(4) The slopes of a linear fit trendline calculated from the individual data collected for fan speed, input power, and load differential during at least three 120-second intervals include both positive and negative values (e.g., two positive and one negative slope value or one positive and two negative slope values). If three positive or three negative slopes are determined in succession, additional sampling intervals are required until slopes from three successive 120-second intervals include both positive and negative values.

2.6. Calculation of Ambient Air Density.

For any references to ambient air density, ρ0, in AMCA 230–23, calculate ρ0, expressed in kg/m3 when using SI units or lbm/ft3 when using I–P units, as follows:

$$\rho_0 = \left(\frac{p_b - 0.378p_p}{R(t_{d0} + 273.15)}\right) \quad \text{SI}$$

$$\rho_0 = 70.73\left(\frac{p_b - 0.378p_p}{R(t_{d0} + 459.67)}\right) \quad \text{I-P}$$

where p_b is the measured barometric pressure of the air, T_{d0} is the measured dry-bulb temperature of the air, p_p is the partial vapor pressure, R is the gas constant, which are all determined according to section 8.2 of AMCA 230–23.

[FR Doc. 2023–15712 Filed 8–7–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–702]

RIN 1117–AB73

Dispensing of Narcotic Drugs To Relieve Acute Withdrawal Symptoms of Opioid Use Disorder

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is revising existing regulations to expand access to medications for the treatment of opioid use disorder pursuant to the Easy Medication Access and Treatment for Opioid Addiction Act (the Act). The Act directed DEA to revise its regulation to allow practitioners to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both).

DATES: This final rule is effective on August 8, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

I. Legal Authority and Background

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA), and the Controlled Substances Import and Export Act (CSIEA), as amended.[1] DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to end. These regulations are designed to ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed system of control for the manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA.[2] The CSA authorizes the Administrator of DEA (by delegation of authority from the Attorney General) to register an applicant to manufacture, distribute or dispense controlled substances if the Administrator determines such registration is consistent with the public interest.[3] The CSA further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA.[4]

[1] 21 U.S.C. 801–971.

[2] 21 U.S.C. 822 (all persons must register with DEA unless they meet an exception as provided for in 21 U.S.C. 822(c) or qualify for a waiver of registration under a regulation promulgated pursuant to 21 U.S.C. 822(d)).

[3] 21 U.S.C. 823.

[4] 21 U.S.C. 871(b) and 958(f).

II. Background and Summary of Changes

To combat substance use disorders and assist individuals in receiving proper treatment, DEA published regulations in October 1974 to implement the Narcotic Addict Treatment Act of 1974 (NATA), allowing for practitioners to administer and dispense certain narcotic medications for detoxification or maintenance treatment as long as they were separately registered as a narcotic treatment program (NTP).[5] An ''emergency treatment'' section was added to DEA regulations to allow physicians to administer (but not prescribe) one day's worth of narcotic drugs, for not more than three continuous days, ''for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.'' [6] This rule became known as the ''Three Day Rule,'' and is currently codified at 21 CFR 1306.07(b). The current regulation allows for ''a physician who is not specifically registered to conduct a narcotic treatment program'' to administer (but not prescribe) narcotic drugs for not more than one day at one time for not more than three days ''for the purpose of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment.'' [7]

On December 11, 2020, the President signed the Easy Medication Access and Treatment for Opioid Addiction Act (the Act) into law as Public Law 116–215. One of the provisions of the Act directed DEA to revise 21 CFR 1306.07(b) ''so that practitioners . . . are allowed to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating

[5] 39 FR 37986; see also 21 CFR 1306.07(a).

[6] 39 FR 37986; see also 21 CFR 1306.07(b).

