ECONOMIC IMPACT ANALYSIS
of
Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder
[Docket No. DEA-450]

Drug Enforcement Administration
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1. INTRODUCTION

This document describes the economic analysis conducted by the Drug Enforcement Administration (DEA) in support of the regulatory analysis statements published with the final rule on "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder."

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) became law. One section of the CARA amended the Controlled Substances Act (CSA) to expand the categories of practitioners who may, under certain conditions on a temporary basis, dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. Separately, the Department of Health and Human Services (HHS), by final rule effective August 8, 2016, increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA for that purpose. The DEA is amending its regulations to incorporate these statutory and regulatory changes.

2. REGULATORY ANALYSES INVESTIGATED

2.1 EXECUTIVE ORDERS 12866 AND 13563

Pursuant to Executive Order 12866 of September 30, 1993(58 FR 51735, Oct. 4, 1993), an agency must submit to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA) a regulatory impact analysis for "significant regulatory actions."

> [A] "significant regulatory action" [is] any regulatory action that is likely to result in a rulemaking 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 [Executive Order 12866].[1]

Executive Order 13563 of January 18, 2011 (76 FR 3821, Jan. 21, 2011) affirms and supplements Executive Order 12866.

2.2 EXECUTIVE ORDER 13771

Executive Order 13771 was issued on January 30, 2017 and published in the Federal Register on February 3, 2017. 82 FR 9339. This final rule is considered an EO 13771 deregulatory action.

2.3 REGULATORY FLEXIBILITY ACT

The Regulatory Flexibility Act (RFA) requires agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment.[2] The RFA applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553). As explained in the Final Rule, the DEA determined that there was good cause to exempt this Final Rule from notice and comment. Consequently, the RFA does not apply to this Final Rule.

[1] Exec. Order No. 12866, sec. 3(f), 58 FR 51735 (Sept. 30, 1993).
[2] Pub. L. No. 96–354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. 601–612).

2.4 UNFUNDED MANDATES REFORM ACT

The Unfunded Mandates Reform Act (UMRA) was enacted to avoid imposing unfunded Federal mandates on State, local, and tribal governments (SLTGs), or the private sector.[3] Most Most of UMRA's provisions apply to proposed and final rules:

- for which a general notice of proposed rulemaking (NPRM) was published, and
- that include a Federal mandate that may result in the expenditure of funds by SLTGs, in the aggregate, or by the private sector of $100 million or more in any one year, adjusted for inflation.

2.5 CONGRESSIONAL REVIEW ACT

Under the Congressional Review Act (CRA), a rule generally cannot take effect until the agency submits a rule report to each House of Congress and to the Comptroller General of the United States (head of the United States Government Accountability Office).[4] Rules not considered "major" under the CRA may take effect as they otherwise would under other applicable law once a rule report is submitted. However, "any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808(2). A rule is "major" if it results in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, or the ability of United States companies to compete with foreign companies.

[3] Pub. L. No. 104–4, 109 Stat. 48 (1995) (codified at 2 U.S.C. 1501 *et seq*.).
[4] Pub. L. No. 104–121, sec. 251, 110 Stat. 847 (1996) (codified at 5 U.S.C. 801–808).

3. ANTICIPATED ECONOMIC IMPACT OF REGULATORY ACTION

3.1 ANALYSIS OF BENEFITS AND COSTS

This analysis is limited to the provisions associated with the section of the CARA that amended the CSA to expand the categories of practitioners who may, under certain conditions on a temporary basis, dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. The HHS rule that increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA was promulgated under HHS' authority; therefore, that section of the CARA was excluded from this analysis. When HHS published its final rule, it provided an analysis of the provision that allowed an increase in the number of patients per provider. 81 Fed. Reg. 44712, 44727, July 8, 2016. Https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16120.pdf.

Benefits, in the form of economic burden reductions (health care costs, criminal justice costs, and lost productivity costs), are expected to be generated from the expansion of the categories of practitioners who may dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. The DEA anticipates the expansion of the categories of practitioners will lead to an increase in the number of treatment providers, which will lead to an increase in the number of patients (who did not have access to treatment prior to this rule) treated, resulting in the reduction in the economic burden due to opioid abuse.

