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TRICARE
MANAGEMENT ACTIVITY

MB&RB

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**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
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(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: CHAMPUS/TRICARE: INCLUSION OF RETAIL NETWORK PHARMACIES
AS AUTHORIZED TRICARE PROVIDERS FOR THE ADMINISTRATION OF
TRICARE COVERED VACCINES**

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PAGE CHANGE(S): See page 2.

**ATTACHMENT(S): 20 PAGES
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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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(C) Mental health counselor. For the purposes of CHAMPUS, a mental health counselor is an individual who meets the following requirements:

(1) Minimum of a master's degree in mental health counseling or allied mental health field from a regionally accredited institution; and

(2) Two years of post-masters experience which includes 3000 hours of clinical work and 100 hours of face-to-face supervision; and

(3) Is licensed or certified to practice as a mental health counselor by the jurisdiction where practicing (see paragraph (c)(3)(iv)(D) of this section for more specific information); and

(4) May only be reimbursed when:

(i) The CHAMPUS beneficiary is referred for therapy by a physician; and

(ii) A physician is providing ongoing oversight and supervision of the therapy being provided; and

(iii) The mental health counselor certifies on each claim for reimbursement that a written communication has been made or will be made to the referring physician of the results of the treatment. Such communication will be made at the end of the treatment, or more frequently, as required by the referring physician (refer to Sec. 199.7).

(D) The following additional information applies to each of the above categories of extramedical individual providers:

(1) These providers must also be licensed or certified to practice as a certified marriage and family therapist, pastoral counselor or mental health counselor by the jurisdiction where practicing. In jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession.

(2) Grace period for therapists or counselors in states where licensure/certification is optional. CHAMPUS is providing a grace period for those therapists or counselors who did not obtain optional licensure/certification in their jurisdiction, not realizing it was a CHAMPUS requirement for authorization. The exemption by state law for pastoral counselors may have misled this group into thinking licensure was not required. The same situation may have occurred with the other therapist or counselor categories where licensure was either not mandated by the state or was provided under a more general category such as "professional counselors." This grace period pertains only to the licensure/certification requirement, applies only to therapists or counselors who are already approved as of October 29, 1990, and only in those areas where the licensure/certification is optional. Any therapist or counselor who is not licensed/certified in the state in which he/she is practicing by August 1, 1991, will be terminated under the provisions of Sec. 199.9. This grace period does not change any of the other existing requirements which remain in effect. During this grace period, membership or proof of eligibility for full clinical membership in a recognized professional association is required for those therapists or counselors who are not licensed or certified by the state. The following organizations are recognized for therapists or counselors at the level indicated: Full clinical member of the American Association of Marriage and

Family Therapy; membership at the fellow or diplomate level of the American Association of Pastoral Counselors; and membership in the National Academy of Certified Clinical Mental Health Counselors. Acceptable proof of eligibility for membership is a letter from the appropriate certifying organization. This opportunity for delayed certification/licensure is limited to the counselor or therapist category only as the language in all of the other provider categories has been consistent and unmodified from the time each of the other provider categories were added. The grace period does not apply in those states where licensure is mandatory.

(E) Christian Science practitioners and Christian Science nurses. CHAMPUS cost-shares the services of Christian Science practitioners and nurses. In order to bill as such, practitioners or nurses must be listed or be eligible for listing in the Christian Science Journal² at the time the service is provided.

(d) Other providers. Certain medical supplies and services of an ancillary or supplemental nature are coverable by CHAMPUS, subject to certain controls. This category of provider includes the following:

(1) Independent laboratory. Laboratory services of independent laboratories may be cost-shared if the laboratory is approved for participation under Medicare and certified by the Medicare Bureau, Health Care Financing Administration.

(2) Suppliers of portable x-ray services. Such suppliers must meet the conditions of coverage of the Medicare program, set forth in the Medicare regulations, or the Medicaid program in that state in which the covered service is provided.

(3) **Pharmacies.** Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under Sec. 199.21 of this Part implementing the Pharmacy Benefits Program.

(4) Ambulance companies. Such companies must meet the requirements of state and local laws in the jurisdiction in which the ambulance firm is licensed.

(5) Medical equipment firms, medical supply firms, and Durable Medical Equipment, Prosthetic, Orthotic, Supplies providers/suppliers. Any firm, supplier, or provider that is an authorized provider under Medicare or is otherwise designated an authorized provider by the Director, TRICARE Management Activity.