[7] 21 CFR 1306.07(b).

maintenance treatment or detoxification treatment (or both).'' [8] The goal of the Act is to significantly expand immediate and emergency access to medications for individuals suffering from acute withdrawal symptoms while the individual awaits further, long-term treatment. The House Report accompanying the Act explains that expanding medication dispensing to a three-days' supply at one time alleviates the burden on both the patient, specifically transportation issues for those with opioid use disorder (OUD), and on the practitioner from having to treat the same patient multiple days in a row.[9] The Report further states that appropriate treatment can lead to ''better retention rates in treatment and recovery, and lower rates of relapse.'' [10] Additional data underscores this fact—roughly one in twenty patients treated for a non-fatal overdose in an emergency department died within one year of their visit, many within two days; and two-thirds of these deaths can be attributed directly to subsequent opioid-related overdoses.[11]

Allowing a practitioner to supply three days' worth of narcotic drugs at one time may help reduce these deaths by providing a short-term maintenance level of medications while arrangements are made for further, more permanent treatment. Therefore, DEA amends the regulatory language in 21 CFR 1306.07(b) as directed by Congress.

VI. Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), 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.[12] DEA concludes that ''good cause'' exists to promulgate this rule as a final rule rather than a proposed rule for the following reasons.

The Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics estimates 108,642 drug overdose deaths occurred in the U.S. during the 12-month period ending in February 2022, an increase of approximately 11,500 more people or nearly 12 percent more deaths than the previous year.[13] Specifically, the estimated number of overdose deaths from opioids increased from 72,930 for the 12-month period ending in February 2021 to 81,857 in the 12-month period ending in February 2022.[14] Given the increasing number of overdose deaths associated with the opioid epidemic, and because Congress directed DEA to amend 21 CFR 1306.07(b) in the Easy Medication Access and Treatment for Opioid Addiction Act, DEA concludes that it would be unnecessary and contrary to the public interest to undertake a notice and comment rulemaking prior to the implementation of this rule. As such, DEA concludes that ''good cause'' exists within the meaning of the APA to promulgate this rule as a final rule rather than a proposed rule.

Additionally, under the APA, agencies must generally provide a 30-day delayed effective date for final rules.[15] An agency may dispense with the 30-day delayed effective date requirement ''for good cause found and published with the rule'' or for ''a substantive rule which grants or recognizes an exemption or relieves a restriction''.[16] For the reasons just discussed, DEA concludes that such good cause exists to justify an immediate effective date. Therefore, DEA makes this rule effective immediately.

Executive Orders 12866 (Regulatory Planning and Review) and 13563, (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 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). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866.

After consideration of the economic, interagency, budgetary, legal, and policy implications of this final rule, DEA has determined that this rule is not a significant regulatory action under E.O. 12866, and accordingly it has not been reviewed by the Office of Management and Budget. While DEA is unable to quantify the benefits of this final rule, the potential benefits are anticipated to be disproportionally large compared to any cost associated with this rule.

Analysis of Benefits and Costs

This final rule amends DEA regulations to incorporate the Easy Medication Access and Treatment for Opioid Addiction Act (the Act). One of the provisions of the Act directed DEA to revise 21 CFR 1306.07(b) ''so that practitioners . . . are allowed to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both).'' Below is the analysis of the revision to 21 CFR 1306.07(b).

DEA has examined the benefits and costs of this final rule and believes it is of net economic benefit. DEA does not have a good measure of the number of impacted patients or the number of patient-practitioner emergency treatment events pursuant to 21 CFR 1306.07(b). However, the analysis shows that, even on a per-patient basis, the rule will be of net benefit. DEA welcomes any comment on the number of affected patients and patient-provider encounters along with references and sources for information and data.

Baseline Scenarios—Patient Types

DEA examined two baseline scenarios based on types of patients impacted by the final rule. These two types form the two baselines from which the impact of the final rule is analyzed. While emergency treatment of acute withdrawal symptoms is not restricted to the emergency department (ED) of a hospital, DEA believes that the vast majority of the treatment is and will be performed at hospital EDs. Therefore, for the purposes of this analysis, DEA refers to ''ED'' as the location of emergency treatment.

