U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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December 4, 2020

The Honorable Lindsey Graham
Chairman
The Honorable Dianne Feinstein
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Jerrold Nadler
Chairman
The Honorable Jim Jordan
Ranking Member
Committee on the Judiciary
House of Representatives

Subject: *Department of Justice, Drug Enforcement Administration: Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment*

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 Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment" (RIN: 1117-AB55). We received the rule on November 23, 2020. It was published in the *Federal Register* as an interim final rule with request for comments on November 2, 2020. 85 Fed. Reg. 69153. The effective date of this rule is October 30, 2020.

According to DEA, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the SUPPORT Act), which became law on October 24, 2018, amended certain provisions of sections 823(g)(2) and 829a of title 21, United States Code, to expand the conditions a practitioner must meet to provide medication-assisted treatment and expand the options available for a physician to be considered a qualifying physician. *See* Pub. L. No. 115-271, §§ 3201, 3202, 132 Stat. 3894, 3943–3945. DEA stated that the SUPPORT Act removed the time period for a nurse practitioner or physician assistant to be considered a qualifying other practitioner, and revised the definition of a qualifying practitioner. DEA stated further that the SUPPORT Act also allows a pharmacy to deliver prescribed controlled substances to a practitioner's registered location for the purpose of maintenance or detoxification treatment to be administered under certain conditions by a practitioner. DEA noted that it is amending its regulations to make them consistent with the SUPPORT Act and implement the Act's requirements.

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). The 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. § 553(b)(3)(B), 808(2). Here, although DEA did not specifically mention CRA's 60-day delay in effective date requirement, DEA stated that notice and comment procedures are unnecessary, for this interim final rule, and the agency found good cause within the meaning of the Administrative Procedure Act, 5 U.S.C. § 553, to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations with recent amendments to the Controlled Substances Act that have already taken effect. *See* Pub. L. No. 91-513, 84 Stat. 1242 (Oct. 27, 1970). DEA asserted that it has no discretion with respect to these amendments. Finally, DEA noted that this interim final rule merely incorporates the statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication is unnecessary.

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. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Scott A. Brinks
Section Chief
Diversion Control Division, DEA
Department of Justice

ENCLOSURE

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 SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT FOR PATIENTS AND COMMUNITIES ACT OF 2018: DISPENSING AND ADMINISTERING CONTROLLED SUBSTANCES FOR MEDICATION-ASSISTED TREATMENT"
(RIN: 1117-AB55)

(i) Cost-benefit analysis

The Department of Justice, Drug Enforcement Administration (DEA) conducted a cost-benefit analysis for this interim final rule. DEA stated that it estimates the total benefit (in the form of economic burden reduction and other cost savings) is $63 million, $139 million, $227 million, $3,349 million, and $3,400 million in years 1 through 5, respectively; the total cost of treatment is $39 million, $86 million, $140 million, $2,070 million, and $2,102 million in years 1 through 5, respectively; the total treatment cost savings is $2 million, $5 million, $8 million, $118 million, and $120 million in years 1 through 5, respectively; and the total cost of obtaining DATA-waived[1] status is $1 million in each of years 1 through 4, and $0 in year 5. DEA estimated this would result in a net benefit of $25 million, $57 million, $94 million, $1,396 million, and $1,418 million in years 1 through 5, respectively. DEA also stated that it recognizes that accurately calculating the benefits of this rule rests primarily on the number of full time equivalent (FTE) patients in treatment. Thus DEA also provided estimates based on the number of FTE patients treated per provider, plus and minus 10 percent, in order to capture the likely range of benefits surrounding the primary estimate. Lastly, DEA stated that the annualized net cost savings from this rulemaking will be $44 million at a 3 percent discount rate and $42 million at a 7 percent discount rate over the next 5 years.

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

DEA stated that the RFA applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act. DEA determined that there was good cause to exempt this interim final rule from notice and comment procedures. Consequently, according to DEA, the RFA does not apply to this interim final rule.

[1] According to CMS, the term "DATA-waived" is used to describe individual practitioners (physicians, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) who, having received an identification number from DEA, are exempt from separate registration for dispensing or prescribing schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment per 21 C.F.R § 1301.28.

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

DEA determined that this interim 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, and will not significantly or uniquely affect small governments.

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

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

DEA stated that it found good cause within the meaning of the Administrative Procedure Act, 5 U.S.C. § 553, to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations with recent amendments to the Controlled Substances Act that have already taken effect. DEA asserted that it has no discretion with respect to these amendments. *See* Pub. L. No. 91-513, 84 Stat. 1242 (Oct. 27, 1970). Finally, DEA noted that this interim final rule merely incorporates statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication was unnecessary.

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

DEA determined that this interim final rule does not impose a new nor does it modify an existing collection of information requirement under PRA.

Statutory authorization for the rule

DEA promulgated this final rule pursuant to sections 823 and 829a of title 21, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

DEA determined that this interim final rule is economically significant under the Order and it has been submitted to the Office of Management and Budget for review.

Executive Order No. 13132 (Federalism)

DEA determined that this interim final rule does not have federalism implications and it 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.