substance use treatment at a specialty facility refers to substance use treatment at a hospital (only as an inpatient), a drug or alcohol rehabilitation facility (as an inpatient or outpatient), or a mental health center. This definition historically has not considered emergency rooms, private doctors’ offices, prisons or jails, and self-help groups to be specialty facilities for the receipt of substance use treatment.

Additional Flexibility Regarding the DATA-Waiver Patient Limit

In the IFR, in accordance with § 3201(a) of the SUPPORT Act (formerly codified at 21 U.S.C. 823(h)(2)), DEA revised 21 CFR 1301.28(b)(1)(iii)(B)(2) to provide flexibility to practitioners regarding the number of patients they may treat under a DATA-waiver, without being separately registered as an NTP. In addition to the options that were available before the SUPPORT Act, DEA added more opportunities to increase the applicable number of patients that may be treated under a DATA-waiver from 30 to 100. DEA also revised 21 CFR 1301.28(b)(1)(iii)(B) in the IFR to clarify that a practitioner treating up to 275 patients must meet the requirements set forth in 42 CFR 8.610 to 8.655.¹⁰

Elimination of Time Limit for Certain Qualifying Practitioners and Expanding the Definition of Qualifying Other Practitioner

Prior to passage of the Omnibus, the CSA mandated that a practitioner who dispensed narcotic drugs for maintenance treatment or detoxification treatment under a DATA-waiver be a qualifying practitioner, which included “qualifying physicians” and “qualifying other practitioners.” 21 U.S.C. 823(h)(2)(B)(i). Pursuant to §§ 3201(b)-(d) of the SUPPORT Act, the IFR revised 21 CFR 1301.28(b)(1)(i) to permanently allow a nurse practitioner or a physician assistant to be considered a “qualifying other practitioner,” and temporarily (until October 1, 2023) expanded the definition of a “qualifying practitioner” to also include a clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), or a certified nurse midwife (CNM) who meets the qualifications set forth in 21 U.S.C. 823(h)(2)(G)(iv), allowing more flexibility.

Additional Option to Allow a Physician to Become a Qualifying Physician

¹⁰ DEA added the 275 limit in a 2018 final rule (83 FR 3071, January 23, 2018) to reflect limits set by the Department of Health and Human Services (81 FR 44712, July 8, 2016).

Section 3202(a) of the SUPPORT Act added an eighth option for a physician to be considered a “qualifying physician” for purposes of the DATA waiver. In the IFR, DEA revised 21 CFR 1306.04 by adding paragraph (d) to implement this new option. Specifically, paragraph (d) allows a physician to be considered a qualifying physician if they graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States within the five-year period immediately preceding the date that the physician notified the Secretary of the Department of Health and Human Services (HHS) (Secretary of HHS or Secretary) of their intent to dispense narcotic drugs for maintenance or detoxification treatment, and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that included training as further specified in the statute.

Dispensing Controlled Substances for Maintenance or Detoxification Treatment

Section 3204(a) of the SUPPORT Act amended the CSA by adding section 309A (21 U.S.C. 829a), which sets forth the conditions in which a pharmacy may deliver certain prescribed controlled substances to an administering practitioner, where previously a pharmacy could only deliver such prescribed controlled substance to an ultimate user or research subject. The preamble of the IFR explained, at length, the conditions stipulated in 21 U.S.C. 829a for a pharmacy to deliver certain prescribed controlled substances to the prescribing practitioner’s or administering practitioner’s registered location for the purpose of maintenance or detoxification treatment to be administered to a patient. See 85 FR 69153, 69155. Briefly, 21 U.S.C. 829a allowed a pharmacy to deliver narcotic drugs in schedule III, IV, or V, or combinations of such drugs, approved by FDA for use in maintenance or detoxification treatment, in accordance with a prescription, to a practitioner for the purpose of administration by injection or implantation. Under the SUPPORT Act, the prescription was required to be issued by a qualifying practitioner and the prescription could not be used to supply any practitioner with a stock of

controlled substances for the purpose of general dispensing to patients. In the IFR, DEA implemented these conditions by adding § 1306.07(f).

In addition, at the time, 21 U.S.C. 829a stipulated that the practitioner must administer the controlled substance (by implantation or injection) to the patient named on the prescription not later than 14 days after the date of receipt by the practitioner. DEA implemented this requirement in § 1306.07(f)(5).

Finally, 21 U.S.C. 829a stipulates that the practitioner and pharmacy need to be authorized to conduct these activities in the State in which such activities take place. The prescribing practitioner and administering practitioner must maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of, including the persons to whom controlled substances were delivered and such other information that the Attorney General may require by regulations. DEA implemented these specific conditions in the IFR, again in § 1306.07(f).

Changes After Publication of the Interim Final Rule

Following passage of the Omnibus, the separate registration requirement in 21 U.S.C. 823(h) is only applicable to practitioners dispensing narcotic drugs in schedule II for the purpose of maintenance or detoxification treatment. Any practitioner wishing to dispense narcotic drugs in schedule II for the purpose of maintenance or detoxification treatment must obtain a separate registration as an NTP pursuant to that section.

By limiting the applicability of 21 U.S.C. 823(h) to only narcotic drugs in schedule II, Congress eliminated the need for practitioners to obtain a waiver of the requirement for a separate registration to dispense narcotic drugs in schedules III, IV, and V for maintenance or detoxification treatment. As such, Congress eliminated the waiver described in 21 U.S.C. 823(h)(2) and all conditions for such waiver, including the requirement to notify the Secretary of HHS, the applicable number, and the requirement

to be a “qualifying practitioner” and associated definition. These amendments require DEA to remove 21 CFR 1301.28. DEA also must eliminate 21 CFR 1306.05(b) and make conforming changes to 21 CFR 1306.04(c) and (d), and 1306.07(a), (d) and (f)(2). In so doing, DEA is revising 21 CFR 1306.04(c) to state in an affirmative manner the prescribing authorities that exist after the passage of the Omnibus.

In Section 1263 of the Omnibus, Congress added training requirements to 21 U.S.C. 823(m) as a condition of receiving a DEA registration for any qualified practitioner to dispense controlled substances in schedules II - V. These requirements are similar to those previously applicable to DATA-waiver practitioners under the repealed 21 U.S.C. 823(h)(2), although the new 21 U.S.C. 823(m) includes more provisions. Section 1263 defined the term “qualified practitioner” as a practitioner who is licensed under State law to prescribe controlled substances and is not solely a veterinarian.

Prior to the Omnibus, training was only required for qualifying practitioners who wished to obtain a waiver of the requirement for a separate registration to dispense controlled substances in schedule III, IV, or V for maintenance treatment or detoxification treatment. Now, all practitioners (except those who are practicing solely as a veterinarian) seeking a DEA registration or registration renewal to dispense controlled substances in schedule II, III, IV, or V are required to satisfy a one-time training requirement. This new requirement applies to any registration or renewal application submitted on or after June 27, 2023. These amendments require a modification to 21 CFR 1301.11 and to the definitions in 21 CFR 1300.01.

Last, Section 1264 of the Omnibus amended 21 U.S.C 829a(a)(5) by changing the number of days before which a controlled substance that was delivered by a pharmacy to an administering practitioner must be administered (by implantation or injection) to the named patient. As stated above, 21 U.S.C. 829a(a)(5) initially mandated 14 days

however the Omnibus has amended the statutory requirement to be 45 days. This requires a modification to § 1306.07(f)(5).

Discussion of Comments

DEA received 55 comments from the public, companies, associations, and state representatives; however, a few of these comments were duplicates. Each issue is summarized below, along with DEA's responses.

Increase in Number of Patients Who May be Treated Under a DATA Waiver

Issue: Overall, many commenters praised the IFR's increase in the number of patients that a practitioner may treat for maintenance treatment or detoxification treatment, without separately being registered as an NTP. However, there were some who expressed concern with the increase saying that it could lead to harmful and undesirable outcomes. Commenters expressed concern that while there aren't enough providers to treat addiction, simply allowing providers to treat more patients will not address the shortage. It was stated that treatments need to be carefully monitored by providers and stated that many providers, even those who have undergone training, do not understand that it takes a minimum of six months to address opioid use disorders. Commenters also asserted that the number of patients should be reflective of the administrative support, expertise, and experience of each individual physician.

Commenters also mentioned that with the increase, there is the potential for patients to fall through the safety net of their provider so DEA should make sure that physicians aren't pressured to take on more patients than they can handle. It was further suggested that DEA should set clear guidelines for legal ramifications of mistreatment, and add a requirement to this rule that will force practitioners to follow their patients more closely, along with some incentive for patients to return to their providers more regularly.

