



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 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: Interim final rule with request for comments.

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 and expand the options available for a physician to be considered a qualifying physician. The SUPPORT Act removed the time period for a nurse practitioner or physician assistant to be considered a qualifying other practitioner, and revised the definition of a qualifying practitioner. The SUPPORT Act also allows 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 amends its regulations to make them consistent with the SUPPORT Act and implement its requirements.

DATES: This interim final rule is effective on October 30, 2020. Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference “RIN 1117-AB55 Docket No. DEA-499” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on <http://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW,

Diversion Control Division; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW) Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your

comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this interim final rule is available at <http://www.regulations.gov> under FDMS Docket ID: DEA-499 (RIN 1117-AB55/ Docket Number DEA-499) for ease of reference.

Legal Authority

Pertinent Provisions of the SUPPORT Act

On October 24, 2018, the President signed the SUPPORT Act into law as Public Law 115-271. Sections 3201 and 3202 of the SUPPORT Act amended certain provisions of 21 U.S.C. 823(g)(2), which is the subsection of the Controlled Substances Act (CSA) that sets forth the conditions under which a practitioner may, without being separately registered under subsection 823(g)(1), dispense a narcotic drug in schedule III, IV, or V

for the purpose of maintenance treatment¹ or detoxification treatment.² Section 3204 of the SUPPORT Act amended the CSA by adding section 309A (21 U.S.C. 829a), which sets forth the conditions under which a pharmacy may deliver a controlled substance to an administering practitioner. All of the changes to the CSA, from these sections of the SUPPORT Act, will be fully described below.

Background

Opioid Abuse and Treatment Need

Opioid abuse and addiction in the United States continues to impact disparate communities and populations. According to the report “Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health” released by the Substance Abuse and Mental Health Services Administration (SAMHSA), an estimated 2 million people (0.7 percent of the population) aged 12 or older had an opioid use disorder (OUD) in 2018.³ The share of the population estimated to have had an OUD in 2015, 2016, and 2017 was 0.9 percent, 0.8 percent, and 0.8 percent, respectively. Among people aged 12 or older with an OUD in 2018, about 400,000 received treatment at a specialty facility in the past year, or 19.7 percent of all those with an OUD. The percentage of those with an OUD that received treatment at a

¹ 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.

² 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.

³ U.S. Department of Health and Human Services. SAMHSA. Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health. 2019.

specialty facility in 2015, 2016, and 2017 was estimated to be 21.7 percent, 21.1 percent, and 28.6 percent, respectively.

According to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) report titled “Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder” published in January, 2020, 40 percent of U.S. counties have no “DATA-waived” providers,⁴ and another 24 percent have low patient capacity.⁵ The provisions of the SUPPORT Act being implemented into DEA regulation by this interim final rule directly address this bottleneck in available providers, and provider capacity by increasing the total number of providers eligible to prescribe buprenorphine to OUD patients.

Additional Flexibility Regarding the Patient Limit for Purposes of 21 U.S.C.

823(g)(2)

Section 3201(a) of the SUPPORT Act amended the CSA, 21 U.S.C. 823(g)(2)(B)(iii)(II), to provide flexibility to practitioners regarding the number of patients they may treat, without being separately registered as a narcotic treatment program, by adding more opportunities to increase the applicable number of patients that may be treated to 100. In general, the applicable number of patients that may be treated

⁴ 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 narcotic controlled drugs to be registered as a Narcotic Treatment Program (NTP) in addition to the practitioner's personal registration. Hence, the term “DATA-waived” is used to describe individual practitioners (physicians, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) who, having received an identification number from DEA, are exempt from separate registration for dispensing or prescribing schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment per 21 CFR 1301.28.

⁵ Office of Inspector General, HHS, 2020. *Geographic Disparities Affect Access To Buprenorphine Services For Opioid Use Disorder*. U.S. Department of Health and Human Services.

at one time is 30. Prior to the SUPPORT Act, the CSA set the applicable number of patients a practitioner may treat at 100 only when a practitioner submitted a second notification to the Secretary of HHS for the need and intent of the practitioner to treat up to 100 patients, no sooner than one year after the date on which the initial notification was submitted.

After promulgation of the SUPPORT Act, a practitioner may treat up to 100 patients under two additional circumstances: (1) if the practitioner holds additional credentialing,⁶ or (2) if a practitioner provides medication-assisted treatment⁷ using covered medications⁸ in a qualified practice setting.⁹

Section 3201(a) also allows a practitioner to treat more patients, increasing the applicable number to 275 patients if a practitioner meets the requirements set forth in 42 CFR 8.610 – 8.655. DEA added this additional applicable number to its regulations in a January 2018 final rule,¹⁰ to reflect new limits set by HHS in a July 2016 final rule.¹¹ Under this rule, DEA is updating the regulations to reflect the new description in section 3201(a).

DEA is implementing these changes to the CSA by revising DEA regulations in 21 CFR 1301.28(b)(1)(iii)(B)-(C).

⁶ “Additional credentialing” is defined as “board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine.” 42 CFR 8.2.

⁷ 42 CFR 8.2 defines *medication-assisted treatment* as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder.

⁸ “Covered medications” are “the drugs or combinations of drugs that are covered under 21 U.S.C. 823(g)(2)(C).” 42 CFR 8.2.

⁹ A “qualified practice setting” is described in 42 CFR 8.615.

¹⁰ 83 FR 3071, January 23, 2018.

¹¹ 81 FR 44712, July 8, 2016.

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

The CSA mandates that a practitioner who dispenses narcotic drugs for maintenance treatment or detoxification treatment must be a qualifying practitioner. 21 U.S.C.

823(g)(2)(B)(i). Prior to the SUPPORT Act, the CSA defined a qualifying practitioner, under 21 U.S.C. 823(g)(2)(G)(iii), as a qualifying physician¹² and also temporarily (until October 1, 2021) as a “qualifying other practitioner,” which included a nurse practitioner or physician assistant who meets certain qualifications set forth in 21 U.S.C.

823(g)(2)(G)(iv). Sections 3201(b) through (d) of the SUPPORT Act updated the CSA to by permanently allowing a nurse practitioner or a physician assistant to be considered a “qualifying other practitioner,” and temporarily (until October 1, 2023) expanding the definition of a “qualifying practitioner” to also include a clinical nurse specialist, certified registered nurse anesthetist, or a certified nurse midwife who meets certain qualifications set forth in 21 U.S.C. 823(g)(2)(G)(iv), allowing more flexibility. Those qualifications for clinical nurse specialists, certified registered nurses, or certified nurse midwives, pertaining to training, experience, and supervision, are the same as those that previously only applied to nurse practitioners or physician assistants.

DEA is implementing these changes to the CSA by revising DEA regulations in 21 CFR 1301.28(b)(1)(i).

New Option to Allow a Physician to Become a Qualifying Physician

¹² The CSA defines a “qualifying physician” as a physician who is licensed under State law and who meets one or more of certain listed conditions. 21 U.S.C. 823(g)(2)(G)(ii).

Section 3202(a) of the SUPPORT Act amended 21 U.S.C. 823(g)(2)(G)(ii) by adding a new option for a physician to be considered a “qualifying physician.” Prior to the SUPPORT Act, a physician could become a qualifying physician through seven different options. The additional option 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 submitted a written notification to the Secretary of HHS 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. This curriculum or residency must have included at least eight hours of training on treating and managing opioid-dependent patients, and, at a minimum, included training described in 21 U.S.C. 823(g)(2)(G)(IV)(aa)-(gg), and any other training the Secretary of HHS determines should be included in the curriculum, including training on pain management, and the assessment and appropriate use of opioid and non-opioid alternatives. The SUPPORT Act added this training requirement to the CSA at 21 U.S.C. 823(g)(G)(ii)(VIII), however, there is no corresponding regulation in the Code of Federal Regulations that DEA needs to revise and update because the definition of “qualifying physician” is only referred to in the regulations. *See* 21 CFR 1301.28 (b)(1)(i).

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 a controlled substance to an administering practitioner. Specifically, the new section 829a

allows a pharmacy to deliver, notwithstanding the definition of dispense (21 U.S.C. 802(10)),¹³ a prescribed controlled substance (that meets the requirements issued by the Attorney General under title 21 of the U.S.C.) 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 under specific conditions. Prior to this new section 829a, pharmacies were only allowed to deliver controlled substances to the ultimate user or research subject.

Under section 829a, a pharmacy is allowed to dispense prescribed narcotic drugs in schedule III, IV, or V, or combinations of such drugs, to a practitioner for the purpose of maintenance or detoxification treatment under 21 U.S.C. 823(g)(2) and certain conditions. Specifically, the prescription must be issued by a qualifying practitioner and the prescription issued cannot be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients. In addition, the practitioner must meet the following conditions:

1. The practitioner must administer the controlled substance to the patient named on the prescription:
 - a. by implantation or injection;
 - b. within 14 days after the date of receipt of the controlled substance by the practitioner.