Scenario 1—Returning Patients: who would, under current regulations, return to the ED for second and third days of medication. With the final rule implemented, these patient actions are

[8] Easy Medication Access and Treatment for Opioid Addiction Act, Public Law 116–215, Division B, Title III, Section 1302 (Dec. 11, 2020); see also 21 U.S.C. 829 note.

[9] See pg. 2–3 of the House Report of the Committee on Energy and Commerce on H.R. 2281 (Report 116–587).

[10] *Id.*

[11] *Many People Treated for Opioid Overdose in Emergency Departments Die Within 1 Year,* National Institute on Drug Abuse. *https://nida.nih.gov/news-events/nida-notes/2020/04/many-people-treated-opioid-overdose-in-emergency-departments-die-within-1-year.* Published April 2, 2020. Last accessed November 4, 2022.

[12] 5 U.S.C. 553(b)(B).

[13] Provisional Drug Overdose Death Counts, National Center for Health Statistics, Centers for Disease Control and Prevention. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.* Updated July 13, 2022. Last accessed July 19, 2022.

[14] Ibid.

[15] 5 U.S.C. 553(d).

[16] 5 U.S.C. 553(d)(1), (3).

estimated to result in a lower net burden to patient and practitioner.

Scenario 2—One-time Patients: who would, under current regulations, not return to the ED after the first day of medication. With the final rule implemented, these patient actions are estimated to result in a small increase in costs associated with medication and potentially a large benefit from successful treatment.

DEA does not currently have a basis to estimate the number of each patient type. The analysis evaluates the impact of the final rule for a single emergency treatment event for both baseline scenarios. Additionally, there is a third possible patient type, where the patient returns for the second but not the third day of medication. However, this third type is not analyzed because the analysis of the two baseline scenarios described above is expected to provide the low and high estimates, and the impact of the third possible patient type is expected to be somewhere between the two baseline scenarios described above.

The analysis below examines the impact of the final rule in three general areas:

(1) Impact on treatment providers.

(2) Impact on patients.

(3) Cost and benefit of treatment.

Bureau of Labor Statistics (BLS) occupational wage data is used to calculate labor cost and cost savings for treatment providers and patients.[17] While there are many occupations in the BLS data that may represent treatment providers, DEA selected the occupation that best corresponds with ED personnel that would provide treatment or other service. The occupation and mean hourly wage is:

- 29–1228 Physicians, All Other; and Ophthalmologists, Except Pediatric, $85.70.[18]

The occupation code that best represents the patient and the corresponding mean hourly wage is:

- 00–0000 All Occupations, $27.07.[19]

Additionally, BLS reports that average benefits for private industry is 29.2 percent of total compensation. The 29.2 percent of total compensation equates to 41.2 percent (29.2 percent/70.8 percent) load on wages and salaries.[20] The load of 41.2 percent is added to each of the hourly rates to estimate the loaded hourly rates.

Table 1 lists the hourly wage, load, and loaded hourly wage for physicians ($85.70 + 35.31 = $121.01) and patients ($27.07 + $11.15 = $38.22) for each of the occupations.

TABLE 1—LOADED HOURLY WAGES

Occupation	Hourly wage ($)	Load for benefits ($)	Loaded hourly wage ($)
Physician	85.70	35.31	121.01
Patient	27.07	11.15	38.22

* Weighted average of Physician, NP, and PA.

Scenario 1: Returning Patients

Under current regulations, the patient returns for two additional visits, where the physician is estimated to spend time to examine and administer the narcotic drug for each of the visits. Additionally, the patient is expected to incur cost of travel to the ED.

Under the final rule, the patient is assumed to receive one day's dose during the emergency treatment and leave the treatment facility with dosages for the second and third days and would not need to return to the provider, saving costs for both provider and patient.

Additionally, DEA anticipates the ED will also save administrative cost from not needing to check-in and check-out a patient. However, DEA does not have a basis to quantify the administrative cost.

