

Dated: July 14, 2003.

S.K. Moon,

Lieutenant Commander, Coast Guard, Acting Captain of the Port Detroit.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AL68

Medication Prescribed by Non-VA Physicians

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: This rule amends VA's medical regulations that govern the provision of medication to veterans when the medication is prescribed by non-VA physicians. The rule provides that, in limited circumstances, VA may provide medication prescribed by a non-VA physician to veterans enrolled in VA's health care system prior to July 25, 2003, if the veterans have requested an initial appointment for primary care in a VA health care facility before July 25, 2003, and were unable to obtain an initial appointment for primary care within 30 days. The rule establishes specific requirements that veterans must meet to receive such medications and it establishes limits on the types and quantities of medication VA may provide. VA's intent is to assist enrolled veterans who have requested primary care appointments but who have not been able to obtain one within 30 days.

DATES: *Effective Date:* This interim final rule is effective on July 25, 2003; except for 38 CFR 17.96(e) which is effective August 25, 2003.

Comment Dates: Comments on the rule must be received on or before September 8, 2003; except that comments on the request for emergency approval of the collection of information provisions must be received on or before August 25, 2003.

Applicability Date: Benefits may be provided commencing September 22, 2003.

ADDRESSES: Mail or hand-deliver written comments to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or fax comments to (202) 273-9026; or e-mail comments to OGCRegulations@mail.va.gov. Comments should indicate that they are submitted in response to "RIN 2900-AL68." All comments received will be

available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273-9515 for an appointment.

FOR FURTHER INFORMATION CONTACT:

Kendra Drew, Chief Business Office (16), at (202) 254-0329 and Virginia Torrise, Pharmacy Benefits Management, Deputy Chief Consultant (119), at (202) 273-8426. These individuals are in the Veterans Health Administration of the Department of Veterans Affairs, located at 810 Vermont Avenue, NW., Washington, DC 20420.

SUPPLEMENTARY INFORMATION: Under existing law and regulations, a veteran desiring medical care from VA must enroll in VA's health care system, except for veterans whose service-connected disabilities are 50% or greater, or any veteran seeking treatment for a service-connected condition. When a veteran first enrolls in the VA system, and requests an appointment for care, VA schedules an appointment for a visit with a primary care physician. During that first appointment, a VA health care provider examines the veteran and determines what care the veteran needs. That primary care physician generally learns from the veteran what medication the veteran is taking, if any, assesses the need for medication, and writes prescriptions for any needed medication. Those prescriptions written by the VA physician are then filled by a VA pharmacy.

In recent years, VA has faced an extraordinary increase in demand for health care services. The increased demand has been caused, at least in part, by veterans enrolling in the VA health care system to obtain pharmacy benefits at no cost or at a reasonable cost. With dramatically increased enrollment, VA has been unable to provide all enrolled veterans with services in a timely manner. In many places that means veterans may wait a considerable length of time to receive an initial primary care visit. Many of those veterans have prescriptions, written by non-VA physicians, that VA primary care physicians may confirm and renew when the veterans are able to have initial primary care visits. In an effort to ease the financial burden on enrolled veterans currently waiting lengthy periods of time for their initial primary care visits, VA will provide these veterans with medications prior to their initial primary care visits at VA if these veterans present valid prescriptions from their non-VA physicians. VA will fill prescriptions written by non-VA physicians only for the period of time

such veterans are awaiting a scheduled appointment with a VA health care provider. VA anticipates asking the veterans whether they want to have the next available appointment, or whether they want to postpone the initial appointment. VA will schedule the veterans' initial appointments within the period covered by the prescriptions written by their non-VA physicians. VA anticipates that some veterans will choose to postpone the initial appointment, shortening waiting lists and making appointment dates available to other veterans.

VA anticipates that in the near future, it will be able to provide all enrolled veterans with primary care in a timely manner. That would effectively eliminate the need for providing medications under this rule. However, it is important that VA have such regulations in place until such time as waiting periods can be reduced.

VA is undertaking this rulemaking pursuant to its authority under 38 U.S.C. 1710(a) to furnish needed medical services. As clarified in paragraph (a) of this rule, VA does not generally fill prescriptions for veterans that are written by non-VA physicians. Instead, VA usually provides only medications prescribed by VA physicians or VA contractors retained for that purpose. This is consistent with the primary purpose of the Veterans Health Administration, which is to provide integrated comprehensive health care for veterans, not simply act as a conduit for furnishing prescription medications.

