U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Washington, DC 20548

B-328692

December 28, 2016

The Honorable Johnny Isakson
Chairman
The Honorable Richard Blumenthal
Ranking Member
Committee on Veterans' Affairs
United States Senate

The Honorable Jeff Miller
Chairman
The Honorable Mark Takano
Acting Ranking Member
Committee on Veterans' Affairs
House of Representatives

Subject: *Department of Veterans Affairs: Tiered Pharmacy Copayments for Medications*

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 Veterans Affairs (VA) entitled "Tiered Pharmacy Copayments for Medications" (RIN: 2900-AP35). We received the rule on December 15, 2016. It was published in the *Federal Register* as a final rule on December 12, 2016. 81 Fed. Reg. 89,383.

The final rule amends regulations concerning copayments charged to certain veterans for medication required on an outpatient basis to treat nonservice-connected conditions. The final rule establishes three classes of medications for copayment purposes, identified as Tier 1, Tier 2, and Tier 3. These tiers are distinguished in part based on whether the medications are available from multiple sources, or a single source, with some exceptions. The following copayment amounts are fixed and would vary depending upon the class of medication: $5 for a 30-day or less supply of a Tier 1 medication, $8 for a 30-day or less supply of a Tier 2 medication, and $11 for a 30-day or less supply of a Tier 3 medication. According to VA, for non-exempt veterans these copayment amounts will result in lower out-of-pocket costs, thereby encouraging greater adherence to taking prescribed medications and reduce the risk of fragmented care that results when veterans use non-VA pharmacies. The final rule is effective on February 27, 2017.

Enclosed is our assessment of VA'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 VA 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: Michael P. Shores
Acting Director, Office of Regulation
Policy, and Management
Department of Veterans Affairs

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF VETERANS AFFAIRS
ENTITLED
"TIERED PHARMACY COPAYMENTS FOR MEDICATIONS"
(RIN: 2900-AP35)

(i) Cost-benefit analysis

The Department of Veterans Affairs' (VA) cost-benefit analysis was not summarized in the final rule, but can be found on VA's Web site at http://www.va.gov/orpm/, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

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

VA certified that the final rule will not have a significant economic impact on a substantial number of small entities. In the final rule, VA states that it will generally be small business neutral. VA therefore determined that this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

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

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule 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. VA states that the final rule will have no such effect on state, local, and tribal governments, or on the private sector.

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

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

On January 5, 2016, VA issued a proposed rule. 81 Fed. Reg. 196. The public comment period closed on March 7, 2016, and VA received nine comments, all of which were generally supportive. VA responded to the comments in the final rule.

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

According to VA, the final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act.

Statutory authorization for the rule

VA cited 38 U.S.C. §§ 501, 1722A (a) as authority for the final rule.

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

VA examined the economic, interagency, budgetary, legal, and policy implications of the final rule and determined it to be a significant regulatory action under Executive Order 12,866 because it is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal government communities.

Executive Order No. 13,132 (Federalism)

VA did not address Executive Order 13,132 in the final rule.