OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
16401 EAST CENTRETECH PARKWAY
AURORA, CO 80011-9066

DEFENSE
HEALTH AGENCY

MB&RO

CHANGE 60
32 CFR 199
DECEMBER 11, 2013

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

INTERIM 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: **CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)/TRICARE: PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM**

FEDERAL REGISTER: Vol 78, No 238 (Pages 75245 - 75248)

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 60
32 CFR 199
DECEMBER 11, 2013

REMOVE PAGE(S)	**INSERT PAGE(S)**
CHAPTER 21	
Table of Contents, pages i and ii	Table of Contents, pages i and ii
Chapter page 15	Chapter pages 15 through 17

TABLE OF CONTENTS — PART 199.21

PHARMACY BENEFITS PROGRAM

(a) General-- . . . 1
(1) Statutory authority. . . . 1
(2) Pharmacy benefits program. . . . 1
(i) Applicability. . . . 1
(ii) Applicability exception. . . . 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. . . . 3

(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. . . . 5

(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
(4) Transition to the Uniform Formulary. . . . 6

(h) Obtaining pharmacy services under the retail network pharmacy benefits program. . . . 6
(1) Points of service. . . . 6
(2) Availability of formulary pharmaceutical agents. . . . 6
(i) General. . . . 6
(ii) Availability of formulary pharmaceutical agents at military treatment facilities (MTF). . . . 6
(3) Availability of non-formulary pharmaceutical agents-- . . . 7
(i) General. . . . 7
(ii) Availability of non-formulary pharmaceutical agents at military treatment facilities. . . . 7

TMA Version - April 2005

TMA Version - April 2005

(iii) Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services. 7
(iv) Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP. 7
(4) Availability of vaccines/immunizations. 7

(i) Cost-sharing requirements under the pharmacy benefits program-- 8
(1) General. 8
(2) Cost-sharing amounts. 8
(3) Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent. 9

(j) Use of generic drugs under the pharmacy benefits program. 10

(k) Preauthorization of certain pharmaceutical agents. 11

(l) TRICARE Senior Pharmacy Program. 11

(m)Effect of other health insurance. 11

(n) Procedures. 11

(o) Preemption of State laws. 12

(p) General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program. 12

(q) Pricing standards for retail pharmacy program-- 12
(1) Statutory requirement. 12
(2) Manufacturer written agreement. 13
(3) Refund procedures. 13
(4) Remedies. 14
(5) Beneficiary transition provisions. 14

(r) Refills of maintenance medications for TRICARE for Life beneficiaries through the mail order pharmacy program-- 15
(1) In general. 15
(2) Medications covered. 15
(3) Refills covered. 15
(4) Waiver of requirement. 15
(5) Procedures. 16
(6) Nonparticipation through opt-out from program. 16
(7) Expiration of program. 17

(r) Refills of maintenance medications for TRICARE for Life beneficiaries through the mail order pharmacy program--(1) In general. Consistent with section 716 of the National Defense Authorization Act for Fiscal Year 2013, this paragraph requires that for covered maintenance medications, TRICARE for Life 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, TRICARE for Life beneficiaries are those enrolled in the Medicare wraparound coverage option of the TRICARE program made available to the beneficiary under section 1086(d) of title 10, United States Code.

(2) Medications covered. The Director, TMA 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.

(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), 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

TMA Version - April 2005

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, TMA.

(5) Procedures. Under the program established by paragraph (r)(1) of this section, the Director, TMA 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 covered under the program. Beneficiaries will be advised that they may receive up to two 30 day fills at retail while they transition their prescription to the mail order program. The beneficiary will be contacted after each of these two fills reminding the beneficiary that the prescription must be transferred to mail.

(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 paragraph (r) of this section 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) Nonparticipation through opt-out from program. Any beneficiary who has been covered by the program under paragraph (r)(1) of this section for a period of at least one year may opt out of continuing to participate in the program.

(i) For this purpose, the starting date for this one-year period is the first date after the effective date of paragraph (r)(1) of this section on which the beneficiary had a maintenance medication prescription filled through the mail order pharmacy program.

(ii) The beneficiary may exercise his or her right to opt out of the program by contacting the

TMA Version - April 2005

PBM.

(iii) Following an opt out, the beneficiary may obtain prescriptions from a retail pharmacy, subject to limitations under the TRICARE Pharmacy Benefits Program other than those under paragraph (r) of this section. These beneficiaries may also, if they wish, obtain refills from military treatment facility pharmacies and the mail order pharmacy program.

(7) Expiration of program. The program and requirements established under paragraph (r)(1) of this section will expire December 31, 2017, unless Congress enacts a statutory extension of the program. If this happens, the program will automatically continue, 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]

TMA Version - April 2005