In light of the backlog of veterans seeking VA care, however, the Secretary has determined that the filling of some prescriptions written by non-VA physicians is needed during the period of time such veterans are awaiting a scheduled appointment with a VA health care provider. As a result, paragraph (b) of this rule states that beginning September 22, 2003, VA may furnish medications for veterans enrolled in VA's health care system prior to July 25, 2003, if the veterans have requested an initial appointment for primary care in a VA health care facility before July 25, 2003, and the next available appointment date is scheduled more than 30 days after the veteran requests the appointment. VA chose the 30-day limitation because it is generally considered reasonable in the community at large to expect that one could obtain a first time primary care visit with a physician within 30 days. VA chose to limit the provision of medications in question to only those veterans enrolled prior to July 25, 2003, in order to specifically address the

problems of currently enrolled veterans facing lengthy waits for initial primary care appointments in a cost-effective manner. (See 38 U.S.C. 1706(a) requiring VA to "design, establish and manage health care programs in such a manner as to promote cost-effective delivery of health care services"). Moreover, without these limitations, the very issuance of the new rule could invite an influx of new enrollments and requests for appointments, exacerbating the wait-time problem the rule is intended to address. This rule also should benefit those who enroll after the effective date or attempt to make appointments after that date. By allowing those presently enrolled and waiting more than 30 days to reschedule appointments at dates closer to expiration of presently held non-VA prescriptions, additional near term appointments should become available for those who are not entitled to this limited benefit. Thus, the out-of-pocket costs for prescriptions filled while waiting for VA appointments should also be reduced for those not specifically included in this rule because their waiting time should be reduced.

Paragraph (c) of this rule states that VA may furnish an amount of medication that will appropriately meet the treatment needs of veterans until the date of the veterans' initial appointment for primary care in a VA facility. If veterans choose to postpone their initial appointment date until they have used all of the medication prescribed by the non-VA provider, VA will furnish the amount prescribed, including refills. VA will furnish such medications consistent with long-standing pharmacy practices. The decision on the precise quantity of medication that would be needed is generally considered to be a medical determination and would be left to appropriate VA clinicians including pharmacists.

Paragraph (d) of this rule states that if VA reschedules an initial appointment for primary care in a VA health care facility for veterans eligible under this rule, or if veterans reschedule their appointments for good reasons, as determined by the local VA medical facility, VA may furnish the eligible veterans with a quantity of medication that is sufficient to meet the treatment needs of the veterans until the date of the veterans' rescheduled appointments for primary care in a VA health care facility. If VA reschedules veterans' initial primary care visits, it is reasonable that VA would provide additional medication to meet the veterans' needs until the date of their rescheduled appointments. VA also

understands that there are occasions when, for good cause, veterans might be forced to cancel appointments. For example, if the veteran had to reschedule an appointment because of inclement weather, or because of the illness or death of a family member, VA would not disqualify the veteran from continuing to receive the benefits of this remedial program. However, VA would not furnish medications to veterans who simply cancel or reschedule and extend their appointments without good reasons.

Paragraph (e) of this rule states that VA may furnish medications beginning on September 22, 2003, only if veterans provide VA with written current prescriptions for their medications signed by duly licensed physicians within the previous 90 days. To ensure the health and safety of veterans, VA will only fill prescriptions when veterans present VA with written prescriptions signed by licensed physicians. VA will not accept prescriptions called in by veterans' non-VA pharmacies or non-VA health care providers. VA lacks the resources to accept and manage those calls.

Paragraph (f) of this rule states that VA may furnish only medication under paragraph (b) that (1) must be dispensed by prescription, (2) is not an over-the-counter medication, (3) is not listed as a controlled substance under schedule I through V of the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. 812, (4) is included on VA's National Formulary, unless VA determines a non-Formulary medication is medically necessary, and (5) is not an acute medication, intravenous medication, nor one required to be administered only by a medical professional. By providing only medications that must be dispensed by prescription, VA is not furnishing over-the-counter drugs. Veterans can easily purchase over-the-counter medications without regard to whether they are able to schedule visits with a physician. For patient health and safety reasons, VA will not furnish controlled substances without a VA physician first seeing the patient and ordering the medication. VA will furnish veterans with medications prescribed by non-VA physicians only if the medication is on VA's National Formulary, or approved in advance through a special approval process. If a veteran provides VA with a prescription for medications that are not on VA's formulary, VA will contact the physician who wrote the prescription to determine whether a medication on VA's formulary is appropriate, and if not, the medical reasons why it is not appropriate. If VA determines that a

medication is medically necessary, but is not on VA's formulary, VA will provide that medication. Finally, acute medications, intravenous medications, and medications required to be administered only by a medical professional will not be furnished because under this rule prescriptions will be filled only by mail.

