

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new temporary § 165.T11–182 to read as follows:

§ 165.T11–182 Safety Zone; IJSBA World Finals; Lower Colorado River, Lake Havasu, AZ.

(a) *Location.* The following area is a safety zone: All waters of Lake Havasu, from surface to bottom, encompassed by lines connecting the following points: Beginning at 34°28.49' N, 114°21.33' W; thence to 34°28.55' N, 114°21.56' W; thence to 34°28.43' N, 114°21.81' W; thence to 34°28.32' N, 114°21.71' W; thence along the shoreline returning to 34°28.49' N, 114°21.33' W.

These coordinates are based upon NAD 83.

(b) *Enforcement Period.* This section will be enforced from sunrise to sunset on October 3, 2010 through October 10, 2010. If the International Jet Sports Boating Association World Finals concludes prior to the scheduled termination of the effective period, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Definitions.* The following definition applies to this section: *Designated representative* means any Commissioned, Warrant, or Petty Officers of the Coast Guard or Coast Guard Auxiliary, and local, state, and federal law enforcement officers who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port San Diego or his designated representative.

(2) Mariners desiring to enter or operate in the safety zone may request authorization to do so from the Patrol Commander (PATCOM). The PATCOM

may be contacted on VHF–FM Channel 16.

(3) All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port or his designated representative.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel must proceed as directed.

(5) The Coast Guard may be assisted by other federal, state, or local agencies.

Dated: September 17, 2010.

P.J. Hill,

Commander, U.S. Coast Guard, Acting Captain of the Port San Diego.

[FR Doc. 2010–25193 Filed 10–5–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS**38 CFR Part 17**

RIN 2900–AN15

Charges Billed to Third Parties for Prescription Drugs Furnished by VA to a Veteran for a Nonservice-Connected Disability

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: This document amends the medical regulations of the Department of Veterans Affairs (VA) concerning “reasonable charges” for medical care or services provided or furnished by VA to a veteran for a nonservice-connected disability. More specifically, VA amends the regulations regarding charges billed for prescription drugs not administered during treatment by changing the billing formula to reflect VA’s actual drug costs for each drug rather than using a national average drug cost for all prescriptions dispensed. The revised formula for calculating reasonable charges for prescription drug costs will also continue to include an average administrative cost for each prescription. The purpose is to provide VA with a more accurate billing methodology for prescription drugs.

DATES: Effective Date: This final rule is effective on March 18, 2011.

Applicability Date: The final rule will apply to prescriptions filled on or after March 18, 2011.

FOR FURTHER INFORMATION CONTACT: Romona Greene, Manager of Rates and Charges, VHA Chief Business Office (168), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC

20420, (202) 461–1595. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1729, VA has the right to recover or collect reasonable charges for medical care or services (including the provision of prescription drugs) from a third party to the extent that the veteran or the provider of the care or services would be eligible to receive payment from the third party for:

- A nonservice-connected disability for which the veteran is entitled to care (or the payment of expenses of care) under a health plan contract, 38 U.S.C. 1729(a)(2)(D), 38 CFR 17.101(a)(1)(i);
- A nonservice-connected disability incurred incident to the veteran’s employment and covered under a worker’s compensation law or plan that provides reimbursement or indemnification for such care and services, 38 U.S.C. 1729(a)(2)(A), 38 CFR 17.101(a)(1)(ii); or
- A nonservice-connected disability incurred as a result of a motor vehicle accident in a State that requires automobile accident reparations (no-fault) insurance, 38 U.S.C. 1729(a)(2)(B), 38 CFR 17.101(a)(1)(iii).

However, under current 38 CFR 17.101(a)(4), which implements 38 U.S.C. 1729(c)(2)(B), a third-party payer liable for such medical care and services under a health plan contract has the option of paying, to the extent of its coverage, either the billed charges or the amount the third-party payer demonstrates it would pay for care or services furnished by providers other than entities of the United States for the same care or services in the same geographic area.

Prior to the effective date of this document, VA billed for prescription drugs not administered during treatment based on the sum of two components: (1) The national average of VA’s drug costs for all prescriptions, and (2) the national average of VA’s administrative costs associated with furnishing prescription drugs. Further, in accordance with § 17.102(h), prior to the effective date of this document, VA billed \$51 for each prescription filled (see 70 FR 66866, Nov. 3, 2005).