Cost of the rule is associated with treatment cost and the cost to practitioners of obtaining authority to dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance

treatment or detoxification treatment. The costs of obtaining dispensing authority and treating patients are required to generate the benefits of the rule, and thus, included in this analysis. Although the new treatment providers in the expanded category, 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 section 3.1.7 Other Potential Costs. 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 treatment or detoxification treatment. This risk is discussed in section 3.1.8 Risk of Diversion.

3.1.1 Increase in the Number of Data-Waived Providers

Specifically, section 303 of the CARA temporarily expands the types of practitioners who may dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment without being separately registered as a narcotic treatment program to include "qualifying other practitioner," a nurse practitioner (NP) or physician assistant (PA) who meets certain qualifications set forth in paragraph 823(g)(2)(G)(iv) during the period beginning on the date of enactment (July 22, 2016) and ending October 1, 2021. The CARA further provides that the Secretary of Health and Human Services may, by regulation, revise the foregoing requirements for being a qualifying other practitioner. Individual practitioners who received an exemption 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, are commonly referred to as "DATA-waived."[5]

[5] On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000 (DATA), amending the Controlled Substances Act (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.

As the eligibility of NPs and PAs for DATA-waived status is new, the DEA does not have a strong basis to estimate the number of NPs and PAs that would request DATA-waived status. Due to the temporary nature of this provision and the mandatory 24 hour training requirement (physicians are required to attend only 8 hours of training), NPs and PAs may be less inclined to invest time and resources to become DATA-waived. However, the lower labor cost of NPs and PAs may incentivize practices that wish to have a DATA-waivered practitioner on staff to have the practitioner/s be NPs and PAs rather than physicians and be able treat more patients.[6] The DEA assumes these factors will partially offset each other and the ratio of DATA-waived NPs and PAs to total NPs and PAs will be two-thirds that of DATA-waived physicians to total physicians. The DEA also assumes that all DATA-waived NPs and PAs will be certified in years one and two as the burden of obtaining DATA-waived status outweighs the incentives as the expiration of the temporary provision nears.

To estimate the number of NPs and PAs that may become DATA-waived, the DEA calculated the ratio of DATA-waived physicians to all physicians and applied two-thirds of this ratio to the number of NPs and PAs. Based on DEA records, as of 2/21/2017, there are 33,663 DATA-waived physicians (including all patient limits) to 1,247,716 total physicians for a ratio of 0.0270-to-1. Two-thirds of this ratio is 0.018-to-1. Applying this ratio to a total

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1222). Prior to DATA, the Controlled Substances Act 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, and physician assistants) 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.

[6] A large majority of NPs (72%) and PAs (80%) work in 'Office of Physicians' and 'General Medical and Surgical Hospitals' as reported in the U.S. Bureau of Labor Statistics (BLS) Occupational Employment Statistics, Occupational Employment and Wages, May 2016, for 29-1171 Nurse Practitioners and 29-1071 Physician Assistants. Likewise, the DEA anticipates the majority of DATA-waived NPs and PAs will be in 'Office of Physicians' and 'General Medical and Surgical Hospitals' with DATA-waived physicians.

of 291,048 NPs and PAs, the DEA estimates 5,235 NPs and PAs will become DATA-waived.

For the purposes of this analysis, "year 1" corresponds to 7/22/2016-9/30/2017; "year 2" corresponds to 10/1/2017-9/30/2018; "year 3" to 10/1/2018-9/30/2019; "year 4" to 10/1/2019-10/1/2019-9/30/2020; and "year 5" to 10/1/2020-9/30/2021. The DEA anticipates that all NP and PA applications for DATA-waived status will occur in years 1 and 2. This anticipated leveling off, implies that any NPs and PAs interested in applying for DATA-waived status will do so by the end of year 2. The DEA records indicate that there were 3,504 DATA-waived NPs and PAs at the end of year 1 (based on internal DEA report dated 9/28/2017).[7] The DEA estimates an additional 1,731 for a total of 5,235 in year 2, and the number of DATA-waived NPs and PAs will remain steady at 5,235 in years 3, 4, and 5.

3.1.2 Increase in the Number of Patients Receiving Treatment

As discussed above, the expansion of DATA-waived providers to include NPs and PAs is expected to result in more opioid-addicted patients treated. The number of "full-time-equivalent"[8] patients for each newly DATA-waived NPs and PAs is expected to be low in the first year and steadily increase as their practices mature. While the patient limit is set at 30 patients[9] per DATA-waived NP or PA, the actual number of patients treated on a "full-time-equivalent" basis is expected to be lower for a variety of reasons: delays in patient referrals;

[7] DEA's count of number of DATA-waived NPs and PAs may not precisely correspond with those verified by SAMHSA, due to time required to process the modification request and/or subsequent lapse in registration. As of December 2017 there were 4,665 DATA-waived NPs and PAs.