The commenters also discussed the two additional circumstances under which a DATA-waived practitioner may treat up to 100 patients (i.e., if the practitioner holds

additional credentialing or if a practitioner provides MAT within a qualified practice setting¹¹), saying that the circumstances may stunt the positive impact. Many commenters brought up the socioeconomic factors, stating that in the areas most affected, the practitioners that are most likely to benefit are primary care physicians and they would lack the additional credentialing required to take advantage of the increase in patients. It was suggested that there be a requirement for a provider to register if they are providing treatment with the expanded flexibilities but not condition the ability to treat more patients upon being able to meet these two “proposed” circumstances. One commenter stated that a provider should be required to inform DEA if they are treating an expanded number of patients or if they are providing treatment in an unqualified practice setting. This commenter also suggested that DEA redefine “additional credentialing” by allowing the credentials to be a provider’s unrestricted license to provide MAT within their scope of practice.

DEA also received comments supporting the increase implemented in the IFR, stating the increase will allow practitioners to treat more people and improve the lives of those who suffer from opioid use disorders. The commenters also mentioned that allowing practitioners to treat more patients will benefit rural and underserved areas that are suffering from increased rates of opioid addiction by removing barriers for treatment in underserved regions.

DEA Response: DEA acknowledges the concerns for potential harm expressed by commenters, however the Omnibus has removed the DATA-waiver provisions in 21 U.S.C. 823(h)(2) and all conditions on those waivers. As such, there is no longer a federal limit on the number of patients that a practitioner may treat for maintenance treatment or detoxification treatment, without separately being registered as NTP. Accordingly, DEA is removing the applicable number of patients in this final rule.

¹¹ DEA notes that a “qualified practice setting” is defined in the SAMHSA regulations at 42 CFR 8.615.

Elimination of Time Limit for Certain Qualifying Practitioners and Temporary Expansion of the Definition of Qualifying Other Practitioner

Issue: Prior to the SUPPORT Act, the CSA defined a “qualifying practitioner” under 21 U.S.C. 823(h)(2)(G)(iii), for purposes of the DATA waiver, to include a “qualifying other practitioner” which temporarily (until October 21, 2021) included NPs and PAs who met certain conditions. The SUPPORT Act made the inclusion of NPs and PAs permanent. Some commenters supported the permanent inclusion of NPs and PAs as qualifying other practitioners for purposes of the DATA-waiver, with one commenter noting that this elimination of the temporary time limit was one of the most important amendments of the SUPPORT Act. Commenters stated that this elimination and the expansion of the definition of “qualifying other practitioner” (temporarily until October 1, 2023, to include a CNS, a CRNA, or a CNM who meets certain conditions) increases the number of providers qualified to prescribe drugs used in MAT for OUD.

Commenters also mentioned that the bottleneck of patients waiting to be seen in a detoxification or maintenance treatment center existing at the time of the IFR will be reduced or eliminated and patients will be treated more quickly; however, DEA should ensure that prescribers have an understanding of MAT, as the mismanagement of MAT by physicians could decrease the effectiveness and even be harmful. A commenter suggested that DEA, SAMHSA, and other relevant stakeholders provide additional education and support for MAT.

Commenters supported the elimination of the time limit for NPs and PAs, stating that this expands the number of quality practitioners available and the amount of patients that can receive care. Commenters explained that NPs and PAs are qualified to address addiction since they can specialize their course of study and they can write prescriptions for narcotics. Commenters added that this elimination will be a benefit because it will help lessen the workload of physicians. Commenters said that this allows NPs and PAs

to continue their relationships with their patients, encouraging steady, uninterrupted treatment and increasing affordability and patient-provider trust.

In addition, commenters supported the SUPPORT Act's temporary inclusion of CNSs, CRNAs, and CNMs as qualifying other practitioners, stating that the expansion will allow for flexibilities in underserved regions that may not have physician coverage. One commenter also mentioned that the expansion would allow for an expanded "team based" coverage at facilities, but suggested that DEA should further explain the flexibilities and ensure that qualifying other practitioners and qualifying practitioners¹² are sufficiently trained to identify patients with opioid addiction and administer narcotics for maintenance and/or detoxification treatments due to the immense risks and challenges to healthcare organizations and the patients.

DEA received comments disapproving of the time limit elimination for NPs and PAs, stating that care for opioid use disorders should be led by a physician. One commenter expressed that while health professionals should collaborate, regulations shouldn't be implemented which undermine the physician-led team-based care models that have proven to be effective. Commenters also stated that the skillset of an NP and a PA is not interchangeable with that of a fully trained physician.

Some commenters did not support the temporary expansion to include CNSs, CRNAs, and CNMs, stating that this could endanger patients by allowing the nursing specialties to prescribe buprenorphine when it is not their typical scope of practice. Commenters suggested that CRNAs and CNMs do not possess qualifications that guide them in caring for patients with opioid addiction.

¹² The comment being discussed originally used the term "qualified" other practitioners and "qualified" practitioners. The accurate term at the time of the comment's submission was "qualifying" practitioners. However, after the passage of the Omnibus, the designation of "qualifying" practitioner no longer exists and the current defined term is "qualified" practitioner. The text here uses "qualifying" practitioner for clarity and consistency.

Commenters also expressed socioeconomic concerns that, while the expansion of the definition of qualifying other practitioners may help improve access in low-income and rural communities, it may lead to more practitioners in suburban and higher-income communities. A commenter suggested that there needs to be specific legislative efforts that prioritize expanding access to low income and rural communities so that they are granted access to these opportunities.

DEA Response: The amendments made in the IFR are no longer applicable due to the implementation of the Omnibus. With the removal of paragraph (2) of 21 U.S.C. 823(h), the CSA no longer uses the classifications of qualifying practitioner and qualifying other practitioner. DEA recognizes that there are socioeconomic factors that come into play with the additions to the regulations that have already been implemented by the IFR. The elimination of the time limit for NPs and PAs along with the expansion of the definition of “qualifying other practitioner” opens up possibilities for those in low income and rural areas to have greater access to more providers.

DEA notes that many commenters were concerned about the educational qualifications for NPs, PAs, CNSs, CRNAs, and CNMs. In the Omnibus, Congress added training requirements for all qualified practitioners who wish to register to dispense controlled substances in schedule II-V. The CSA no longer explicitly states that CNSs, CRNAs, and CNMs can qualify to dispense. To obtain a DEA registration, all non-physician practitioners must be legally authorized by the State to dispense controlled substances in schedule II-V and, if they do not practice solely as a veterinarian, must satisfy one of the training conditions set forth in 21 U.S.C. 823(m)(1)(B). DEA is making changes in this final rule from the provisions that had previously been adopted in the IFR to implement the Omnibus training requirements.

Additional Option to Allow a Physician to Become a Qualifying Physician

Issue: As noted above, the SUPPORT Act added an eighth method by which physicians could be considered qualifying practitioners for purposes of the DATA waiver. Multiple commenters did not support the requirement in this eighth option that the medical school, from which the physician graduated in good standing, be located within the United States. The commenters said that all physicians must pass the same licensing exams to enter residency, regardless of their school's location, and residency is a requirement to practice medicine in the United States. A commenter also expressed concern that this will marginalize the skill and expertise of a pool of potential providers, as 25 percent of the physicians in the US are international medical graduates. The commenter further stated that these graduates tend to specialize in primary care and practice in underserved areas. Commenters also opposed the SUPPORT Act limitation that no more than five years may have elapsed between the physician's successful completion of a particular medical school curriculum or residency and the physician's notification to HHS that they intend to begin dispensing certain narcotic drugs to patients for maintenance or detoxification treatment under 21 U.S.C. 823(h)(2)(B)), noting that it neglects to consider the physicians that have been practicing medicine for more than five years.

Another commenter was concerned about this SUPPORT Act option because it only requires graduating in good standing from an accredited institution and only eight hours of training, stating that this frames opioid dependence as something that is simple. This commenter added that this option does not take into account that this disorder is a complex condition that requires a level of expertise.

Other commenters supported the additional option saying that requiring the additional training allows clinicians to make improvements to deal with the opioid epidemic. Various commenters also said this will enable physicians to educate their patients on opioid medication and offer alternatives. Commenters spoke to the training requirement

having a positive impact, as practitioners will be more likely to review patients' history in order to ensure they do not have an opioid use disorder.

DEA Response: DEA appreciates the numerous commenters' views regarding the additional training option for a physician to be considered a "qualifying physician" eligible for a DATA-waiver. Section 3202(a) of the SUPPORT Act amended the CSA to add this option and the IFR merely implemented Federal legislation. DEA does not have the authority to change the statutory provisions set forth by Congress. Due to the amendments made in the Omnibus, DEA is omitting these provisions related to the DATA-waiver from this final rule by removing the corresponding provision in 21 CFR 1306.04(d) and as such, this option is no longer relevant. However, Congress enacted a similar, but not identical, provision in the new training requirements for dispensers of controlled substances in schedules II, III, IV, and V.