The economic impact for Returning Patients is detailed below:

(1) *Provider Time Savings:* The provider cost savings is estimated by applying the estimated time for treatment to the hourly wage rate of a provider. Based on Emergency Medicine Provider Productivity by American College of Emergency Physicians, a physician is expected to spend 20 minutes (or 40 minutes for two visits) to provide emergency treatment.[21] From Table 1, the provider average loaded hourly wage is $121.01. As can be seen on Table 2, applying 40 minutes to the loaded hourly wage results in an estimated cost savings of $80.67.

(2) *Patient Wait and Treatment Time Savings:* The patient wait and treatment time cost savings is estimated by applying the estimated amount of time a patients is in an ED by the hourly wage of the patient. Based on data from the CDC,[22] patient wait and treatment time is three hours. Since two visits are saved, the total times savings is six hours. From Table 1, the patient average loaded hourly wage is $38.22. As can be seen on Table 3, applying six hours to the loaded hourly wage results in an estimated cost savings of $229.32.

(3) *Patient Travel Time Benefit:* The patient travel time cost savings is estimated by applying the estimated amount of time a patient travels (both to and from the ED) by the hourly wage of the patient. Based on research from the Pew Research Center, rural travel time is 17.0 minutes, suburban is 11.9 minutes, and urban is 10.4 minutes.[23] Most people in the U.S. do not live in rural areas.[24] While a larger population in urban areas is likely to lead to more patients seeking emergency treatment at lower travel times, DEA does not have a basis to determine the proportion of affected patients that are in rural, urban, and suburban areas. As such, DEA does not have a strong basis on which to weigh the times, so the middle of the three times was used to estimate patient travel time to an ED, or 11.9 minutes. The travel time to and from the ED for each visit is then 23.8 minutes, or 47.6 minutes for two trips. From Table 1, the patient average loaded hourly wage is

[17] BLS, May 2020 National Occupational Employment and Wage Estimates United States. *https://www.bls.gov/oes/current/oes_nat.htm.* (Access 2/27/2022.)

[18] Id.

[19] BLS, May 2020 National Occupational Employment and Wage Estimates United States. *https://www.bls.gov/oes/current/oes_nat.htm.* (Access 2/27/2022.)

[20] BLS, ''Employer Costs for Employee Compensation—September 2021'' (ECEC).

[21] ACEP Emergency Medicine Practice Committee. Emergency Medicine Provider Productivity. *American College of Emergency Physicians.* September 2009.

[22] National Hospital Ambulatory Medical Care Survey: 2018 Emergency Department Summary Tables. *CDC.*

[23] Pew Research Center. How far Americans live from the closest hospital differs by community type. *www.pewresearch.org/fact-tank/2018/12/12/how-far-americans-live-from-the-closest-hospital-differs-by-community-type/,* December 12, 2018.

[24] Ratcliff M, Burd C, Holder K, Fields. Defining Rural at the U.S. Census Bureau, U.S. Census Bureau. Issued December 2016.

$38.22. As can be seen on Table 3, applying 47.6 minutes in hours to the loaded hourly wage results in an estimated cost savings of $30.32.

(4) *Patient Travel Cost Benefit:* The patient travel cost savings is estimated by applying the number of miles a patient travels to and from the ED by the cost per mile. Based on research from the Pew Research Center, rural travel distance to the ED is 10.5 miles, suburban is 5.6 miles, and urban is 4.4 miles.[25] Most people in the U.S. do not live in rural areas.[26] While a larger population in urban areas is likely to lead to more patients seeking emergency treatment at lower travel times, DEA does not have a basis to determine the proportion of affected patients that are in rural, urban, and suburban areas. As such, DEA does not have a strong basis on which to weigh the distances, so the middle of the three distances was used to estimate patient travel distance to an ED, or 5.6 miles. Travel mileage cost can be estimated using the Internal Revenue Service travel reimbursement rate for businesses of 58.5 cents per mile.[27] The cost of travel for one trip is then $3.28. As can be seen on Table 3, the total cost of travel to and from the ED for both visits is $13.10 ($5.6 \times \$0.585 \times 4$).