In a document published in the **Federal Register** on July 9, 2009 (74 FR 32819), we proposed to change the billing methodology for prescription drugs not administered during treatment. With respect to the portion of the billing concerning VA’s cost for such prescription drugs, we proposed to bill based on the actual cost to VA of each prescription drug rather than the national average of drug costs for all prescriptions. In this regard, we proposed to bill the total of:

- The actual cost to VA for prescription drugs (*i.e.*, the cost to the facility that purchased the drugs); and
- The average national administrative cost associated with dispensing the drugs for each prescription.

We provided a 30-day comment period that ended on August 10, 2009. We received comments from three commenters and the issues they raised are discussed below. Based on the rationale set forth in the proposed rule and this document, we are adopting the proposed rule with the nonsubstantive changes discussed below.

Two commenters indicated that the final rule should ensure that insurance companies pay VA in response to VA billing, and thereby reduce or eliminate the veterans' copayment. We agree that the payment practices of third-party payers need to be addressed. However, those practices are not within the scope of this rulemaking. This rulemaking concerns VA's methodology for determining reasonable charges for prescription drugs. We did not propose to amend other VA regulations regarding third-party payment procedures or to promulgate new regulations regarding such procedures. However, we intend to separately publish a proposed rule to address issues regarding requirements for third-party payers making payments to VA.

Another commenter raised a number of issues. All of these issues are discussed below.

The commenter indicated that the VA acquisition cost for prescription drugs could be more than the third-party payer cost for the same prescription drugs and seemed to suggest that the billing amount for the cost of the drugs should not be more than the amount that the third-party payer would be required to pay for the same prescription drugs. The commenter also indicated that the VA administrative fee of \$11.17 is more than the average private dispensing fee and that private industry has been successful in negotiating such fees in the range of \$1.50 to \$2.00. We clarified what is meant by administrative costs but made no other changes based on these comments.

Under the provisions of 38 U.S.C. 1729, VA has authority to bill third-party payers in an amount constituting "reasonable charges." We believe that the billing formula is warranted under the statute. Moreover, VA has taken steps to keep costs at a minimum.

In most cases VA purchases drugs in bulk at discounted prices. Also, insofar as possible, VA prescribes generic drugs.

Further, the \$1.50 to \$2.00 amounts quoted by the commenter were represented as negotiated fees and not represented as covering the actual administrative costs. We question whether these negotiated fees include all of the actual administrative costs. The VA administrative costs include general overhead costs, such as costs of buildings and maintenance, utilities, billing, and collections, and includes dispensing costs, such as costs of the labor of the pharmacy department, packaging, and mailing.

Even so, in some cases, a third party payor may be allowed to pay less than the VA billed amount. In this regard, under section 1729 a third party payor has the option of paying, to the extent of its coverage, either the billed charges or the amount the third-party payor would pay for the prescription drugs to private sector providers in the same geographic area. Accordingly, this alternative will continue to be available to third party payors in accordance with the statutory mandate (*see* 38 CFR 17.101(a)(4)).

The commenter questioned how VA will determine the price point within the drug file and how this information will be communicated to health plan payers. We made no changes based on this comment. The proposed rule stated that the prescription cost will be obtained from the Outpatient Pharmacy Prescription file or the Drug file at each VA facility (74 FR 32820). The product cost of the prescription will be calculated using the most recent purchase price of the product used by VA to fill the prescription. VA's bill will reflect the cost of the drugs, taking into consideration the quantity dispensed and VA's national administrative cost. The total prescription cost will be transmitted on a bill to a third-party payer.

In addition, the commenter also questioned what billing claim field VA will use for submitting cost information. We made no changes based on this comment. VA will combine the drug costs plus administrative costs and provide the total prescription cost in the appropriate field in the form submitted, *e.g.*, National Council for Prescription Drug Programs electronic format, UB04; Centers for Medicare and Medicaid Services (CMS) 1500.

