

Part 199.21

Pharmacy Benefits Program

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(a) General--(1) *Statutory authority.* Title 10, U.S. Code, Section 1074g requires that the Department of Defense establish an effective, efficient, integrated pharmacy benefits program for the Military Health System. This law is independent of a number of sections of Title 10 and other laws that affect the benefits, rules, and procedures of TRICARE, resulting in changes to the rules otherwise applicable to TRICARE Prime, Standard, and Extra.

(2) *Pharmacy benefits program.* (i) *Applicability.* The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Geographically, except as specifically provided in paragraph (a)(2)(ii) of this section, this program is applicable to all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)), the TRICARE pharmacy benefits program may be implemented in areas outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the ASD(HA) may also authorize modifications to the pharmacy benefits program rules and procedures as may be appropriate to the area involved.

(ii) *Applicability exception.* The pharmaceutical benefit under the TRICARE smoking cessation program under Sec. 199.4(e)(30) is available to TRICARE beneficiaries who are not entitled to Medicare benefits authorized under Title XVIII of the Social Security Act. Except as noted in Sec. 199.4(e)(30), the smoking cessation program, including the pharmaceutical benefit, is not applicable or available to beneficiaries who reside overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, except that under the authority of Sec. 199.17 active duty service members and active duty dependents enrolled in TRICARE Prime residing overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, shall have access to smoking cessation pharmaceuticals through either an MTF or the TMOP program where available.

(3) *Uniform formulary.* The pharmacy benefits program features a uniform formulary of pharmaceutical agents as defined in Sec. 199.2.

(i) The uniform formulary will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized as basic program benefits.

(ii) As required by 10 U.S.C. 1074g(a)(2) and implemented under the procedures established by paragraphs (e) and (f) of this section, pharmaceutical agents in each therapeutic class are selected for inclusion on the uniform formulary based upon the relative clinical effectiveness and cost effectiveness of the agents in such class. If a pharmaceutical agent in a therapeutic class is determined by the Department of Defense Pharmacy and Therapeutics Committee not to have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other pharmaceutical agents included on the uniform formulary, the Committee may recommend it be

classified as a non-formulary agent. In addition, if the evaluation by the Pharmacy and Therapeutics Committee concludes that a pharmaceutical agent in a therapeutic class is not cost effective relative to other pharmaceutical agents in that therapeutic class, considering costs, safety, effectiveness, and clinical outcomes, the Committee may recommend it be classified as a non-formulary agent.

(iii) Pharmaceutical agents which are used exclusively in medical treatments or procedures that are expressly excluded from the TRICARE benefit by statute or regulation will not be considered for inclusion on the uniform formulary. Excluded pharmaceutical agents shall not be available as non-formulary agents, nor will they be cost-shared under the TRICARE pharmacy benefits program.

(b) Definitions. For most definitions applicable to the provisions of this section, refer to Sec. 199.2. The following definitions apply only to this section:

(1) *Clinically necessary.* Also referred to as clinical necessity. Sufficient evidence submitted by a beneficiary or provider on behalf of the beneficiary that establishes that one or more of the following conditions exist: The use of formulary pharmaceutical agents is contraindicated; the patient experiences significant adverse effects from formulary pharmaceutical agents in the therapeutic class, or is likely to experience significant adverse effects from formulary pharmaceutical agents in the therapeutic class; formulary pharmaceutical agents result in therapeutic failure, or the formulary pharmaceutical agent is likely to result in therapeutic failure; the patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur an unacceptable clinical risk; or there is no alternative pharmaceutical agent on the formulary.

(2) *Therapeutic class.* A group of pharmaceutical agents that are similar in chemical structure, pharmacological effect, and/or clinical use.

(3) *Over-the-counter drug.* A drug that is not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(c) Department of Defense Pharmacy and Therapeutics Committee--(1) *Purpose.* The Department of Defense Pharmacy and Therapeutics Committee is established by 10 U.S.C. 1074g to assure that the selection of pharmaceutical agents for the uniform formulary is based on broadly representative professional expertise concerning relative clinical and cost effectiveness of pharmaceutical agents and accomplishes an effective, efficient, integrated pharmacy benefits program.

(2) *Composition.* As required by 10 U.S.C. 1074g(b), the committee includes representatives of pharmacies of the uniformed services facilities and representatives of providers in facilities of the uniformed services. Committee members will have expertise in treating the medical needs of the populations served through such entities and in the range of pharmaceutical and biological medicines available for treating such populations.

(3) *Executive Council.* The Pharmacy and Therapeutics Committee may have an Executive Council, composed of those voting and non-voting members of the Committee who are military or civilian employees of the Department of Defense. The function of the Executive Council is to review and analyze issues relating to the operation of the uniform formulary, including issues of an inherently governmental nature, procurement sensitive information, and matters affecting military readiness. The Executive Council presents information to the Pharmacy and Therapeutics Committee, but is not authorized to act for the Committee.