¹³ The term dispense means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery 21 U.S.C. 802(10).

2. The practitioner and pharmacy are authorized to conduct these activities in the State in which such activities take place.

3. The prescribing practitioner and administering practitioner of the controlled substance maintain complete and accurate records of all controlled substances delivered, received, administered, and disposed including the persons to whom controlled substances were delivered and such other information that the Attorney General may require by regulations.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring the publication of a prior notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest.

DEA finds there is good cause within the meaning of the APA to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations with recent amendments to the CSA that have already taken effect. DEA has no discretion with respect to these amendments. This rule merely incorporates the statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication is unnecessary. *See* 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). “[W]hen regulations

merely restate the statute they implement, notice-and-comment procedures are unnecessary.” *Gray Panthers Advocacy Committee v. Sullivan*, 936 F.2d 1284, 1291 (D.C. Cir. 1991); *see also United States v. Cain*, 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, “with regulations that merely restate or interpret statutory obligations,” which do not); *Komjathy v. Nat. Trans. Safety Bd.*, 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule “does no more than repeat, virtually verbatim, the statutory grant of authority” notice-and-comment procedures are not required).

In addition, because the statutory changes at issue have already been in effect since October 24, 2018, DEA finds good cause exists to make this rule effective immediately upon publication. *See* 5 U.S.C. 553(d). Therefore, DEA is issuing these amendments as an interim final rule, effective October 30, 2020. DEA is publishing this rule as an interim final rule and is establishing a docket to receive public comment on this rule. To the extent required by law, DEA will consider and respond to any relevant comments received.

As explained above, DEA is obligated to issue this interim final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the SUPPORT Act. In issuing this interim final rule, DEA has not gone beyond the statutory text enacted by Congress. Thus, DEA would have to issue this interim final rule regardless of the outcome of the agency's regulatory analysis. Nonetheless, DEA conducted this analysis as discussed below.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This interim final rule was developed in accordance with the principles of Executive Orders (EO) 12866 and 13563. EO 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). EO 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in EO 12866. EO 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the EO.

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined and it has been determined to be an economically

significant regulatory action under EO 12866 with a net annualized benefit of \$543 million over five years, and therefore, has been submitted to OMB for review.

EO 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017, and published in the *Federal Register* on February 3, 2017. 82 FR 9339. Section 2(a) of EO 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of EO 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from OMB, issued on April 5, 2017, explains that the above requirements only apply to each new “significant regulatory action that . . . imposes costs.”

DEA estimates that this interim final rule will expand the number of DATA-waived treatment providers, qualifying it as an “enabling rule” according to EO 13771 guidance from OMB issued on April 5, 2017. Therefore, DEA expects that this interim final rule will be classified as an EO 13771 deregulatory action by OMB.

A. Need for the Rule

On October 24, 2018, the SUPPORT Act became law. With this interim final rule, DEA is amending its regulations governing providers of medication-assisted treatment (MAT) to incorporate statutory changes made to the CSA by the SUPPORT Act.

B. Alternative Approaches

This interim final rule amends DEA regulations only to the extent necessary to be consistent with current Federal law as modified by the SUPPORT Act. Because DEA is

obligated to implement these provisions of the SUPPORT Act, DEA has no discretion not to amend its regulations as is being done in this interim final rule. Indeed, the new provisions issued under this interim final rule are already in effect by virtue of the SUPPORT Act, and this interim final rule simply updates DEA regulations to reflect these new provisions; thus, no alternative approaches are possible.

C. Analysis of Benefits and Costs

This analysis is limited to the provisions of the interim final rule implementing into regulation the following statutory changes of the SUPPORT Act: revising the definition of a qualifying practitioner, permanently allowing a nurse practitioner (NP) or physician assistant (PA) to be considered a qualifying other practitioner, expanding the options available for a physician to be considered a qualifying physician, and allowing a pharmacy to deliver prescribed controlled substances to a practitioner's registered location for the purpose of maintenance or detoxification treatment.

Benefits of the interim final rule, in the form of economic burden reductions and other cost savings (health care costs, criminal justice costs, and lost productivity costs), are expected from permanently allowing NPs or PAs to dispense narcotic drugs for maintenance and detoxification treatment, and from granting qualified clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM) the same dispensing privileges as NPs and PAs for a five year period ending on October 1, 2023. These benefits are significant and are quantified in the following analysis and discussion. DEA anticipates the expansion of the categories of practitioners will lead to an increase in the number of treatment providers, and to an increase in the number of patients (who did not have access to treatment prior to this rule)

treated, resulting in a reduction in the economic burden of opioid abuse. DEA also expects benefits by allowing maintenance or detoxification treatment providers to treat up to 100 patients, expanding the options available for a physician to be considered a qualifying physician, and allowing a pharmacy to deliver prescribed controlled substances to a practitioner's registered location for the purpose of maintenance or detoxification treatment. These benefits will be discussed qualitatively in the following analysis.

Costs of the interim final rule are associated with the treatment cost of opioid addicted patients and the cost to practitioners of obtaining authority to dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance or detoxification treatment. The costs of obtaining dispensing authority and treating patients are required to generate the benefits of the rule, and thus, are included in this analysis. Although the new treatment providers in the expanded category and qualifying other practitioners will also need to comply with treatment-specific recordkeeping requirements, the cost of compliance is included in the estimated cost of treatment as explained in the section "Other Potential Costs." DEA also estimates that there will be a cost savings resulting from patients being able to access buprenorphine treatment through treatment providers that are not physicians. Finally, there is potential for added risk of diversion from more practitioners having the authority to dispense narcotic drugs in schedule III, IV, or V for the purpose of maintenance or detoxification treatment. This risk is discussed in the section "Risk of Diversion."

Increase in the Number of Data-Waived Providers Eligible to Treat 100 Patients

Section 3201(a) of the SUPPORT Act amended the CSA, specifically 21 U.S.C. 823(g)(2)(B)(iii)(II), to allow for additional circumstances in which DATA-waived providers may treat up to 100 patients for maintenance and detoxification treatment, instead of the default 30 patient limit. Prior to the SUPPORT Act, providers were required to wait one year before notifying SAMHSA of their desire to increase their DATA-waived patient limit to 100. Now, DATA-waived practitioners may immediately treat up to 100 patients if the practitioner holds additional credentialing in addiction medicine, or provides MAT using covered medications, in a qualified practice setting. This provision only affected qualifying practitioners that became immediately eligible in the first year after the SUPPORT Act became law, and the following analysis is limited to this group of practitioners.

DEA assumes that there are some qualifying practitioners that, within the first year of obtaining a DATA-waiver, quickly reach the 30 patient limit. These high-capacity MAT providers were most likely to benefit from the additional flexibility provided by the SUPPORT Act by beginning to treat up to 100 patients immediately rather than waiting a full year. DEA does not have a good basis to estimate the number of qualifying practitioners who took advantage of this flexibility within the first year of the SUPPORT Act becoming law; however, it is believed to be minimal for two reasons. First, in general, DEA believes it is unlikely that many practitioners develop a capacity to treat more than 30 MAT patients within their first 12 months of obtaining a DATA-waiver. There are many factors that influence how many patients a DATA-waived practitioner's treats, including, but not limited to patient demand for treatment; insufficient time, staff,

and office space;¹⁴ Medicaid and insurance reimbursement rates;¹⁵ and a regulatory environment perceived to be overly burdensome.¹⁶ The vast majority of newly-DATA-waived providers are likely to be conservative in the first year of delivering MAT as they consider these factors and navigate a changing regulatory environment, whether they have advanced training in addiction medicine or not.

Second, for qualifying practitioners that do take on up to 30 patients in their first year of practicing, it is not likely that they are able to build their patient base to an amount greater than 30 before they would have previously been eligible to apply for the 100-patient DATA-waiver. DEA assumes that the growth in patients under treatment for any qualifying practitioner advances quickly in the beginning, but slows and eventually levels off as their practice matures. A recent academic study supports this, finding that practitioners possessing DATA-waivers to treat up to 100 patients (therefore having been DATA-waived for at least one full year) do not approach this limit, and instead have an average monthly patient census of 42.9.¹⁷ Thus, DEA believes it is reasonable to assume that if a high-capacity practitioner reached the 30 patient limit within the first year of the SUPPORT Act becoming law, it is not likely that practitioner was able to expand their

¹⁴ Andrilla CHA, Coulthard C, and Larson EH. “Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder.” *The Annals of Family Medicine* 15, no. 4 (2017): 359–62. <https://doi.org/10.1370/afm.2099>.

