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DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP87

Extension of Pharmacy Copayments for Medications

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. This rulemaking freezes copayments at the current rate for veterans in priority groups 2 through 8 through February 26, 2017.

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 (00REG), 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-AP87-Copayments for Medications in 2017.” 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: Bridget Souza, Office of Community Care (10D), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 382-2537. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay at least 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, the copayment amount for veterans in priority groups 2 through 6 of VA's health care system is \$8 through December 31, 2016. 38 CFR 17.110(b)(1)(i). The copayment amount for veterans in priority groups 7 and 8 is \$9 through December 31, 2016. 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). Using this methodology would generally result in increased medication prices for veterans.

Currently § 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 groups 2 through 6. Through December 31, 2016, 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 in priority categories 2 through 6.

On October 27, 2014, we published an interim final rulemaking that “froze” copayments for veterans in priority categories 2 through 6 at \$8 and for veterans in priority groups 7 and 8 at \$9, through December 31, 2015. 79 FR 63819. This interim final rule was made final on September 16, 2015. 79 FR 55545. In that

final rulemaking, we extended the copayment freeze to be effective through December 31, 2016. We stated that this extended timeframe would permit the freeze to be in effect all of calendar year 2016 for the continued benefit of veterans, and would allow VA to continue to develop and publish proposed and final rules to implement a tiered copayment structure for certain medications, which will further align VA's medication copayment structure with other Federal agencies and the commercial sector. In these rulemakings, we stated that this freeze was appropriate because failure to take the action would result in higher copayments, and, as described in prior rulemakings, higher copayments reduced the utilization of VA pharmacy benefits and caused VA patients to instead rely on external providers for medications. 79 FR 63820. 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 both VA and non-VA providers are issuing prescriptions to a veteran, there is a greater risk of adverse interactions and harm to the patient because it is more difficult for each provider to assess whether the patient is taking any other medications.

On January 5, 2016, we published a proposed rule that would establish a tiered medication copayment structure. 81 FR 196. In that proposed rule, we indicated that VA intended to publish a final rule that would make the proposed changes effective January 1, 2017. VA proposed an effective date of January 1,

2017 based on our assumption that the necessary system changes would be in place by that date to allow us to publish a final rule implementing a tiered medication copayment structure. VA will be unable to meet that timeline. However, VA thinks that the necessary changes will be in place in February 2017, and that a final rule establishing a tiered medication copayment regime can be published with an effective date of February 27, 2017.

In this rulemaking, we are removing December 31, 2016, in each place it appears in paragraphs (b)(1)(i)-(iii) and (b)(2), and inserting February 26, 2017, to continue to keep copayment rates and caps at their current levels until the tiered copayment system is established.

If we fail to extend the medication copayment freeze past December 31, 2016, affected veterans would be subject to increased medication copayments until such time as the anticipated final rule implementing the tiered medication copayment structure is effective. In that case, beginning January 1, 2017, VA would use 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 groups 2 through 8. At that time, the copayment amounts would be adjusted to a higher rate based on changes in the CPI-P over the past five years, and the annual copayment cap would also be raised by \$120 for each \$1 increase in the copayment amount. The end result would be increased medication copayments, and a higher annual cap on copayments until the effective date of the anticipated final rule implementing tiered medication copayments. VA believes this would not only have an adverse financial effect on

veterans subject to medication copayments, but would also cause unnecessary confusion by making two changes to veterans' medication copayment amounts over a two-month period. Thus, the intended effect of this interim final rule is to prevent increases in copayment amounts and the copayment cap for veterans in priority groups 2 through 8 until VA has published a final rule establishing a new copayment structure. At that time, veterans' copayments will be determined according to the methodology contained in the final rule that VA will publish to establish a tiered copayment system. If VA has not established a new tiered copayment system by the end of February, copayments and the copayment cap will increase as prescribed in current § 17.110(b) in the absence of further rulemaking.

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. If the medication copayment freeze is not extended, on January 1, 2017, affected veterans would be subject to increased medication copayments based on changes to the CPI-P since 2010, as well as an upward adjustment to

the annual copayment cap. VA believes that this might cause a significant financial hardship for those affected veterans and may decrease patient adherence to medical plans and have other unpredictable negative health effects. Further, VA believes that failing to extend the current medication copayment freeze, without interruption, would likely result in confusion for the public and affected veterans because the new tiered medication copayment regime will go into effect within a relatively short period of time. Lastly, allowing the current medication copayment freeze to expire on December 31, 2016, would create programmatic issues that would be difficult for VA to administratively manage. Within a 60-day period IT algorithms that are currently in place would have to be removed, new copayment amounts and annual cap amounts would have to be calculated and implemented along with the necessary system changes, followed by application of the new IT changes necessary for establishing a new tiered medication copayment scheme.

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.”

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. 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 website.

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 interim rule directly affects individual VA patients 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. Gina S. Farrisee, Deputy Chief of Staff,

Department of Veterans Affairs, approved this document on October 3, 2016, for publication.

Dated: December 2, 2016.

Michael Shores,
Acting Director,
Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

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.

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, and as noted in specific sections.

Sections 17.640 and 17.647 also issued under Pub. L. 114-2, sec. 4.

Sections 17.641 through 17.646 also issued under 38 U.S.C. 501(a) and Pub. L. 114-2, sec. 4.

§17.110 [AMENDED]

2. Amend § 17.110 as follows:

- a. In paragraphs (b)(1)(i), (ii), and (iii), remove all references to “December 31, 2016” and add in each place “February 26, 2017”.

- b. In paragraph (b)(2), remove all references to “December 31, 2016” and add in each place “February 26, 2017”.

[FR Doc. 2016-29337 Filed: 12/6/2016 8:45 am; Publication Date: 12/7/2016]