Paragraph (g) of this rule provides that the existing copayment requirements applicable to VA furnishing medication will apply to medications furnished under this rule. Statutes (e.g., 38 U.S.C. 1722A) require application of the copayment requirements.

Paragraph (h) of this rule provides that VA will furnish medications under this rule only by having the medication mailed to the veteran, typically by one of VA's Consolidated Mail Out-patient Pharmacies, or with VA contract pharmacies. Therefore, this benefit is not useful for veterans who require acute medications, intravenous medications, or medications to be administered only by a medical professional. VA pharmacies will not directly furnish medications or reimburse veterans for medications that they obtain from non-VA pharmacies.

Paragraph (i) of this rule restates, with no substantive change, longstanding regulatory provisions regarding prescriptions found in § 17.96.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553, we have found for this rule that notice and public procedure are impracticable, unnecessary, and contrary to the public interest, and that we have good cause to dispense with notice and comment on this rule and to dispense with a 30-day delay of its effective date. This is an effort to ease the financial burden on enrolled veterans currently waiting lengthy periods of time for their initial primary care visits. Delaying implementation of this benefit would only exacerbate the problems veterans are experiencing while waiting for VA treatment.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, 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 proposed amendment would have no such effect on State, local, or tribal governments, or the private sector.

Paperwork Reduction Act

OMB assigns a control number for each collection of information it approves. Except for emergency approvals under 44 U.S.C. 3507(j), VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The interim final rule at § 17.96(e) contains collections of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521). Accordingly, under section 3507(d) of the Act, VA has submitted a copy of this rulemaking action to OMB for its review of the collections of information. We have requested OMB to approve the collection of information on an emergency basis by August 25, 2003. If OMB does not approve the collections of information as requested, we will immediately remove § 17.96(e) or take such other action as is directed by OMB.

We are also seeking an approval of the information collection on a non-emergency basis. Accordingly, we are also requesting comments on the collection of information provisions contained in § 17.96(e) on a non-emergency basis. Comments must be submitted by September 23, 2003.

OMB assigns a control number for each collection of information it approves. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Comments on the collections of information should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, or faxed to 202 395–6974, with copies mailed or hand-delivered to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420. Comments should indicate that they are submitted in response to “RIN 2900–AL68.”

Title: Medication Prescribed by non-VA Physicians.

Summary of collection of information: The interim final rule at § 17.96(e) contains application provisions for written prescriptions and information requirements. The interim rule at § 17.96(e) contains requirements for provision of medication to veterans when the medication is prescribed by non-VA physicians.

Application Provisions for Written Prescriptions and Information Requirements.

Description of the need for information and proposed use of information: This information is needed to determine eligibility for provision of medication to veterans when the medication is prescribed by non-VA physicians.

Description of likely respondents: veterans and treating physicians.

Estimated number of respondents per year: 181,723.

Estimated frequency of responses per year: 1.

Estimated total annual reporting and recordkeeping burden: 33,316 hours.

Estimated annual burden per collection: 11 minutes.

The Department considers comments by the public on collections of information in—

- Evaluating whether the collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including responses through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

OMB is required to make a decision concerning the collections of information contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the interim final rule.

Executive Order 12866

The Office of Management and Budget has reviewed this document under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment 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 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: July 17, 2003.

Anthony J. Principi,
Secretary of Veterans Affairs.

■ For the reasons set out in the preamble, VA is amending 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, 1721, unless otherwise noted.

■ 2. Section 17.96 is revised to read as follows:

§ 17.96 Medication prescribed by non-VA physicians.

(a) *General.* VA may not furnish a veteran with medication prescribed by a duly licensed physician who is not an employee of the VA or is not providing care to the veteran under a contract with the VA, except as provided in paragraphs (b) through (i) of this section.

(b) *Medication furnished prior to an initial primary care appointment.* Beginning on September 22, 2003, VA may furnish medication prescribed by a non-VA physician for a veteran enrolled under § 17.36 of this part prior to July 25, 2003, who had prior to July 25, 2003, requested an initial appointment for primary care in a VA health care facility, and the next available appointment date was more than 30 days from the date of the request.

(c) *Quantity of medication.* VA may furnish a quantity of medication under

paragraph (b) of this section that is sufficient to appropriately meet the treatment needs of the veteran until the date of the veteran's initial appointment for primary care in a VA health care facility.

(d) *Appointment cancellation.* If VA reschedules a veteran eligible under paragraph (b) for an initial appointment for primary care in a VA health care facility, or if such a veteran reschedules the appointment for good cause, as determined by the local VA treatment facility, VA may furnish the eligible veteran with a quantity of medication under paragraph (b) of this section that is sufficient to appropriately meet the treatment needs of the veteran until the date of the veteran's rescheduled appointment for primary care in a VA health care facility.

