



**OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS**

16401 EAST CENTRETECH PARKWAY
AURORA, COLORADO 80011-9043

TRICARE
MANAGEMENT ACTIVITY

MB&RB

**CHANGE 23
32 CFR 199
MARCH 17, 2009**

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TITLE 32 - CODE OF FEDERAL REGULATIONS - PART 199
(TMA VERSION)**

FINAL RULE

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: CHAMPUS/TRICARE: INCLUSION OF TRICARE RETAIL
PHARMACY PROGRAM IN FEDERAL PROCUREMENT OF
PHARMACEUTICALS**

FEDERAL REGISTER: Vol 74, No 50 (Pages 11279 - 11293)

PAGE CHANGE(S): See page 2.

**ATTACHMENT(S): 5 PAGES
DISTRIBUTION: 32 CFR 199**

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT

CHANGE 23
32 CFR 199
MARCH 17, 2009

REMOVE PAGE(S)

INSERT PAGE(S)

CHAPTER 21

Table of Contents, pages i and ii

Chapter page 11

Table of Contents, pages i and ii

Chapter pages 11 through 13

PHARMACY BENEFITS PROGRAM

(a) General-- 1
 (1) Statutory authority. 1
 (2) Pharmacy benefits program. 1
 (3) Uniform formulary. 1

(b) Definitions. 2
 (1) Clinically necessary. 2
 (2) Therapeutic class. 2

(c) Department of Defense Pharmacy and Therapeutics Committee-- 2
 (1) Purpose. 2
 (2) Composition. 2
 (3) Executive Council. 2

(d) Uniform Formulary Beneficiary Advisory Panel. 2

(e) Determinations regarding relative clinical and cost effectiveness for the selection of pharmaceutical agents for the uniform formulary-- 3
 (1) Clinical effectiveness. 3
 (2) Cost effectiveness. 4

(f) Evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary. 4

(g) Administrative procedures for establishing and maintaining the uniform formulary-- 5
 (1) Pharmacy and Therapeutics Committee determinations. 5
 (2) Beneficiary Advisory Panel. 5
 (3) Uniform formulary final decisions. 5

(h) Obtaining pharmacy services under the pharmacy benefits program-- 5
 (1) Points of service. 5
 (2) Availability of formulary pharmaceutical agents-- 6
 (i) General. 6
 (ii) Availability of formulary pharmaceutical agents at military treatment facilities. 6
 (3) Availability of non-formulary pharmaceutical agents-- 6
 (i) General. 6
 (ii) Availability of non-formulary pharmaceutical agents at military treatment facilities. 6
 (iii) Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services. 6
 (iv) Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP. 6

TMA Version - April 2005

TMA Version - April 2005

- (i) **Cost-sharing requirements under the pharmacy benefits program--** 7
 - (1) General. 7
 - (2) Cost-sharing amounts..... 7
 - (3) Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent..... 8
- (j) **Use of generic drugs under the pharmacy benefits program.**..... 9
- (k) **Preauthorization of certain pharmaceutical agents.** 10
- (l) **TRICARE Senior Pharmacy Program.**..... 10
- (m)**Effect of other health insurance.** 10
- (n) **Procedures.** 10
- (o) **Preemption of State laws.**..... 10
- (p) **General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program.**..... 11
- (q) **Pricing standards for retail pharmacy program--**..... 11
 - (1) **Statutory requirement.**..... 11
 - (2) **Manufacturer written agreement.** 11
 - (3) **Refund procedures.** 12
 - (4) **Remedies.**..... 13
 - (5) **Beneficiary transition provisions.**..... 13

(2) Based on the determination set forth in paragraph (o)(1) of this section, any State or local law relating to health insurance, prepaid health plans, or other health care delivery or financing methods is preempted and does not apply in connection with TRICARE pharmacy contracts. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal authority to enforce them in relation to the TRICARE pharmacy contracts. However, the Department of Defense may by contract establish legal obligations on the part of TRICARE contractors to conform with requirements similar or identical to requirements of State or local laws or regulations.

(3) The preemption of State and local laws set forth in paragraph (o)(1) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of the statutes identified in paragraph (o)(1) of this section. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD pharmacy services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD pharmacy services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(p) General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program. All fraud, abuse, and conflict of interest requirements for the basic CHAMPUS program, as set forth in this part 199 (see applicable provisions of Sec. 199.9 of this part) are applicable to the TRICARE pharmacy benefits program. Some methods and procedures for implementing and enforcing these requirements may differ from the methods and procedures followed under the basic CHAMPUS program.

(q) Pricing standards for retail pharmacy program--(1) Statutory requirement. (i) As required by 10 U.S.C. 1074g(f), with respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. 8126 to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

(ii) Under subparagraph (q)(1)(i) of this section, all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126.

(2) **Manufacturer written agreement.** (i) A written agreement by a manufacturer to honor the pricing standards required by 10 U.S.C. 1074g(f) and referred to in paragraph (q)(1) of this section for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for:

(A) Inclusion of that drug on the uniform formulary under this section; and

(B) Availability of that drug through retail network pharmacies without preauthorization under paragraph (k) of this section.

TMA Version - April 2005

(ii) A covered drug not under an agreement under paragraph (q)(2)(i) of this section requires preauthorization under paragraph (k) of this section to be provided through a retail network pharmacy under the Pharmacy Benefits Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126, but does not include:

- (A) A drug that is not a covered drug under 38 U.S.C. 8126;
- (B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);
- (C) A drug that is not provided through a retail network pharmacy under this section;
- (D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;
- (E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or
- (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 section 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under Sec. 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 subparagraph (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 an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in Sec. 199.11 of this section, 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 Sec. 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 Sec. 199.11 of this part.

(4) Remedies. In the case of the failure of a manufacturer of a covered drug to make or 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.

[69 FR 17048, Apr. 1, 2004; 74 FR 11292, Mar. 17, 2009]

TMA Version - April 2005

