(10) Care or services authorized under 38 U.S.C. 1720E for certain veterans regarding cancer of the head or neck;

(11) Publicly announced VA public health initiatives (*e.g.*, health fairs) or an outpatient visit solely consisting of preventive screening and immunizations (*e.g.* influenza immunization, pneumonococcal immunization, hypertension screening, hepatitis C screening, tobacco screening, alcohol screening, hyperlipidemia screening, breast cancer screening, cervical cancer screening, screening for colorectal cancer by fecal occult blood testing, and education about the risks and benefits of prostate cancer screening); and

(12) Laboratory services, flat film radiology services, and electrocardiograms.

(f) *Additional care not subject to outpatient copayment.* Outpatient care is not subject to the outpatient copayment requirements under this section when provided to a veteran during a day for which the veteran is required to make a copayment for extended care services that were provided either directly by VA or obtained for VA by contract.

(Authority: 38 U.S.C. 1710)

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AK85

Copayments for Medications

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends VA's medical regulations to set forth copayment requirements for medications. This is necessary to implement provisions of the Veterans Millennium Health Care and Benefits Act.

DATES: *Effective Date:* February 4, 2002.

FOR FURTHER INFORMATION CONTACT: Nancy L. Howard at (202) 273–8198, Revenue Office (174), Office of Finance, Veterans Health Administration, 810 Vermont Avenue NW., Washington, DC 20420. (This is not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on July 16, 2001, we proposed to amend VA's medical regulations to set forth copayment requirements for medications provided to veterans by VA (66 FR 36960). Interested persons were given 60 days to submit comments. We received over 1000 comments, almost all of which opposed all or portions of the proposal. Based on the rationale set forth in the proposed rule and this document, we are adopting the provisions of the proposed rule as a final rule.

A number of commenters asserted that VA should not charge any veteran a medication copayment. Other commenters asserted that VA should not charge veterans who had combat service a medication copayment. Other commenters asserted that military retirees should not be charged a medication copayment. Other commenters asserted that veterans who are service-connected should not be charged a medication copayment for any condition. No changes are made based on these comments. With certain statutory exceptions set forth in § 17.110(c) of this final rule, the provisions of 38 U.S.C. 1722A require veterans to pay a copayment for each 30-day or less supply of medication furnished on an outpatient basis. The applicable statutory provisions do not allow an exemption based merely on the fact that an individual is a veteran, that an individual was a combat veteran, or that a veteran is a military retiree. The provisions in the final rule concerning service-connection are also reflections of statutory requirements. The final rule exempts from the copayment requirements medication for a veteran who has a service-connected disability rated 50% or more based on a service-connected disability or unemployability. The final rule also exempts from the copayment requirements medication for a veteran's service-connected disability. However, VA has no authority to exempt from the medication copayments medication for a nonservice-connected condition of a veteran whose total service-connected disabilities are rated at less than 50%.

The vast majority of commenters opposed the proposal to increase the copayment amount from $2 to $7. Some asserted there should be no increase at all. Others asserted that the increase was just too great. Others asserted that the increase would cause them a financial hardship. Some of the commenters asserted that the Prescription Drug Component of the Medical Consumer Price Index should not be used to determine whether the copayment amount should be increased since this is typically greater than the overall inflation rate. A number of the commenters also asserted that the copayment increase also would cause the annual caps to be too high. A few were in favor of the proposal. No changes are made based on these comments.

