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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1301**

**[Docket No. DEA-450]**

**RIN 1117-AB42**

**Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Comprehensive Addiction and Recovery Act (CARA) of 2016, which became law on July 22, 2016, 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, 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 Drug Enforcement Administration (DEA) is hereby amending its regulations to incorporate these statutory and regulatory changes.

**DATES:** Effective: January 22, 2018.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:** It has been determined this is a major rule within the meaning of the Congressional Review Act (CRA). 5 U.S.C. 804(2). Major rules generally cannot take effect until 60 days after the date on which the rule is published in the Federal Register. 5 U.S.C. 801(a)(3). However, the CRA provides that “any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor 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. As is discussed below, DEA finds there is good cause to issue these amendments as a final rule without notice and comment, because these amendments merely conform the implementing regulations with recent amendments to the CSA contained in CARA that have already taken effect. Accordingly, DEA has determined this rule will take effect January 22, 2018.

## **Background and Legal Authority**

### **Pertinent Provisions of the CARA**

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) into law as Public Law 114-198. Section 303 of the CARA amended certain provisions of 21 U.S.C. 823(g)(2), which is the subsection of the Controlled Substance 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 treatment or detoxification treatment. Maintenance treatment is the dispensing of a narcotic drug, in excess of twenty-one days, for the treatment of dependence upon heroin or other morphine-like drugs (21 U.S.C. 802(29)). A detoxification treatment is the term given when a narcotic drug is dispensed in decreasing doses, not exceeding one hundred and eighty days, "to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug," with the ultimate goal of bringing a patient to a narcotic drug-free state (21 U.S.C. 802(30)).

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. Whereas prior to the CARA, only qualified *physicians* were permitted to dispense narcotic drugs in this manner, the CARA now temporarily permits certain nurse practitioners and physician assistants to qualify to do so. The CARA achieves this result by (1) inserting the term "qualifying practitioner" in place of "qualifying physician" in 21 U.S.C. 823(g)(2)(B)(i) and (2) defining "qualifying practitioner" to include not only a physician, but also (until October 1, 2021) a "qualifying other practitioner," which includes a nurse practitioner or physician assistant who meets certain qualifications set forth in paragraph 823(g)(2)(G)(iv).

More precisely, section 303 of the CARA defines "qualifying other practitioner" as a nurse practitioner or physician assistant who satisfies each of the following criteria:

- (I) The nurse practitioner or physician assistant is licensed under State law to

prescribe schedule III, IV, or V medications for the treatment of pain;

(II) The nurse practitioner or physician assistant must complete not fewer than 24 hours of initial training.

(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician; and

The Secretary determines in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner can treat and manage opiate-dependent patients. The Secretary may, by regulation, revise the requirements for being qualifying other practitioner.

This section of the CARA further provides that the Secretary of Health and Human Services (HHS) may, by regulation, revise the foregoing requirements for being a qualifying other practitioner.

The CARA also makes some technical revisions to 21 U.S.C. 823(g)(2) that do not materially alter the meaning of this subsection. Nonetheless, because the DEA regulations currently contain the older statutory language, DEA is hereby revising this part of the regulations to reflect the new statutory language.

**HHS Final Rule Increasing the Patient Limit for Purposes of 21 U.S.C. 823(g)(2)**

Under the CSA, the Secretary of HHS may, by regulation, increase the maximum number of patients that a practitioner may treat pursuant to 21 U.S.C. 823(g)(2). 21

U.S.C. 823(g)(2)(B)(iii)(III). On July 8, 2016, the Secretary issued a final rule increasing this number to 275. 81 FR 44712. As stated therein, to be eligible for the patient limit of 275, the practitioner must possess a current waiver to treat up to 100 patients under 21 U.S.C. 823(g)(2) and meet additional criteria set forth in 42 CFR 8.610-8.625.<sup>1</sup> DEA is hereby amending its regulations to reflect these new limits.

**Good Cause for Issuing this Rule as a Final Rule without Notice and Comment**

As indicated, this final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under 21 U.S.C. 823(g)(2), and where HHS does so, DEA is obligated to apply that number. As a result, DEA has no discretion not to amend its regulations as is being done in this final rule. Indeed, the new provisions issued under this final rule are already in effect by virtue of the CARA and the HHS final rule regarding patient limits. This final rule simply updates the DEA regulations to reflect these new provisions. Public comment on these amendments to the DEA regulations would therefore serve no purpose. Because notice and public comment are unnecessary, DEA finds there is good cause within the meaning of the Administrative Procedure Act (APA) to issue these amendments as a final rule without notice and comment, because these amendments

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<sup>1</sup> The HHS final rule further provides that the approval by HHS to treat up to 275 patients is for a term of three years and that the practitioner must submit a renewal request with HHS every three years to continue to treat up to 275 patients. 42 CFR 8.625-8.655.

merely conform the implementing regulations with recent amendments to the CSA contained in CARA that have already taken effect (*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 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). Therefore, we are issuing these amendments as a final rule, effective upon publication in the Federal Register. This rule constitutes final action on these changes under the APA (5 U.S.C. 553).

### **Regulatory Analysis**

As explained above, DEA is obligated to issue this final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the CARA and the HHS final rule increasing the patient limit under 21 U.S.C. 823(g)(2). In issuing this final rule, DEA has not gone beyond the statutory text enacted by Congress or the final rule issued by HHS. Thus, DEA would have to issue this 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) and 13563, (Improving Regulation and Regulatory Review*

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

1. The DEA expects that this final rule will have an annual effect on the economy of \$100 million or more in at least one year and therefore is an economically significant regulatory action. The analysis of benefits and costs is below.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is

therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under 21 U.S.C. 823(g)(2), and where HHS does so, DEA is obligated to apply that number.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. The Diversion Control Fee Account, which the DEA administers and which involves registration fees, is not directly affected. This regulatory action temporarily expanding the types of practitioners and increasing the maximum number of patients that a practitioner may treat as described in detail above represents a minor modification to the registration procedures within the Diversion Control Program and does not necessitate a change in registration fees.