[8] For the purposes of this analysis, "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 is also used by Substance Abuse and Mental Health Services Administration (SAMHSA) in its estimate of patient increases. Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 44712, 44733 (July 8, 2016).

[9] The "patient limit" is the "…total number of patients at any one time…" 21 U.S.C. 823(g)(2)(B)(iii)(I). Additionally after one year, the NP or PA may notify the Secretary of HHS to treat up to 100 patients. As stated earlier, the Secretary may by regulation change the patient limit; and on July 8, 2016, the Secretary issued a final rule increasing this number to 275. 81 Fed. Reg. 44712. For the purposes of this analysis, the DEA conservatively assumes that the patient limit of 30 will apply for NPs and PAs over the analysis period.

patients discontinuing treatment without 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 patient limit; demands on NPs and PAs to treat patients for other than maintenance and detoxification; private insurance and Medicaid coverage limitations[10]; travel difficulties for patients located in rural areas[11]; etc.

For the purposes of this analysis, the DEA assumes the average full-time-equivalent patients for each DATA-waived NP or PA will be 5 in the first year, 6.5 in the second year, 8 in the third year, 9.5 in the fourth year, and 11 in the fifth year.

Any increase in the number of patients receiving treatment as result of this rule will depend not only on the size of the expansion in the number of providers offering to provide services, but also on the number of opioid addicts who currently would like to participate in a recovery program, but are unable to because no providers are available. DEA does not have data on the numbers of such addicts. There are currently about 2 million people in the U.S. who meet the diagnostic criteria for prescription opioid abuse and dependence.[12] Of these, about 10% have received any type of treatment in the past year.[13] DEA assumes that there is sufficient demand to join a recovery program among the remaining 90%, that the expanded patient capacity created by this rule will be filled.

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[10] Rinaldo SG, 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.

[11] Sigmon SC. Access to treatment for opioid dependence in rural America: challenges and future directions. JAMA Psychiatry. 2014;71(4):359-360. doi:10.1001/jamapsychiatry.2013.4450.

[12] 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)

[13] https://addiction.surgeongeneral.gov/chapter-4-treatment.pdf. The 10% 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.

Applying the assumed average full-time-equivalent patients for each group of DATA-waived NPs or PAs in the year they obtained DATA-waived status, the DEA estimated the number of full-time-equivalent patients expected to be treated for each year. The average full-time-equivalent patients treated of 5, 6.5, 8, 9.5, and 11in years 1, 2, 3, 4, and 5, respectively, were applied to Group 1 (the group of 3,504 NPs and PAs that obtained DATA-waived status in year 1) to estimate the number of patients treated by this group in each of the five years. The average full-time-equivalent patients treated of 5, 6.5, 8, and 9,5 in years 2, 3, 4, and 5 were applied to Group 2 (the group of 1,731 NPs and PAs that obtained DATA-waived status in year 2) to determine the number of patients treated by this group in each of the four remaining years. Adding the number of full-time-equivalent patients treated by the two groups, the DEA estimates a total of 17,520, 31,431, 39,284, 47,136, and 54,989 full-time-equivalent patients 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: NPs and PAs obtaining DATA-waived status in year 1	3,504	3,504	3,504	3,504	3,504
Average full-time-equivalent patients treated per NP/PA per year for Group 1	5.0	6.5	8.0	9.5	11.0
Patients treated by Group 1	17,520	22,776	28,032	33,288	38,544
Group 2: NPs and PAs obtaining DATA-waived status in year 2	-	1,771	1,771	1,771	1,771
Average full-time-equivalent patients treated per NP/PA per year for Group 2	-	5.0	6.5	8.0	9.5
Patients treated by Group 2	-	8,655	11,252	13,848	16,445
Total Number of DATA-waived NPs and PAs	3,504	5,235	5,235	5,235	5,235
Full-time-equivalent patients treated	17,520	31,431	39,284	47,136	54,989