The copayment amount was set at $2 in 1990 by 38 U.S.C. 1722A for each 30-day or less supply of medication and until now has never been changed. The Veterans Millennium Health Care and Benefits Act, Public Law 106–117, amended 38 U.S.C. 1722A authorizing VA to increase the copayment amount and to establish maximum annual copayment amounts. Clearly, the statutory intent was for VA to increase the copayment amount. In helping VA to determine the amount of the copayment, the House Conference Report (H. Rept. 106–237, July 16, 1999) specifically noted that the copayment for DOD's Tricare Prime Plan included a $9 copayment for each 30-day prescription. Further, the House Conference Report indicated, at page 42, that ''[a] survey of copayment trends in 1996–7 found the most common [prescription drug] copayment among members of the American Association of Health Plans * * * [to be] in the range of $5 to $10 per prescription.'' Also, as we stated in the proposal, we believe that the proposed $7 medication copayment would be lower than or equal to most medication copayments charged by the private health care industry. Many recent newspaper articles have reported dramatic increases throughout the health care industry for medication copayment amounts which are reflective of increases in medication costs. Accordingly, even with the increase we may have one of the lowest copayment amounts. Under these circumstances, we believe that a $7 copayment amount is reasonable. Further, we believe that increases should be based on the Prescription Drug Component of the Medical Consumer Price Index since it is most relevant to the cost of prescriptions and thereby should be relevant to any general increases in medication copayments in the private sector.

Also, as we stated in the proposal, under 38 U.S.C. 1722A, VA may not require a veteran to pay an amount in excess of the actual cost of the medication and the pharmacy administrative costs related to the dispensing of the medication. VHA conducted a study of the pharmacy administrative costs relating to the dispensing of medication on an outpatient basis and found that VA incurred a cost of $7.28 to dispense an outpatient medication even without consideration of the actual cost of the medication. This amount covers the cost of consultation time, filling time,

dispensing time, an appropriate share of the direct and indirect personnel costs, physical overhead and materials, and supply costs. Under these circumstances, we believe that a $7 copayment would not exceed VA's costs.

A number of commenters asserted that the increase in the medication copayment would cause them a financial hardship, particularly in those cases when a veteran would obtain multiple prescriptions requiring multiple copayments. No changes are made based on these comments. The issue of financial hardship caused by copayments was addressed by statute. The text portion of this document restates statutory provisions by providing that certain veterans whose income is less than the VA pension level are exempt from the copayment requirements. Moreover, the final rule includes an annual cap to help eliminate financial hardships for veterans who in unusual circumstances need a significant number of prescriptions. Furthermore, VA has statutory authority under 38 U.S.C. 5302 to waive debts arising from a veteran's failure to pay the pharmacy copayment when collection of the debt would be against equity and good conscience. One factor VA uses in determining whether collection would be against equity and good conscience is whether it would cause undue hardship by depriving the veteran and his or her family of basic necessities.

One commenter asserted that the income threshold for requiring a medication copayment should be raised. No changes are made based on this comment. This reflects a statutory requirement and we have no authority to change the amount.

A number of commenters indicated that they would return to private-sector health care if the copayment were increased. Although some might choose not to obtain their medications from VA, as we indicated above, we believe that our copayment amount is still on the low end of the private-sector copayment scale.

A number of commenters asserted that VA should not charge copayments in those cases when VA is reimbursed by Medicare. No changes are made based on these comments. Medicare does not provide medication coverage and does not reimburse VA for medication costs.

One commenter suggested that the copayment amount should vary based on geographic location. No changes are made based on this comment. We do not believe that this would be administratively feasible.

One commenter suggested that we refrain from establishing a new copayment amount based on the conclusion that the copayment authority is scheduled to expire September 30, 2002. No changes are made based on this comment. We anticipate that a timely extension of the copayment authority will be enacted into law. If this does not occur we would delete the copayment provisions.

Compliance With the Congressional Review Act and Executive Order 12866

This rule is economically significant under Executive Order 12866 and constitutes a major rule under the Congressional Review Act. The rule is necessary to implement the provisions of section 201 of Public Law 106–117, The Veterans Millennium Health Care and Benefits Act. These provisions, which are set forth at 38 U.S.C. 1722A, authorize VA to set the copayment charge for medications.