¹⁵ Stein BD, Gordon AJ, Dick AW, Burns RM, Pacula RL, Farmer CM, Leslie DL, and Sorbero M. “Supply of Buprenorphine Waivered Physicians: The Influence of State Policies.” *Journal of Substance Abuse Treatment* 48, no. 1 (2015): 104–11. <https://doi.org/10.1016/j.jsat.2014.07.010>.

¹⁶ Haffajee RL, Bohnert ASB, and Lagisettey PA. “Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment.” *American Journal of Preventive Medicine* 54, no. 6 (2018). <https://doi.org/10.1016/j.amepre.2017.12.022>.

¹⁷ Thomas CP, Doyle E, Kreiner PW, Jones CM, Dubenitz J, Horan A, and Stein BD. “Prescribing Patterns of Buprenorphine Waivered Physicians.” *Drug and Alcohol Dependence* 181 (2017): 213–18. <https://doi.org/10.1016/j.drugalcdep.2017.10.002>.

number of patients under treatment to more than 30 before they would have been previously eligible for a 100-patient waiver prior to this provision of the SUPPORT Act.

Since DEA does not have a good basis for estimating the number of practitioners that qualified, nor how many more patients these high-capacity practitioners treated in their first year of becoming DATA-waived after the SUPPORT Act became law, DEA is unable to quantify the benefit of this enabling provision.

Permanently Allowing Nurse Practitioners and Physician Assistants to Practice as “Qualifying Practitioners”

The SUPPORT Act makes permanent the five-year temporary exception for NPs and PAs to become DATA-waived and practice as “Qualifying Practitioners,” originally authorized by the Comprehensive Addiction and Recovery Act (CARA) of 2016. The temporary authorization was incorporated into DEA regulations through promulgation of a 2018 final rule.¹⁸ DEA’s analysis of the benefits and costs of this 2018 final rule concluded that all qualified NPs and PAs that would become DATA-waived would do so in the first two years of eligibility (July 22, 2016 to September 30, 2018),¹⁹ as the temporary nature of the exception and uncertainty of the long-term status of this group’s eligibility would disincentivize their investment in becoming DATA-waived in years three through five. This temporary exception for NPs and PAs was made permanent by the SUPPORT Act at the beginning of their third year of eligibility, thus incentivizing this group’s long-term investment in obtaining DATA-waivers.

¹⁸ 83 FR 3071 (January 23, 2018).

¹⁹ DEA’s analysis of the benefits and costs of this 2018 final rule used the following date ranges to correspond with years one through five of temporary DATA-waived eligibility for NPs and PAs: year one corresponds to 7/22/2016-9/30/2017; year two corresponds to 10/1/2017-9/30/2018; year three to 10/1/2018-9/30/2019; year four to 10/1/2019-9/30/2020; and year five to 10/1/2020-9/30/2021. The SUPPORT Act was signed into law on October 24, 2018, shortly after the beginning of year three.

Absent the permanent eligibility granted to NPs and PAs by the SUPPORT Act, the DATA-waivers of all “Qualifying Practitioners” would expire on October 1, 2021, roughly three years after the SUPPORT Act became law, and the end of year three of this analysis. For the purposes of this analysis, year one corresponds to October 25, 2018, through August 15, 2019; year two corresponds to August 16, 2019, through October 31, 2020; year three to November 1, 2020, through October 31, 2021; year four to November 1, 2021, through October 31, 2022; and year five to November 1, 2022, through October 1, 2023.²⁰ According to DEA registration data, as of April, 2020, mid-way through year two, there are 18,373 DATA-waived NPs and PAs.²¹ Because DEA does not have a good basis to forecast how many more NPs and PAs might become DATA-waived through the conclusion of year five of this analysis, DEA conservatively assumes that the number of DATA-waived NPs and PAs will remain constant at the current level of 18,373 through October 1, 2023.

Because even in the absence of the SUPPORT Act, NPs and PAs would be eligible for a DATA-waiver due to the temporary authorization provided by CARA through September 30, 2021, only the estimated number of DATA-waived NPs and PAs in year four and year five are relevant to this analysis. The following table illustrates how each

²⁰ DEA chose to limit the analysis period of this interim final rule to five years due to the evolving nature of the opioid epidemic and the long-term uncertainty of the laws and rules being implemented to combat it.

²¹ DEA’s internal registration database currently does not distinguish between DATA-waived CNS, CRNAs, or CNMs and DATA-waived NPs and PAs. In order to avoid double counting, DEA must adjust the number of DATA-waived mid-level NPs and PAs as of April, 2020 (19,409) downward by the estimated increase in DATA-waived CNS/CRNA/CNMs to date. As detailed in the following section, DEA estimates that 691 CNS/CRNA/CNMs become DATA-waived in each of the first two years of this analysis. Because, at the time of this writing, year two is roughly 50 percent complete, DEA estimates that 1,037 ($691 + (691/2) = 1,037$) CNS/CRNA/CNMs have obtained a DATA-waiver thus far. Subtracting 1,037 from 19,409 results in an estimated 18,373 NPs and PAs that are currently DATA-waived.

year of this analysis corresponds to the DATA-waiver eligibility for NPs and PAs provided by CARA and the SUPPORT Act, respectively.

	DATA-waiver eligibility provided by CARA			DATA-waiver eligibility provided by SUPPORT Act	
	Year 1	Year 2	Year 3	Year 4	Year 5
Total Number of DATA-waived NPs and PAs	-	-	-	18,373	18,373

Therefore, DEA estimates that 18,373 NPs and PAs would lose their DATA-waiver eligibility and their ability to provide MAT to patients in year four and year five of this analysis if not for the SUPPORT Act.

Expanding the Definition of “Qualifying Other Practitioner”

This interim final rule also implements the SUPPORT Act provision that allows CNS, CRNAs, or CNMs to apply for DATA-waived status and practice as “Qualifying Other Practitioners” for a temporary period ending October 1, 2023. The DATA-waived eligibility of CNS/CRNA/CNMs is new, and as a result, DEA does not have a strong basis to estimate the number of CNS/CRNA/CNMs that would request DATA-waived status. Because DEA’s internal registration database currently does not distinguish between DATA-waived CNS/CRNA/CNMs and DATA-waived NPs and PAs, it is likely that any CNS/CRNA/CNMs that have become DATA-waived since the SUPPORT Act became law are currently being categorized as “Mid-Level Practitioner – DATA-waived Nurse Practitioner” (MLP-DW NP) or “Mid-Level Practitioner – DATA-waived Physician Assistant” (MLP-DW PA). Because of this, it is not possible to determine how

many CNS/CRNA/CNMs have already obtained DATA-waived status in their first year of eligibility. However, DEA believes this number to be low since CNS/CRNA/CNM eligibility is new, and many businesses and individuals are still weighing the personal benefits and costs of becoming or employing a DATA-waived CNS/CRNA/CNM.

For the purposes of this analysis, DEA conservatively assumes the ratio of DATA-waived CNS/CRNA/CNMs to all CNS/CRNA/CNMs authorized to prescribe controlled substances will be equal to the ratio of DATA-waived NPs and PAs to all DEA registered NPs and PAs. Based on DEA records, as of August 15, 2019, the end of year one of this analysis, four percent of DEA-registered NPs and PAs are DATA-waived. DEA estimates that 69,128²² CNS/CRNA/CNMs are eligible to prescribe controlled substances in the United States. Four percent of 69,128 is 2,765. Therefore, DEA estimates that 2,765 CNS/CRNA/CNMs will become DATA-waived during the temporary eligibility period.

DEA also assumes that all DATA-waived CNS/CRNA/CNMs will be certified in year one through four²³ as the burden of obtaining DATA-waived status outweighs the

²² Bureau of Labor Statistics (BLS) state-level employment data of 41,800 CRNAs and 6,500 CNMs (<https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-6>) were used to calculate the total U.S. employment for this group. However, BLS does not differentiate between all Registered Nurses (RNs) and the more specialized CNS, which are considered Advanced Practice Registered Nurses (APRN) because of their education, training, and duties, because there is no separate Standard Occupational Classification (SOC) code for CNS. Therefore, DEA chose to use a U.S. employment estimate of 72,000 CNS provided by the National Association of Clinical Nurse Specialists (<https://explorehealthcareers.org/career/nursing/clinical-nurse-specialist/>) and assumed that the percentage of CNS employment distributed per state matches the distribution of RN employment by state. DEA then excluded employment data from states that do not allow CNS/CRNA/CNMs to prescribe controlled substances, resulting in 40,298 CNS with prescribing authority, 23,920 CRNAs with prescribing authority and 4,910 CNMs with prescribing authority. This results in a total of 69,128 CNS/CRNA/CNMs with prescribing authority in the U.S.