(5) *Medication Cost and Patient Outcome:* Medication cost and patient outcome is expected to be essentially the same. Under current regulations, the patient returns to the ED for two additional days of medicine. Under the final rule, the patient is dispensed two additional days of medicine. Assuming the patient takes the medication as directed by the provider, the patient received the same medical and medicine-assisted treatment. Therefore, patient outcome is expected to be essentially the same.

TABLE 2—SCENARIO 1—IMPACT ON PROVIDER

	Current			DFR			Net cost/ (cost savings)
	Loaded hourly rate ($)	Minutes	Amount ($)	Loaded hourly rate ($)	Minutes	Amount ($)	
Provider time savings (2 visits)	121.01	40	80.67				(80.67)
Cost (Cost Savings)							(80.67)

TABLE 3—SCENARIO 1—IMPACT ON PATIENT

	Current			DFR			Net cost/ (cost savings)
	Loaded hourly rate ($)	Minutes	Amount ($)	Loaded hourly rate ($)	Minutes	Amount ($)	
Travel Cost to ER (2 visits)	38.22	47.6	30.32				(30.32)
Wait time plus treatment time (2 visits)	38.22	360	229.32				(229.32)
Cost of Travel to ER	N/A	N/A	4.96				(13.10)
Cost of Medication	N/A	N/A	*49.29	N/A	N/A	*49.29	
Cost (Cost Savings)							(272.74)

*$49.29 comes from daily medication pricing of $16.43 per day for 3 days. The pricing calculation can be found later under Scenario 2, economic impact (3), Medication Cost.

In summary, for scenario 1, where the patients would have returned to the ED for the second- and third-days' medication, the final rule will allow for a considerable cost savings for both the patient and provider. The reduction in time in the ED for the patient represents the bulk of the benefit, or $229.32. Including cost savings for travel time and travel cost, the total cost savings per patient is $272.74. The provider is expected to have a time savings of $80.67 per patient.

Therefore, the combined net cost savings is $353.41 ($80.67 + $272.74) for each patient under baseline scenario 1.

Scenario 2—One-Time Patients

Under current regulations, if the patient does not return, the patient will only receive one day of medication. The practitioner will have examined the patient and dispensed only one day of medication.

Under the final rule, the patient will be able to receive three days of medication with just one visit to the ED. The increased medication may lead to an improved patient outcome, resulting in benefits associated with lower societal cost of opioid use disorder, discussed below. Furthermore, additional physician's time will not be needed to dispense medication, resulting in time and cost savings to the ED.

The economic impact for One-time Patients is detailed below:

(1) *Provider Time:* There is no change in the required provider time and cost because there is only one visit and one examination under both the current regulation and the final rule.

(2) *Patient Wait and Treatment Time, Travel Time, and Travel Cost:* There is no change in patient wait and treatment time, travel time, and travel cost because the patient does not return to the ED under both current regulations and the final rule.

[25] Pew Research Center. How far Americans live from the closest hospital differs by community type. *www.pewresearch.org/fact-tank/2018/12/12/how-far-americans-live-from-the-closest-hospital-differs-by-community-type/,* December 12, 2018.

[26] Ratcliff M, Burd C, Holder K, Fields. Defining Rural at the U.S. Census Bureau, U.S. Census Bureau. Issued December 2016.

[27] Internal Revenue Service. Standard Mileage Rates. *www.irs.gov/tax-professionals/standard-mileage-rates,* Accessed March 9, 2022.

(3) *Medication Cost:* The increased flexibility from the rule will allow a greater amount of medication to be dispensed, adding to the cost of medication. Because buprenorphine is predominantly used for maintenance, detoxification, or maintenance and detoxification treatment of opioid use disorder in EDs, the cost of buprenorphine is used to estimate the cost of medication. Based on a 2021 research report from the National Institute on Drug Abuse (NIDA), the estimated cost of buprenorphine is $115 per week, or $16.43 per day.[28] As shown in Table 5, the two additional days of medication equates to an additional medication cost of $32.86 (16.43 × 2).