(e) *Written prescription and information requirements.* VA may furnish medication under paragraph (b) of this section only if the veteran provides VA with a written prescription for the medication signed by a duly licensed physician within the previous 90 days.

(1) *The veteran must furnish the following information:*

- (i) Name;
- (ii) Date of Birth;
- (iii) Social Security Number;
- (iv) Home address;
- (v) Phone number (with area code);
- (vi) Name of Health Insurance Company and Health Insurance Policy Number;
- (vii) List of any allergies;
- (viii) History of any adverse reaction to any medication;
- (ix) List of current medications, including over-the-counter medications or herbal supplements; and
- (x) Indication of whether the VA pharmacist may call a non-VA physician for information regarding medications.

(2) *The non-VA physician must furnish the following information:*

- (i) Name;
- (ii) Group practice name;
- (iii) Social Security Number or Tax ID number;
- (iv) License Number;
- (v) Office address;
- (vi) Phone number and fax number; and
- (vii) E-mail address.

(f) *Medications that may be furnished.* VA may furnish medication under paragraph (b) of this section only if the medication:

- (1) Must be dispensed by prescription;
- (2) Is not an over-the-counter medication;
- (3) Is not listed as a controlled substance under schedule I through V of

the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. 812;

(4) Is included on VA's National Formulary, unless VA determines a non-Formulary medication is medically necessary; and

(5) Is not an acute medication, an intravenous medication nor one required to be administered only by a medical professional.

(g) *Copayments.* Copayment provisions in § 17.110 of this part apply to medication furnished under paragraph (b) of this section.

(h) *Mailing of Medications.* VA may furnish medication under paragraph (b) of this section only by having the medication mailed to the veteran.

(i) *Medications for veterans receiving increased compensation or pension.* Any prescription, which is not part of authorized Department of Veterans Affairs hospital or outpatient care, for drugs and medicines ordered by a private or non-Department of Veterans Affairs doctor of medicine or doctor of osteopathy duly licensed to practice in the jurisdiction where the prescription is written, shall be filled by a Department of Veterans Affairs pharmacy or a non-VA pharmacy in a state home under contract with VA for filling prescriptions for patients in state homes, provided:

(1) The prescription is for:

(i) A veteran who by reason of being permanently housebound or in need of regular aid and attendance is in receipt of increased compensation under 38 U.S.C. chapter 11, or increased pension under section 3.1(u) (Section 306 Pension) or section 3.1(w) (Improved Pension), of this title, as a veteran of the Mexican Border Period, World War I, World War II, the Korean Conflict, or the Vietnam Era (or, although eligible for such pension, is in receipt of compensation as the greater benefit), or

(ii) A veteran in need of regular aid and attendance who was formerly in receipt of increased pension as described in paragraph (a)(1) of this section whose pension has been discontinued solely by reason of excess income, but only so long as such veteran's annual income does not exceed the maximum annual income limitation by more than \$ 1,000, and

(2) The drugs and medicines are prescribed as specific therapy in the treatment of any of the veteran's illnesses or injuries.

(Authority: 38 U.S.C. 1706, 1710, 17.12(d))

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL7529-6]

RIN 2060-AK67

Protection of Stratospheric Ozone: Ban on Trade of Methyl Bromide with Non-Parties to the Montreal Protocol

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: With this action, EPA is taking direct final action on the regulations that govern the production, import, and export of substances that deplete the ozone layer under the authority of Title VI of the Clean Air Act (CAA or the Act) and in accordance with U.S. obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). Specifically, today's amendments reflect the Montreal Amendments to the Protocol, which ban the import or export of methyl bromide (class I, Group VI controlled substance) from or to countries that are not Parties to the 1992 Copenhagen Amendments.

DATES: This rule is effective on October 23, 2003 without further notice, unless EPA receives adverse comment by August 25, 2003, or, if a public hearing is requested, by September 18, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

Written comments on this rule must be received on or before August 25, 2003, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the contact person listed below by 5 p.m. Eastern Standard Time on August 4, 2003. If a hearing is requested it will be held August 19, 2003.

ADDRESSES: Comments may be submitted by mail to Air and Radiation. Send two copies of your comments to: Air and Radiation Docket (6102), Air Docket No. A-92-13, Section XIII, U.S. Environmental Protection Agency, Mailcode 6205J, 1200 Pennsylvania Ave. NW., Washington, DC 20460. The Docket's hours of operation are 8:30 a.m. until 4:30 p.m. Monday through Friday. Comments may also be submitted electronically, through hand delivery or courier. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving