the attorneys and non-attorney representatives who appear before the Department are from larger firms. For these reasons, the Chief Counsel for Regulation certified this rule would not result in a significant economic impact to a substantial number of small entities.

Paperwork Reduction Act

It has been determined that this rulemaking does not contain an information collection subject to the Paperwork Reduction Act.

Executive Order 12866

It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

Executive Order 13132

It has been determined that the proposed rulemaking does not contain federalism implications warranting the preparation of a federalism assessment.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping duties, Countervailing duties.

Dated: June 15, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

For the reasons stated above, the Department proposes to amend 19 CFR part 351 as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

2. Add § 351.313 to subpart C to read as follows:

§ 351.313 Attorneys or representatives.

No register of attorneys or representatives who may practice before the Department is maintained. No application for admission to practice is required. Any person desiring to appear as attorney or representative before the Department may be required to show to the satisfaction of the Secretary his acceptability in that capacity. Any attorney or representative practicing before the Department, or desiring so to practice, may for good cause shown be suspended or barred from practicing before the Department, or have imposed on him such lesser sanctions (e.g., public or private reprimand) as the Secretary deems appropriate, but only after he has been accorded an opportunity to present his views in the matter. The Department will maintain a public register of attorneys and representatives suspended or barred from practice. ''Attorney'' pursuant to this subpart and ''legal counsel'' in § 351.303(g) have the same meaning. ''Representative'' pursuant to this subpart and in § 351.303(g) has the same meaning.

[FR Doc. 2012–15381 Filed 6–25–12; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2012–HA–0049]

RIN 0720–AB57

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE: TRICARE Retail Pharmacy Program

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This proposed rule would make several administrative changes to the TRICARE Pharmacy Benefits Program regulations in order to conform them more closely to the statute and to clarify some procedures regarding the operation of the uniform formulary. Specifically, the proposed rule would: conform the regulation to the statute regarding point-of-service availability of non-formulary drugs; clarify the process for formulary placement of newly approved drugs; streamline the process for updating copayment requirements; specify the method for applying the statutory formula for maximum non-formulary drug copayments; and clarify several other uniform formulary practices. This rule is separate from, but not inconsistent with, the legislative proposal made by the Department to implement portions of the President's Budget for Fiscal Year 2013 relating to the TRICARE Pharmacy Benefits Program.

DATES: Written comments received at the address indicated below by August 27, 2012 will be considered and addressed in the final rule.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Federal Docket Management System Office, 4800 Mark Center Drive, 2nd floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Rear Admiral Thomas McGinnis, Chief, Pharmacy Operations Directorate, TRICARE Management Activity, telephone 703–681–2890.

SUPPLEMENTARY INFORMATION:

A. Executive Summary

1. Purpose of the Proposed Rule

The purpose of this proposed rule is to make several administrative changes to the TRICARE Pharmacy Benefits Program regulation to conform more closely to the statute (10 U.S.C. 1074g) and to clarify some procedures regarding the uniform formulary.

The legal authority for this proposed rule is 10 U.S.C. 1074g.

2. Summary of the Major Provisions of the Proposed Rule

a. It would conform the regulation to the statute regarding the number of points of service where non-formulary drugs are required to be available. They would be generally required only in the mail order program.

b. It would clarify the process for formulary placement of newly approved drugs by the Food and Drug Administration (FDA), giving the Pharmacy and Therapeutics Committee up to 120 days to recommend tier placement on the uniform formulary.

c. It would streamline the process for updating cost sharing requirements by eliminating the process step of a recommendation from the P&T Committee.

d. It would state there is no regulatory requirement, just as there is no statutory requirement, that copayment amounts are the same for active duty dependents as they are for retired members and their dependents.

e. It would specify the method for applying the current statutory formula for maximum non-formulary drug copayments, stating that they would be calculated based on the average government cost of all prescriptions, other than generic drug prescriptions, in

four groups based on beneficiary category and point of service.

3. *Costs and Benefits.* This proposed rule is limited to administrative changes. It does not itself affect costs. The benefits of the proposed rule are that it will more closely conform the regulation to the statute and facilitate more effective administration of the TRICARE Pharmacy Benefits Program.

B. Background

In 1999, Congress enacted 10 U.S.C. 1074g to, among other things, establish a uniform formulary program to incentivize the use of more cost-effective pharmaceutical agents and points of service. There are four points of service under the Pharmacy Benefits Program—military facility pharmacies, retail network pharmacies, retail non-network pharmacies, and the TRICARE mail order pharmacy program (TMOP)—and three uniform formulary tiers—First Tier for generic drugs, Second Tier for preferred brand name drugs (also referred to as ''formulary drugs''), and Third Tier for non-preferred brand name drugs (also referred to as ''non-formulary drugs''). In addition to establishing procedures for assigning drugs to one of the three tiers, the statute includes several other specifications, such as: That formulary drugs are generally available in all three points of service; that non-formulary drugs are available in at least one point of service; that TRICARE may establish copayment requirements for all formulary tiers and all points of service, but the maximum copayment may not exceed for non-formulary drugs amounts generally equal to 20% for active duty family members and 25% for retirees and their family members; and that when clinically necessary, non-formulary drugs are provided at the copayment level of formulary drugs.

