



G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-319546

April 20, 2010

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Justice, Drug Enforcement Administration: Electronic Prescriptions for 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 “Electronic Prescriptions for Controlled Substances” (RIN: 1117-AA61). We received the rule on April 5, 2010. It was published in the *Federal Register* as an interim final rule with request for comment on March 31, 2010. 75 Fed. Reg. 16,236. The effective date of the interim final rule is June 1, 2010.

The interim final rule revises DEA’s regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The interim final rule will also permit pharmacies to receive, dispense, and archive these electronic prescriptions.

The interim final rule, a major rule under the Congressional Review Act (CRA), has an announced effective date of June 1, 2010. 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 rule was published in the *Federal Register* on March 31, 2010, but we did not receive the rule until April 5, 2010. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of the 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, with the exception of the effective date, 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: Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
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
"ELECTRONIC PRESCRIPTIONS FOR
CONTROLLED SUBSTANCES"
(RIN: 1117-AA61)

(i) Cost-benefit analysis

DEA performed a cost-benefit analysis in conjunction with the final rule. DEA estimates that the total annual costs will be:

- for practitioners' offices: \$30,244,615, using a 7-percent discount rate (\$29,602,769 using a 3-percent discount rate),
- for hospitals: \$6,241,658 using a 7-percent discount rate (\$5,352,737 using a 3-percent discount rate),
- for pharmacies: \$2,026,046 using a 7-percent discount rate (\$1,936,927 using a 3-percent discount rate), and
- for application providers: \$4,817,509 using a 7-percent discount rate (\$4,886,478 using a 3-percent discount rate).

DEA estimates that the total annualized costs associated with the interim final rule will be \$43,328,829 using a 7-percent discount rate (\$41,778,910 using a 3-percent discount rate).

DEA estimates that the annualized gross benefits of the final rule from eliminating a number of callbacks to clarify prescriptions from pharmacies to doctors will be \$419,745,516 using a 7-percent discount rate (\$438,502,110 using a 3-percent discount rate). The interim final rule could also reduce the patient's wait time at the pharmacy, which DEA estimates will provide annualized savings over 15 years of \$1 billion using a 7-percent discount (\$1.03 billion using a 3-percent discount). However, the estimate for public wait time is an upper bound, and DEA did not include it in the primary estimate for the benefits of the interim final rule. The interim final rule will also allow pharmacies to eliminate file cabinets currently used to store original prescriptions for 2 years, which DEA estimates will provide a cost-savings for pharmacies of \$1.38 million using a 7-percent discount rate (\$1.4 million using a 3-percent discount rate). DEA also lists other benefits, which it did not attempt to quantify or monetize. DEA believes the interim final rule will directly affect drug diversion effectuated through stealing prescription pads, altering legitimate prescriptions, or altering a record at a pharmacy to hide diversion from pharmacy

stock. DEA also believes that the interim final rule will help reduce adverse drug events that result from medication errors.

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

DEA determined that although the interim final rule will impact a substantial number of small entities, it will not impose a significant economic impact on any small entity directly subject to the rule.

(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 net expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more in any one year, and that the interim final rule 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 published a notice of proposed rulemaking on June 27, 2008. 73 Fed. Reg. 36,722. DEA received 229 comments in response to the proposed rule, including comments from 21 practitioner organizations, 24 pharmacy organizations, 18 states (state licensing boards of medicine and pharmacy, and three state health departments), and 18 application providers. DEA responded to comments in the final rule. 75 Fed. Reg. 16,236.

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

The interim final rule contains information collection requirements under the Paperwork Reduction Act, and those requirements have been submitted to the Office of Management and Budget for approval. DEA estimates that in the first 3 years of implementation 217,740 practitioners, 8,688 hospitals, and 65,421 pharmacies will adopt electronic prescribing for a total of 291,849 respondents. To respond, DEA expects the average practitioner to spend 0.17 hours, the average hospital or clinic to spend 2.23 hours, and the average pharmacy 0.36 hours annually or an average across all respondents of 0.27 hours per year. DEA estimates that the total 3-year burden hours will be 296,848 hours, or 98,949 hours annually.

Statutory authorization for the rule

The interim final rule is authorized by the Comprehensive Drug Abuse Prevention and Control Act of 1970, also referred to as the Controlled Substances Act, and the Controlled Substances Import and Export Act (21 U.S.C. §§ 801-971), as amended.

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

The interim final rule was determined to be an “economically significant regulatory action.” The interim final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

DEA states that this interim final rule does not have federalism implications under the Executive Order.