Because the new training requirements in 21 U.S.C. 823(m)(1)(A) discusses the condition of graduation from an accredited institution within the 5-year period immediately preceding the date on which the physician first registers with DEA,¹³ DEA wants to clarify that additional options are available for those physicians who have been practicing longer than five years. DEA notes that a designation of "qualifying practitioner" no longer exists. Instead, relevant practitioners would be considered "qualified practitioners." Physicians that have been practicing longer than five years can use one of the alternative options for meeting the training requirements, including the option applicable to physicians that are already board certified or trained in addiction medicine or addiction psychiatry. Alternatively, 21 U.S.C. 823(m)(1)(A) allows physicians to meet the training requirements by completing not less than 8 hours of training on the specified topics provided by the types of organizations mentioned in the law. However, a newer graduate would be less likely to be board certified and will have

¹³ 21 U.S.C. 823(m)(1)(A)(v).

likely gone through a curriculum similar to the additional training. As such, this provision allows a practitioner who is a physician to meet the training requirements if they have recently (within the previous five years) graduated from an accredited allopathic or osteopathic medical school or dental surgery or dental medicine curriculum in the United States and completed a curriculum or an accredited medical residency which included not less than eight hours of training on treating and managing patients with opioid or other substance use disorders, or the other topics now mentioned in 21 U.S.C. 823(m)(1)(A)(v). As stated above, the requirement that the medical school be in the United States is a statutory mandate and cannot be changed.

Dispensing Controlled Substances for Maintenance or Detoxification Treatment

Issue 1: The IFR implemented section 3204(a) of the SUPPORT Act to allow a pharmacy to deliver a controlled substance to the prescribing practitioner's or administering practitioner's registered location, rather than only to the ultimate user or research subject, pursuant to a valid prescription for administration to the patient for purposes of maintenance or detoxification treatment within 14 days from when the practitioner receives the controlled substance (14-day limit). DEA received many comments stating that allowing a pharmacy to deliver a controlled substance in this manner will help to ensure that patients are receiving the treatment they need and complying with drug treatment plans, and that opioids are ending up with the correct person. Commenters also opined that this is a good step in ensuring that opioids are properly distributed while still increasing access. Commenters suggested that this will streamline service to patients, can decrease costs along the line of care, and will allow patients to access treatment directly within facilities under the direct supervision of their providers, hopefully increasing the level of care received.

While many commenters believe this delivery method to the practitioner will further allow for the ability to successfully treat patients in underserved regions, other

commenters said this provision does not take into account low-income communities, where care would be inaccessible due to the lack of insurance and shortage of treatment options. The commenters said MAT centers and health care facilities are often far from rural and low-income communities and transportation is often an issue. One commenter said “clear and specific legislative efforts” are needed that prioritize the expansion of access to low income and rural communities. They also mentioned that while transportation is not the fault of DEA, DEA can work towards filling the gap of health care access “by focusing on equaling the distribution of MAT, through waived and qualified practitioners, across the nation.” Another commenter also stated that DEA is not considering patients who are being released from jail/prison. The commenter mentioned that upon release from jail, care coordinators need time to find appropriate medical care and practitioners to support the patient’s recovery, which can take weeks.

DEA Response 1: DEA agrees with the many commenters’ assertions that Congress’s decision to allow pharmacies to deliver these medications to the prescribing or administering practitioner’s location will be helpful for patients receiving treatment. While the IFR, as well as this rule, are not focused solely on rural and low-income areas, DEA is committed to creating regulations that allow access to care regardless of the socioeconomic status or location of the patient. For example, DEA has incorporated alternative methods to bring treatment to those in rural or other areas (see 85 FR 11008, Feb. 26, 2020) and patients can reach out to state opioid treatment authorities, which provide oversight and support to opioid treatment programs, for other alternatives for treatment. DEA acknowledges the commenters’ wants for clear and specific legislative efforts addressing low income and rural communities, however DEA is only responsible for the implementation of legislation created and mandated by Congress, but does not actually create the legislation.

DEA believes that the delivery method defined in 21 U.S.C. 829a and 21 CFR 1306.07(f) increases provider options, helps to address the socioeconomic issues that commenters have expressed, and helps increase access to treatment in low-income and rural communities. As mentioned by commenters, the IFR did not address issues created by patients' lack of insurance, as insurance was outside the scope of the rule and the legislation on which the IFR was based. However, DEA believes that allowing a pharmacy to deliver these medications to the prescribing or administering practitioner may reduce burdens on patients by reducing other costs to access the medication, including the cost of transportation to the pharmacy. This delivery provision coupled with the provision discussed below where an administering practitioner does not have to be DATA-waived are steps toward filling the gap of MAT access.

In addition, the increase in provider options for administering should ease some concerns relating to the time needed to find care for patients being released from jail. While care coordinators are finding the appropriate medical care to support the patient's recovery, patients will be able to find an initial practitioner to whom the prescription can be sent for administration temporarily.

In this final rule, DEA is making no changes from the provisions that had previously been adopted in the IFR regarding to whom the prescription can be delivered.

Issue 2: Many companies, associations, and organizations requested that DEA clarify whether practitioners who are not DATA-waived can administer long-acting injectable (LAI) and implantable buprenorphine pursuant to a lawful prescription by a DATA-waived practitioner. According to these commenters, DATA-waived practitioners may not have the facility to administer the injections, so non-DATA waived practitioners should be permitted to administer injections ordered by a DATA-waived provider.

DEA Response 2: Since the DATA-waiver program no longer exists, DEA is not making any clarification. Instead, DEA is amending 21 CFR 1306.07(f)(2) to align with the amendments made by the Omnibus.

Issue 3: Companies, associations, organizations, and other commenters requested that DEA clarify that pharmacists are administering practitioners under 21 U.S.C. 829a, and are allowed to administer controlled substances pursuant to a valid prescription from a DATA-waived practitioner and to the extent authorized by state law. Three of these commenters provided a detailed rationale for why a pharmacist who is employed by a DEA-registered pharmacy and is authorized by state law to dispense controlled substances should be included in the CSA's definition of "practitioner," which is found at 21 U.S.C. 802(21),¹⁴ and therefore, should be able to administer such substances. Commenters also noted that Congress did not expressly require that the administering practitioner be a "qualifying practitioner." Commenters also said that pharmacists have been appropriately trained and therefore, DEA should treat pharmacists as practitioners who may administer LAI buprenorphine to the extent authorized by state law.

Commenters suggested various limitations for the pharmacists to be considered an administering practitioner. Some stated that the pharmacist must be employed at a pharmacy while others specified that such pharmacy must hold a DEA registration. Still others noted that certain states allow a pharmacist to administer LAI buprenorphine under specified conditions and thus such administration would be within the scope of the pharmacist's practice. In addition, one commenter noted that DEA itself recognizes pharmacists in certain states as registered mid-level practitioners (MLPs) with specified

¹⁴ The commenters noted that the CSA definition for "practitioner" includes, among others, a "pharmacy" or "other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . , to distribute, dispense, . . . administer . . . a controlled substance in the course of professional practice or research."

controlled substance authority including administration.¹⁵ Most commenters suggested that pharmacists be permitted to administer both LAI and implantable controlled substances; however, one commenter stipulated that the pharmacist's administration should only include injectables, not implantables.

Commenters stated that the clarification that pharmacists can be administering practitioners is necessary to avoid delays or disruptions in care when a DATA-waived practitioner is unavailable to administer the substance. The commenters maintained that this clarification will have a positive effect on patients in rural areas and in residential care facilities, and those receiving regular treatment via telemedicine, during natural disasters and during pandemics.

DEA Response 3: As noted by three commenters, the CSA's definition of "practitioner" includes a "pharmacy... or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices..., to distribute, dispense, ... administer... a controlled substance in the course of professional practice or research." Section 3204(a) of the SUPPORT Act required only that the prescribing practitioner be a "qualifying practitioner" and placed no such limitations on the administering practitioner. DEA has considered the commenters' positions on pharmacists being considered an administering practitioner.