²³ DEA considered an estimate of the growth of CNS/CRNA/CNMs that ceased at the end of year two, however, it is likely that CNS/CRNA/CNMs will expect this temporary exception to become permanent just as the exception for NPs and PAs has, encouraging growth of this category until year four.

incentives as the expiration of the temporary provision nears. Smoothing the estimated 2,765 DATA-waived CNS/CRNA/CNMs over four years results in an estimated yearly increase of 691 (rounded). Thus, DEA estimates 691 CNS/CRNA/CNMs have become DATA-waived in year one of this analysis which will increase to 1,382 in year two, and this calculation progresses linearly until a grand total of 2,765 is reached in year four, and remains steady for year five. The table below summarizes this calculation.

	Year 1	Year 2	Year 3	Year 4	Year 5
Group 1: CNS/CRNA/CNMs obtaining DATA-waived status in year 1	691	691	691	691	691
Group 2: CNS/CRNA/CNMs obtaining DATA-waived status in year 2	-	691	691	691	691
Group 3: CNS/CRNA/CNMs obtaining DATA-waived status in year 3	-	-	691	691	691
Group 4: CNS/CRNA/CNMs obtaining DATA-waived status in year 4	-	-	-	691	691
Total Number of DATA-waived CNS/CRNA/CNMs	691	1,382	2,073	2,765	2,765

New Option for a Physician to Become a Qualifying Physician

This enabling provision of the interim final rule provides another option for a physician to become qualified to apply for a DATA waiver. While DEA does not have a good basis to quantify the impact of this change, this provision is expected to increase the number of new qualifying physicians, and thus, increase the number of full-time equivalent (FTE) patients²⁴ treated.

²⁴ “Full-time-equivalent” patient is a notional value equivalent to a patient under treatment for the full year. For example, if two patients were under treatment for 6 months, they would total 1 full-time-equivalent patient. The equivalent full-time patient concept has been previously used by DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) in its estimate of patient increases. Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder, 83 FR 3071 (January 23, 2018), and Medication Assisted Treatment for Opioid Use Disorders, 81 FR 66191 (July 8, 2016).

This new option essentially shifts the eight-hour training requirement for a physician to become DATA-waived from post-residency Continuing Medical Education (CME) to medical school or residency for physicians that complete a medical school curriculum or residency that includes at least eight hours of training on treating and managing opioid-dependent patients. While this option streamlines the training for physicians that complete medical school or residency featuring curriculum that meets the training standard; it does not eliminate the eight-hour training requirement. DEA does not have a good basis to estimate the number of medical school curriculums that currently meet this eight-hour training requirement but assumes it to be low, but likely to increase in the future. Therefore, DEA is unable to quantify the expected cost savings of this provision.

Allowing Pharmacies to Deliver Controlled Substances to a Practitioner's Registered Location

Prior to this enabling provision of the SUPPORT Act, pharmacies were only allowed to deliver controlled substances to the ultimate user or research subject. However, for patients prescribed extended-release injectable or implantable MAT drugs, DEA provided an exception to this restriction and allowed the delivery of medication directly from the pharmacy to the practitioner in order for the patient to have their monthly (injectable) or semi-annual (implantable) dosage administered directly in the providers' office without first requiring a trip to the pharmacy. The SUPPORT Act has now made this exception permanent by allowing pharmacies to deliver prescribed narcotic drugs in schedule III, IV, or V, or combinations of such drugs, to a practitioner for the purpose of maintenance and detoxification to be administered by a practitioner through injection or implantation to patients.

Because this provision of the interim final rule is simply codifying previous DEA practice and the current law, DEA expects this provision of the interim final rule to result in no costs or benefits.

Increase in the Number of Patients Receiving Treatment

As discussed above, the expansion of DATA-waived providers to include CNS/CRNA/CNMs on a temporary basis, and NPs and PAs on a permanent basis, is expected to result in more opioid-addicted patients treated. Any increase in the number of patients receiving treatment as a result of this interim final rule will depend not only on an increase in the number of providers offering services, but also on the number of patients currently unable to obtain treatment due to a lack of providers. There is a well-documented treatment gap in the United States between prescription opioid abusers or people dependent on opioids and MAT providers.^{25, 26} Therefore, DEA assumes that there is sufficient demand for treatment services that will be met with the expanded patient capacity created by the SUPPORT Act.

The number of FTE patients treated by each newly DATA-waived CNS/CRNA/CNM is expected to be low in the first year and steadily increase as their practices mature. While the patient limit for DATA-waived CNS/CRNA/CNM is set at 30 patients²⁷, the actual number of patients treated on a FTE basis is expected to be lower for a variety of reasons, including delays in patient referrals; patients discontinuing treatment without

²⁵ Jones et al., “National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment” *American Journal of Public Health* 105, no 8 (2015):e55-63.

²⁶ Office of Inspector General, HHS, 2020. *Geographic Disparities Affect Access To Buprenorphine Services For Opioid Use Disorder*. U.S. Department of Health and Human Services.

²⁷ The “patient limit” is the “total number of such patients of the practitioner at any one time...” 21 U.S.C. 823(g)(2)(B)(iii)(I). The Secretary of HHS may by regulation change the patient limit, but for the purposes of this analysis, DEA conservatively assumes that the patient limit of 30 will apply for CNS/CRNA/CNMs over the analysis period.

notifying the practitioner; the difference in duration of treatments among patients and inability to perfectly time the replacing of one patient for another while at the patient limit; demands on CNS/CRNA/CNMs to treat patients for conditions other than maintenance and detoxification; private insurance and Medicaid coverage limitations²⁸; travel difficulties for patients located in rural areas²⁹; and etc.

A recent study regarding the prescribing patterns of MAT providers found that practitioners with 30-patient DATA-waivers treated an average of 13.6 patients per month.³⁰ For the purposes of this analysis, and consistent with this research, DEA assumes CNS/CRNA/CNMs will slowly build to treating 13.5 average FTE patients over five years. Therefore, this analysis assumes each DATA-waived CNS/CRNA/CNM, upon becoming DATA-waived, will treat 7.5, 9, 10.5, 12, and 13.5 FTE patients in years 1, 2, 3, 4, and 5, respectively.

Applying the assumed average FTE patients for each group of DATA-waived CNS/CRNA/CNM in the year they obtained DATA-waived status, DEA estimated the number of FTE patients expected to be treated for each year. The average FTE patients treated of 7.5, 9, 10.5, 12, and 13.5 in years 1, 2, 3, 4, and 5, respectively, were applied to Group 1 (the group of 691 CNS/CRNA/CNMs that obtained DATA-waived status in year one) to estimate the number of patients treated by this group in each of the five years. The average FTE patients treated of 7.5, 9, 10.5, and 12, in years 2, 3, 4, and 5 were

²⁸ Rinaldo SG and Rinaldo DW. Availability Without Accessibility? State Medicaid Coverage and Authorization Requirements for Opioid Dependence Medications. 2013. http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.

²⁹ Sigmon SC. Access to treatment for opioid dependence in rural America: challenges and future directions. *JAMA Psychiatry*. 2014;71(4):359-360. <https://doi.org/10.1001/jamapsychiatry.2013.4450>.

³⁰ Thomas, et al., "Prescribing Patterns of Buprenorphine Waivered Physicians," *Drug and Alcohol Dependence*, 181, Supplement C (2017): 213-218.

applied to Group 2 (the group of 691 CNS/CRNA/CNMs that obtain DATA-waived status in year two) to estimate the number of patients treated by this group in each of the four remaining years. Similar calculations were performed for Groups 3 (the group of 691 CNS/CRNA/CNMs that obtain DATA-waived status in year three) and 4.³¹ Adding the number of FTE patients treated by the four groups, DEA estimates a total of 5,183; 11,402; 18,657; 26,949; and 31,095 FTE patients are treated in years 1, 2, 3, 4, and 5, respectively. The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5
Group 1: CNS/CRNA/CNMs obtaining DATA-waived status in year 1	691	691	691	691	691
Average full-time-equivalent patients treated per CNS/CRNA/CNMs per year for Group 1	7.5	9	10.5	12	13.5
Patients treated by Group 1	5,183	6,219	7,256	8,292	9,329
Group 2: CNS/CRNA/CNMs obtaining DATA-waived status in year 2	-	691	691	691	691
Average full-time-equivalent patients treated per CNS/CRNA/CNMs per year for Group 2	-	7.5	9	10.5	12
Patients treated by Group 2	-	5,183	6,219	7,256	8,292
Group 3: CNS/CRNA/CNMs obtaining DATA-waived status in year 3	-	-	691	691	691
Average full-time-equivalent patients treated per CNS/CRNA/CNMs per year for Group 3	-	-	7.5	9	10.5
Patients treated by Group 3	-	-	5,183	6,219	7,256
Group 4: CNS/CRNA/CNMs obtaining DATA-waived status in year 4	-	-	-	691	691
Average full-time-equivalent patients treated per CNS/CRNA/CNMs per year for Group 4	-	-	-	7.5	9
Patients treated by Group 4	-	-	-	5,183	6,219
Total Number of CNS/CRNA/CNMs obtaining DATA-waived status	691	1,382	2,073	2,765	2,765
Total Full-time-equivalent patients treated	5,183	11,402	18,657	26,949	31,095

³¹ DEA assumes that all DATA-waived CNS/CRNA/CNMs will be certified in years one through four as the burden of obtaining DATA-waived status outweighs the incentives as the expiration of the temporary provision nears. Therefore, there is no “Group 5”.

