



This document is scheduled to be published in the Federal Register on 10/27/2014 and available online at <http://federalregister.gov/a/2014-25454>, and on [FDsys.gov](http://FDsys.gov)

DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP15

Copayments for Medications in 2015

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. But for this rulemaking, beginning on January 1, 2015, the copayment amount would increase based on a formula set forth in regulation. The maximum annual copayment amount payable by veterans would also increase. This rulemaking freezes copayments for 2015 at the current rate for veterans in priority categories 2 through 8, and thereafter resumes increasing copayments in accordance with the regulatory formula.

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

Comment date: 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 e-mail through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont

Avenue, NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to “RIN 2900-AP15-Copayments for Medications in 2015.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, 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. (This is not a toll-free number.) 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, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 382-2508. (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 non-service-connected disability or condition unless a veteran has a service-connected disability rated 50 percent or more, is a former prisoner of war, or has an annual income at or below the maximum annual rate of VA pension that would be payable if the veteran were eligible for pension. Under 38 U.S.C. 1722A(b), VA “may,” by regulation, increase that copayment amount and establish a maximum annual

copayment amount (a “cap”). We have consistently interpreted 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. We have implemented this statute in 38 CFR 17.110.

Under 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, 2014, 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)(i). For the period July 1, 2010, through December 31, 2014, the copayment amount for veterans in priority categories 7 and 8 is \$9. 38 CFR 17.110(b)(1)(ii). 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 (CPI-P), set forth in 38 CFR 17.110(b)(1)(iii).

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, 2014, the annual 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 December 30, 2013, we published an interim final rulemaking that “froze” copayments for veterans in priority categories 2 through 6 at \$8 and for veterans in priority categories 7 and 8 at \$9, through December 31, 2014. 78 FR 79317, Dec. 30, 2013. This interim final rule was made final on May 27, 2014. 79 FR 30043, May 27, 2014. In these rulemakings, we stated that this freeze was appropriate because, as justified in prior rulemakings, higher copayments reduced the utilization of VA pharmacy benefits. 78 FR 79315. We continue to believe this to be the case. The ability to ensure that medications are taken as prescribed is essential to effective health care management. VA can monitor whether its patients are refilling prescriptions at regular intervals while also checking for medications that may interact with each other when these prescriptions are filled by VA. When non-VA providers are also issuing prescriptions, there is a greater risk of adverse interactions and harm to the patient because it is more difficult for each provider to assess if the patient is taking any other medications.

Specifically, we are removing December 31, 2014, in each place it appears in paragraphs (b)(1)(i)-(iii) and (b)(2), and inserting December 31, 2015, to continue to keep copayment rates and caps at their current levels.

At the end of calendar year 2015, unless additional rulemaking is initiated, VA will once again utilize the CPI-P methodology in § 17.110(b)(1)(iii) to determine whether to increase copayments and calculate any mandated increase in the copayment amount for veterans in priority categories 2 through 8. At that time, CPI-P as of September 30, 2015, 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 8, following which copayments and the copayment cap will increase as prescribed in current § 17.110(b).

Although we continue to believe that the CPI-P is one relevant indicator of the costs of prescriptions nationwide, and because VA has maintained copayment amounts at the same level since July 1, 2010, we are studying whether an alternative approach of determining pharmacy copayments would be appropriate. Until we are able to complete our study of whether the current methodology for establishing copayment amounts is appropriate for all veterans, consistent with our responsibility under 38 U.S.C. 1722A to require a copayment to control health care costs, we are extending the current copayment and cap amounts through 2015. Any change in the copayment amount and cap, along with the associated basis for the change, would be made through a final rule published in the Federal Register.

### Administrative Procedure Act

The Secretary of Veterans Affairs finds 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. 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, 2015, might cause a significant financial hardship for some veterans and may decrease patient adherence to medical plans and have other unpredictable negative health effects.

For the above reasons, 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

Title 38 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent

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 interim final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (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,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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.”

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and has concluded that it is an economically significant rule under Executive Order 12866 because it is likely to result in a regulatory action that may have an annual effect on the economy of \$100 million or more. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www1.va.gov/orpm/>, by following the link for “VA Regulations Published.”

### Congressional Review Act

This regulatory action may be considered a major rule under the Congressional Review Act, 5 U.S.C. 801–08, because it may result in an annual effect on the economy of \$100 million or more. Although this regulatory action may constitute a major rule within the meaning of the Congressional Review Act, 5 U.S.C. 804(2), it is not subject to the 60-day delay in effective date applicable to major rules under 5 U.S.C. 801(a)(3) because the Secretary finds that good cause exists under 5 U.S.C. 808(2) to make this regulatory action effective on January 1, 2015, consistent with the reasons given for the publication of this



interim final rule. Increasing the copayment amount on January 1, 2015, might cause a significant financial hardship for some veterans and may decrease patient adherence to medical plans and have other unpredictable negative health effects. Accordingly, the Secretary finds that additional advance notice and public procedure thereon are impracticable, unnecessary, and contrary to the public interest. In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis (RIA).

#### 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 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. This interim final rule will 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 will 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. This rule directly affects individuals and

will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

#### Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document 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. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on September 25, 2014, 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: October 22, 2014

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William F. Russo,  
Acting Director,  
Office of Regulation Policy & Management,  
Office of the General Counsel,  
U.S. Department of Veterans Affairs.

For the reasons set out 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.

§17.110 [Amended]

2. Amend § 17.110 as follows:

- a. In paragraphs (b)(1)(i), (ii), and (iii), remove all references to “December 31, 2014” and adding in each place “December 31, 2015”.

- b. In paragraph (b)(2) remove all references to “December 31, 2014” and adding in each place “December 31, 2015”.

[FR Doc. 2014-25454 Filed 10/24/2014 at 8:45 am; Publication Date: 10/27/2014]