3.1.3 Economic Burden of Prescription Opioid Abuse

The total U.S. economic burden (healthcare costs, criminal justice costs, and lost costs) of prescription opioid abuse in 2013 was estimated at $78.5 billion.[14] The lost productivity costs were approximately 53% of the total economic burden, healthcare substance abuse treatment costs) were approximately 37% of the total economic burden, and criminal justice costs were approximately 10% of the total economic burden.[15] As stated in the research article, the estimated $78.5 billion ($81.8 billion USD in 2016)[16] in total U.S. economic burden is based on the 1.935 million opioid abuse patients reported by Substance Abuse and Mental Health Services Administration's (SAMHSA) 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), the DEA estimates the total economic burden is $75.7 billion ($78.9 billion USD in 2016).[17] Dividing this total economic burden by the number of patients, the DEA

[14] 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 also references this estimate for total economic burden of prescription drug abuse.

[15] *Id.*

[16] Adjusted to 2016 dollars using the GDP deflator, released December 31, 2017, consistent with OMB's Guidance for Executive Order 13771. 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). All figures given below are 2016 dollars unless otherwise indicated.

[17] 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 $78.9B after backing out baseline substance abuse treatment cost and adjusting for USD 2016).

estimates the annual economic burden of prescription opioid abuse is $41,000 per person (USD in 2016).

3.1.4 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. This success rate rate dropped to 8.6 percent once Suboxone was discontinued.[18] Reductions in prescription 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.[19] [20]

For the purposes of this analysis, the DEA assumes a patient (or full-time-equivalent) who is successfully undergoing treatment will generate an economic burden reduction of $41,000 annually. Patients are expected to have varying lengths of treatment. Some patients are expected to receive extended treatments while others discontinue their treatment. Based on the figures above, the DEA estimates a success rate of 29% (average of 49% and 8.6% from above) in treating abuse and addiction and generating economic burden reductions.[21] Several other

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[18] This success rate was measured two months after treatment terminated.

[19] *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.

[20] 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%. 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 October 19, 2017.

[21] NIH's report describes that 49% and 8.6% "reduced" abuse, not "eliminated," suggesting the potential of reducing the $41,000 in economic burden, not eliminating the costs. The DEA does not have a basis on which to

studies have also shown that office based buprenorphine treatment has 50-60% retention rates at 6-months.[22]

Applying the $41,000 economic burden reduction and a success rate of 29% to the estimated 17,520, 31,431, 39,284, 47,136, and 54,989 full-time-equivalent patients treated in years 1, 2, 3, 4, and 5, respectively, the estimated total economic burden reduction is $208 million, $374 million, $467 million, $560 million, and $654 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	17,520	31,431	39,284	47,136	54,989
Economic burden reduction per patient ($MM)	0.041	0.041	0.041	0.041	0.041
Treatment success rate	29%	29%	29%	29%	29%
Total economic burden reduction ($MM)	208	374	467	560	654

Figures are rounded.

3.1.5 Cost of Treatment

As stated previously, while the cost of treatment is not directly attributable to this rule, 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

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quantify this reduction. However, considering that there are patients that are successfully treated and no longer under treatment, the DEA believes a success rate of 29% 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,

[22] *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

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.[23]

A May 2017 report from National Institute on Drug Abuse estimates "buprenorphine for a stable patient provided in a certified OTP including medication and twice-weekly visits: $115.00 per week or $5,980.00 per year."[24] SAMHSA estimates the cost for buprenorphine and additional medical services, including behavioral health and psychosocial services, at $4,349 per patient per year ($4,649 USD in 2016).[25] Another estimate expects patients without health insurance to pay approximately $500 per month ($6,000 annually) for buprenorphine treatment.[26] Based on the average of the abovementioned estimates, the DEA estimates the cost of buprenorphine treatment is $5,543 per year per full-time-equivalent patient (USD in 2016). Public funds currently account for 90% of substance abuse treatments in the United States.[27] A 2015 National Survey on Drug Use and Health study found that among individuals who made an effort to get treatment but did not receive treatment, 30% reported that they did not have

[23] 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

[24] *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 May 2017). The base year was not provided for the cost figure, and thus is assumed to be in (or not materially different from) 2016 USD based on the date of the report.

[25] 81 Fed. Reg. 44712, 44732 (July 8, 2016).

[26] Clinical Tools, Inc., *Cost of Buprenorphine Treatment to Patients*, BUPPRACTICE, https://www.buppractice.com/node/4368 (last visited July 24, 2017). The base year was not provided for the cost figure, and thus is assumed to be in (or not materially different from) 2016 USD based on the date of the data.