DEA used similar assumptions and calculation methods to determine how many FTE patients will be treated by NPs and PAs that remain DATA-waived in years four and five of this analysis due to the SUPPORT Act providing permanent DATA-waiver eligibility. Only FTE patients treated in years four and five are relevant because even in the absence of the SUPPORT Act, NPs and PAs would be eligible for a DATA-waiver through September 30, 2021 (the end of year three of this analysis) due to the temporary authorization provided by CARA. DEA assumes that the 18,373 DATA-waived NPs and PAs will treat, on average, 13.5 FTE patients in years four and five. Multiplying 18,373 by 13.5 results in an estimated 248,036 FTE patients treated in years four and five due to the SUPPORT Act. The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total Number of NP and PA remaining DATA-waived	-	-	-	18,373	18,373
Average full-time-equivalent patients treated per NP and PA per year	-	-	-	13.5	13.5
Total Full-time-equivalent patients treated	-	-	-	248,036	248,036

Economic Burden of Prescription Opioid Abuse

The total U.S. economic burden (healthcare costs, criminal justice costs, and lost productivity costs) of prescription opioid abuse in 2013 was estimated to be \$78.5 billion.³² Lost productivity costs represented approximately 53 percent of the total economic burden, healthcare (including substance abuse treatment costs) represented approximately 37 percent of the total economic burden, and criminal justice costs

³² Florence CS, Zhou C, Luo F & Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 Med Care 901 (2016). DEA's 2017 National Drug Threat Assessment (NDTA) also references this estimate for total economic burden of prescription drug abuse. No estimate of the economic burden of prescription opioid abuse is given in the most recent NDTA for 2018.

represented approximately 10 percent of the total economic burden.³³ This study estimated \$78.5 billion (\$85.2 billion in 2018)³⁴ in total U.S. economic burden is based on the 1.935 million opioid abuse patients reported by SAMHSA's National Survey on Drug Use and Health as meeting the Diagnostic and American Psychiatric Association's Statistical Manual of Mental Disorders (DSM-IV) criteria for abuse or dependence. Adjusting for substance abuse treatment costs included in the economic burden calculation (because the baseline level of substance abuse treatment cost is not expected to decrease with more treatment), DEA estimates the total economic burden to be \$75.7 billion (\$82.14 billion USD in 2018).³⁵ Dividing this total economic burden by the number of patients, DEA estimates the annual economic burden of prescription opioid abuse is \$42,000 per person (USD in 2018).

Economic Burden Reduction

Successful treatment of opioid abuse or dependence is expected to generate economic burden reductions. On November 8, 2011, the National Institutes of Health (NIH) announced the results of a large scale study on treatment of prescription opioid addiction. According to the announcement,

[r]esults showed that approximately 49 percent of participants reduced prescription painkiller abuse during extended (at least 12-week) Suboxone treatment.

³³ *Id.*

³⁴ Adjusted to 2018 dollars using the GDP deflator published by the Federal Reserve Bank of St. Louis (<https://fred.stlouisfed.org/series/GDPDEF>, accessed on 8/15/2019). All figures given below are 2018 dollars unless otherwise indicated.

³⁵ The Council of Economic Advisers (CEA) reported that it estimates in 2015, the economic cost of opioid crisis was \$504 billion ("The Underestimated Cost of the Opioid Crisis," CEA, November, 2017). Among several differences in analysis methods, the CEA's estimate is based on all opioids (prescription and illegal), while Florence et al. reported cost of \$78.5B is based only on prescription opioids. To limit the scope of this analysis to the economic burden of prescription opioid abuse and to be consistent with DEA's 2017 National Drug Threat Assessment, this analysis uses the Florence et al. estimated 2013 economic burden of \$78.5B (or \$82.14B after backing out baseline substance abuse treatment cost and adjusting for USD 2018).

This success rate dropped to 8.6 percent once Suboxone was discontinued.³⁶ Reductions in prescription painkiller abuse were seen regardless of whether or not the patient reported suffering chronic pain, and participants who received intensive addiction counseling did not show better outcomes when compared to those who did not receive this additional counseling.^{37 38}

DEA estimates a patient (or FTE) successfully undergoing treatment will generate an economic burden reduction of \$42,000 annually.³⁹ Based on the figures above, DEA estimates a success rate of 29 percent (average of 49 percent and 8.6 percent from above) in treating abuse and addiction, which would result in economic burden reductions.⁴⁰ Several other studies have also shown that office-based buprenorphine treatment has 50-60 percent retention rates at 6-months.⁴¹

Applying the \$42,000 economic burden reduction and a success rate of 29 percent to the estimated 5,183, 11,402, 18,657, 274,985, and 279,131 total FTE patients treated in

³⁶ This success rate was measured two months after treatment terminated.

³⁷ *Painkiller Abuse Treated by Sustained Buprenorphine/Naloxone*, NATIONAL INSTITUTES OF HEALTH (November 8, 2011), <https://www.nih.gov/news-events/news-releases/painkiller-abuse-treated-sustained-buprenorphine/naloxone>.

³⁸ At an 18-month follow up study, it was found that many patients currently or recently re-engaged in opioid agonist therapy, and the abstinence rate was found to have rebounded to 51.2 percent. NIDA. Long-Term Follow-Up of Medication-Assisted Treatment for Addiction to Pain Relievers Yields “Cause for Optimism.” National Institute on Drug Abuse website. <https://www.drugabuse.gov/news-events/nida-notes/2015/11/long-term-follow-up-medication-assisted-treatment-addiction-to-pain-relievers-yields-cause-optimism>. November 30, 2015. Accessed August 15, 2019.

³⁹ DEA notes that the methodology presented here for calculating the benefits of treatment differs from the methodology employed by HHS in the final rule Medication Assisted Treatment for Opioid Use Disorders, published at 81 FR 44711, on July 8, 2016. HHS calculated the value of Quality Adjusted Life Years gained from treatment and applied this value to their estimated number of additional patients in treatment per year. HHS calculates the average annual benefit per new patient in treatment to be \$51,000 while assuming a 43.3 percent treatment completion rate for a 6-month treatment course. For individuals that do not complete treatment, it is assumed that half of the annual benefits are realized.

⁴⁰ NIH’s report describes that 49 percent and 8.6 percent “reduced” abuse, not “eliminated,” suggesting the potential of reducing the \$42,000 in economic burden, not eliminating the costs. DEA does not have a basis on which to quantify this reduction. However, considering that there are patients that are successfully treated and no longer under treatment, DEA believes a success rate of 29 percent for the overall patient population is a reasonable estimate. The success rate is applied to FTE patients (meaning patients under active treatment) in the following paragraph to estimate economic burden reduction,

⁴¹ *Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment*. THE AMERICAN SOCIETY OF ADDICTION MEDICINE (June 2013). https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.pdf?sfvrsn=cee262c2_25

years 1, 2, 3, 4, and 5, by all practitioners (NPs, PAs, CRNAs, CNS, and CNMs) respectively, the estimated total economic burden reduction is \$63 million, \$139 million, \$227million, \$3,349 million, and \$3,400 million in years 1, 2, 3, 4, and 5, respectively.

The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5
Full-time-equivalent patients treated	5,183	11,402	18,657	274,985	279,131
Economic burden reduction per patient (\$MM)	0.042	0.042	0.042	0.042	0.042
Treatment success rate	29%	29%	29%	29%	29%
Total economic burden reduction (\$MM)	63	139	227	3,349	3,400

Figures are rounded.