(4) *Treatment Benefit:* The increased medication dispensed at the ED is expected to result in better patient outcomes for some patients. Under current regulations, the patient receives only one day of medicine and does not return. Under the final rule, the patient is dispensed two additional days of medicine. Assuming the patient takes the medication as directed by the provider, the patient is more likely to have a better outcome.

In the short term, the benefit is from a lower chance of an overdose or death following discharge from an ED. While not everyone seeking emergency treatment is an overdose patient, according to a 2020 study, ''. . . emergency department patients with nonfatal opioid or sedative/hypnotic drug overdose have exceptionally high risks of death from unintentional overdose, suicide, and other causes. ED-based interventions offer potential for reducing these patients' overdose and other mortality risks.'' [29]

In the long term, initiating opioid treatment by dispensing up to three days' supply may increase the odds for a successful treatment of opioid use disorder. In a 2015 study of the efficacy of various interventions for opioid dependence, the study concludes that among opioid-dependent patients, ED-initiated buprenorphine treatment ''significantly increased engagement in addiction treatment, reduced self-reported illicit opioid use, and decreased use of inpatient addiction treatment services.'' [30]

A study published in 2021 of the societal costs for OUD found that the ''[C]osts for opioid use disorder and fatal opioid overdose in 2017 were estimated to be $1.02 trillion. The majority of the economic burden is due to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdose.'' [31] According to the report, in 2017 total non-fatal costs are $471 billion and total fatal costs are $550 billion and there were 2.1 million persons ages 12 years and older with an OUD, and 47,000 fatal opioid overdoses.[32] Non-fatal costs include costs associated with health care, substance use disorder treatment, criminal justice, lost productivity, and the value of reduced quality of life. Dividing the total non-fatal cost of $471 billion by the number of persons ages 12 and older with an OUD, 2.1 million, the societal cost of non-fatal OUD is approximately $224,000 ($471 billion/2.1 million) per person per year. While DEA is unable to quantify how many of the affected patients will be successfully treated for OUD or how many fatal opioid overdoses will be avoided as a result of this final rule, the potential economic benefit is disproportionally large compared to any cost associated with this rule.

TABLE 4—SCENARIO 2—IMPACT ON PROVIDER

	Current			DFR			Net cost
	Loaded hourly rate ($)	Minutes	Amount ($)	Loaded hourly rate ($)	Minutes	Amount ($)	
Provider time savings (2 visits)	.....	.....	.....	.....	.....	.....	.....
Cost (Cost Savings)	.....	.....	.....	.....	.....	.....	.....

TABLE 5—SCENARIO 2—IMPACT ON PATIENT

	Current			DFR			Net cost
	Loaded hourly rate ($)	Minutes	Amount ($)	Loaded hourly rate ($)	Minutes	Amount ($)	
Travel Cost to ER (2 visits)	.....	.....	.....	.....	.....	.....	.....
Wait time plus treatment time (2 visits)	.....	.....	.....	.....	.....	.....	.....
Cost of Travel to ER	.....	.....	.....	.....	.....	.....	.....
Cost of Medication	N/A	N/A	16.43	N/A	N/A	49.29	32.86
Cost (Cost Savings)	.....	.....	.....	.....	.....	.....	32.86

In summary, for scenario 2, where patients would not have returned to the ED for second- and third-days' medication, the primary economic impact of this final rule is from improved patient outcomes. In the short

[28] NIDA. ''How much does opioid treatment cost?'' National Institute on Drug Abuse, 13 Apr. 2021, *https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-much-does-opioid-treatment-cost.* Accessed 20 Sep. 2022.