(6) Mammography suppliers. Mammography services may be cost-shared only if the supplier is certified by Medicare for participation as a mammography supplier, or is certified by the American College of Radiology as having met its mammography supplier standards.

² Copies of this journal can be obtained through the Christian Science Publishing Company, 1 Norway Street, Boston, MA 02115-3122 or the Christian Science Publishing Society, P.O. Box 11369, Des Moines, IA 50340.

(e) Extended Care Health Option Providers.—(1) General. (i) Services and items cost-shared through Sec. 199.5 must be rendered by a CHAMPUS-authorized provider.

(ii) A Program for Persons with Disabilities (PPPWD) provider with TRICARE-authorized status on the effective date for the Extended Care Health Option (ECHO) Program shall be deemed to be a TRICARE-authorized provider until the expiration of all outstanding PFPWD benefit authorizations for services or items being rendered by the provider.

(2) ECHO provider categories--(i) ECHO inpatient care provider. A provider of residential institutional care, which is otherwise an ECHO benefit, shall be:

(A) A not-for-profit entity or a public facility; and

(B) Located within a state; and

(C) Be certified as eligible for Medicaid payment in accordance with a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) as a Medicaid Nursing Facility, or Intermediate Care Facility for the Mentally Retarded, or be a TRICARE-authorized institutional provider as defined in paragraph (b) of this section, or be approved by a state educational agency as a training institution.

(ii) ECHO outpatient care provider. A provider of ECHO outpatient, ambulatory, or in-home services shall be:

(A) A TRICARE-authorized provider of services as defined in this section; or

(B) An individual, corporation, foundation, or public entity that predominantly renders services of a type uniquely allowable as an ECHO benefit and not otherwise allowable as a benefit of Sec. 199.4, that meets all applicable licensing or other regulatory requirements of the state, county, municipality, or other political jurisdiction in which the ECHO service is rendered, or in the absence of such licensing or regulatory requirements, as determined by the Director, TRICARE Management Activity or designee.

(iii) ECHO vendor. A provider of an allowable ECHO item, such as supplies or equipment, shall be deemed to be a TRICARE-authorized vendor for the provision of the specific item, supply or equipment when the vendor supplies such information as the Director, TRICARE Management Activity or designee determines necessary to adjudicate a specific claim.

(3) ECHO provider exclusion or suspension. A provider of ECHO services or items may be excluded or suspended for a pattern of discrimination on the basis of disability. Such exclusion or suspension shall be accomplished according to the provisions of Sec. 199.9.

(f) Corporate services providers—(1) General. (i) This corporate services provider class is established to accommodate individuals who would meet the criteria for status as a CHAMPUS authorized individual professional provider as established by paragraph (c) of this section but for the fact that they are employed directly or contractually by a corporation or foundation that provides principally professional services which are within the scope of the CHAMPUS benefit.

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- (ii) Payment for otherwise allowable services may be made to a CHAMPUS-authorized corporate services provider subject to the applicable requirements, exclusions and limitations of this part.
- (iii) The Director, OCHAMPUS, or designee, may create discrete types within any allowable category of provider established by this paragraph (f) to improve the efficiency of CHAMPUS management.
- (iv) The Director, OCHAMPUS, or designee, may require, as a condition of authorization, that a specific category or type of provider established by this paragraph (f):
 - (A) Maintain certain accreditation in addition to or in lieu of the requirement of paragraph (f)(2)(v) of this section;
 - (B) Cooperate fully with a designated utilization and clinical quality management organization which has a contract with the Department of Defense for the geographic area in which the provider does business;
 - (C) Render services for which direct or indirect payment is expected to be made by CHAMPUS only after obtaining CHAMPUS written authorization; and
 - (D) Maintain Medicare approval for payment when the Director, OCHAMPUS, or designee, determines that a category, or type, of provider established by this paragraph (f) is substantially comparable to a provider or supplier for which Medicare has regulatory conditions of participation or conditions of coverage.
 - (v) Otherwise allowable services may be rendered at the authorized corporate services provider's place of business, or in the beneficiary's home under such circumstances as the Director, OCHAMPUS, or designee, determines to be necessary for the efficient delivery of such in-home services.
 - (vi) The Director, OCHAMPUS, or designee, may limit the term of a participation agreement for any category or type of provider established by this paragraph (f).
 - (vii) Corporate services providers shall be assigned to only one of the following allowable categories based upon the predominate type of procedure rendered by the organization;
 - (A) Medical treatment procedures;
 - (B) Surgical treatment procedures;
 - (C) Maternity management procedures;
 - (D) Rehabilitation and/or habilitation procedures; or
 - (E) Diagnostic technical procedures.
 - (viii) The Director, OCHAMPUS, or designee, shall determine the appropriate procedural category of a qualified organization and may change the category based upon the provider's CHAMPUS claim characteristics. The category determination of the Director, OCHAMPUS,

designee, is conclusive and may not be appealed.

(2) Conditions of authorization. An applicant must meet the following conditions to be eligible for authorization as a CHAMPUS corporate services provider:

(i) Be a corporation or a foundation, but not a professional corporation or professional association; and

(ii) Be institution-affiliated or freestanding as defined in Sec. 199.2; and

(iii) Provide:

(A) Services and related supplies of a type rendered by CHAMPUS individual professional providers or diagnostic technical services and related supplies of a type which requires direct patient contact and a technologist who is licensed by the state in which the procedure is rendered or who is certified by a Qualified Accreditation Organization as defined in Sec. 199.2; and

(B) A level of care which does not necessitate that the beneficiary be provided with on-site sleeping accommodations and food in conjunction with the delivery of services; and

(iv) Complies with all applicable organizational and individual licensing or certification requirements that are extant in the state, county, municipality, or other political jurisdiction in which the provider renders services; and

(v) Be approved for Medicare payment when determined to be substantially comparable under the provisions of paragraph (f)(1)(iv)(D) of this section or, when Medicare approved status is not required, be accredited by a qualified accreditation organization, as defined in Sec. 199.2; and

(vi) Has entered into a participation agreement approved by the Director, OCHAMPUS, or designee, which at least complies with the minimum participation agreement requirements of this section.

(3) Transfer of participation agreement. In order to provide continuity of care for beneficiaries when there is a change of provider ownership, the provider agreement is automatically assigned to the new owner, subject to all the terms and conditions under which the original agreement was made.

(i) The merger of the provider corporation or foundation into another corporation or foundation, or the consolidation of two or more corporations or foundations resulting in the creation of a new corporation or foundation, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation or foundation into the provider corporation or foundation does not constitute change of ownership.

(iii) The surviving corporation or foundation shall notify the Director, OCHAMPUS, or designee, in writing of the change of ownership promptly after the effective date of the transfer or change in ownership.

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(4) Pricing and payment methodology: The pricing and payment of procedures rendered by a provider authorized under this paragraph (f) shall be limited to those methods for pricing and payment allowed by this part which the Director, OCHAMPUS, or designee, determines contribute to the efficient management of CHAMPUS.

(5) Termination of participation agreement. A provider may terminate a participation agreement upon 45 days written notice to the Director, OCHAMPUS, or designee, and to the public.

[51 FR 24008, Jul 1, 1986; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 68 FR 65174, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44591, Jul 28, 2004; 69 FR 51568, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 70 FR 61378, Oct 24, 2005; 72 FR 63988, Nov 14, 2007; 74 FR 44755, Aug 31, 2009; 74 FR 55777, Oct 29, 2009; [74 FR 65438, Dec 10, 2009](#)]

EDITORIAL NOTE: For Federal Register citations affecting Sec. 199.6, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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- (7) Scheduled review of a therapeutic class; and
- (8) Requests from Pharmacy and Therapeutics Committee members, military treatment facilities, or other Military Health System officials.

(g) Administrative procedures for establishing and maintaining the uniform formulary--(1) Pharmacy and Therapeutics Committee determinations. Determinations of the Pharmacy and Therapeutics Committee are by majority vote and recorded in minutes of Committee meetings. The minutes set forth the determinations of the committee regarding the pharmaceutical agents selected for inclusion in the uniform formulary and summarize the reasons for those determinations. For any pharmaceutical agent (including maintenance medications) for which a recommendation is made that the status of the agent be changed from the formulary tier to the non-formulary tier of the uniform formulary, or that the agent requires a pre-authorization, the Committee shall also make a recommendation as to effective date of such change that will not be longer than 180 days from the final decision date but may be less. The minutes will include a record of the number of members voting for and against the Committee's action.

(2) Beneficiary Advisory Panel. Comments and recommendations of the Beneficiary Advisory Panel are recorded in minutes of Panel meetings. The minutes set forth the comments and recommendations of the Panel and summarize the reasons for those comments and recommendations. The minutes will include a record of the number of members voting for or against the Panel's comments and recommendations.