However, DEA declines to specifically list pharmacists as an administering practitioner in this final rule. DEA believes that Congress intended 21 U.S.C. 829a to allow a pharmacy to deliver a controlled substance to a different location from the pharmacy (i.e., to the location listed on the certificate of registration of the prescribing practitioner or to the location listed on the certificate of registration of the administering practitioner). In furtherance of that intent, DEA is requiring the administering

¹⁵ See DEA's guidance, MID LEVEL PRACTITIONERS - Controlled Substance Authority by Discipline within State, available at https://www.dea.gov/diversion/usdoj.gov/drugreg/practitioners/mlp_by_state.pdf, last updated on December 2, 2022, last accessed January 18, 2024.

practitioner be individually registered under 21 U.S.C. 823(g) (pursuant to which DEA issues registrations) to dispense, and acting within the scope of such registration. While states also regulate pharmacists and decide what a pharmacist licensed in their state is authorized to do, currently, only a limited number of states allow MLPs individually registered with DEA as Registered Pharmacists to administer controlled substances.

Note, in this final rule, that DEA does not need to clarify that an administering practitioner is not required to be DATA-waived because the DATA-waiver program no longer exists.

Issue 4: Many commenters suggested that DEA use the authority granted by Congress under section 3204 of the SUPPORT Act (codified at 21 U.S.C. 829a) to modify the 14-day limit for administering such controlled substances to the patient named on the prescription. Commenters requested that DEA increase the 14-day limit to 30 or 60 days. Specifically, these commenters noted that section 3204 expressly allows DEA (under authority delegated by the Attorney General), in coordination with HHS, to change the time limit after the publication of a required report by the U.S. Government Accountability Office (GAO) on “access to and potential diversion of controlled substances administered by injection or implantation.” Some of the commenters also mentioned that the required GAO report, issued in August 2020, concluded that there is low use of implantable and injectable buprenorphine and the risk of diversion of implantable and injectable buprenorphine has been reduced.

Commenters had many concerns with the 14-day limit and expressed that this provision discourages providers from treating these patients. A commenter expressed concern that the 14-day limit could lead to overdose due to patients not being able to access the medication the remaining 16 days of the month. Commenters mentioned that patients have difficulty keeping appointments for reasons such as patient needs, insecure housing, transportation issues, problems with insurance, and holidays. They stated that

the 14-day restriction puts an undue burden on the use of the valuable product because often times a patient is unable to schedule or reschedule within 14 days, and that after that time the provider would have to send the medication back and absorb the costs. Commenters also mentioned that when a patient requests a change in dosage strength after a medication has been delivered, the doctor would have to absorb the cost of the delivered patient-specific medication if the doctor cannot retain the medication in their inventory longer than 14 days. Commenters said that starting the process again after 14 days is taxing on staff and slows down the effort to help patients suffering from the opioid epidemic.

Companies, associations, and other DEA registrants mentioned that the alternative, non-patient-specific method by which practitioners can obtain these medications, “buy and bill,” is costly and many practitioners cannot bear the financial risks, especially when considering the uncertainty over whether a patient’s insurance will reimburse, and if so, how much. These commenters also noted that non-patient-specific medication obtained by “buy and bill” is permitted to be stored until the medication expires.

Multiple commenters stated that 14 days is impracticable, as administering within this timeframe involves coordination of many components, including the pharmacy, practitioner, and patient. Commenters also informed DEA that there is a forthcoming product that will be shipped with four separate weekly injections at a time. Commenters said that the 14-day limit does not consider delays in shipping from retail and specialty pharmacies and is proving unworkable for providers and patients.

Commenters also said the requirement to destroy the received controlled substance after 14 days creates a large potential for waste. They opined that providers will be deterred from using this option due to fears that they may have to destroy it and incur significant costs in doing so.

DEA Response 4: DEA acknowledges the concerns regarding the 14-day limit. With the enactment of the Omnibus, Congress increased the 14-day limit to 45 days in section 309A(a)(5) of the CSA (21 U.S.C. 829a(a)(5)). Because 45 days is the new baseline requirement, which DEA may modify in coordination with the Secretary of HHS pursuant to section 309A(b)(2) (21 U.S.C. 829a(b)(2)), DEA is implementing the increase to 45 days in this final rule. DEA will consider whether it is necessary to modify the 45-day limit, in consultation with the Secretary, in the future.

Finally, DEA notes that the time expended in obtaining insurance authorizations or during shipping does not affect the 45-day limit. The 45-day timeframe established by 21 U.S.C. 829a(a)(5) and 21 CFR 1306.07(f)(5) runs from the date the controlled substance is received by the practitioner. Additionally, DEA notes that neither the CSA nor DEA regulations require the destruction of the dispensed controlled substance after the 45-day period elapses. To the extent that destruction is required by state authorities, commenters may wish to engage with those state authorities.

Economic Impact

Issue: One commenter expressed skepticism regarding DEA's analysis of the anticipated economic impact of the IFR. This commenter took issue with DEA's estimates regarding the number of qualifying providers, the number of patients receiving treatment, the treatment success rate of 29 percent, societal cost savings, and, as a result, the economic burden reduction derived from these estimates. In fact, the commenter believed the effect might instead add another cost burden on local, State, and Federal governments, and urged DEA to do further evaluations before finalizing the IFR.

More specifically, the commenter believed the projected number of NPs, PAs, CNSs, CRNAs, and CNMs providers is too high, the estimated number of two million patients with OUD is not accurate, estimated "cost reduction" by twenty-nine percent is too high, and the lost productivity savings and criminal justice cost savings are too high.

DEA Response: While this commenter questioned the underlying assumptions of DEA’s economic analysis, the commenter did not provide any studies, data sources, or alternative calculations that would assist DEA in refining its analysis. DEA’s analysis is based firmly upon many academic studies, its own provider data, and making reasonable assumptions where specific data is not available. Data sources are clearly cited in the IFR. The projection for providers is based on DEA’s registration data. The number of patients with opioid use disorder is based on published research (noted in the IFR) which includes the number of patients with opioid use disorder reported by SAMHSA’s National Survey on Drug Use and Health as meeting the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) criteria for abuse or dependence.¹⁶ Furthermore, DEA believes the commenter misunderstood the use of “twenty-nine percent” in the analysis. The commenter believed the “twenty-nine percent” represented cost reduction; however, it represents the treatment success rate in the analysis. Therefore, DEA does not have enough additional information to alter the conclusions of the analysis, or to warrant further evaluations. The economic analysis in the Regulatory Analysis section below focuses on the impact of the limited changes from the IFR to the Final Rule.

Provisions of this Final Rule

While DEA considered the public comments submitted on the IFR, the Omnibus repealed many of the statutory provisions on which the IFR is based. Through this final rule, DEA is finalizing the IFR with modifications pursuant to the Omnibus. As such, DEA is removing many of the provisions that had been implemented by the IFR on the basis of now-repealed laws. DEA is implementing minor changes to some regulations to conform to the new statutory language adopted through the Omnibus. Additionally, DEA

¹⁶ In this final rule, the DEA used results from the 2019 National Survey on Drug Use and Health, which used criteria specified in the *Diagnostic and Statistical Manual for Mental Disorders*, 4th edition (DSM-IV).

is implementing in this rulemaking the separate registration requirement for NTPs that was implemented in the CSA by the NATA. Through this rule, DEA is also making modifications where necessary to clarify issues presented by commenters.

Definition of “Qualified Practitioner”

First, DEA is including the definition of “qualified practitioner” in the regulations pursuant to the definition set forth in 21 U.S.C. 823(m)(4)(B). A qualified practitioner is a practitioner who is licensed under State law to prescribe controlled substances and who is not solely a veterinarian. This definition is found in 21 CFR 1300.01.

Registration

Second, in 21 CFR 1301.11, DEA is setting forth the requirement that NTPs obtain a separate registration for that purpose, annually. This will be found in the new paragraph (b), with the current paragraph (b) being moved to paragraph (d). This corresponds to the requirement in 21 U.S.C. 823(h).

Training Requirements

In the newly added paragraph (c) of 1301.11, DEA is including the training requirement for “qualified practitioners” who wish to obtain a registration from DEA to dispense controlled substances, as found in 21 U.S.C. 823(m). The 21 U.S.C. 823(m) training requirements are determined by whether the qualified practitioner is or is not a physician, as defined by 42 U.S.C. 1395x(r). In accordance with moving the current paragraph (b) to paragraph (d), DEA is also revising paragraph (a) to update the reference to paragraph (b).

In accordance with these new training requirements for qualified practitioners, DEA has modified its forms 224 and 224a to require practitioners to self-attest to training when applying for registration and renewing their registration. The Omnibus requires the practitioners to meet the training requirement starting with the first applicable registration. The first applicable registration is defined in 21 U.S.C. 823(m)(4)(A) as the

first registration or renewal of registration by a qualified practitioner that occurs on or after 180 days of the date of enactment of the Omnibus. That date is June 27, 2023.