(d) Uniform Formulary Beneficiary Advisory Panel. As required by 10 U.S.C. 1074g(c), a Uniform Formulary Beneficiary Advisory Panel reviews and comments on the development of the uniform formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the TRICARE mail-order pharmacy program, and TRICARE network providers. The panel will meet after each Pharmacy and Therapeutics Committee quarterly meeting. The Panel's comments will be submitted to the Director, TRICARE Management Activity. The Director will consider the comments before implementing the uniform formulary or any recommendations for change made by the Pharmacy and Therapeutics Committee. The Panel will function in accordance with the Federated Advisory Committee Act (5 U.S.C. App. 2).

(e) Determinations regarding relative clinical and cost effectiveness for the selection of pharmaceutical agents for the uniform formulary--(1) *Clinical effectiveness.* (i) It is presumed that pharmaceutical agents in a therapeutic class are clinically effective and should be included on the uniform formulary unless the Pharmacy and Therapeutics Committee finds by a majority vote that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over the other pharmaceutical agents included on the uniform formulary in that therapeutic class. This determination is based on the collective professional judgment of the DoD Pharmacy and Therapeutics Committee and consideration of pertinent information from a variety of sources determined by the Committee to be relevant and reliable. The DoD Pharmacy and Therapeutics Committee has discretion based on its collective professional judgment in determining what sources should be reviewed or relied upon in evaluating the clinical effectiveness of a pharmaceutical agent in a therapeutic class.

(ii) Sources of information may include but are not limited to:

(A) Medical and pharmaceutical textbooks and reference books;

(B) Clinical literature;

(C) U.S. Food and Drug Administration determinations and information;

(D) Information from pharmaceutical companies;

(E) Clinical practice guidelines, and

(F) Expert opinion.

(iii) The DoD Pharmacy and Therapeutics Committee will evaluate the relative clinical effectiveness of pharmaceutical agents within a therapeutic class by considering information about their safety, effectiveness, and clinical outcome.

(iv) Information considered by the Committee may include but is not limited to:

(A) U.S. Food and Drug Administration approved and other studied indications;

(B) Pharmacology;

(C) Pharmacokinetics;

- (D) Contraindications;
 - (E) Warnings/precautions;
 - (F) Incidence and severity of adverse effects;
 - (G) Drug to drug, drug to food, and drug to disease interactions;
 - (H) Availability, dosing, and method of administration;
 - (I) Epidemiology and relevant risk factors for diseases/conditions in which the pharmaceutical agents are used;
 - (J) Concomitant therapies;
 - (K) Results of safety and efficacy studies;
 - (L) Results of effectiveness/clinical outcomes studies, and
 - (M) Results of meta-analyses.
- (2) *Cost effectiveness.* (i) In considering the relative cost effectiveness of pharmaceutical agents in a therapeutic class, the DoD Pharmacy and Therapeutics Committee shall evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes of the other agents in the class.
- (ii) Information considered by the Committee concerning the relative cost effectiveness of pharmaceutical agents may include but is not limited to:
- (A) Cost of the pharmaceutical agent to the Government;
 - (B) Impact on overall medical resource utilization and costs;
 - (C) Cost-efficacy studies;
 - (D) Cost-effectiveness studies;
 - (E) Cross-sectional or retrospective economic evaluations;
 - (F) Pharmacoeconomic models;
 - (G) Patent expiration dates;
 - (H) Clinical practice guideline recommendations, and
 - (I) Existence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts.
- (3) *Special rules for best clinical effectiveness.* (i) Under the authority of 10 U.S.C. 1074g(a)(10), the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary

actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures under 10 U.S.C. 1074g(a)(2), (5) and (6) and the related provisions of this section.

(ii) Actions under paragraph (e)(3)(i) of this section may include a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. A partial exclusion may be implemented through any means recommended by the Pharmacy and Therapeutics Committee, including but not limited to preauthorization under paragraph (k) of this section. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded.

(iii) Actions under paragraph (e)(3)(i) of this section may also include giving preferential status to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.

(f) Evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary. The DoD Pharmacy and Therapeutics Committee will periodically evaluate or re-evaluate individual pharmaceutical agents and therapeutic classes of pharmaceutical agents for determinations regarding inclusion or continuation on the uniform formulary. Such evaluation or re-evaluation may be prompted by a variety of circumstances including, but not limited to:

- (1) Approval of a new pharmaceutical agent by the U.S. Food and Drug Administration;
- (2) Approval of a new indication for an existing pharmaceutical agent;
- (3) Changes in the clinical use of existing pharmaceutical agents;
- (4) New information concerning the safety, effectiveness or clinical outcomes of existing pharmaceutical agents;
- (5) Price changes;
- (6) Shifts in market share;
- (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 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.

(5) *Administrative procedure for newly approved drugs.* In the case of a newly approved innovator drug, other than a generic drug, the innovator drug will, not later than 120 days after the date of approval by the Food and Drug Administration, be added to the uniform formulary unless prior to that date the P&T Committee has recommended that the agent be listed as a non-formulary drug. If the Director, DHA subsequently approves that recommendation, the drug will be so listed. If the Director, DHA disapproves the recommendation to list the drug as non-formulary Third Tier, the drug will be then classified per the Director's decision. If, prior to the expiration of 120 days, the P&T Committee recommends that the agent be added to the uniform formulary and the recommendation is approved by the Director, DHA, that will be done as soon as feasible. Pending action under this paragraph (g)(5), the newly approved pharmaceutical agent will be considered to be in a classification pending status and will be available to beneficiaries under Third Tier terms applicable to all other non-formulary agents.