(3) Uniform formulary final decisions. The Director of the TRICARE Management Activity makes the final DoD decisions regarding the uniform formulary. Those decisions are based on the Director's review of the final determinations of the Pharmacy and Therapeutics Committee and the comments and recommendations of the Beneficiary Advisory Panel. No pharmaceutical agent may be designated as non-formulary on the uniform formulary unless it is preceded by such recommendation by the Pharmacy and Therapeutics Committee. The decisions of the Director of the TRICARE Management Activity are in writing and establish the effective date(s) of the uniform formulary actions.

(4) Transition to the Uniform Formulary. Beginning in Fiscal Year 2005, under an updated charter for the DoD P&T Committee, the committee shall meet at least quarterly to review therapeutic classes of pharmaceutical agents and make recommendations concerning which pharmaceutical agents should be on the Uniform Formulary, the Basic Care Formulary (BCF), and Extended Core Formulary (ECF). The P&T Committee will review the classes in a methodical, but expeditious manner. During the transition period from the previous

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methodology of formulary management involving only the MTFs and the TMOP Program, previous decisions by the predecessor DoD P&T Committee concerning MTF and Mail Order Pharmacy Program formularies shall continue in effect. As therapeutic classes are reviewed under the new formulary management process, the processes established by this section shall apply.

(h) Obtaining pharmacy services under the retail network pharmacy benefits program. (1) Points of service. There are four outpatient pharmacy points of service:

- (i) Military Treatment Facilities (MTFs);
- (ii) Retail network pharmacies: Those are non-MTF pharmacies that are a part of the network established for TRICARE retail pharmacy services;
- (iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services, and
- (iv) the TRICARE Mail Order Pharmacy (TMOP).

(2) Availability of formulary pharmaceutical agents--(i) General. Subject to paragraph (h)(2)(ii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all of the points of service identified in paragraph (h)(1) of this section.

(ii) Availability of formulary pharmaceutical agents at military treatment facilities (MTF). Pharmaceutical agents included on the uniform formulary are available through facilities of uniformed services, consistent with the scope of health care services offered in such facilities and additional determinations by the P&T Committee of the relative clinical effectiveness and cost effectiveness, based on costs to the Program associated with providing the agents to beneficiaries. The BCF is a subset of the uniform formulary and is a mandatory component of formularies at all full-service MTF pharmacies. The BCF contains the minimum set of pharmaceutical agents that each full-service MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Limited-service MTF pharmacies (e.g., specialty pharmacies within an MTF or pharmacies servicing only active duty military members) are not required to include the entire BCF on their formularies, but may limit their formularies to those BCF agents appropriate to the needs of the patients they serve. An ECF may list preferred agents in drug classes other than those covered by the BCF. Among BCF and ECF agents, individual MTF formularies are determined by local P&T Committees based on the scope of health care services provided at the respective MTFs. All pharmaceutical agents on the local formulary of full-service MTF pharmacies must be available to all categories of beneficiaries.

(3) Availability of non-formulary pharmaceutical agents--(i) General. Non-formulary pharmaceutical agents are generally available under the pharmacy benefits program from the retail network pharmacies, retail non-network pharmacies, and the TRICARE Mail Order Pharmacy (TMOP) at the non-formulary cost-share.

(ii) Availability of non-formulary pharmaceutical agents at military treatment facilities. Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through the MTF pharmacies for

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prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent.

(iii) Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services. The pharmacy benefits program is required to assure the availability of clinically appropriate pharmaceutical agents to members of the uniformed services, including, where appropriate, agents not included on the uniform formulary. Clinically appropriate pharmaceutical agents will be made available to members of the Uniformed Services, including, where medical necessity has been validated, agents not included on the uniform formulary. MTFs shall establish procedures to evaluate the clinical necessity of prescriptions written for members of the uniformed services for pharmaceutical agents not included on the uniform formulary. If it is determined that the prescription is clinically necessary, the MTF will provide the pharmaceutical agent to the member.

(iv) Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP. Eligible beneficiaries will receive non-formulary pharmaceutical agents at the formulary cost-share when medical necessity has been established by the beneficiary and/or his/her provider. The peer review provisions of Sec. 199.15 shall apply to the clinical necessity pre-authorization determinations. TRICARE may require that the time for review be expedited under the pharmacy benefits program.