Elimination of the DATA-Waiver Program and Provisions

Third, DEA is removing 21 CFR 1301.28 in its entirety and will be reserving that section for future use. This regulation implemented 21 U.S.C. 823(h)(2) by describing the DATA-waiver program, which has now been removed from the CSA by the Omnibus. There is no longer the opportunity or requirement to receive a waiver from the separate NTP registration requirement to dispense controlled substances in schedule III-V for maintenance or detoxification. There is no longer a definition for “qualifying physician,” “qualifying practitioner,” and “qualifying other practitioner.” In addition, there is no longer an applicable number to limit how many patients can be treated by a practitioner.

Next, DEA is modifying 21 CFR 1306.04(c) to remove the reference to 21 CFR 1301.28 since it will be deleted. Also, DEA is revising 21 CFR 1306.04(d) by removing references to “qualifying” throughout the paragraph and the applicable references to conform to the CSA.

DEA is also modifying 21 CFR 1306.05 by removing and reserving paragraph (b). Paragraph (b) required a prescription issued under the DATA-waiver program to include the identification number issued by DEA when registering for the program. However, now that the DATA-waiver program no longer exists, this regulation is no longer valid. In addition, DEA is revising 21 CFR 1306.07(d) by removing the citation reference to 21 CFR 1301.28 and adding a corresponding clarification in 21 CFR 1306.07(a). Again, 21 CFR 1301.28 is being removed and the new training requirements can now be found in 21 CFR 1301.11, which now applies to all qualified practitioners.

DEA is also revising 21 CFR 1306.07(f)(2) to align with the amendments to the CSA. Specifically, DEA is removing the citation to the now-revoked DATA-waiver program in

the CSA, as well as the requirement that a prescribing practitioner be a qualifying practitioner, and is repeating in the regulatory text the language of 21 U.S.C. 829a(a)(2) as enacted by the Omnibus. DEA is also amending 21 CFR 1306.07(f)(5) to modify the current 14-day limit (the time for the practitioner to administer the controlled substance to a patient from when the practitioner receives the controlled substance) to 45 days, as now set forth in the CSA.¹⁷ In response to commenters of the IFR, DEA is also revising 21 CFR 1306.07(f)(1) to use abbreviated language for clarity. Specifically, rather than repeating “the practitioner administering the controlled substance” in several paragraphs of this subsection, DEA is adding the parenthetical “(in this paragraph referred to as the ‘administering practitioner’)” in 1306.07(f)(1) and then making the relevant textual replacements in 1306.07(f)(3) and (f)(6).

This final rule also revises the existing language in 21 CFR 1306.07(f)(3) for clarity and consistency. While the current text exactly reflects the language of 21 U.S.C. 829a(a)(3), DEA is revising the term “practitioner” to read “the prescribing practitioner, and the administering practitioner” to be consistent with the remainder of paragraph (f). This change is non-substantive, as this is the only possible reading of the statutory text, and does not change the meaning of the existing regulatory text.

Recordkeeping Requirements

Last, DEA is making a minor, non-substantive change to include a cross-reference in 21 CFR 1306.07(f)(6). DEA’s regulations in 21 CFR 1304.03(c) and 1304.06 define recordkeeping requirements relating to controlled substances that are prescribed. Under 21 CFR 1304.03(c), prescribers must maintain records of all substances that are prescribed in the course of maintenance or detoxification treatment of an individual, which would include controlled substances prescribed in the course of maintenance or detoxification treatment pursuant to 21 U.S.C. 829a. DEA notes that under 21 U.S.C.

¹⁷ 21 U.S.C. 829a(a)(5).

827(a)(3), DEA-registered pharmacies must maintain complete and accurate records of all controlled substances delivered, which would include deliveries of controlled substances to the prescribing or administering practitioner under 21 U.S.C. 829a.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from provisions of the Administrative Procedure Act (APA) requiring public notice and comment prior to implementation (5 U.S.C. 553(b)(B)), if it is determined to be unnecessary, impracticable, or contrary to the public interest. Portions of this rule were originally introduced as an IFR, with an opportunity for comment; however, after passage of the Omnibus, the legal provisions underlying much of the already implemented provisions of the rule were eliminated.

Along with the elimination of old provisions, Congress also created new provisions in the Omnibus, and DEA identified another existing statutory provision that had never been incorporated into DEA's regulations. Specifically, DEA is adding a new provision in 21 CFR 1301.11(b) based on the NATA, which was previously incorporated into the CSA. This rule merely incorporates the existing statutory provision into DEA regulations without any changes. Additionally, while this rule does implement Congress's new requirement that certain practitioners complete training to receive a DEA registration number, DEA is not adding any additional requirements beyond those mandated by Congress. DEA is adding a cross-reference to recordkeeping requirements currently contained in other sections of DEA's regulations, without expanding the existing requirements. As such, DEA concludes that it is unnecessary to accept comment on provisions that implement the Omnibus or other Federal laws, that cross-reference existing regulatory provisions for clarity without changing or expanding their applicability, or that standardize language without making any new interpretation.

Executive Orders 12866, 13563, and 14192 (Regulatory Review)

DEA has determined that this rulemaking is a “significant regulatory action” under section 3(f)(1) of Executive Order (E.O.) 12866, Regulatory Planning and Review. Accordingly, this final rule has been submitted to the Office of Management and Budget (OMB) for review. This final rule has been drafted and reviewed in accordance with E.O. 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation; E.O. 13563, “Improving Regulation and Regulatory Review,” section 1(b), General Principles of Regulation; and E.O. 14192, “Unleashing Prosperity Through Deregulation.”

The interim final rule was determined to be a significant regulatory action under E.O. 12866 with a net annualized benefit of \$543 million over five years, and accordingly, the interim final rule was reviewed by OMB.

The interim final rule was estimated to have a net present value of benefits (in form of cost savings) of \$2,627 million and \$2,226 million at 3 percent and 7 percent discount rates, respectively, and an annualized net benefit of \$574 million and \$543 million at 3 percent and 7 percent, respectively.¹⁸ The net present value of the estimated maximum cost is \$3,141 million and \$2,725 million at 3 percent and 7 percent discount rates, respectively. Applying a factor of 1.23 to adjust IFR figures to 2024 dollars, the IFR net present value of benefits (cost savings) is \$3,231 million and \$2,738 million at 3 percent and 7 percent discount rates, respectively.¹⁹ The combined effect of the IFR and final rule is the sum of net present value of benefits (cost savings) of the IFR and the net present value of costs of this final rule. At 3 percent discount rate, the combined effect is \$90 million (\$3,231 million - \$3,134 million) in cost savings. At 7 percent discount rate,

¹⁸ 85 FR 69153; November 2, 2020.

¹⁹ U.S. Department of Commerce, Bureau of Economic Analysis, National Income and Product Accounts, Table 1.1.9 Implicit Price Deflators for Gross Domestic Product. (Accessed 5/12/2026). Line 1 Gross domestic product: 2018 = 102.291; 2024 = 125.428. $125.428 / 102.291 = 1.23$.

the combined effect is \$13 million (\$2,738 million - \$2,725 million) in cost savings. These net cost savings do not include expected, but not quantified, cost savings from treatment of OUD anticipated in this final rule.

The following discussion analyzes the economic impact of the changes from the interim final rule to this final rule.

DEA has examined the benefits and costs of this final rule and believes this rule will be of net economic benefit. DEA does not have a good measure of the number of impacted practitioners or the number of additional patients that will be treated as a result of this rule. However, based on an estimated maximum number of impacted practitioners, DEA has estimated a maximum annualized cost of \$368,278,282 and \$387,997,558 at 3 percent and 7 percent, respectively. However, due to potentially high societal cost savings from the expected increase in the number of patients treated for OUD, the break-even is low. For example, in the first year of the analysis period, the break-even is 3,047 patients treated for OUD by the 639,821 practitioners who would be newly authorized to provide MAT. This is a ratio of 210 practitioners to one patient. DEA believes this rule has a low break-even point and the economic impact of this rule will be a net cost savings. The analysis below details the aforementioned figures and other benefits/cost savings.

This final rule adopts the provisions of the interim final rule that are still applicable as final, with minor changes. In addition, this final rule implements the provisions of the Restoring Hope for Mental Health and Well-Being Act of 2022 that relate to this rule by way of the Consolidated Appropriations Act, 2023 (Omnibus). This final rule makes the following changes to the interim final rule. First, DEA is removing the DATA-waiver program and is including new training requirements for a qualified practitioner's registration. Second, DEA is setting forth the requirement that NTPs obtain a separate registration for that purpose, annually. Third, DEA is modifying the current 14-day limit

(the time for the practitioner to administer the controlled substance to a patient from when the practitioner receives the controlled substance) to 45 days, as now set forth in 21 U.S.C. 829a. Finally, DEA is making a minor, non-substantive change to recordkeeping requirements for clarity. The analysis of these changes is below.