(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 paragraphs (h)(2)(ii) and (h)(2)(iii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all 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.

(iii) Pharmaceutical agents prescribed for smoking cessation are not available for coverage when obtained through a retail pharmacy. This includes network and non-network retail pharmacies.

(3) *Availability of non-formulary pharmaceutical agents.* --(i) *General.* Non-formulary pharmaceutical agents are generally not available in military treatment facilities or in the retail point of service. They are available in the mail order program.

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities.* Even when particular non-formulary agents are not generally available at military treatment facilities, they will be made available to eligible covered beneficiaries through the non-formulary special approval process as noted in this paragraph (h)(3)(ii) when there is a valid 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.* 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 only 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 Sec. 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.

(5) *Availability of selected over-the-counter (OTC) drugs under the pharmacy benefits program.* Although the pharmacy benefits program generally covers only prescription drugs, in some cases over-the-counter drugs may be covered and may be placed on the uniform formulary.

(i) An OTC drug may be included on the uniform formulary upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. Clinical need is judged by the criteria found in paragraph (e)(1)(i) and (ii) of this section. Cost effectiveness is determined based on criteria found in paragraph (e)(2) of this section.

(ii) OTC drugs placed on the uniform formulary, in general, will be treated the same as generic drugs on the uniform formulary for purposes of availability in MTF pharmacies, retail pharmacies, and the mail order pharmacy program and other requirements. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the requirement for a prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under paragraph (i)(2)(xii) of this section for OTC drugs specifically used in certain emergency care treatment situations.

(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.

(2) *Cost-sharing amounts.* Active duty members of the uniformed services do not pay cost-shares or annual deductibles. For other categories of beneficiaries, after applicable annual deductibles are met, cost-sharing amounts prior to October 1, 2016, are set forth in this paragraph (i)(2):

(i) For pharmaceutical agents obtained from a military treatment facility, there is no cost-sharing or annual deductible.

(ii) For pharmaceutical agents obtained from a retail network pharmacy, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a \$0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy, except as provided in paragraph (i)(2)(vi) of this section, there is a 20 percent or \$20.00 cost-share (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For pharmaceutical agents obtained under the TRICARE mail order program, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a \$0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program.

(v) [Reserved]

(vi) For TRICARE Prime beneficiaries there is no annual deductible applicable for pharmaceutical agents obtained from retail network pharmacies or the TRICARE mail-order program. However, for TRICARE Prime beneficiaries who obtain formulary or generic pharmaceutical agents from retail nonnetwork pharmacies, an enrollment year deductible of \$300 per person and \$600 per family must be met after which there is a beneficiary cost-share of 50 percent per prescription for up to a 30-day supply of the pharmaceutical agent.

(vii) For TRICARE Select beneficiaries the annual deductible which must be met before the cost-sharing amounts for pharmaceutical agents in paragraph (i)(2) of this section are applicable is as provided for each category of TRICARE Select enrollee in Sec. 199.17(l)(2).

(viii) For TRICARE beneficiaries not otherwise qualified to enroll in TRICARE Prime or Select, the annual deductible which must be met before the cost-sharing amounts for pharmaceutical agents in paragraph (i)(2) of this section are applicable is as provided in Sec. 199.4(f).

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

(x) For any year after 2027, the cost-sharing amounts under this paragraph shall be equal to the cost-sharing amounts for the previous year adjusted by an amount, if any, determined by the Director to reflect changes in the costs of pharmaceutical agents and prescription dispensing, rounded to the nearest dollar. These cost changes, if any, will consider costs under the TRICARE pharmacy benefits program calculated separately for each of the following categories based on prescriptions filled in the most recent period for which TRICARE cost data are available, updated to the current year, if necessary, by appropriate industry data:

(A) Generic drugs in the retail point of service;

(B) Formulary drugs in the retail point of service;

- (C) Generic drugs in the mail order point of service;
- (D) Formulary drugs in the mail order point of service;
- (E) Non-formulary drugs.

(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.

(xii) *Special copayment rule for OTC drugs in the retail pharmacy network.* As a general rule, OTC drugs placed on the uniform formulary under paragraph (h)(5) of this section will have copayments equal to those for generic drugs on the uniform formulary. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the copayment may be established at \$0.00 for any particular OTC drug in the retail pharmacy network.

(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.

(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.

(4) Upon the recommendation of the Pharmacy and Therapeutics Committee, a generic drug may be classified as non-formulary if it is less cost effective than non-generic formulary drugs in the same drug class.

(5) The beneficiary copayment amount for any generic drug prescription may not exceed the total charge for that prescription.

(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 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 paragraph (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.

(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 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 non-generic 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 non-generic 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) 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 result in 100% patient cost shares and will be blocked from any TRICARE payments 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) This program will remain in effect indefinitely with any adjustments or modifications required by law.

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