Cost of Treatment

As stated previously, this interim final rule does not directly impact the cost of treatment, however, the treatment is required to generate these economic burden reductions, and thus, included in this analysis. Research shows that the treatment period encompasses three phases: induction, stabilization, and maintenance. The induction phase usually lasts about one week, with the goal of helping the patient discontinue or tremendously decrease the use of other opioids. Stabilization usually takes about one to two months. The patient is seen at least weekly, with the goal of finding the minimum dose necessary to treat the symptoms of opioid addiction. During the first two phases, it is recommended that a patient receives daily dosing. The final stage is the maintenance phase, which is also the longest, as it could be a lifetime process. During this phase, it is important to monitor and address social and family life, as well as cravings and other

drug and alcohol use. At this point, a patient should be seen at less frequent intervals, but at least once a month.⁴²

The National Institute on Drug Abuse estimates buprenorphine for a stable patient provided in a certified opioid treatment program, including medication and twice-weekly visits costs \$115 per week or \$5,980 per year.⁴³ SAMHSA, in their final rule on MAT for opioid use disorders, estimated the cost for buprenorphine and additional medical services, including behavioral health and psychosocial services, is \$4,349 per patient per year (\$4,852 USD in 2018).⁴⁴ Based on the average of these estimates, DEA estimates the cost of buprenorphine treatment is \$5,416 per year per FTE patient (USD in 2018). Public funds currently account for 90 percent of substance abuse treatments in the United States.⁴⁵ A 2015 National Survey on Drug Use and Health study found that among individuals who sought, but did not receive treatment, 30 percent reported that they did not have insurance coverage and could not afford to pay for treatment.⁴⁶ The costs of care, lack of insurance coverage, and shortage of treatment options deter some patients from seeking treatment. DEA also estimates the opportunity cost of treatment for the FTE patient to be \$2,113 per year. This includes \$302.48 in transportation costs and

⁴² McNicholas, M.D., Ph.D., *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, <https://store.samhsa.gov/shin/content/SMA05-4003/SMA05-4003.pdf>

⁴³ *How Much Does Opioid Treatment Cost?*, NATIONAL INSTITUTE ON DRUG ABUSE, <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-much-does-opioid-treatment-cost> (last updated June 2018). The base year was not provided for the cost figure, and thus is assumed to be in (or not materially different from) 2018 USD based on the date of the report.

⁴⁴ 81 FR 44712, 44732 (July 8, 2016).

⁴⁵ Note 30.

⁴⁶ <https://addiction.surgeongeneral.gov/chapter-4-treatment.pdf>. The 10 percent figure is for all diagnosed with substance use disorder, not specific to prescription opioids. Figures specific to prescription opioid substance use disorder is not available.

\$1,810.34 of forgone wages (37 visits/year multiplied by loaded hourly wage of \$24.46 multiplied by 2 hours of patient time/visit).⁴⁷ Therefore, the estimated combined total cost of treatment is \$7,529 per year per FTE patient. DEA assumes the funding of treatment cost will be available through private insurance, public assistance, private funds, or any combination thereof, to generate the economic burden reductions discussed above.

After applying the total treatment cost of \$7,529 per year to the estimated 5,183; 11,402; 18,657; 274,985; and 279,131 FTE patients treated in years 1, 2, 3, 4, and 5, respectively, the estimated total cost of treatment is \$39 million, \$86 million, \$140 million, \$2,070 million, and \$2,102 million in years 1, 2, 3, 4, and 5, respectively. The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5
Full-time-equivalent patients treated	5,183	11,402	18,657	274,985	279,131
Annual cost of treatment per patient (\$MM)	0.0075	0.0075	0.0075	0.0075	0.0075
Cost of treatment (\$MM)	39	86	140	2,070	2,102

Figures are rounded.

Treatment Cost Savings

DEA estimates that there will be cost savings from being able to dispense buprenorphine through NPs and PAs on a permanent basis, and through CNS, CRNAs,

⁴⁷ For purpose of this analysis, the estimated typical number of visits for a 6-month period patient and multiplied by two to reflect the 37 FTE visits. The transportation cost of \$302.48 is based on 2018 IRS mileage reimbursement rate of \$0.545 per mile times an assumed 30 miles round-trip times 37 visits. The loaded hourly wage of \$24.46 is based on the median hourly wages for Occupation Code 00-0000 All Occupations (\$18.58). May 2018 National Occupational Employment and Wage Estimates, United States, BUREAU OF LABOR STATISTICS, https://www.bls.gov/current/oes_nat.htm#00-0000 (last visited August 16, 2019). Average benefits for employees in private industry is 29.9 percent of total compensation. Employer Costs for Employee Compensation – June 18, 2019, BUREAU OF LABOR STATISTICS, <https://www.bls.gov/news.release/pdf/ecec.pdf> (last visited August 16, 2019). Adjusting for employer-paid legally required benefits, benefits are 22.2 percent (29.9 percent - 7.7 percent). The 22.2 percent of total compensation equates to 31.67 percent (22.2 percent / 70.1 percent) load on wages and salaries. $\$18.58 \times (1 + 0.3167) = \24.46 .

and CNMs on a temporary basis. Medicare reimburses NPs, PAs, and CNS at 85 percent of the rates for physicians under the Medicare Physician Fee Schedule (MPFS), while CRNAs and CNMs are reimbursed at 80 percent of the amount a physician is paid under the MPFS.⁴⁸ While not all treatment is funded by Medicare, public funds currently account for 90 percent of substance abuse treatments in the United States.⁴⁹ Based on the MPFS reimbursement rates, DEA estimates that MAT provided by NPs, PAs, CNS, CRNAs, and CNMs costs 17 percent⁵⁰ less than treatment provided by physicians, resulting in a cost savings relative to the full cost of treatment in the baseline regulatory environment in which NPs and PAs lose DATA-waived status in year four, and DATA-waived physicians are the only providers of MAT in years four and five.

The treatment cost of \$7,529 per FTE patient estimated in the previous section includes \$2,113 in opportunity cost, which accounts for transportation costs and forgone wages. The remaining treatment cost of \$5,416 includes the cost of medication and physician visits. Because physicians set their own rates, there is no standard price of an office visit for buprenorphine treatment, so comprehensive data are not available. However, according to an article published on www.suboxonedirectory.com, the initial evaluation appointment can range from \$200 – \$300 per hour, while the induction appointment can range from \$200 – \$400 per hour.⁵¹ After this, follow up appointments

⁴⁸ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Advanced Practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants,” October 2016. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Medicare-Information-for-APRNs-AAs-PAs-Booklet-ICN-901623.pdf>.

⁴⁹ Florence CS, Zhou C, Luo F & Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, 54 Med Care 901 (2016).

⁵⁰ $(15 \text{ percent} + 15 \text{ percent} + 15 \text{ percent} + 20 \text{ percent} + 20 \text{ percent}) / 5 = 17 \text{ percent}$.

⁵¹ “How Much Does Suboxone Cost?” The Suboxone Directory. Accessed April 16, 2020. <https://www.suboxone-directory.com/suboxone-treatment/how-much-does-suboxone-cost/>.

can cost \$125 – \$250 per visit. DEA assumes that after the evaluation and induction visits, a buprenorphine patient will visit their doctor’s office on a monthly basis. Taking the midpoint of these cost estimates, DEA estimates that the annual cost for buprenorphine treatment office visits to be \$2,800.⁵² Seventeen percent savings on \$2,800 equates to a savings of \$476 for a total treatment cost of \$7,053 (\$7,529 - \$476) per year.

After applying the reduced total treatment cost of \$7,053 per year to the estimated 5,183, 11,402, 18,657, 274,985, and 279,131 FTE patients treated in years 1, 2, 3, 4, and 5, respectively, the estimated total cost of treatment is \$37 million, \$81 million, \$132 million, \$1,952 million, and \$1,982 million in years 1, 2, 3, 4, and 5, respectively. These figures represent a treatment cost savings of \$2 million, \$5 million, \$8 million, \$118 million, and \$120 million in years 1, 2, 3, 4, and 5, respectively, or a total treatment cost savings of \$253 million over five years. The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
<i>Baseline Cost of treatment (\$MM)</i>	39	86	140	2,070	2,102	
Full-time-equivalent patients treated	5,183	11,402	18,657	274,985	279,131	
Reduced annual cost of treatment per patient (\$MM)	0.0071	0.0071	0.0071	0.0071	0.0071	
Reduced cost of treatment (\$MM)	37	81	132	1,952	1,982	
Treatment Cost Savings from Baseline (\$MM)	(2)	(5)	(8)	(118)	(120)	(253)

Figures are rounded

Cost of Obtaining DATA-waived Status

For the purposes of this analysis, DEA conservatively includes the cost of obtaining DATA-waived status as a cost of this interim final rule. Similar to the treatment cost, this

⁵² Evaluation (\$250) + induction (\$300) + 12 monthly visits (\$187.50*12) = \$2,800.

cost is not a direct result of the rule, but necessary to generate the economic burden reductions. DEA considers only CRNAs, CNS, and CNMs to be relevant to this portion of the analysis since the estimated 18,373 NPs and PAs that retain the DATA-waived eligibility as a result of the SUPPORT Act would have incurred the cost of obtaining their DATA-waiver due to the temporary eligibility granted by CARA. Therefore, NPs and PAs are excluded from this portion of this analysis.