(4) Availability of vaccines/immunizations. This paragraph (h)(4) applies to the following three immunizations: H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. A retail network pharmacy may be an authorized provider under the Pharmacy Benefits Program when functioning within the scope of its state laws to provide authorized vaccines/immunizations to an eligible beneficiary. The Pharmacy Benefits Program will cover the vaccine and its administration by the retail network pharmacy, including administration by pharmacists who meet the applicable requirements of state law to administer the vaccine. A TRICARE authorized vaccine/immunization includes vaccines/immunizations authorized as preventive care under the basic program benefits of Sec. 199.4 of this Part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of section 199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of Sec. 199.18 for preventive care vaccines/immunizations received from a retail network pharmacy that is a TRICARE authorized provider. Any additional policies, instructions, procedures, and guidelines appropriate for implementation of this benefit may be issued by the TMA Director, or designee.

(i) **Cost-sharing requirements under the pharmacy benefits program--**(1) General. Under 10 U.S.C. 1074g(a)(6), cost-sharing requirements are established in this section for the pharmacy benefits program independent of those established under other provisions of this Part. Cost-shares under this section partially defray government costs of administering the pharmacy benefits program when collected by the government for prescriptions dispensed through the retail network pharmacies or the TRICARE Mail Order Pharmacy. The higher cost-share paid for prescriptions dispensed by a non-network retail pharmacy is established to encourage the use of the most economical venue to the government. Cost-sharing requirements are based on the classification of a pharmaceutical agent as generic, formulary, or non-formulary, in conjunction with the point of service from which the agent is acquired.

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(2) Cost-sharing amounts. Active duty members of the uniformed services do not pay cost-shares. For other categories of beneficiaries, cost-sharing amounts are as follows:

(i) For pharmaceutical agents obtained from a military treatment facility, there is no co-payment.

(ii) For pharmaceutical agents obtained from a retail network pharmacy there is a:

(A) \$9.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment per prescription for up to a 30-day supply of a non-formulary pharmaceutical agent.

(D) \$0.00 co-payment for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy there is a 20 percent or \$9.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20 percent or \$22.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(v) For pharmaceutical agents obtained under the TMOP program there is a:

(A) \$9.00 co-payment per prescription for up to a 90-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent.

(vi) For TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies, the enrollment year deductible for outpatient claims is \$300 per individual; \$600 per family; and a point of service cost-share of 50 percent thereafter applies in lieu of the 20 percent co-payment.

(vii) Except as provided in paragraph (h)(2)(viii) of this section, for pharmaceutical agents acquired by TRICARE Standard beneficiaries from retail non-network pharmacies, beneficiaries are subject to the \$150.00 per individual or \$300.00 maximum per family annual fiscal year deductible.

(viii) Under TRICARE Standard, dependents of members of the uniformed services whose pay grade is E-4 or below are subject to the \$50.00 per individual or \$100.00 maximum per family annual fiscal year deductible.

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(ix) The TRICARE catastrophic cap limits apply to pharmacy benefits program cost-sharing.

(x) The per prescription co-payments established in this paragraph (i)(2) of this section may be adjusted periodically based on experience with the uniform formulary, changes in economic circumstances, and other appropriate factors. Any such adjustment may be made upon the recommendation of the Pharmacy and Therapeutics Committee and approved by the Assistant Secretary of Defense (Health Affairs). Any such adjusted amount will maintain compliance with the requirements of 10 U.S.C. 1074g(a)(6).

(xi) For a Medicare-eligible beneficiary, the cost-sharing requirements may not be in excess of the cost-sharing requirements applicable to all other beneficiaries covered by 10 U.S.C. 1086.

(3) Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent. (i) When there is a clinical necessity for the use of a non-formulary pharmaceutical agent that is not otherwise excluded as a covered benefit, the pharmaceutical agent will be provided at the same co-payment as a formulary pharmaceutical agent can be obtained.

(ii) A clinical necessity for use of a non-formulary pharmaceutical agent is established when the beneficiary or their provider submits sufficient information to show that one or more of the following conditions exist:

(A) The use of formulary pharmaceutical agents is contraindicated;

(B) The patient experiences significant adverse effects from formulary pharmaceutical agents, or the provider shows that the patient is likely to experience significant adverse effects from formulary pharmaceutical agents;

(C) Formulary pharmaceutical agents result in therapeutic failure, or the provider shows that the formulary pharmaceutical agent is likely to result in therapeutic failure;

(D) The patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur unacceptable clinical risk; or

(E) There is no alternative pharmaceutical agent on the formulary.