Alternative Approaches

This final rule amends the DEA regulations only to the extent necessary to implement the provisions of the Omnibus and NATA.²⁰ The Omnibus amended the CSA to remove the DATA-waiver program and added new training requirements for registration. Additionally, the Omnibus amended the CSA by changing the number of days before which a controlled substance that was delivered by a pharmacy to an administering practitioner is to be administered (by implantation or injection) to the named patient from 14 days to 45 days. NATA amended the CSA to require separate registrations for NTPs, which DEA is now including in 21 CFR 1301.11(b). DEA is obligated to implement these amendments to the CSA. As a result, DEA has no discretion not to amend its regulations as is being done in this final rule. This final rule simply updates the DEA regulations to reflect these new provisions; thus, no alternative approaches are possible.

Analysis of Changes

Change 1: DATA-waiver removal and new training requirement

The Omnibus removed the DATA-waiver program and sets new requirements for qualified practitioners. “Qualified practitioner” means a practitioner who is licensed under State law to prescribe controlled substances; and is not solely a veterinarian. [21 U.S.C. 823(m)(4)(B)].

²⁰ This final rule also changes 21 CFR 1306.07(f)(6), which is not part of the Omnibus. This is a minor, non-substantive change to clarify that, the prescribing practitioners must keep complete and records of all controlled substances for which a prescription was issued. Therefore, alternatives to this clarification are not considered.

As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

If the practitioner is a physician, the practitioner must meet one or more of the following conditions:

1. Hold a board certification as specified in 21 U.S.C. 823(m)(1)(A)(i)-(iii),
2. Completed not less than eight hours of training as specified in 21 U.S.C. 823(m)(1)(A)(iv), or
3. Graduated in good standing as specified in 21 U.S.C. 823(m)(1)(A)(v).

If the practitioner is not a physician, the practitioner must be legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V, dispense such substances within such State in accordance with all applicable State laws, and meet one or more of the following conditions:

1. Completed not less than eight hours of training as specified in 21 U.S.C. 823(m)(1)(B)(i), or
2. Graduated in good standing as specified in 21 U.S.C. 823(m)(1)(B)(ii).

The CSA no longer explicitly states that CNSs, CRNAs, and CNMs can qualify to dispense. Therefore, beginning June 27, 2023, to obtain a DEA registration, all non-physician practitioners must be legally authorized by the State to dispense controlled substances in the schedules for which they are seeking registration and, if they do not practice solely as a veterinarian, must satisfy one of the training conditions set forth in 21 U.S.C. 823(m)(1)(B).

The Omnibus requires all qualified practitioners to meet the condition above starting with the first applicable registration that occurs on or after the date that is 180 days after December 29, 2022.

A. Benefits/Cost Savings

This change, removing the DATA-waiver program, greatly expands the number of practitioners who will be authorized to dispense narcotic drugs in schedules III, IV, and V for maintenance or detoxification treatment. With this change, all DEA-registered practitioners are authorized under the CSA to dispense narcotic drugs in schedules III, IV, and V for maintenance or detoxification treatment, greatly expanding the number of practitioners authorized to provide treatment.

Additionally, treatment providers will not be subject to any patient limits. The expansion in the number of practitioners authorized to dispense narcotic drugs in schedules III, IV, and V for maintenance or detoxification treatment is expected to lead to more patients being treated for OUD and the increase in the number of patients treated is expected to result in better patient outcomes and societal benefits.

While DEA is unable to quantify the number of additional patients that will be treated as a result of this final rule, DEA anticipates there will be an increase. DEA anticipates the increase in the number of patients receiving treatment authorized by this final rule will generate a substantial benefit in the form of societal cost savings. In a 2015 study of the efficacy of various interventions for opioid dependence, the study concluded that among opioid-dependent patients, practitioner-initiated buprenorphine treatment “significantly increased engagement in addiction treatment, reduced self-reported illicit opioid use, and decreased use of inpatient addiction treatment services.”²¹

A study published in 2021 of the societal costs for OUD found that the “Costs for opioid use disorder and fatal opioid overdose in 2017 were estimated to be \$1.02 trillion. The majority of the economic burden is due to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdose.”²² According to the

²¹ D’Onofrio G, O’Connor P, Pantalon M, Chawarski M, Et al. Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: A Randomized Clinical Trial. *JAMA*. 2015 April 28; 313(16): 1636–1644.

²² Florence C, Luo F, Rice K. The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017. *Drug Alcohol Depend*. 2021; 218:108350. doi: 10.1016/j.drugalcdep.2020.108350.

report, in 2017 total non-fatal costs are \$471 billion and total fatal costs are \$550 billion, there were 2.1 million persons ages 12 years and older with an OUD, and 47,600 fatal opioid overdoses. The \$471 billion in non-fatal costs include costs associated with health care (\$31 billion), substance use disorder treatment (\$4 billion), criminal justice (\$15 billion), lost productivity (\$31 billion), and the value of reduced quality of life (\$390 billion). The \$550 billion in fatal costs include costs associated with lost productivity (\$69 billion), health care (\$0 billion),²³ and value of statistical life lost (\$481 billion).²⁴ Dividing the total non-fatal costs of \$471 billion by the number of persons ages 12 and older with an OUD, 2.1 million, the societal cost of non-fatal OUD is approximately \$224,000 (\$471 billion / 2.1 million) per person per year. Dividing the total fatal costs of \$550 billion by the number of fatal opioid overdoses, 47,600, the societal cost of fatal overdoses is approximately \$11.6 million (\$550 billion / 47,600) per person. While DEA is unable to quantify how many of the affected patients will be successfully treated for OUD or how many fatal opioid overdoses will be avoided as a result of this final rule, the potential cost savings are disproportionately large compared to any cost associated with this rule.

B. Costs

DEA first calculated the unit cost for a practitioner that may need to obtain training, then applied that unit cost to the estimated number of practitioners that will need to obtain training.

Unit Cost

With the Omnibus implemented, in order to obtain a DEA registration to dispense controlled substances in schedule II, III, IV, or V, all practitioners who are not solely a

²³ \$260 million in report, rounded to \$0 billion.

²⁴ As stated in the report, the authors followed issued guidelines for regulatory impact analysis by the U.S. Department of Health and Human Services (HHS) (Office of the Assistant Secretary for Planning and Evaluation, 2016), adjusted to 2017 dollars. “The value of life lost due to opioid overdose was determined by multiplying the number of overdose cases by the consensus VSL estimates for 2017 (VSL=\$10.1 million).”

veterinarian will need to meet the training requirements in 21 U.S.C. 823(m). DEA estimates some practitioners already meet the requirements, resulting in no cost, and others will need to obtain eight hours of training at a cost.

- Scenario 1: the practitioner already meets training requirement, there is no additional cost as a result of this change.
- Scenario 2: the practitioner does not meet training requirement and the practitioner will need to obtain eight hours of training.

In both scenarios, the practitioner, or prospective practitioner, will need to self-attest on the registration application to meeting training requirements. The cost of self-attestation is expected to be minimal.

For scenario 2, the eight-hour training course for physicians and non-physicians is available online, free of charge.²⁵ As the eight-hour training is online and free, cost of this requirement is limited to the practitioners' opportunity cost associated with obtaining the training.

DEA estimates a total time of eight hours and 10 minutes (8.17 hours) to complete the training requirement, eight hours to complete the training and an additional 10 minutes for logging in or creating an account. To estimate the training opportunity cost, DEA applied the required hours to the estimated loaded hourly wage for physicians and non-physicians. DEA used the physician median wage to estimate the wage of a practitioner who is a physician; and as physician assistants and nurse practitioners are the majority of practitioners who are not physicians, DEA used the average wages of physician assistants and nurse practitioners to estimate the wages of a practitioner who is not a physician. The U.S. Bureau of Labor Statistics (BLS) data indicates that median hourly wage for physicians, physician assistants, and nurse practitioners are \$107.41, \$60.58, and \$58.47,

²⁵ Providers Clinical Support System (PCSS), Medications for Opioid Use Disorder (MOUD), <https://pcssnow.org/medications-for-opioid-use-disorder/>. (Accessed 1/3/2024.)

respectively.²⁶ The average wage of physician assistants and nurse practitioners is \$59.53 $((\$60.58 + \$58.47) / 2)$. According to the BLS Employer Costs for Employee Compensation (ECEC), for private industry workers, average total benefits are 29.5 percent and wages and salaries are 70.5 percent of total compensation.²⁷ The total benefits of 29.5 percent equate to a 41.8 $(29.5/70.5)$ percent load on wages and salaries. Adding the 41.8 percent load on the median salaries, the loaded median hourly wage for a physician and a non-physician practitioner are \$152.31 $(\$107.41 \times 1.418)$ and \$84.41 $(\$59.53 \times 1.418)$, respectively. Applying eight hours of training (8.17 hours) to each of the estimated loaded hourly wages, the labor cost of obtaining training for a physician practitioner and a non-physician practitioner, under Scenario 2, are \$1,244 $(\$152.31 \times 8.17)$ and \$690 $(\$84.41 \times 8.17)$ per person.

