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The Department of Defense, Office of the Secretary, has authorized the following addition(s)/revision(s) to 32 CFR Part 199, reissued April 2005.

CHANGE TITLE: **CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)/TRICARE: REFILLS OF MAINTENANCE MEDICATIONS THROUGH MILITARY TREATMENT FACILITY PHARMACIES OR NATIONAL MAIL ORDER PHARMACY PROGRAM**

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(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) Refund procedures. (i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to Sec. 199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to Sec. 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under paragraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor a requirement or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in Sec. 199.11, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a

refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) Remedies. In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) Beneficiary transition provisions. In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

(r) Refills of maintenance medications for eligible covered beneficiaries through the mail order pharmacy program--(1) In general. Consistent with section 702 of the National Defense Authorization Act for Fiscal Year 2015, this paragraph requires that for covered maintenance medications, beneficiaries are generally required to obtain their prescription through the national mail-order pharmacy program or through military treatment facility pharmacies. For purposes of this paragraph, eligible covered beneficiaries are those defined under sections 1072 and 1086 of title 10, United States Code.

(2) Medications covered. The Director, DHA, will establish, maintain, and periodically revise and update a list of covered maintenance medications subject to the requirement of paragraph (r)(1) of this section. The current list will be accessible through the TRICARE Pharmacy Program Internet Web site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will meet the following requirements:

(i) It will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

(ii) It will be clinically appropriate to dispense the medication from the mail order pharmacy.

(iii) It will be cost effective to dispense the medication from the mail order pharmacy.

(iv) It will be available for an initial filling of a 30-day or less supply through retail pharmacies.

(v) It will be generally available at military treatment facility pharmacies for initial fill and refills.

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- (vi) It will be available for refill through the national mail-order pharmacy program.
- (3) Refills covered. For purposes of the program under paragraph (r)(1) of this section, a refill is:
- (i) A subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription; or
 - (ii) A new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.
- (4) Waiver of requirement. A waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in the following circumstances:
- (i) There is a blanket waiver for prescription medications that are for acute care needs.
 - (ii) There is a blanket waiver for prescriptions covered by other health insurance.
 - (iii) There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, DHA.
- (5) Procedures. Under the program established by paragraph (r)(1) of this section, the Director, DHA will establish procedures for the effective operation of the program. Among these procedures are the following:
- (i) The Department will implement the program by utilizing best commercial practices to the extent practicable.
 - (ii) An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented.
 - (iii) Beneficiaries with active retail prescriptions for a medication on the maintenance medication list will be notified that their medication is included under the program. Beneficiaries will be advised that they may receive two 30 day fill at retail while they transition their prescription to the mail order program.
 - (iv) Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance.
 - (v) The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program.
 - (vi) In any case in which a beneficiary required under this paragraph (r) to obtain a maintenance medication prescription refill from national mail order pharmacy program and

attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver, consistent with paragraph (r)(4)(iii) of this section, or in taking any other appropriate action to meet the beneficiary's needs and to implement the program.

(vii) The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

(6) This program will remain in effect indefinitely with any adjustments or modifications required by law.

[69 FR 17048, Apr 1, 2004; 74 FR 11292, Mar 17, 2009; 74 FR 55776, Oct 29, 2009; 74 FR 65438, Dec 10, 2009; 75 FR 63397, Oct 15, 2010; 76 FR 41065, Jul 13, 2011; 78 FR 13241, Feb 27, 2013; 78 FR 75247, Dec 11, 2013; 80 FR 44272, Jul 27, 2015; 80 FR 46798, Aug 6, 2015]

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