[27] Note 12.

insurance coverage and could not afford to pay for treatment.[28] The costs of care, lack of insurance coverage, and shortage of treatment options are deterrents for some addicts on why they do not seek treatment. The DEA also estimates the opportunity cost of treatment for the full-time equivalent patient to be $2,046 per year. This includes $299.70 in transportation and $1,745.89 of forgone wages (37 visits/year multiplied by loaded hourly wage of $23.59 multiplied by 2 hours of patient time/visit).[29] Therefore, the combined total cost of treatment $7,589 per year per full-time-equivalent patient. The DEA assumes the funding of treatment will be available through private insurance, public assistance, private funds, or any combination thereof, in order to generate the economic burden reductions discussed above.

Applying the total treatment cost of $7,589 per year to the estimated 17,520, 31,431, 39,284, 47,136, and 54,989 full-time-equivalent patients treated in years 1, 2, 3, 4, and 5, respectively, the estimated total cost of treatment is $133 million, $238 million, $298 million, $358 million, and $417 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	17,520	31,431	39,284	47,136	54,989
Annual cost of treatment per patient ($MM)	0.0076	0.0076	0.0076	0.0076	0.0076

[28] Note 13.

[29] 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 full-time equivalent visits. The transportation cost of $299.70 is based on 2016 IRS mileage reimbursement rate of $0.54 per mile times an assumed 30 miles round-trip times 37 visits. The loaded hourly wage of $23.59 is based on the median hourly wages for Occupation Code 00-0000 All Occupations ($17.81). May 2016 National Occupational Employment and Wage Estimates, United States, BUREAU OF LABOR STATISTICS, http://www.bls.gov/oes/current/oes_nat.htm (last visited August 8, 2017). Average benefits for employees in private industry is 30.4% of total compensation. Employer Costs for Employee Compensation – March 2017, BUREAU OF LABOR STATISTICS, https://www.bls.gov/news.release/pdf/ecec.pdf (last visited August 8, 2017). Adjusting for employer-paid legally required benefits, benefits are 22.6% (30.4% - 7.8%). The 22.6% of total compensation equates to 32.5% (22.6% / 69.6%) load on wages and salaries. $17.81 x (1 + 0.325) = $23.59.

	Year 1	Year 2	Year 3	Year 4	Year 5
Cost of treatment ($MM)	133	238	298	358	417

Figures are rounded.

3.1.6 Cost of Obtaining DATA-waived Status

For the purposes of this analysis, the DEA treats the cost of obtaining DATA-waived status as a cost. One view may be that resources expended by NPs and PAs are investments that would be paid back in the form of patient visitation fees, and therefore, the cost is included in the patient treatment cost estimated above. However, attributing the portions of treatment cost as "offset" for the initial cost of obtaining DATA-waived status is arguable. Therefore, the DEA conservatively includes the cost of obtaining DATA-waived status as a cost. Similar to the treatment cost, this cost is not a direct result of the rule, but necessary to generate the economic burden reductions.

To obtain DATA-waived status, the NP or PA 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 the DEA, the prospective DATA-waived NP or PA must obtain 24 hours of instruction in subject areas by training providers specified in CARA. Generally, once verified by SAMHSA, SAMHSA will notify DEA that SAMHSA has verified that a particular NP or PA 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, the DEA estimates an additional 3 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 NPs and PAs of $69.91,[30] the 27 hours of training and administrative tasks equate to $1,888 per person. Additionally, the enrollment cost for the 24 hours of training is estimated to cost $199. Although, SAMHSA provides its courses for free, not all the courses have been developed as of the date of this analysis, and the DEA conservatively estimates an enrollment cost of $199 per person.[31] In total, the DEA estimates the cost of obtaining DATA-waived status is $2,087 per person, rounded up to $2,100 per NP or PA. Applying $2,100 per person to the 3,504 applicants in year 1 and 1,731 in year 2, the DEA estimates the total cost of obtaining DATA-waived status is $7 million and $4 million in years 1 and 2, respectively. The table below summarizes this analysis.

