



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

B-332414

August 17, 2020

The Honorable Lindsay 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: Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants*

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 "Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants" (RIN: 1117-AB51). We received the rule on August 6, 2020. It was published in the *Federal Register* as a final rule on July 24, 2020. 85 Fed. Reg. 44710. The final rule has an effective date of October 1, 2020.

According to DEA, the final rule adjusts the fee schedule for registration and reregistration fees necessary to recover the costs of its Diversion Control Program relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and list I chemicals as mandated by the Controlled Substances Act, Pub. L. No. 91-513, title II, 84 Stat. 1242 (Oct. 27, 1970), *classified at* 21 U.S.C. §§ 801 *et al.* DEA stated the final rule changes the fee schedule and codifies existing practices of the issuance of refunds by DEA for applicant registration fees.

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 final rule was published in the *Federal Register* on July 24, 2020. 85 Fed. Reg. 44710. The *Congressional Record* does not indicate that either House of Congress received the final rule, and the agency informed our office that it was in the process of mailing the final rule to both chambers. Email from Program Analyst, DEA, to Senior Staff Attorney, GAO (Aug. 11, 2020). The final rule has an effective date of October 1, 2020. Therefore, the final rule does not have the required 60-day delay in effective date.

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.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive, flowing style.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Scott A. Brinks  
Section Chief  
Diversion Control Division, DEA  
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  
“REGISTRATION AND REREGISTRATION FEES FOR  
CONTROLLED SUBSTANCE AND LIST I CHEMICAL REGISTRANTS”  
(RIN: 1117-AB51)

(i) Cost-benefit analysis

The Drug Enforcement Administration (DEA) estimated the primary benefit of the final rule is the continued support to the Diversion Control Program without the need for additional congressional appropriations. DEA stated the program is responsible for preventing, detecting, and eliminating the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. According to DEA, the absence of, or significant reduction in, this program would result in enormous costs for the citizens and residents of the U.S. due to the diversion of controlled substances and listed chemicals into the illicit market. DEA stated there are not costs associated with the final rule as fees to DEA are transfer payments.

DEA estimates the final rule will lead to an increase of \$318 million in fees over the 3-year period from fiscal years 2021 to 2023, or approximately \$106 million annually.

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

DEA determined the final rule would not have a significant economic impact on a substantial number of small entities.

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

DEA determined the final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$154 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.*

On March 16, 2020, DEA published a proposed rule. 85 Fed. Reg. 14810. DEA received 12 comments in response to the rule. According to DEA, of these comments, five comments were out of scope in their entirety and did not address the fee calculation or the issuance of refunds by DEA for applicant registration fees. DEA further stated two comments supported the proposed rule in part, and the remainder of the comments expressed concern about the fee increase.

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

DEA determined the final rule contained no information requirements subject to the Act.

Statutory authorization for the rule

DEA promulgated the final rule pursuant to sections 802, 821, 822, 823, 824, 830, 831, 871, 875, 877, 886a, 951, 952, 953, 956, 957, 958, and 965 of title 21, United States Code.

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

DEA determined the final rule was economically significant and stated it had been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

DEA determined the final rule does not preempt or modify any provision of state law, nor does it impose enforcement responsibilities on any state, nor does it diminish the power of any state to enforce its own laws.