[29] Goldman-Mello S, Olfson M, Lidon-Moyano C, Schoenbaum M. Mortality following nonfatal opioid and sedative/hypnotic drug overdose. *Am J Prev Med*. 2020.59:59–67.

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

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

[32] Id.

term, the benefit is from a lower chance of an overdose or death following discharge from an ED. In the long term, initiating opioid treatment by dispensing up to three days' supply may increase the odds for a successful treatment of opioid use disorder, reducing the societal cost of opioid use disorder. As discussed above, the societal cost of non-fatal cost of opioid use disorder is approximately $224,000 per person per year.

As discussed above, in order to obtain the patient outcome benefit, the only increased cost will be an increase in medication dispensed that will cost the patient an additional $32.86.

Summary of Benefits and Costs

DEA examined the economic impact of the final rule for two baseline scenarios based on anticipated patient actions: (1) Returning Patients and (2) One-time Patients. As discussed above, this final rule is expected to have net positive benefits and costs.

For scenario 1, where the patients would have returned to the ED for second- and third-days' medication, the final rule is estimated to generate a total cost savings of $272.74 to each patient and a net cost savings to a provider of $80.67, for a combined net cost savings of $353.41 for each patient treated under baseline scenario 1.

For scenario 2, where patients would not have returned to the ED for second- and third-days' medication, the primary economic impact is from improved patient outcomes. In the short term, the benefit is a lower chance of an overdose or death following discharge from an ED. In the long term, initiating opioid treatment by dispensing up to three days' supply may increase the odds for a successful treatment of opioid use disorder, reducing the societal cost of opioid use disorder. As discussed above, the societal cost of non-fatal cost of OUD is approximately $224,000 per person per year, while the cost of this rule under scenario 2 is $32.86 per patient.

While DEA is unable to estimate the number of patients under scenario 1 or 2, DEA estimates that there is a net benefit for both scenarios, and therefore, the economic impact of this final rule will be a net benefit.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on 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 has determined that there is good cause to exempt this final rule from pre-publication notice and comment. Consequently, the RFA does not apply to this final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This final rule does not impose a new collection requirement under the Paperwork Reduction Act of 1995 (PRA).[33] This final rule does not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rulemaking is not a ''major rule'' under the Congressional Review Act.[34] DEA will submit a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 2, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, the Drug Enforcement Administration amends 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

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

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

■ 2. In § 1306.07, revise paragraph (b) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

* * * * *

(b) Nothing in this section shall prohibit a practitioner, who is not specifically registered to conduct a narcotic treatment program, from dispensing (but not prescribing) narcotic drugs, in accordance with applicable Federal, State, and local laws relating to controlled substances, to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both). Not more than a three-day supply of such medication may be dispensed to the person or for the person's use at one time while arrangements are being made for referral for treatment. Such

[33] 44 U.S.C. 3501–3521.

[34] 5 U.S.C. 804(2)(A)–(C).

emergency treatment may not be renewed or extended.

* * * * *

[FR Doc. 2023–16892 Filed 8–7–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 230331–0089; RTID 0648–XD229]

Pacific Halibut Fisheries of the West Coast; 2023 Catch Sharing Plan; Automatic Action

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces closure of the Pacific halibut recreational fishery in the California Coast subarea of the International Pacific Halibut Commission's regulatory Area 2A. The California Coast subarea will close on August 4, 2023 at 11:59 p.m. This action is intended to conserve Pacific halibut.

DATES: Effective August 4, 2023, at 11:59 p.m., through November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Heather Fitch, 360–320–6549, *heather.fitch@noaa.gov*.

