



441 G St. N.W.
Washington, DC 20548

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February 7, 2018

The Honorable Chuck Grassley
Chairman
The Honorable Dianne Feinstein
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Bob Goodlatte
Chairman
The Honorable Jerrold Nadler
Ranking Member
Committee on the Judiciary
House of Representatives

Subject: *Department of Justice, Drug Enforcement Administration: Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Justice, Drug Enforcement Administration (DEA) entitled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (RIN: 1117-AB42). We received the rule on January 24, 2018. It was published in the *Federal Register* as a final rule on January 23, 2018, with an effective date of January 22, 2018. 83 Fed. Reg. 3071.

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 CSA for that purpose. DEA is amending its regulations to incorporate these statutory and regulatory changes.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). However, CRA also 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(2). DEA found that there is good cause to issue the final rule without notice and comment, because it conforms the implementing

regulations with recent amendments to CSA contained in CARA that have already taken effect. Therefore, DEA determined this final rule will take effect January 22, 2018.

Enclosed is our assessment of DEA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that DEA complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Susan A. Gibson
Deputy Assistant Administrator, Diversion Control Division
Drug Enforcement Administration
Department of Justice

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF JUSTICE,
DRUG ENFORCEMENT ADMINISTRATION
ENTITLED
“IMPLEMENTATION OF THE PROVISION OF THE COMPREHENSIVE ADDICTION
AND RECOVERY ACT OF 2016 RELATING TO THE DISPENSING OF
NARCOTIC DRUGS FOR OPIOID USE DISORDER”
(RIN: 1117-AB42)

(i) Cost-benefit analysis

The Department of Justice, Drug Enforcement Administration (DEA) summarized the cost and benefits of this final rule. DEA stated that 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. DEA also stated that the cost of compliance for new treatment providers in the expanded category is included in the estimated cost of treatment. DEA estimated the total cost of treatment to be \$133 million, \$238 million, \$298 million, \$358 million, and \$417 million in years 1, 2, 3, 4, and 5, respectively. DEA also estimated the total cost of obtaining Drug Addiction Treatment Act-waived status is \$7 million and \$4 million in years 1 and 2, respectively.

DEA highlighted that there are benefits in the form of economic burden (health care costs, criminal justice costs, and lost productivity costs) reductions. Furthermore, 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 treated, resulting in the reduction in the economic burden due to opioid abuse. DEA estimated the total benefit to be \$208 million, \$374 million, \$467 million, \$560 million, and \$654 million in years 1, 2, 3, 4, and 5 respectively.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

DEA determined that there was good cause to exempt this final rule from notice and comment. Therefore, DEA found that RFA does not apply to this final rule.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

DEA stated that 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 million or more (adjusted for inflation) in any one year.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

DEA determined that this final rule updates DEA regulations to be consistent with current federal law (as modified by The Comprehensive Addiction and Recovery Act) and current federal regulations issued by the Department of Health and Human Services. DEA stated that public comment on these amendments to DEA regulations would therefore serve no purpose. For this reason, DEA found good cause within the meaning of the Administrative Procedure Act to issue the final rule without notice and comment.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

DEA found that this final rule does not impose a new collection of information requirement under the Act.

Statutory authorization for the rule

DEA stated that it promulgated this rule pursuant to 21 U.S.C. §§ 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, and 965.

Executive Order No. 12,866 (Regulatory Planning and Review)

DEA determined 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 action. DEA stated that it provided a summary of costs and benefits in the final rule.

Executive Order No. 13,132 (Federalism)

DEA found that 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 among the various levels of government.