	Year 1	Year 2
Number of DATA-waived NPs and PAs	3,504	1,731
Cost of obtaining DATA-waived status per NP/PA ($MM)	0.0021	0.0021
Total cost of obtaining DATA-waived status ($MM)	7	4

3.1.7 Other Potential Cost

The DEA also examined the cost of compliance. A DATA-waived NP or PA 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

[30] Average of median hourly wages for Occupation Code 29-1171 Nurse Practitioners ($48.52) and 29-1071 Physician Assistants ($48.79) is $48.66. *May 2016 National Occupational Employment and Wage Estimates, United States*, BUREAU OF LABOR STATISTICS, http://www.bls.gov/oes/current/oes_nat.htm (last visited August 8, 2017). Average benefits for employees in private industry is 30.4% of total compensation. *Employer Costs for Employee Compensation – March 2017*, BUREAU OF LABOR STATISTICS, https://www.bls.gov/news.release/pdf/ecec.pdf (last visited August 8, 2017). The 30.4% of total compensation equates to 43.7% (30.4% / 69.6%) load on wages and salaries. $48.66 x (1 + 0.437) = $69.91.

[31] *See, e.g.*, Clinical Tools, Inc., BUPPRACTICE, https://www.buppractice.com/ (last visited August 10, 2017).

compliance costs. Therefore, these costs have been determined to be included in the cost of treatment; and therefore, recordkeeping compliance cost is excluded from this analysis.

3.1.8 Risk of Diversion

The CARA expands the categories of practitioners, to include NPs and PAs, who may dispense FDA approved narcotic drug in schedule III, IV, or V for the purpose of opioid maintenance treatment or detoxification treatment. The DEA understands that there is potential for the abuse of these drugs, which could be worsened by the increase in dispensing.

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.[32] However, the primary reason for prescription buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone) diversion is the failure to access legitimate addiction treatment.[33] This finding suggests that increasing, not limiting, buprenorphine treatment may be an effective response to the diversion of buprenorphine.[34]

The diversion of buprenorphine for self-treatment is also supported by studies of abuse rate of buprenorphine (Subutex) and buprenorphine/naloxone (Suboxone). A study of abuse of buprenorphine and buprenorphine/naloxone by opioid-dependent research subjects showed a

[32] Lofwall, Michelle R., Havens, Jennifer R., Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine, Drug Alcohol Dependence, Dec. 1. 2012.
[33] Id.
[34] Id,

strong preference for buprenorphine (which does not include naloxone in the formula).[35] This preference is notable because the naloxone blocks the agonist effect of the buprenorphine, and therefore users of buprenorphine with naloxone are less likely to experience euphoria from the drug.[36] The low endorsement[37] 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.[38] In another study of untreated injection drug users found that three out of four respondents said their intended use of buprenorphine or buprenorphine/naloxone was to self-medicate for addiction and/or to treat withdrawal.[39] While buprenorphine and buprenorphine/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. Additionally, since the NPs and PAs seeking to obtain the authority to dispense under the CARA already have the authority to dispense controlled substances, and the CARA 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, the DEA believes any added risk as a result of this rule would not be significant.

[35] Martin, Judith, Providers' Clinical Support System for Medication Assisted Treatment Guidance, January 10, 2014.
[36] Id,
[37] "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.
[38] Id.
[39] Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators, JBS International, Inc., Maxwell, Jane C. November 30, 2016

3.1.9 Cost to DEA

As part of its core function, the DEA's Diversion Control Division manages over 1.7 million DEA registrations (processing new and renewal registration applications, processing registration modification request, issuing certificates of registration, issuing renewal notifications, conducting due diligence, maintaining and operating supporting information systems, etc.). The DEA does not anticipate it will incur any additional cost as a result of conducting due diligence and processing 5,235 registration modifications for DATA-waived status. 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 December 2017, the DEA has absorbed any extra work in processing over 4,600 registration modifications related to this final rule with preexisting resources, without increase in cost to DEA. Likewise, the DEA anticipates it will continue to absorb any additional work in processing the registration modifications for the duration of the 'qualifying other practitioner' provision (ending October 1, 2021) without incurring additional costs.