To obtain DATA-waived status, the CRNA, CNS, or CNM first needs to meet SAMHSA's requirements and obtain approval from SAMHSA. In addition to being licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain and registered with DEA, the prospective DATA-waived CRNA, CNS, or CNM must obtain 24 hours of instruction in subject areas by training providers specified in CARA. Generally, once verified by SAMHSA, DEA is notified that a particular CRNA, CNS, or CNM meets all of the criteria. Then, upon successful completion of routine due diligence, DEA will issue a modified registration, which indicates "DATA-waived" status. There is no additional fee to DEA for the registration modification.

In addition to 24 hours of training, DEA estimates an additional three hours of administrative tasks, such as signing up for training, receiving training certificates, applying for waivers with SAMHSA, etc. Using a loaded median hourly wage for CRNAs, CNS, and CNMs of \$78.52,⁵³ the 27 hours of training and administrative tasks

⁵³ The average of the median hourly wages for Occupation Code, 29-1151 Nurse Anesthetists (\$80.75), 29-1161 Certified Nurse Midwives (\$49.89), and 29-1141 Registered Nurses (\$34.48) is \$55.04. *May 2018 National Occupational Employment and Wage Estimates, United States*, BUREAU OF LABOR STATISTICS, http://www.bls.gov/oes/current/oes_nat.htm (last visited August 15, 2019). DEA chose to average these occupational codes since they are all considered Advanced Practice Registered Nurses (APRN) because of their education, training, and duties. However, BLS does not differentiate between all Registered Nurses (RNs) and the more specialized CNS because there is no separate Standard Occupational Classification (SOC) code for CNS. Thus, wage data for Registered Nurses are used in their place. Average benefits for

equate to \$2,119.93 per person. SAMHSA provides its courses free of charge. Rounding the \$2,119.93 to \$2,100 per CRNA, CNS, or CNM and applying it to the 691 applicants in years 1, 2, 3, 4, and 5, respectively, DEA estimates the total cost of obtaining DATA-waived status is \$1 million, \$1 million, \$1 million, \$1 million, and \$0 in years 1, 2, 3, 4, and 5 respectively. The table below summarizes this analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of DATA-waived CRNAs, CNS, or CNMs	691	691	691	691	-
Cost of obtaining DATA-waived status per NP/PA (\$MM)	0.0021	0.0021	0.0021	0.0021	-
Total cost of obtaining DATA-waived status (\$MM)	1	1	1	1	0

Other Potential Costs

DEA also examined the cost of compliance. Newly DATA-waived NPs, PAs, CRNAs, CNS, and CNMs would be required to comply with various treatment-related record keeping requirements, imposing additional costs. However, a portion of the patient visitation fee can be directly attributed to compliance costs. Therefore, these costs have been included in the cost of treatment; and therefore, recordkeeping compliance cost is excluded from this analysis.

Risk of Diversion

The SUPPORT Act expands the number of DATA-waived practitioners able to treat up to 100 patients, the number of DATA-waived NPs and PAs, and the categories of practitioners, to include CRNAs, CNS, and CNMs, who may dispense FDA approved

employees in private industry is 29.9 percent of total compensation. Employer Costs for Employee Compensation – June 18, 2019, BUREAU OF LABOR STATISTICS, <https://www.bls.gov/news.release/pdf/ecec.pdf> (last visited August 16, 2019). The 29.9 percent of total compensation equates to 42.7 percent (29.9 percent / 70.1 percent) load on wages and salaries. $\$55.04 \times (1 + 0.427) = \78.52 .

narcotic drugs in schedule III, IV, or V for the purpose of opioid maintenance or detoxification treatment. DEA understands that there is potential for the abuse of these drugs, which could be worsened by the expansion in the number and types of dispensers.

Since office based opioid treatment with buprenorphine was introduced by the FDA in 2004, buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone) have become widely available in the United States. With this availability has come increased reports of misuse and diversion of buprenorphine. Studies have shown that buprenorphine is primarily diverted from prescriptions written for the treatment of addiction.⁵⁴ However, the primary reason for prescription buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone) diversion is the failure to access legitimate addiction treatment.⁵⁵ This finding suggests that increasing, not limiting, buprenorphine treatment may be an effective response to the diversion of buprenorphine.⁵⁶

The diversion of buprenorphine for self-treatment is also supported by studies of abuse rates of buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone). A study of abuse of buprenorphine and buprenorphine combined with naloxone by opioid-dependent research subjects showed a strong preference for buprenorphine (which does not include naloxone in the formula).⁵⁷ This preference is notable because the naloxone blocks the agonist effect of the buprenorphine, and

⁵⁴ Lofwall MR and Havens JR, Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine, *Drug Alcohol Dependence*, Dec. 1. 2012.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Martin, Judith, Providers' Clinical Support System for Medication Assisted Treatment Guidance, January 10, 2014. <https://pcssnow.org/wp-content/uploads/2014/02/PCSS-MATGuidanceAdherence-diversion-bup.Martin.pdf>

therefore users of buprenorphine with naloxone are less likely to experience euphoria from the drug.⁵⁸ The low endorsement⁵⁹ of the use of buprenorphine with naloxone and the low prescription rate of buprenorphine (without naloxone) in the United States indicates that the potential for abuse of these drugs is relatively low.⁶⁰ Another study of untreated injection drug users found that three out of four respondents said their intended use of buprenorphine or buprenorphine combined with naloxone was to self-medicate for addiction and/or to treat withdrawal.⁶¹ While buprenorphine and buprenorphine combined with naloxone are schedule III narcotics with a potential for diversion and abuse, academic literature seems to indicate that the diversion is not motivated by addiction to buprenorphine, but rather as a method to treat opioid addiction problems.⁶² Additionally, since NPs, PAs, CRNAs, CNS, and CNMs seeking to obtain the authority to dispense under the SUPPORT Act already have the authority to dispense controlled substances, and the SUPPORT Act only allows them to treat a specific group of patients with specific ailments, and will often be done in collaboration with or under the supervision of a qualified physician, DEA believes any added risk as a result of this rule would not be significant.

⁵⁸ Id.

⁵⁹ “Low endorsement” means that the Suboxone is not as highly sought after because the naloxone in the formula acts as an antagonist to the buprenorphine, meaning patients cannot experience the euphoria from the drug.

⁶⁰ Id.

⁶¹ Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators, JBS International, Inc., Maxwell, Jane C. November 30, 2006.

⁶² Cicero, Theodore J., Matthew S. Ellis, and Howard D. Chilcoat. “Understanding the Use of Diverted Buprenorphine.” *Drug and Alcohol Dependence* 193 (2018): 117–23. <https://doi.org/10.1016/j.drugalcdep.2018.09.007>.

Cost to DEA

As part of its core function, DEA's Diversion Control Division manages over 1.9 million DEA registrations (processing new and renewal registration applications, processing registration modification requests, issuing certificates of registration, issuing renewal notifications, conducting due diligence, maintaining and operating supporting information systems, etc.). DEA does not anticipate it will incur any additional costs as a result of conducting due diligence and processing 19,659 registration modifications for DATA-waived status over five years. DEA's Registration Section and field office representatives conduct similar registration-related due diligence and process registration modifications as part of their routine operations. As of August 2019, DEA has absorbed any extra work in processing over 5,600 registration modifications related to this interim final rule with preexisting resources, without an increase in cost to DEA. Likewise, DEA anticipates it will continue to absorb any additional work in processing the registration modifications for the duration of the analysis period.

Summary of Benefits and Costs

As described above, DEA estimates the total benefit (in the form of economic burden reduction and other cost savings) is \$63 million, \$139 million, \$227 million, \$3,349 million, and \$3,400 million in years 1, 2, 3, 4, and 5, respectively; the total cost of treatment is \$39 million, \$86 million, \$140 million, \$2,070 million, and \$2,102 million in years 1, 2, 3, 4, and 5, respectively; the total treatment cost savings is \$2 million, \$5 million, \$8 million, \$118 million, and \$120 million in years 1, 2, 3, 4, and 5, respectively; and the total cost of obtaining DATA-waived status is \$1 million, \$1 million, \$1 million, \$1 million, and \$0 in years 1, 2, 3, 4, and 5, respectively; resulting in a net benefit of \$25

million, \$57 million, \$94 million, \$1,396 million, and \$1,418 million in years 1, 2, 3, 4, and 5, respectively. The table below summarizes the benefits and costs.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total benefit (\$MM)	63	139	227	3,349	3,400
Cost of treatment (\$MM)	39	86	140	2,070	2,102
Treatment cost savings (\$MM)	(2)	(5)	(8)	(118)	(120)
Cost of obtaining DATA-waived status (\$MM)	1	1	1	1	-
Total cost (\$MM)	38	82	133	1,953	1,982
Annual net benefit (\$MM)	25	57	94	1,396	1,418

Figures are rounded.