Number of Registrations Under Scenario 2

DEA estimated the number of practitioners under Scenario 2 based on DEA's registration records. There are two categories of registrants that fall under Scenario 2: 1) applicants for renewal registration for existing registrants, and 2) applicants for new registrations. Although the new 21 U.S.C. 823(m) includes more provisions, the training requirements are similar to those previously applicable to DATA-waiver practitioners under the repealed 21 U.S.C. 823(h)(2). Therefore, previously DATA-waived practitioners are presumed to already meet the training requirements.

DEA is unable to precisely estimate the number of renewal applicants who will need to obtain training because many registrants may already meet the training requirements and DEA does not track a practitioner's board certification or education curriculum. However, based on the number of DATA-waived practitioners (as of December 2022),

²⁶ BLS, May 2022 National Occupational Employment and Wage Estimates, United States. Occupation code 29-1229 Physicians, All Other; 29-1071 Physician Assistants; 29-1171 Nurse Practitioners. https://www.bls.gov/oes/current/oes_nat.htm. (Accessed 09/15/2023)

²⁷ BLS, Employer Cost for Employee Compensation-June 2023 (ECEC) <https://www.bls.gov/news.release/pdf/ecec.pdf> (Accessed 09/15/2023)

who had met prior similar training requirements, DEA is able to estimate the maximum number of practitioners who will need to obtain training.

Based on DEA’s registration data, DEA estimated the maximum number of practitioners, physician and non-physician, who will need to obtain training. Because practitioner registrations are three-year registrations, renewal applicants who may need to obtain training would only exist for three years for those already registered prior to June 27, 2023. Any new applicant on or after this date are required to meet the training requirement in order to register. Therefore, based on the number of practitioner and mid-level practitioner registrations as of June 2023,²⁸ adjusting for the estimated number of practitioners who are not solely veterinarians²⁹ and adjusting for the number of previously DATA-waived practitioners,³⁰ on Table 1, DEA summarizes the maximum number of renewal applicants who will need to obtain training.

Table 1. Maximum renewal applicant practitioners who will need to obtain training

<u>Year</u> ³¹	<u>Physician</u>	<u>Non-Physician</u>
1	348,067	139,937
2	347,628	149,226
3	354,017	163,297
4	-	-
5	-	-
6	-	-
7	-	-
8	-	-
9	-	-
10	-	-

Source: DEA

Similarly, DEA is unable to precisely estimate the number of new applicants who may need to obtain training to meet the training requirements of the rule. As mentioned

²⁸ DEA, Registrant Population-Summary, <https://apps.deadiversion.usdoj.gov/RAPR/raprRegistrantPopulationSummary.xhtml#no-back-button>.

²⁹ DEA’s registration system.

³⁰ DEA, Qualifying Practitioners by State, <https://apps.deadiversion.usdoj.gov/RAPR/raprQualifyingPractitionersByState.xhtml#no-back-button>.

³¹ “Year 1” corresponds to the period 6/27/2023-6/26/2024; “year 2” corresponds to the period 6/27/2024-6/26/2025; “year 3” corresponds to the period 6/27/2025-6/26/2026, etc.

earlier, DEA does not track a practitioner’s board certification or education curriculum. Additionally, education institutions may include the requisite curriculum without additional cost to the prospective new applicant. However, DEA is able estimate the maximum number of new applicants who will need training.

Based on historical number of new applicants, DEA estimated the number of new applicants for a ten-year period; then adjusted for the estimated baseline number of practitioners who are veterinarians; then adjusted for the estimated baseline number of DATA-waived practitioners. Table 2 summarizes the resulting maximum number of new practitioners who will need to obtain required training at an additional cost.

Table 2. Maximum new applicant practitioners who will need to obtain training

Year	<u>Physician</u>	<u>Non-Physician</u>
1	86,970	64,847
2	90,812	68,815
3	94,823	73,026
4	99,012	77,495
5	103,385	82,238
6	107,952	87,270
7	112,721	92,611
8	117,699	98,278
9	122,898	104,293
10	128,327	110,676
Total	1,064,599	859,549

Source: DEA

Combining the figures in Table 1 and Table 2, the maximum number of practitioners who will need training as a result of this rule is presented in Table 3.

Table 3. Maximum combined, renewal and new applicant practitioners who will need to obtain training

Year	Physician	Non-Physician	Total
1	435,037	204,784	639,821
2	438,440	218,041	656,481
3	448,840	236,323	685,163
4	99,012	77,495	176,507
5	103,385	82,238	185,623
6	107,952	87,270	195,222

Year	Physician	Non-Physician	Total
7	112,721	92,611	205,332
8	117,699	98,278	215,977
9	122,898	104,293	227,191
10	128,327	110,676	239,003
Total	2,114,311	1,312,009	3,426,320

Applying the unit opportunity cost, estimated earlier, of \$1,244 and \$690 for physicians and non-physicians, respectively, Table 4 lists the estimated maximum cost of this rule.

Table 4. Maximum opportunity costs of this rule

Year	Physician (\$)	Non-Physician (\$)	Total (\$)
1	541,186,028	141,300,960	682,486,988
2	545,419,360	150,448,290	695,867,650
3	558,356,960	163,062,870	721,419,830
4	123,170,928	53,471,550	176,642,478
5	128,610,940	56,744,220	185,355,160
6	134,292,288	60,216,300	194,508,588
7	140,224,924	63,901,590	204,126,514
8	146,417,556	67,811,820	214,229,376
9	152,885,112	71,962,170	224,847,282
10	159,638,788	76,366,440	236,005,228
Total	2,630,202,884	905,286,210	3,535,489,094

The net present value of the estimated maximum cost is \$3,141,488,447 and \$2,725,132,486 at 3 percent and 7 percent discount rates, respectively. Additionally, the annualized maximum cost is \$368,278,282 and \$387,997,558 at 3 percent and 7 percent, respectively.

While the maximum costs seem large, the potential cost savings per treated patient is also large – resulting in a low break-even point. For example, from Tables 3 and 4, in Year 1, the maximum number of registrants that will need to obtain training is 639,821 at a cost of \$682,486,988. As stated earlier, the societal cost of non-fatal OUD is approximately \$224,000 per person per year. The resulting break-even is 3,047 (\$682,486,988 / \$224,000) patients treated by the 639,821 practitioners who are able to

provide MAT as a result of this rule. Therefore, this rule ‘breaks even’ if 639,821 practitioners, authorized to provide MAT as a result of this rule in Year 1, successfully treat the OUD of 3,047 patients for one year in Year 1 or if the practitioners are able to avoid 59 deaths (\$682 million / \$11.6 million). This is a ratio of 210 practitioners to one case of non-fatal OUD avoided or successfully treated. DEA believes this is a low break-even point and the economic impact of this provision will be a net cost savings.

Change 2: NTP Registration

Following passage of the Omnibus, the separate registration requirement in 21 U.S.C. 823(h) is only applicable to practitioners dispensing narcotic drugs in schedule II for the purpose of maintenance or detoxification treatment. Any practitioner wishing to dispense narcotic drugs in schedule II for the purpose of maintenance or detoxification treatment must obtain annually a separate registration as an NTP pursuant to that section.

While this provision is a change to the regulations based on statute, this change continues the current requirements for practitioners dispensing narcotic drugs in schedule II for maintenance treatment or detoxification treatment. Prior to Omnibus, to dispense a narcotic drug in schedule II for maintenance or detoxification treatment, a practitioner was required to obtain a separate registration annually, as DATA-waiver only applied to the dispensing of schedule III-V narcotic approved by the FDA for maintenance or detoxification treatment. Therefore, any economic impact of this change is minimal.

Furthermore, 85 of 2,235 currently registered NTPs are authorized to dispense only narcotic drugs in schedule III.³² It is plausible some of the 85 NTPs may find an NTP registration unnecessary and decide to not renew its registration. The annual registration fee is \$296 per year. If all 85 NTPs did not renew its registration, there would be a decrease of \$25,160 (\$296 x 85) in fees paid to DEA. However, since all of the 85 NTPs obtained their registration after 180 days of the enactment of the Omnibus (June 27,

³² Source: DEA, as of 9/12/2024.

