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DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AO28

Copayments for Medications in 2012

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its medical regulations concerning the copayment required for certain medications. Under current regulations, beginning on January 1, 2012, the copayment amount must be increased based on the prescription drug component of the Medical Consumer Price Index, and the maximum annual copayment amount must be increased when the copayment is increased. A prior action “froze” the copayment amount for veterans in VA’s health care system enrollment priority categories 2 through 6 and allowed for increased copayments, as required by the current regulation, only for veterans in priority categories 7 and 8. This document freezes copayments at the current rate for veterans in priority categories 2 through 6 for the next 12 months, and thereafter resumes increasing copayments in accordance with any change in the prescription drug component of the Medical Consumer Price Index (CPI-P).

DATES: Effective Date: This rule is effective on [Insert date of publication in the FEDERAL REGISTER].

Comments must be received on or before [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted by email through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue., N.W., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026.

Comments should indicate that they are submitted in response to “RIN 2900-AO28, Copayments for Medications in 2012.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Kristin Cunningham, Director, Business Policy, Chief Business Office, 810 Vermont Avenue, Washington, D.C. 20420, 202-461-1599 (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay a \$2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a nonservice-connected disability or condition. Under 38 U.S.C. 1722A(b), VA “may,” by regulation,

increase that copayment and establish a maximum annual copayment (a “cap”). We interpret section 1722A(b) to mean that VA has discretion to determine the appropriate copayment amount and annual cap amount for medication furnished on an outpatient basis for covered treatment, provided that any decision by VA to increase the copayment amount or annual cap amount is the subject of a rulemaking proceeding. The copayment amount cannot exceed the cost to the Secretary of this medication (including administrative costs). In 66 Fed Reg 63499 we determined a method for calculating this cost. We have implemented this statute in 38 CFR 17.110.

Under current 38 CFR 17.110(b)(1), veterans are “obligated to pay VA a copayment for each 30-day or less supply of medication provided by VA on an outpatient basis (other than medication administered during treatment).” Under the current regulation, for the period from July 1, 2010, through December 31, 2011, “the copayment amount for veterans in priority categories 2 through 6 of VA’s health care system . . . is \$8.” 38 CFR 17.110(b)(1)(ii). “For veterans in priority categories 7 and 8 of VA’s health care system (see § 17.36), the copayment amount from July 1, 2010, through December 31, 2011, is \$9.” 38 CFR 17.110(b)(1)(iii). Thereafter, the copayment amount for all affected veterans is to be established using a formula based on the prescription drug component of the Medical Consumer Price Index, set forth in 38 CFR 17.110(b)(1)(iv).

Current § 17.110(b)(2) also includes a “cap” on the total amount of copayments in a calendar year for a veteran enrolled in one of VA’s health care

enrollment system priority categories 2 through 6. Through December 31, 2011, that cap is set at \$960. Thereafter, the cap is to “increase[] by \$120 for each \$1 increase in the copayment amount” applicable to veterans enrolled in one of VA’s health care enrollment system priority categories 2 through 6.

On February 22, 2011, we published a final rulemaking that established the copayment amounts discussed above, effective through December 31, 2011. 76 FR 9646. In the interim final rule which announced our intent to freeze copayments through December 31, 2011, we made clear that we would return to the CPI-P methodology “unless additional rulemaking is initiated.” 75 FR 32670. We are now undertaking “additional rulemaking” to extend the freeze in copayment rates.

In our prior rulemaking, we indicated that we were reviewing whether to revise the current regulatory formula. 76 FR 9647. We are still considering such revision, and will continue to review the matter in 2012. Therefore, as before, we continue to believe that a freeze is appropriate in light of this anticipated review and given the current economic climate, and propose to continue to delay implementation of the increase in the copayment amount (and the corresponding \$120 increase in the cap) until the completion of our review for veterans in priority categories 2 through 6 of VA’s health care system. 76 FR 9647. We continue to believe that it is appropriate to maintain the current copayment amount for these groups while we review our overall copayment methodology because these groups would be impacted more by the increase in the copayment

due to their likely greater need for medical care due to their disabilities or conditions of service. Therefore, we will continue the copayment amount at the current \$8 rate for veterans in priority categories 2 through 6 through December 31, 2012, in order to complete the review of indicators to base our copayment amounts. The cap will also remain at the current level (\$960) for these veterans. Depending on the results of the review described above, the Secretary may initiate a new rulemaking on this subject rather than continue to rely on the CPI-P escalator provision to determine the copayment amount.

At the end of calendar year 2012, unless additional rulemaking is initiated, VA will once again utilize the CPI-P methodology in § 17.110(b)(1)(iv) to determine whether to increase copayments and calculate any mandated increase in the copayment amount for veterans in priority categories 2 through 6. At that time, the CPI-P as of September 30, 2012, will be divided by the index as of September 30, 2001, which was 304.8. The ratio will then be multiplied by the original copayment amount of \$7. The copayment amount of the new calendar year will be rounded down to the whole dollar amount. As mandated by current § 17.110(b)(2), the annual cap will be calculated by increasing the cap by \$120 for each \$1 increase in the copayment amount. Any change in the copayment amount and cap, along with the associated calculations explaining the basis for the increase, will be published in a Federal Register notice. Thus, the intended effect of this rule is to temporarily prevent increases in copayment amounts and the copayment cap for veterans in priority categories 2 through 6, following which

copayments and the copayment cap will increase as prescribed in current § 17.110(b).

At the same time, in light of the statutory requirement to share costs under 38 U.S.C. 1722A and the distinctions noted above regarding veterans in priority categories 2 through 6, we will not implement a freeze on any copayment increase pursuant to the regulatory formula for veterans in priority categories 7 and 8. A copayment increase for these veterans will depend upon the Medical Consumer Price Index.

We note that we have not yet proposed a new methodology to establish copayments and, for that reason, request public comment only on the effect of this rulemaking, which is to freeze the copayment amount for veterans in priority categories 2 through 6 while we study alternative methodologies to calculate appropriate copayment amounts for all veterans.

Administrative Procedure Act

In accordance with 5 U.S.C. 553(b)(3)(B) and (d)(3), the Secretary of Veterans Affairs finds that there is good cause 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. As stated above, this 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. Increasing the copayment amount on January 1, 2012, might cause a significant financial hardship for some veterans.

For the above reason, the Secretary issues this rule as an interim final rule. VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the Federal Register.

Effect of Rulemaking

The Code of Federal Regulations, as revised by this rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures are authorized. All VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving

Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) 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 governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined to be a significant regulatory action. Accordingly, the Office of Management and Budget has reviewed this interim final rule.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an 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 given year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601- 612. This interim final rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. The interim final rule affects individuals and has no impact on any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number and title for this rule are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019,

Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on December 2, 2011, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure; Alcohol abuse; Alcoholism; Claims;
Day care; Dental health; Drug abuse; Foreign relations; Government contracts;
Grant programs-health; Grant programs-Veterans; Health care; Health facilities;
Health professions; Health records; Homeless; Medical and dental schools;
Medical devices; Medical research; Mental health programs; Nursing homes;
Philippines, Reporting and recordkeeping requirements; Scholarships and
fellowships, Travel and transportation expenses, Veterans.

Dated: December 15, 2011

Robert C. McFetridge,
Director of Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set forth in the preamble, VA amends 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501(a), and as noted in specific sections.

2. In § 17.110, paragraphs (b)(1)(ii), and (b)(2), remove “December 31, 2011” each place it appears and add, in each place, “December 31, 2012”.

[FR Doc. 2011-32532 Filed 12/19/2011 at 8:45 am; Publication Date:
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