I. Benefits Costs

This rule would directly impact veterans who receive prescriptions for other than service-connected conditions and who have been paying a $2 copayment. Based on VA records for fiscal year 2000, we found that approximately 1.1 million veterans averaged 47 30-day supply prescriptions per year. VA collected $101 million in fiscal year 2000 as copayments. This rule would increase the copayment from the current $2 level to $7. We do not believe the increase in the copayment amount will have an impact upon utilization. It is anticipated that the same number of veterans will continue to receive the same average number of prescriptions generating an increase in collections of $250 million annually.

II. Administrative Costs

The estimated administrative cost for these increased collections would remain the same at the current collection expense of $17 million. This is based upon an average cost of a GS–5 at $12/hour x 8.2 million bills per year at the average rate of 10.3 minutes per bill.

III. Alternatives

In addition to alternatives discussed above, VA considered establishing higher and lower copayment and cap amounts and considered whether or not to have escalator provisions. However, for the reasons discussed above, we believe that the copayment and cap amounts, and the escalator provisions, are appropriate.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Unfunded Mandates

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

OMB Review

This rule is economically significant under Executive Order 12866 and major under the Congressional Review Act. This rule has been reviewed by OMB.

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. This amendment would not directly affect any small entities. Only individuals could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers for the programs affected by this document are 64.005, 64.007, 64.008, 64.009, 64.010, 64.011, 64.012, 64.013, 64.014, 64.015, 64.016, 64.018, 64.019, 64.022, and 64.025.

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.

Approved: November 30, 2001.

Anthony J. Principi,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

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

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. Section 17.110 is added under the undesignated center heading COPAYMENTS to read as follows:

§ 17.110 Copayments for medication.

(a) *General.* This section sets forth requirements regarding copayments for medications provided to veterans by VA.

(b) *Copayments.* (1) Unless exempted under paragraph (c) of this section, a veteran is 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). For the period from February 4, 2002 through December 31, 2002, the copayment amount is $7. The copayment amount for each calendar year thereafter will be established by using the Prescription Drug component of the Medical Consumer Price Index as follows: For each calendar year beginning after December 31, 2002, the Index as of the previous September 30 will be divided by the Index as of September 30, 2001. The ratio so obtained will be multiplied by the original copayment amount of $7. The copayment amount for the new calendar year will be this result, rounded down to the whole dollar amount.

Note to Paragraph (b)(1): Example for determining copayment amount. If the ratio of the Prescription Drug component of the Medical Consumer Price Index for September 30, 2003, to the corresponding Index for September 30, 2001, is 1.2242, then this ratio multiplied by the original copayment amount of $7 would equal $8.57, and the copayment amount for calendar year 2004, rounded down to the whole dollar amount, would be $8.

(2) The total amount of copayments in a calendar year for a veteran enrolled in one of the priority categories 2 through 6 of VA's health care system (see § 17.36) shall not exceed the cap established for the calendar year. The cap for calendar year 2002 is $840. If the copayment amount increases after calendar year 2002, the cap of $840 shall be increased by $120 for each $1 increase in the copayment amount.

(c) *Medication not subject to the copayment requirements.* The following are exempt from the copayment requirements of this section:

(1) Medication for a veteran who has a service-connected disability rated 50% or more based on a service-connected disability or unemployability;

(2) Medication for a veteran's service-connected disability;

(3) Medication for a veteran whose annual income (as determined under 38 U.S.C. 1503) does not exceed the maximum annual rate of VA pension which would be payable to such veteran if such veteran were eligible for pension under 38 U.S.C. 1521;

(4) Medication authorized under 38 U.S.C. 1710(e) for Vietnam-era herbicide-exposed veterans, radiation-exposed veterans, Persian Gulf War veterans, or post-Persian Gulf War combat-exposed veterans;

(5) Medication for treatment of sexual trauma as authorized under 38 U.S.C. 1720D;

(6) Medication for treatment of cancer of the head or neck authorized under 38 U.S.C. 1720E; and

(7) Medications provided as part of a VA approved research project authorized by 38 U.S.C. 7303.

(Authority: 38 U.S.C. 501, 1710, 1720D, 1722A)

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