TRICARE's regulations implementing this statute, issued in 2004, established or continued prior rules for, among other things: assigning drugs to a formulary tier based on cost-effectiveness; point of service availability for the respective tiers; copayment requirements that are lower for more cost-effective drugs and points of service; and updates over time of the copayment amounts. Although the statute required Third Tier drugs to be available in only one point of service, the regulations made them available in two. And while the statute allows copayments for prescriptions in all points of service and formulary tiers, the regulations exempted military facility pharmacies.

TRICARE's administration of the Pharmacy Benefits Program has achieved some improvements in cost-effectiveness. However, overall costs of the TRICARE Pharmacy Benefits Program have continued to increase substantially, from approximately $2 billion in fiscal year 2001, to approximately $8 billion projected for fiscal year 2012. For fiscal year 2012, the program updated for the first time since 2001 copayment amounts, increasing retail network pharmacy copayments from $3/$9/$22 to $5/$12/$25 for the respective tiers, and changing mail order program copayments from $3/$9/$22 to $0/$9/$25. Co-payments for retail prescriptions are for up to a 30 day supply; mail order prescriptions for up to a 90 day supply. This difference is part of the incentive for beneficiaries to use the more cost-effective mail order program, as is the recent elimination of copayments for mail order program generic drugs. Encouraging increased use of DoD's more cost-effective points of service (i.e., the highly convenient mail order pharmacy or a military treatment facility pharmacy) and more cost-effective pharmaceutical products (i.e., those on First Tier and Second Tier) continues to be a TRICARE program objective.

C. Provisions of the Proposed Rule

The purpose of this proposed rule is to make several administrative changes to the TRICARE Pharmacy Benefits Program regulation to conform more closely to the statute (10 U.S.C. 1074g) and to clarify some procedures regarding the uniform formulary. One change is to conform the regulation to the statute regarding the number of points of service where non-formulary drugs are required to be available. The statute requires availability in one of the three primary points of service (military facility, retail network, and mail order program); the current regulation specifies that non-formulary drugs are generally unavailable in military facilities and generally available in the retail network and mail order. This change would provide that non-formulary drugs are available only in TMOP, unless medical necessity is established for dispensing in one of the other venues. This change would reinforce DoD policy encouraging use of more cost-effective drugs and points of service, without adverse effect on beneficiaries. A beneficiary always has the option of asking the health care provider to change the prescription to a comparable formulary drug, or, in cases of medical necessity, obtaining approval for dispensing the non-formulary drug at the formulary copayment amount. Another option for most prescriptions when the beneficiary prefers a non-formulary drug is to have the prescription transferred to TMOP.

Another administrative change would clarify the process for formulary placement of newly approved drugs by the Food and Drug Administration (FDA). Current practice for brand name drugs is that they are placed in the Second Tier the day FDA approves the drug. This practice has not lead to the most cost-effective placement of these newly approved drugs. DoD proposes that at the next quarterly meeting of the Pharmacy and Therapeutics (P&T) Committee following FDA approval, the drug will be evaluated for its relative clinical benefit and relative cost in comparison to other drugs in the drug class and a recommendation will be made to the Director of the TRICARE Management Activity for Tier placement of the drug. The current regulation does not specifically address the status of the drug from the date of date of FDA approval to the date the P&T Committee's recommendation is eventually implemented. The proposed rule would address this by providing a period of up to 120 days for the P&T Committee to act. This will normally be the next quarterly meeting, but in cases when the FDA approval happens too close to a scheduled meeting for the necessary research to be done, it would be the following meeting. The 120 day time period accommodates this. During the period prior to a decision on Tier placement, the newly approved drug will be covered by TRICARE under terms comparable to those applicable to Third Tier drugs.

Several additional administrative changes in this proposed rule relate to the process for updating copayment amounts. First, as a ''housekeeping'' matter, the proposed rule would update the regulation to incorporate the copayment adjustments that were implemented for fiscal year 2012, as noted above. Second, it would streamline the process for updating cost sharing requirements by eliminating the process step of a recommendation from the P&T Committee. Factors pertinent to updating copayment amounts relate mostly to government-wide, industry-wide, or program-wide developments, rather than specific drug-by-drug clinical and cost considerations, which is the P&T Committee's primary mission. The decision maker for copayment updates would continue to be the Assistant Secretary of Defense for Health Affairs. Third, the proposed rule would state there is no regulatory requirement, just as there is no statutory requirement, that copayment amounts are the same for active duty dependents

as they are for retired members and their dependents. Fourth, it would specify the method for applying the statutory formula for maximum non-formulary drug copayments. The statute provides that the maximum copayment may not exceed for non-formulary drugs amounts generally equal to 20% for active duty family members and 25% for retirees and their family members, but the current regulations do not indicate how this maximum amount will be calculated. The proposed rule would specify that it will be calculated based on the average government cost of all prescriptions, other than generic drug prescriptions, in four groups: retail prescriptions for active duty dependents; retail prescriptions for retirees and their dependents; mail order prescriptions for active duty dependents; and mail order prescriptions for retirees and their dependents. This part of the proposed rule should not be interpreted as suggesting that TRICARE intends to establish different copayments for active duty dependents from copayments for retirees and their dependents or to increase copayments to the maximum level allowed. This part of the rule is simply to clarify the applicable requirements and how the maximum copayment frame of reference will be calculated.