SUPPLEMENTARY INFORMATION: On April 11, 2023, NMFS published a final rule approving changes to the Pacific halibut Area 2A Catch Sharing Plan and implementing recreational (sport) management measures for the 2023 Area 2A recreational fisheries (88 FR 21503), as authorized by the Northern Pacific Halibut Act of 1982 (16 U.S.C. 773–773(k)). The Pacific Fishery Management Council (Council) 2023 Catch Sharing Plan provides a recommended framework for NMFS' annual management measures and subarea allocations based on the 2023 Area 2A Pacific halibut catch limit of 1,520,000 pounds (lb) (689 metric tons (mt)) set by the International Pacific Halibut Commission (IPHC). The Area 2A catch limit and recreational fishery allocations were adopted by the IPHC and were published in the **Federal Register** on March 7, 2023 (88 FR 14066) after acceptance by the Secretary of State, with concurrence from the Secretary of Commerce, in accordance with 50 CFR 300.62. The Area 2A Pacific halibut management measures include recreational fishery season dates, bag limits, and subarea allocations. Federal regulations at 50 CFR 300.63(c)(3) state that once NMFS has determined an area or subarea has attained or is projected to attain its area or subarea allocation, NMFS will take automatic action to close the fishery and that such closures will be determined without prior notice or opportunity to comment.

The final rule (88 FR 21503, April 11, 2023) opened the California Coast subarea May 1 through November 15, or until the subarea allocation is estimated to have been taken and the season is therefore closed, whichever is earlier. The California Coast subarea allocation is projected to be attained on August 4, 2023; therefore, the subarea will close on that date. Notice of the subarea closure will also be announced on the NMFS hotline at 206–526–6667 or 800–662–9825.

Weekly catch monitoring reports for the recreational fisheries in Washington, Oregon, and California are available on their respective state Fish and Wildlife agency websites. NMFS and the IPHC will continue to monitor recreational catches in open subareas via state sampling procedures until NMFS has determined there is not sufficient allocation for another full day of fishing, and the area is closed by the IPHC, or the season closes on September 30 in Washington and the Columbia River subarea or October 31 in Oregon, whichever is earlier.

Automatic Action

Description of the action: This automatic action provides notice of closure for the recreational fishery in the California Coast subarea, effective Friday, August 4, 2023 at 11:59 p.m.

Reason for the action: The purpose of this action is to close the California Coast subarea to avoid exceeding the subarea allocation. As of July 31, anglers in the subarea have harvested 37,429 lb (16.98 mt) from an allocation of 39,520 lb (17.93 mt), leaving 2,091 lb (0.95 mt) remaining. Weekly catch amounts have averaged 2,674 lb (1.21 mt). Therefore, NMFS estimates that the subarea allocation will be attained by August 4, 2023, and the subarea is therefore closed on that date.

Classification

NMFS issues this action pursuant to the Northern Pacific Halibut Act of 1982. This action is taken under the regulatory authority at 50 CFR 300.63(c)(3), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(3)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. The California Department of Fish and Wildlife provided updated landings data to NMFS on July 31, 2023, showing that through this date, fishery participants in the recreational fishery off of California had caught 95 percent of the California Coast subarea allocation. NMFS uses weekly catch rates to project when subarea allocations will be attained. This action should be implemented as soon as possible to provide sufficient notice to fishery participants of the subarea closure date. As this action closes the subarea on August 4, 2023, implementing this action through proposed and final rulemaking would risk exceeding the subarea allocation. Implementation of this rulemaking in a timely manner is necessary so that planning for the subarea closure can take place, and for business and personal decision making by the regulated public impacted by this action, which includes recreational charter fishing operations, associated port businesses, and private anglers who do not live near the coastal access points for this fishery, among others. To ensure the regulated public is fully aware of this action, notice of this regulatory action will also be provided to anglers through a telephone hotline, news release, and by the relevant state fish and wildlife agencies. No aspect of this action is controversial, and actions of this nature were anticipated in regulations at 50 CFR 300.63(c)(3).

For the reasons discussed above, there is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date and make this action effective August 4, 2023, as a delay in effectiveness of this action would risk exceeding the subarea allocation.

Authority: 16 U.S.C. 773–773k.

Dated: August 3, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–16958 Filed 8–3–23; 4:15 pm]

BILLING CODE 3510–22–P