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June 9, 2014

The Honorable Bernie Sanders
Chairman
The Honorable Richard Burr
Ranking Member
Committee on Veterans' Affairs
United States Senate

The Honorable Jeff Miller
Chairman
The Honorable Michael H. Michaud
Ranking Member
Committee on Veterans' Affairs
House of Representatives

Subject: *Department of Veterans Affairs: Copayments for Medications in 2014*

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 "Copayments for Medications in 2014" (RIN: 2900-AO91). We received the rule on May 21, 2014. It was published in the *Federal Register* as a final rule on May 27, 2014. 79 Fed. Reg. 30,043.

The final rule adopts without change, an interim final rule that was published on December 30, 2013, (78 Fed. Reg. 79,315) amending the VA medical regulations to freeze the copayments required for certain medications provided by VA until December 31, 2014. Under that rule, the copayment amounts for all veterans were maintained at the same rates as they were in 2013, which were \$8 for veterans in priority groups 2–6 and \$9 for veterans in priority groups 7 and 8. On January 1, 2015, the copayment amounts may increase based on the prescription drug component of the Medical Consumer Price Index (CPI–P).

This final rule is effective on May 27, 2014. 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). However, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. §§ 553(d)(3), 808(2). The Secretary of Veterans Affairs concluded that there is good cause under 5 U.S.C. §§ 553(b)(B) and (d)(3) to dispense with the opportunity for advance notice and opportunity for public comment and good cause to publish this rule with an immediate effective date.

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 all 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: Janet Coleman
Acting Chief, Regulation Policy and Management
Office of the General Counsel
Department of Veterans Affairs

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF VETERANS AFFAIRS
ENTITLED
"COPAYMENTS FOR MEDICATIONS IN 2014"
(RIN: 2900-AO91)

(i) Cost-benefit analysis

Though VA states that it examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, it did not include a cost-benefit analysis in the final rule as published in the *Federal Register* or in the interim final rule (published on December 30, 2013, 78 Fed. Reg. 79,315). However, VA did prepare a cost-benefit analysis as part of its impact assessment for the final rule, which VA stated was included in the docket for the rule at www.regulations.gov. Although it does not yet appear on that site, VA stated that it was also available on VA's website at www1.va.gov/orpm, by following the link for "VA Regulations Published." VA stated in this impact statement dated December 20, 2013, that there are costs to VA associated with this rulemaking. According to VA, from a society-wide perspective, these effects are categorized as transfers because the costs to VA are offset by gains in value to veterans. VA included a table demonstrating the revenue impact of CY 2014 Medication Copayment Freeze for pharmacy bills, and stated that VA has estimated that the total pharmacy copayment revenue loss based on this policy alone is calculated to be \$93 million in CY 2014 and \$30 million in CY 2015, due to a 90-day holding period for copayments that were incurred from October to December 2014. Alternatively, the estimated total impact is \$63 million in FY 2014 and \$60 million in FY 2015. VA anticipates that the impact of the annual copayment cap is likely to be negligible.

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

The Secretary of Veterans Affairs certified that the final rule will not have a significant economic impact on a substantial number of small entities as they are defined by the Act. The final rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. VA states that the final rule directly affects individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. § 605(b), VA notes that the rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. §§ 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.

The Secretary of VA concluded that there was good cause under 5 U.S.C. §§ 553(b)(B) and (d)(3) to dispense with the opportunity for advance notice and opportunity for public comment and good cause to publish this rule with an immediate effective date. VA states that the final rule freezes at current rates the prescription drug copayment that VA charges certain veterans. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. According to VA, increasing the copayment amount on January 1, 2014, might cause a significant financial hardship for some veterans and may decrease patient adherence to medical plans resulting in other unpredictable negative health effects. Nevertheless, the Secretary invited public comment on the interim final rule but did not receive any comments.

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

VA states that the final rule contains no provisions constituting a collection of information under the Act.

Statutory authorization for the rule

VA did not provide the statutory authorization for the final rule but states that VA adopted the interim final rule as a final rule with no changes. The interim final rule stated that the rule is authorized by 38 U.S.C. § 1722A.

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

VA states that the economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined that it may be an economically significant regulatory action under Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

In its submission to the Comptroller General, VA did not include an analysis of the Order in either the final rule or the interim final rule.