2023), DEA believes registered NTPs that are authorized to dispense only narcotic drugs in schedule III have other reasons for maintaining a DEA registration. Therefore, DEA estimates any impact associated with this change is minimal.

Change 3: Day limit increased

DEA is modifying the current 14-day limit (the time for the practitioner to administer the controlled substance to a patient from when the practitioner receives the controlled substance from pharmacy) to 45 days, as now set forth in 21 U.S.C. 829a.

Increasing the number of days to administer treatments from 14 days to 45 days will increase flexibility in scheduling, increase the number of patients receiving needed medication and improve patient care outcomes. The added flexibility is expected to reduce returns and wastage. DEA has no basis to estimate the cost savings due to reduced returns and wastage or improvements to patient care; however, it cannot be dismissed as negligible.

Change 4: Recordkeeping

Finally, DEA is making a minor, non-substantive change to include a cross-reference to existing regulations describing practitioners' recordkeeping requirements relevant to prescriptions. This cross-reference will increase clarity in regulations while imposing no additional cost to prescribing practitioners, as it effects no change in regulatory requirements.

Summary of Benefits/Cost Savings and Costs

In summary, DEA is making the following changes in this final rule: 1) DATA-waiver removal and new training requirement, 2) NTP registration requirement, 3) day limit increase (from 14 to 45 days), and 4) recordkeeping. The DATA-waiver removal and new training requirement is expected to have a potentially large cost, with the annualized maximum cost of \$368,278,282 and \$387,997,558 at 3 percent and 7 percent, respectively. However, due to the potentially high societal cost savings, the break-even is

low. For example, in Year 1, the break-even is the successful treatment for one year of non-fatal OUD for 3,047 patients treated by the 639,821 practitioners at a ratio of 210 practitioners to one case of OUD. If the training requirement allows for the abatement of fatal OUD cases, the break-even point is even lower. DEA believes this is a low break-even point and the economic impact of this provision will be a net cost savings. The NTP registration requirement continues the pre-existing requirement to dispense narcotic drugs in schedule II for maintenance or detoxification treatment. Increasing the day limit from 14 to 45 days is expected to reduce returns and wastage and improve patient care. While this cost savings cannot be quantified, it cannot be dismissed as minimal. Finally, the recordkeeping requirement is expected to increase clarity while imposing no additional costs.

This final rule is an E.O. 14192 deregulatory action because this is an enabling rule that expands consumption and/or production options. This final rule implements the Omnibus that allows all practitioners to dispense narcotic drugs in schedules III, IV, and V for maintenance or detoxification treatment without obtaining a waiver of the requirement for a separate registration.

Executive Order 14294, Overcriminalization of Federal Regulations

Executive Order 14294 requires agencies promulgating regulations with criminal regulatory offenses potentially subject to criminal enforcement to explicitly describe the conduct subject to criminal enforcement, the authorizing statutes, and the mens rea standard applicable to each element of those offenses. This final rule does not impose a criminal regulatory penalty and is thus exempt from E.O. 14294 requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As explained above,

DEA determined that there is good cause to exempt this final rule from notice and comment.

Consequently, DEA is not required to conduct a Final Regulatory Flexibility Analysis for this final rule. 5 U.S.C. 605.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the National government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This final rule does not have substantial direct effects on the States, on the relationship between the National government and the States, or the distribution of power and responsibilities between the Federal government and Indian tribes.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Congressional Review Act

The Office of Information and Regulatory Affairs has determined that this final rule is a major rule as defined by the Congressional Review Act. 5 U.S.C. 804. This rule is

not subject to the 60-day delayed effective date requirement at 5 U.S.C. 801(a)(3)(A) because the DEA has found, as described above, that prior notice and comment is unnecessary for this rule. 5 U.S.C. 808(2). DEA is submitting the required report under the CRA, together with a copy of this final rule, to both Houses of Congress and to the Comptroller General.

Paperwork Reduction Act of 1995

This final rule involves existing collection 1117-0014 but does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521. The modification mentioned in the rule has already been submitted to the Office of Management and Budget (OMB) and approved through a separate information collection process. A 60-day Federal Register Notice³³ and a 30-day Federal Register Notice³⁴ were published and no comments were received. Also, this final rule does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or other organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Copies of the approved existing information collection may be obtained at

<http://www.reginfo.gov/public/do/PRAMain>.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

³³ The 60-day Federal Register Notice was published on March 3, 2023 and can be found at 88 FR 13469. The comment period closed May 2, 2023.

³⁴ The 30-day Federal Register Notice was published on May 26, 2023 and can be found at 88 FR 34185. The comment period closed June 26, 2023.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, the interim final rule amending 21 CFR parts 1301 and 1306, which published on November 2, 2020 (85 FR 69153) is adopted as a final rule, with the following amendments in parts 1300, 1301, and 1306:

PART 1300—DEFINITIONS

1. The authority citation for part 1300 is revised to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 829, 871(b), 951, 958(f).

2. In § 1300.01, amend paragraph (b) by adding, in alphabetical order, the definition for “Qualified practitioner” to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

Qualified practitioner means a practitioner who:

- (1) Is licensed under State law to prescribe controlled substances; and
- (2) Is not solely a veterinarian.

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

4. Revise and republish § 1301.11 to read as follows:

§ 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any

controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (d) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose.

(c) As a condition on registration under this part and section 303 of the Act (21 U.S.C. 823) to dispense controlled substances in schedule II, III, IV, or V, qualified practitioners, as defined in § 1300.01 of this chapter, must meet the training requirements set forth in section 303(m) of the Act (21 U.S.C. 823(m)). No qualified practitioner is required to complete the training more than once. This requirement applies from the first registration or renewal of registration by a qualified practitioner that occurs on or after June 27, 2023.

(d) As provided in sections 303(f) and 401(h) of the Act (21 U.S.C. 823(f) and 841(h)), it is unlawful for any person who falls within the definition of “online pharmacy” (as set forth in section 102(52) of the Act (21 U.S.C. 802(52)) and § 1300.04(h) of this chapter) to deliver, distribute, or dispense a controlled substance by means of the Internet if such person is not validly registered with a modification of such registration authorizing such activity (unless such person is exempt from such modified registration requirement under the Act or this chapter). The Act further provides that the Administrator may only issue such modification of registration to a person who is

registered as a pharmacy under section 303(f) of the Act (21 U.S.C. 823(f)). Accordingly, any pharmacy registered pursuant to § 1301.13 that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity following the submission of an application in accordance with § 1301.19. This requirement does not apply to a registered pharmacy that does not fall within the definition of an online pharmacy set forth in § 1300.04(h) of this chapter. Under the Act, persons other than registered pharmacies are not eligible to obtain such a modification of registration but remain liable under section 401(h) of the Act (21 U.S.C. 841(h)) if they deliver, distribute, or dispense a controlled substance while acting as an online pharmacy without being validly registered with a modification authorizing such activity.

* * * * *

§ 1301.28 [Removed and Reserved]

5. Remove and reserve § 1301.28.

PART 1306—PRESCRIPTIONS

6. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

7. In § 1306.04, revise paragraphs (c) and (d) to read as follows:

§ 1306.04 Purpose of issue of prescription.

* * * * *

(c) A prescription may be issued by a practitioner for a controlled substance in Schedule III, IV, or V for use in detoxification treatment or maintenance treatment.

(d) A prescription may be issued by a practitioner in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription shall not be used

to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

§ 1306.05 [Amended]

8. In § 1306.05, remove and reserve paragraph (b).

9. In § 1306.07, revise paragraphs (a) introductory text, (d), (f)(1) through (3), (5), and (6) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug in Schedule II to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

* * * * *

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug for use in maintenance or detoxification treatment to a narcotic dependent person.

* * * * *

(f) * * *

(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance (in this paragraph (f) referred to as the “administering practitioner”), as applicable, at the location listed on the practitioner’s DEA certificate of registration;

(2) The controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment and is to be administered by injection or implantation;

(3) The pharmacy, the prescribing practitioner, and the administering practitioner (as applicable) are authorized to conduct such activities specified in this paragraph (f) under the law of the State in which such activities take place;

* * * * *

(5) The controlled substance is to be administered only to the patient named on the prescription not later than 45 days after the date of receipt of the controlled substance by the practitioner; and

(6) Notwithstanding any exceptions under section 307 of the Act (21 U.S.C. 827), the prescribing practitioner and the administering practitioner, as applicable, shall maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this paragraph (f), including the persons to whom the controlled substances were delivered and such other information as may be required under this chapter. Recordkeeping requirements for prescriptions are addressed in §§ 1304.03(c) and 1304.06 of this chapter.

* * * * *

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on June 3, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