3.2 SUMMARY OF BENEFITS AND COSTS

As described above, the DEA estimates the total benefit (economic burden reduction) is $208 million, $374 million, $467 million, $560 million, and $654 million in years 1, 2, 3, 4, and 5, respectively; the total cost of treatment is $133 million, $238 million, $298 million, $358 million, and $417 million in years 1, 2, 3, 4, and 5, respectively; and the total cost of obtaining DATA-waived status is $7 million and $4 million in years 1 and 2, respectively; resulting in a net benefit of $68 million, $132 million, $169 million, $202 million, and $237 million in years 1, 2, 3, 4, and 5, respectively. The table below contains the summary of benefits and costs.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total benefit ($MM)	208	374	467	560	654
Cost of treatment ($MM)	133	238	298	358	417
Cost of obtaining DATA-waived status ($MM)	7	4	-	-	-
Total cost ($MM)	140	242	298	358	417
Annual net benefit ($MM)	68	132	169	202	237

Figures are rounded.

At 3% discount rate, the present value of benefits is $2,044 million, the present value of costs is $1,315 million and the net present value (NPV) is $729 million. At 7% discount rate, the present value of benefits is $1,796 million, the present value of costs is $1,156 million and the NPV is $640 million.[40] The net benefits in years 1 to 5 equate to an annualized net benefit of $159 million at 3% and $156 million at 7% over five years. The table below summarizes the present value and annualized benefit calculations.

	3%	7%
Present value of benefits ($MM)	2,044	1,796
Present value of costs ($MM)	1,315	1,156
Net present value ($MM)	729	640
Annualized net benefit – 5 years ($MM)	159	156

Figures are rounded.

3.3 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 and PAs.
- Number of full-time-equivalent patients treated per NP/PA.

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

- 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% and recording the change in the NPV. The NPV was most sensitive to the change in economic burden reduction per patient and treatment success rate. A 10% change in these variables resulted in a 28% change in the NPV. The NPV was the least sensitive to the change in cost of obtaining DATA-waived status. A 10% change resulted in minimal change in the NPV. The remaining variables were all moderately sensitive. A 10% change in the annual cost of treatment resulted in an 18% change in the NPV; and a 10% change in the number of DATA-waived NPs and PAs or in the number of full-time-equivalent patients treated per NP/PA resulted in a 10% change in the NPV.

The table below summarizes the sensitivity analysis.

	NPV ($MM), 3% discount rate			NPV ($ MM), 7% discount rate		
Variables	10% less	Base	10% more	10% less	Base	10% more
Number of DATA-waived NPs and PAs	654	729	802	573	640	704
Percent of Base	90%	N/A	110%	90%	N/A	110%
Number of Full-time-equivalent patients treated per NP/PA	657	729	799	576	640	701
Percent of Base	90%	N/A	110%	90%	N/A	110%
Economic burden reduction per patient	523	729	933	459	640	819
Percent of Base	72%	N/A	128%	72%	N/A	128%
Treatment success rate	523	729	933	459	640	819
Percent of Base	72%	N/A	128%	72%	N/A	128%
Annual cost of treatment per patient	859	729	599	754	640	526
Percent of Base	118%	N/A	82%	118%	N/A	82%
Annual cost of obtaining DATA-waived license	730	729	729	641	640	639

Percent of Base	100%	N/A	100%	100%	N/A	100%

4. ECONOMIC ANALYSIS RESULTS

4.1 EXECUTIVE ORDERS 12866 AND 13563

This final rule was developed in accordance with the principles of Executive Orders 12866 and 13563. The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866, and therefore, has been submitted to the OMB for review.

4.2 EXECUTIVE ORDER 13771

Executive Order 13771 (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 Fed. Reg. 9339 The guidance on EO 13771 from the Office of Management and Budget (OMB), issued April 5, 2017, explains that EO 13771 deregulatory actions are final actions that have totals costs less than zero. The guidance further explains that “one-time” regulatory actions that expand production options, “enabling rules,” would generally qualify as EO 13771 deregulatory actions. This rule expands the options for opioid treatment. Therefore, this final rule qualifies as an EO 13771 deregulatory action.

Dispensing of buprenorphine by NPs and PAs was previous prohibited. Cost savings are expected to be generated by allowing this previously forgone treatment modality. Although there are some costs to providers from this rule, such as the costs of training, on net there are expected to be cost savings from this rule. This economic impact analysis contains a quantified estimate of the costs of this rule, but the cost savings to providers from being able

to dispense buprenorphine through NPs and PAs, rather than physicians, has not been quantified.

4.3 Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553). As explained in the final rule, the DEA determined that there was good cause to exempt this Final Rule from notice and comment. Consequently, the RFA does not apply to this Final Rule.

4.4 Unfunded Mandates Reform Act

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

4.5 Congressional Review Act

This rule will result in a positive 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. The DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.