(iii) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided to TRICARE for prescriptions submitted to a retail network pharmacy.

(iv) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided as part of the claims processes for non-formulary pharmaceutical agents obtained through non-network points of service, claims as a result of other health insurance, or any other situations requiring the submission of a manual claim.

(v) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may be provided with the prescription submitted to the TMOP contractor.

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(vi) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may also be provided at a later date, but no later than sixty days from the dispensing date, as an appeal to reduce the non-formulary co-payment to the same co-payment as a formulary drug.

(vii) The process of establishing clinical necessity will not unnecessarily delay the dispensing of a prescription. In situations where clinical necessity cannot be determined in a timely manner, the non-formulary pharmaceutical agent will be dispensed at the non-formulary co-payment and a refund provided to the beneficiary should clinical necessity be established.

(viii) Peer review and appeal and hearing procedures. All levels of peer review, appeals, and grievances established by the Contractor for internal review shall be exhausted prior to forwarding to TRICARE Management Activity for a formal review. Procedures comparable to those established under Secs. 199.15 and 199.10 of this part shall apply. If it is determined that the prescription is clinically necessary, the pharmaceutical agent will be provided to the beneficiary at the formulary cost-share. TRICARE may require that the time periods for peer review or for appeal and hearing be expedited under the pharmacy benefits program. For purposes of meeting the amount in dispute requirement of Sec. 199.10(a)(7), the relevant amount is the difference between the cost shares of a formulary versus non-formulary drug. The amount for each of multiple prescriptions involving the same drug to treat the same medical condition and filled within a 12-month period may be combined to meet the required amount in dispute.

(j) Use of generic drugs under the pharmacy benefits program. (1) The designation of a drug as a generic, for the purpose of applying cost-shares at the generic rate, will be determined through the use of standard pharmaceutical references as part of commercial best business practices. Pharmaceutical agents will be designated as generics when listed with an "A" rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the Food and Drug Administration, or any successor to such reference. Generics are multisource products that must contain the same active ingredients, are of the same dosage form, route of administration and are identical in strength or concentration.

(2) The pharmacy benefits program generally requires mandatory substitution of generic drugs listed with an "A" rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA and generic equivalents of grandfather or Drug Efficacy Study Implementation (DESI) category drugs for brand name drugs. In cases in which there is a clinical justification for a brand name drug in lieu of a generic equivalent, under the standards and procedures of paragraph (h)(3) of this section, the generic substitution policy is waived.

(3) When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate.

(k) Preauthorization of certain pharmaceutical agents. (1) Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness.

(2) The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of pharmaceutical agents within a therapeutic class. Pharmaceutical agents that require prior authorization will be identified by a majority vote of the Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee will establish the prior authorization criteria for the pharmaceutical agent.

(3) Prescriptions for pharmaceutical agents for which prior authorization criteria are not met will not be cost-shared under the TRICARE pharmacy benefits program.

(4) The Director, TRICARE Management Activity, may issue policies, procedures, instructions, guidelines, standards or criteria to implement this paragraph (k).

(l) TRICARE Senior Pharmacy Program. Section 711 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (Public Law 106-398, 114 Stat. 1654A-175) established the TRICARE Senior Pharmacy Program for Medicare eligible beneficiaries effective April 1, 2001. These beneficiaries are required to meet the eligibility criteria as prescribed in Sec. 199.3 of this part. The benefit under the TRICARE Senior Pharmacy Program applies to prescription drugs and medicines provided on or after April 1, 2001.

(m) Effect of other health insurance. The double coverage rules of section 199.8 of this part are applicable to services provided under the pharmacy benefits program. For this purpose, the Medicare prescription drug benefit under Medicare Part D, prescription drug benefits provided under Medicare Part D plans are double coverage plans and such plans will be the primary payer, to the extent described in section 199.8 of this part. Beneficiaries who elect to use these pharmacy benefits shall provide DoD with other health insurance information.

(n) Procedures. The Director, TRICARE Management Activity shall establish procedures for the effective operation of the pharmacy benefits program. Such procedures may include restrictions of the quantity of pharmaceuticals to be included under the benefit, encouragement of the use of generic drugs, implementation of quality assurance and utilization management activities, and other appropriate matters.

(o) Preemption of State laws. (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of 10 U.S.C. chapter 55, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States.

(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

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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.

(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.

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(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).

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(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.

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