The commenter also suggested that VA have a graduated or phased implementation so that third-party payers will have time to absorb the increased cost of payments. We do not believe that a graduated or phased implementation is necessary. Although payments made to VA by third party payors will represent an increase in the

amount of collections, we believe that the overall impact on third party payors will be minimal. In 2009, U.S sales of prescription drugs totaled approximately \$300.3 billion. In contrast, VA spent an estimated 4.9 billion on prescription drugs in 2009 (less than 2 per cent of the total sales). A large portion of the prescription drugs distributed in the U.S. are covered by third party payors. However, with or without the changes made by this rule, VA would have collected less than \$200 million in 2009 from third party payors.

Not only do we believe that the overall impact to third party payors will be minimal because of VA's minimal share, but as noted above, in some cases a third party payor may be allowed to pay less than the VA billed amount based on the provisions in section 1729 which provide that a third party payor has the option of paying, to the extent of its coverage, either the billed charges or the amount the third-party payor would pay for the prescription drugs to private sector providers in the same geographic area.

The commenter suggested that the final rule become effective only prospectively, questioned when the changes will become effective, and expressed concerns regarding when VA will make system changes necessary to implement the final rule. We agree with the commenter that the new billing methodology should not be applied retrospectively. This final rule is effective March 18, 2011. The system changes are scheduled to be in place on that date. For further clarification, we have added in the **DATES** section of this document a statement indicating that the final rule will apply to prescriptions filled on or after the effective date of this final rule. This will also provide some lead time for third party payors to prepare for compliance with the amended regulations.

We also added a clarifying change in paragraph (m). We inserted "regarding VA charges" after "Notwithstanding other provisions of this section" to emphasize that paragraph (m) does not concern other aspects of § 17.101, such as the provisions of 38 CFR 17.101(a)(4), which explain that a third-party payer's liability is limited, to the extent of its coverage, to the lesser of the billed charges or the amount that the third-party payer would pay to a provider other than VA.

As required by 38 U.S.C. 1729(c)(2)(A), we consulted with the Comptroller General of the United States prior to promulgating this 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 year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This document contains no collections of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Executive Order 12866

Executive Order 12866 directs agencies to assess all 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, and other advantages; distributive impacts; and equity). The Executive Order classifies as 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 the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this final rule and has concluded that it is a significant regulatory action under Executive Order 12866 because it may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Regulatory Flexibility Act

The Secretary hereby certifies that this 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 final rule will mainly affect large insurance companies. This final rule might have an insignificant impact on a few small entities that do an inconsequential amount of their business with VA. Therefore, pursuant to 5 U.S.C. 605(b), this final rule 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 and titles for the programs affected by this document are 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.

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.

Editorial Note: This document was received in the Office of the Federal Register on September 30, 2010.

Approved: January 11, 2010.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

■ For the reasons stated 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, 1721, and as noted in specific sections.

■ 2. Revise the second sentence of paragraph (a)(2) and paragraph (m) of § 17.101 to read as follows:

§ 17.101 Collection or recovery by VA for medical care or services provided or furnished to a veteran for a nonservice-connected disability.

(a) * * *

(2) * * * In addition, the charges billed for prescription drugs not administered during treatment will be the amount determined under paragraph (m) of this section. * * *

* * * * *

(m) *Charges for prescription drugs not administered during treatment.*

Notwithstanding other provisions of this section regarding VA charges, when VA provides or furnishes prescription drugs not administered during treatment, within the scope of care referred to in paragraph (a)(1) of this section, charges billed separately for such prescription drugs will consist of the amount that equals the total of the actual cost to VA for the drugs and the national average of VA administrative costs associated with dispensing the drugs for each prescription. The actual VA cost of a drug will be the actual amount expended by the VA facility for the purchase of the specific drug. The administrative cost will be determined annually using VA’s managerial cost accounting system. Under this accounting system, the average administrative cost is determined by adding the total VA national drug general overhead costs (such as costs of buildings and maintenance, utilities, billing, and collections) to the total VA national drug dispensing costs (such as costs of the labor of the pharmacy department, packaging, and mailing) with the sum divided by the actual number of VA prescriptions filled nationally. Based on this accounting system, VA will determine the amount of the average administrative cost annually for the prior fiscal year (October through September) and then apply the charge at the start of the next calendar year.

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