303 of title 16, Code of Federal Regulations, as follows:

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

1. The authority citation for part 303 continues to read:

Authority: 15 U.S.C. 70 et seq.

2. Amend §303.19 by revising paragraph (a) to read as follows:

§303.19 Name or other identification required to appear on labels.

(a) The name required by the Act to be used on labels shall be the name under which the person is doing business. Where a person has a word trademark, used as a house mark, registered in the United States Patent Office, such word trademark may be used on labels in lieu of the name otherwise required. No trademark, trade names, or other names except those provided for above shall be used for required identification purposes.

By direction of the Commission.

Donald S. Clark,
Secretary.

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 treat patients suffering from 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 that 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.

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 narcotics 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) 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)(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 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 or physician assistant 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). On July 8, 2016, the Secretary issued a final rule increasing this number to 275. DEA is hereby amending its regulations to reflect this new limit.

**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 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)(2), relating to notice and comment procedures). “When 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 13563 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 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

---

1. 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 8.625–8.625.
Medication Assisted Treatment for Services Administration (SAMHSA) patients treated.

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 and 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. 2 According to research by The Pow 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.’’ 3 Also, patients located in rural areas are negatively impacted by the limits because there are fewer doctors certified to prescribe buprenorphine. 4 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. 5

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 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 coming economic bonanza in addiction treatment. 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.

The 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

3 Christine Vestal, ‘‘Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs,’’ January 13, 2016.


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 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.

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total economic burden reduction (SMM)</td>
<td>208</td>
<td>374</td>
<td>467</td>
<td>560</td>
</tr>
<tr>
<td>Cost of treatment (SMM)</td>
<td>133</td>
<td>238</td>
<td>298</td>
<td>358</td>
</tr>
<tr>
<td>Cost of obtaining DATA-waived status (SMM)</td>
<td>7</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost (SMM)</td>
<td>140</td>
<td>242</td>
<td>298</td>
<td>358</td>
</tr>
<tr>
<td>Annual net benefit (SMM)</td>
<td>68</td>
<td>132</td>
<td>169</td>
<td>202</td>
</tr>
</tbody>
</table>

Figures are rounded.

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 on 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 E.O. 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
DEPARTMENT OF THE INTERIOR
Office of Natural Resources Revenue
30 CFR Part 1218
[Docket No. ONRR–2016–0003; DS63644000 DR2PS0000.CH7000 178D0102R2]
RIN 1012–AA22
Repeal of Regulatory Amendment and Restoration of Former Regulatory Language Governing Service of Official Correspondence
AGENCY: Office of the Secretary, Office of Natural Resources Revenue, Interior.
ACTION: Final rule.
SUMMARY: The Office of Natural Resources Revenue (ONRR) is publishing this rule to repeal a 2013 direct final rule and restore the former regulatory language governing service of official correspondence.
DATES: This rule is effective January 23, 2018.
FOR FURTHER INFORMATION CONTACT: For questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, at (303) 231–3418 or by email to luis.aguilar@onrr.gov. For questions on technical issues, contact Bonnie Robson, Program Manager, Appeals & Regulations, by email to bonnie.robson@onrr.gov.
SUPPLEMENTARY INFORMATION:
I. Background
II. Explanation of Amendments
III. Procedural Matters
I. Background
ONRR’s “official correspondence” includes significant documents we send to industry, such as invoices, notices of audit, orders, and notices of enforcement. Historically, Department of the Interior (Department) regulations authorized ONRR to serve official correspondence by conventional means—U.S. mail, personal delivery, or private mailing service, such as FedEx or U.P.S. On August 23, 2013, ONRR published in the Federal Register a direct final rule amending its regulations on service of official correspondence (78 FR 52431). The 2013 direct final rule augmented the authorized methods of service to include electronic service, as long as the electronic service was secure and provided for a receipt.

II. Explanation of Amendments
This rule repeals the direct final rule (78 FR 52431) and restores the former regulatory language governing service of official correspondence in sections 1218.540(a) and (d) of title 30 of the Code of Federal Regulations (CFR). This rule removes the language that currently appears in section 1218.540(a) allowing ONRR to serve official correspondence using any electronic method of delivery that provides for a receipt of delivery, or, if there is no receipt, the date of delivery otherwise documented. This rule also removes mention of electronic service from section 1218.540(d), which pertains to constructive service. This rule does not make any substantive changes to the regulations or requirements in section 1218.540(a) or (d). It simply restores the original procedures for ONRR’s service of official correspondence by removing the amendments made in the previously published direct final rule.