4. This regulatory action is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under 21 U.S.C. 823(g)(2), and where HHS does so, DEA is obligated to apply that number. This regulatory action therefore does not raise novel legal or policy issues.



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.

#### I. Need for the Rule

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.

In addition to the legal requirement to implement the statute, this rule also implements one of the objectives of the statute; expand availability of medication-assisted treatment (MAT) for opioid addiction. As supported by research, there is a gap between those who need treatment for opioid addiction and treatment providers (“treatment gap”). An increase in treatment availability is expected to result in more patients treated.

Substance Abuse and Mental Health Services Administration (SAMHSA) independently researched the issue of the treatment gap in its recent rule: Medication Assisted Treatment for Opioid Use Disorders, 81 FR 44712, 44729 (July 8, 2016). SAMHSA found that “...there is significant unmet need for MAT treatment among

individuals with opioid use disorders... Evidence suggests that utilization of buprenorphine is limited directly by the existence of treatment limits.” A research article in American Journal of Public Health concluded that there are significant gaps between treatment need and capacity at the state and national levels, with 96% of states and District of Columbia having opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.<sup>2</sup> According to research by The Pew Charitable Trust, “[i]n the U.S. only 49 percent of people with an opioid dependence can potentially receive treatment because too few doctors prescribe the medicine, and those that do can serve only a limited number of patients because of federal restrictions.”<sup>3</sup> Also, patients located in rural areas are negatively impacted by the limits because there are fewer doctors certified to prescribe buprenorphine.<sup>4</sup> One research article examined the availability of MAT by U.S. counties and determined that more than 30 million persons live in counties without access to buprenorphine treatment.<sup>5</sup>

## II. Alternative Approaches

This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA

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<sup>2</sup> Christopher M. Jones, PharmD, MPH, Melinda Campopiano, MD, Grant Baldwin, PhD, MPH, and Elinore McCance-Katz, MD, PhD, “National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment,” *Am J Public Health*, August 2015. Vol 105. No. 8.

<sup>3</sup> Christine Vestal, “Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs,” January 15, 2016.

<sup>4</sup> *The Coming Economic Bonanza In Addiction Treatment*, Anson, Pat, (May 25, 2016), <https://www.painnewsnetwork.org/stories/2016/5/25/the-coming-economic-bonanza-in-addiction-treatment>.

<sup>5</sup> Roger A. Rosenblatt, MD, MPH, MFR1, C. Holly A. Andrilla, MS, Mary Catlin, BSN, MPH, Eric H. Larson, PhD. “Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder,” *Annals of Family Medicine*, Vol. 13, No. 1, January/February 2015.

is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under 21 U.S.C. 823(g)(2), and where HHS does so, DEA is obligated to apply that number. As a result, DEA has no discretion not to amend its regulations as is being done in this final rule. Indeed, the new provisions issued under this final rule are already in effect by virtue of the CARA and the HHS final rule regarding patient limits. This final rule simply updates the DEA regulations to reflect these new provisions; thus, no alternative approaches are possible.

### III. 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. This is a summary; a detailed economic analysis of the proposed rule can be found in the rulemaking docket at <http://www.regulations.gov>.

Benefits, in the form of economic burden (health care costs, criminal justice costs, and lost productivity costs) reductions, 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. While these costs are not directly attributable to this rule, 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. Finally, there is potential for added risk of diversion from more practitioners having the authority to dispense narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment.

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 economic burden reduction (\$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.<sup>6</sup> 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.

#### *Executive Order 12988, Civil Justice Reform*

This 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 final rule does not have substantial direct effects on the

<sup>6</sup> See OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB Circular A-4, REGULATORY ANALYSIS (2003).

States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

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

*Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs*

This final rule is considered an EO 13771 deregulatory action. The rule is an enabling rule which expands the options for opioid treatment. Details on the expected economic effects of this rule can be found in the rule's economic impact analysis.

*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, 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.

*Unfunded Mandates Reform Act of 1995*

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 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. The DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521

**List of Subjects in 21 CFR Part 1301**

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

For the reasons set out above, the DEA amends 21 CFR part 1301 as follows:

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

1. The authority citation for 21 CFR part 1301 is revised 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, revise paragraphs (b)(1)(i), (ii), and (iii) to 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)), or during the period beginning on July 22, 2016 and ending on October 1, 2021, a “qualifying other practitioner” as defined in section 303(g)(2)(G)(iv) of Act (21 U.S.C. 823(g)(2)(G)(iv)). The Secretary of Health and Human Services may, by regulation, revise the requirements for being a qualifying other practitioner.

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the individual practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary of Health and Human Services:

(A) All drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(B) Appropriate counseling and other appropriate ancillary services.

(iii)(A) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section at any one time will not exceed the applicable number. Except as provided in paragraphs (b)(1)(iii)(B) and



(C) of this section, the applicable number is 30.

(B) The applicable number is 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.

(C) The applicable number is 275 for a practitioner who has been approved by the Secretary of Health and Human Services under 42 CFR part 8 to treat up to 275 patients at any one time, and provided further that the practitioner has renewed such approval to the extent such renewal is required under this part of the HHS regulations.

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Dated: January 18, 2018

Robert W. Patterson,  
*Acting Administrator.*

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