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B-335554

September 5, 2023

The Honorable Richard J. Durbin
Chairman
The Honorable Lindsey Graham
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Justice, Drug Enforcement Administration: Partial Filling of Prescriptions for Schedule II Controlled Substances*

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 “Partial Filling of Prescriptions for Schedule II Controlled Substances” (RIN: 1117-AB45). We received the rule on August 28, 2023. It was published in the *Federal Register* as a final rule on July 21, 2023. 88 Fed. Reg. 46983. The effective date is August 21, 2023.

The final rule, according to DEA, amends regulations to conform with a provision of the Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (July 22, 2016), and to provide direction on gaps not addressed by legislation. DEA stated it will also be amending its regulations to update a cross-reference in a paragraph that will be redesignated with this rule.

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 21, 2023. 88 Fed. Reg. 46983. The final rule has a stated effective date of August 21, 2023. Therefore, the final rule does not have the required 60-day delay in its 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
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
“PARTIAL FILLING OF PRESCRIPTIONS FOR SCHEDULE II CONTROLLED SUBSTANCES”
(RIN: 1117-AB45)

(i) Cost-benefit analysis

The Department of Justice, Drug Enforcement Administration (DEA), discussed the costs and benefits of this final rule. DEA estimated that there is a cost to prescribers associated with the time burden of writing instructions for partial fill prescriptions. DEA further stated that the rule is estimated to lower the amount of schedule II medications dispensed and, therefore, expenditures on prescriptions. DEA noted that the rule is expected to reduce the number of unused schedule II controlled substances requiring disposal. According to DEA, partial filling is expected to reduce the quantity of unused schedule II controlled substances, which would decrease the risk of diversion, and the risk that patients or others may develop physical dependence or an addiction to prescribed schedule II controlled substances.

DEA estimated that the total cost savings of the rule will be \$659 million per year, and the total cost will be \$12 million per year, for a net cost savings of \$647 million per year over the next five years. DEA stated that at a three percent discount rate, the net present value of the cost savings over a five-year period is \$2,965 million. DEA further stated that at a seven percent discount rate, the present value of the cost savings is \$2,655 million.

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

DEA’s Administrator certified that this final rule will 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 and certified that this final rule will not result in any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually 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.*

On December 4, 2020, DEA published a proposed rule. 85 Fed. Reg. 78282. DEA received 37 comments in response to the proposed rule including from a nonprofit organization representing hospitals, a trade association representing chain drug stores, an association representing pharmacy boards, three professional pharmacist associations, practicing nurses and nurse

practitioner students, and other individual or anonymous commenters. DEA addressed comments in the final rule.

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

DEA stated that this final rule will create additional recordkeeping requirements for pharmacies regarding partial fills. According to DEA, the collection of information associated with the rule is associated with Office of Management and Budget (OMB) Control Number 1117-NEW, and has a total annual hour burden of 50,521 hours, and no additional cost is anticipated.

Statutory authorization for the rule

DEA promulgated this final rule pursuant to sections 821, 823, 829a, 831, and 871(b) of title 21, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

DEA determined that this final rule is a significant regulatory action under the Order and, therefore, stated it submitted the rule to OMB for review.

Executive Order No. 13132 (Federalism)

DEA determined that this final rule does not have federalism implications warranting application of the Order. Specifically, DEA stated that this 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.