DEA recognizes that accurately calculating the benefits of this rule rests primarily on the number of FTE patients in treatment. While DEA considers its primary estimates presented above to be reasonable, there are also inherent uncertainties in predicting these figures over time. Therefore, DEA varied its estimated number of FTE patients treated per provider plus and minus 10 percent in order to capture the likely range of benefits surrounding the primary estimate. These results are detailed in the following table. The impact of varying additional inputs are summarized in the sensitivity analysis section below.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total benefit (\$MM)	57- 69	125- 153	205- 250	3,014- 3,684	3,060- 3,740
Cost of treatment (\$MM)	35- 43	77- 94	126- 155	1,863- 2,277	1,891- 2,312
Treatment cost savings (\$MM)	(2)- (3)	(4)- (5)	(7)- (9)	(106)- (129)	(107)- (132)
Cost of obtaining DATA-waived status (\$MM)	1	1	1	1	-
Total cost (\$MM)	34- 41	74- 90	120- 147	1,758- 2,149	1,784- 2,180
Annual net benefit (\$MM)	23- 28	51- 63	85- 103	1,256- 1,535	1,276- 1,560

At a 3 percent discount rate, the present value of benefits is \$6,308 million, the present value of costs is \$3,681 million and the net present value (NPV) is \$2,627 million. At a 7 percent discount rate, the present value of benefits is \$5,345 million, the present value of costs is \$3,119 million and the NPV is \$2,226 million.⁶³ The net benefits in years one to five equate to an annualized net benefit of \$574 million at 3 percent discount rate and \$543 million at 7 percent discount rate over five years. The table below summarizes the present value and annualized benefit calculations.

	3%	7%
Present value of benefits (\$MM)	6,308	5,345
Present value of costs (\$MM)	3,681	3,119
Net present value (\$MM)	2,627	2,226
Annualized net benefit – 5 years (\$MM)	574	543

Figures are rounded.

Consistent with OMB’s Guidance for EO 13771,⁶⁴ DEA assessed the costs and cost savings directly attributable to this rule. The costs directly attributable to this rule are the cost to CNS/CRNA/CNMs of obtaining DATA-waived status. The cost savings directly attributable to this rule are the reduction in costs that result from NPs, PAs, CNS, CRNAs, and CNMs providing MAT rather than physicians. Both are discussed in detail above. Below is a summary of the present value of net costs attributable to this interim final rule, with the annualized net cost figure adjusted to 2016 dollars.

	3%	7%
Present value of costs (\$MM)	4	3
Present value of cost savings (\$MM)	(219)	(185)
Net present value (\$MM)	(215)	(182)

⁶³ See OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB Circular A-4, REGULATORY ANALYSIS (2003).

⁶⁴ Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum M-17-21, Implementing Executive Order 13771, Titled “Reducing Regulation And Controlling Regulatory Costs” 10 (2017).

Annualized net costs – 5 years (\$MM)	(44)	(42)
---------------------------------------	------	------

The annualized net cost savings from this rulemaking will be \$44 million at a 3 percent discount rate and \$42 million at a 7 percent discount rate over the next five years.

Sensitivity Analysis

The five-year net benefit and the associated NPV are sensitive to the assumptions and estimates for variables that were factored into the calculation. The variables are:

- Number of DATA-waived NPs, PAs, CRNAs, CNS, and CNMs.
- Number of FTE patients treated per NP/PA.
- Economic burden reduction per patient.
- Treatment success rate.
- Annual cost of treatment per patient.
- Cost of obtaining DATA-waived status.

Sensitivity analysis was conducted by adjusting the variables up and down by 10 percent and recording the change in the NPV. The NPV was most sensitive to the change in the number of DATA-waived practitioners, the economic burden reduction per patient, and the treatment success rate. A 10 percent change in these variables resulted in a 23 percent to 24 percent change in the NPV. The NPV was the least sensitive to the change in cost of obtaining DATA-waived status. A 10 percent change resulted in minimal change in the NPV. The remaining variables were moderately sensitive. A 10 percent change in the annual cost of treatment resulted in a 14 percent change in the NPV, while a 10 percent change in the number of FTE patients treated per provider resulted in a 10 percent change in the NPV, respectively.

The table below summarizes the sensitivity analysis.

Variables	NPV (\$MM), 3% discount rate			NPV (\$ MM), 7% discount rate		
	10% less	Base	10% more	10% less	Base	10% more
Number of DATA-waived NPs, PAs, CRNAs, CNS, and CNMs	2,024	2,627	3,221	1,714	2,226	2,729
Percent of Base	77%	N/A	123%	77%	N/A	123%
Number of Full-time-equivalent patients treated Practitioner	2,365	2,627	2,890	2,003	2,226	2,448
Percent of Base	90%	N/A	110%	90%	N/A	110%
Economic burden reduction per patient	1,997	2,627	3,258	1,692	2,226	2,760
Percent of Base	76%	N/A	124%	76%	N/A	124%
Treatment success rate	1,997	2,627	3,258	1,692	2,226	2,760
Percent of Base	76%	N/A	124%	76%	N/A	124%
Annual cost of treatment per patient	2,995	2,627	2,259	2,537	2,226	1,914
Percent of Base	114%	N/A	86%	114%	N/A	86%
Annual cost of obtaining DATA-waived status	2,627	2,627	2,623	2,226	2,226	2,223
Percent of Base	100%	N/A	100%	100%	N/A	100%

Executive Order 12988, Civil Justice Reform

This interim final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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 Executive Order 13132. The interim 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 interim 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.

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 was good cause to exempt this interim final rule from notice and comment. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

This interim final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted 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

This rule is a major rule as defined by the Congressional Review Act. 5 U.S.C. 804.

This rule will result in an annual effect on the economy of \$100 million or more as a result of economic burden reductions. However, it will not cause a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign based companies in domestic and export markets. DEA has

submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

Paperwork Reduction Act of 1995

This action does not impose a new nor modify an existing collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521.

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, this DEA interim final rule amends 21 CFR parts 1301 and 1306 as follows:

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

1. The authority citation for 21 CFR 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.

2. In § 1301.28:
 - a. Revise the first sentence in paragraph (b)(1)(i);
 - b. Revise (b)(1)(iii)(B); and
 - c. Remove paragraph (b)(1)(iii)(C).

The revisions read as follows:

§ 1301.28 Exemption from separate registration for practitioners dispensing or

prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

* * * * *

(b)(1)* * *

(i) The individual practitioner is registered under § 1301.13 as an individual practitioner and is a “qualifying physician” as defined in section 303(g)(2)(G)(ii) of the Act (21 U.S.C. 823(g)(2)(G)(ii)); a “qualifying other practitioner” as defined in section 303(g)(2)(G)(iv) of the Act (21 U.S.C. 823(g)(2)(G)(iv)) who is a nurse practitioner or physician assistant; or during the period beginning on October 1, 2018 and ending on October 1, 2023, a “qualifying other practitioner” as defined in section 303(g)(2)(G)(iv) of the Act (21 U.S.C. 823(g)(2)(G)(iv)) who is clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.* * *

* * * * *

(iii) * * *

(B) The applicable number is—

(1) 100 if not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of Health and Human Services of the need and intent of the practitioner to treat up to 100 patients;

(2) 100 if the practitioner holds additional credentialing, as defined in 42 CFR 8.2;

(3) 100 if the practitioner provides medication-assisted treatment using covered medications (as such terms are defined in 42 CFR 8.615) in a qualified practice setting

(as described in 42 CFR 8.615); and

(4) 275 if the practitioner meets the requirements specified in 42 CFR 8.610 through 8.655.

* * * * *

PART 1306—PRESCRIPTIONS

3. The authority citation for 21 CFR part 1306 is revised to read as follows:

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

4. In § 1306.04, add paragraph (d) to read as follows:

§ 1306.04 Purpose of issue of prescription.

* * * * *

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)(G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), 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 issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

5. In § 1306.07, add a reserved paragraph (e) and paragraph (f) to read as follows:

§1306.07 Administering or dispensing of narcotic drugs

* * * * *

(f) Notwithstanding the definition of dispense under section 102(10) of the Act (21 U.S.C 802(10)), a pharmacy may deliver a controlled substance to a practitioner, pursuant

to a prescription that meets the requirements under § 1306.04 for the purpose of administering the controlled substance by the practitioner if:

(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location, listed on the practitioner's certificate of registration;

(2) The controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2)(G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii)); and

(i) The practitioner who issued the prescription is a qualifying practitioner as defined in section 303(g) of the Act (21 U.S.C. 823(g)); and

(ii) The controlled substance is to be administered by injection or implantation;

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

(4) The prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) The controlled substance is to be administered only to the patient named on the prescription not later than 14 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 practitioner administering the controlled substance, 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.

Timothy J. Shea,
Acting Administrator.

[FR Doc. 2020-23813 Filed: 10/29/2020 4:15 pm; Publication Date: 11/2/2020]