The proposed rule would continue the current regulatory policy of exempting from copayments prescriptions filled in military facility pharmacies. This is allowed by the statute and arguably spreading copayment requirements across all points of service could reduce the potential need for higher copayments in any one point of service; but the current regulation and this proposed rule specify no copayment for all such prescriptions. Although no change is proposed, DoD invites comments on this provision.

Finally, the proposed rule would incorporate into the regulation several details of current practice. While the current regulation provides that a uniform formulary drug that is not a generic drug may be grouped for copayment purposes with generic drugs if it is judged to be as cost effective as generic drugs in the same drug class, the proposed rule would add that 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. Further, in the case of generic drugs, the beneficiary copayment amount for any prescription may not exceed the total charge for that prescription. Also, the rule would state that active duty members are not authorized to use retail non-network pharmacies.

D. Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders (EOs) 12866 and 13563 require that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of $100 million or more in any one year. The DoD has examined the economic, legal, and policy implications of this proposed rule and has concluded that it is not an economically significant regulatory action under Section 3(f)(1) of the EO. But it is a significant regulatory action and it has been reviewed by the Office of Management and Budget.

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This proposed rule is a not a major rule under the Congressional Review Act.

Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribunal governments, in aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule does not have a significant impact on a substantial number of small entities.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This proposed rule contains no new information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3511).

Executive Order 13132, ''Federalism''

This proposed rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

Public Comments Invited

This is a proposed rule. DoD invites public comments on all of its provisions.

List of Subjects in 32 CFR Part 199

Claims, Health care, Health insurance, Military personnel, Pharmacy benefits.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.21 is amended by adding new paragraph (g)(5), by revising the heading for paragraph (h), by revising paragraphs (h)(1)(iii), (h)(3)(i) and (ii), (i)(2) introductory text, (i)(2)(i) through (v), and (i)(2)(x), and by adding new paragraphs (j)(4) and (5), to read as follows:

§ 199.21 Pharmacy Benefits Program.

* * * * *

(g) * * *

(5) *Administrative procedure for newly approved drugs.* In the case of a newly approved pharmaceutical agent, other than a generic drug, the agent 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, TMA subsequently approves that recommendation, the drug will be so listed. If the Director, TMA disapproves that recommendation, the drug will as soon as feasible be added to the uniform formulary. If, prior to the expiration of 120 days, the P&T Committee recommends that the agent be added to the uniform formulary, that will be done as soon as feasible. Pending action under this paragraph (5), the newly approved pharmaceutical agent will be available to beneficiaries under terms comparable to those applicable to non-formulary agents under this section.

* * * * *

(h) * * *

(1) * * *

(iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services (Note: active duty members are not authorized to use retail non-network pharmacies); and

* * * * *

(3) *Availability of non-formulary pharmaceutical agents.*—(i) *General.* Non-formulary pharmaceutical agents shall be generally available under the pharmacy benefits program from retail non-network pharmacies and the TRICARE Mail Order Pharmacy (TMOP).

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities and retail network pharmacies.* Even when particular non-formulary agents are not generally available at military treatment facilities or retail network pharmacies, they will be made available to eligible covered beneficiaries through those points of service for prescriptions approved through the non-formulary special approval process that validates the medical necessity for use of the non-formulary pharmaceutical agent. In those cases in the retail network, the non-formulary drug will be made available at the formulary copayment amount.

* * * * *

(i) * * *

(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 are no co-payments.

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

(A) $12.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) $5.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent. For especially cost-effective drugs, upon the recommendation of the Pharmacy and Therapeutics Committee, prescriptions for a longer period supply, not to exceed 90 days, may be authorized for the same co-payment.

(C) $25.00 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 20/25 percent or $12.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent. The 20% amount applies to dependents of active duty members and others covered by 10 U.S.C. 1079; the 25% amount applies to retirees and others covered by 10 U.S.C. 1086.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20/25 percent or $25.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent. The 20% amount applies to dependents of active duty members and others covered by 10 U.S.C. 1079; the 25% amount applies to retirees and others covered by 10 U.S.C. 1086.

(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) $0.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) $25.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent.

* * * * *

(x)(A) The per prescription copayments 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 shall be 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) with respect to maximum copayment amounts for non-formulary drugs, which also apply to formulary drugs. In adjusting copayment amounts, there is no requirement that amounts be the same for dependents of active duty members (and other beneficiaries covered by 10 U.S.C. 1079) as for retirees (and other beneficiaries covered by 10 U.S.C. 1086).

(B) For purposes of paragraph (i)(2)(x)(A) of this section (the requirement that non-formulary cost sharing shall not exceed amounts generally comparable to 20 percent for active duty dependents and 25 percent for retirees and their dependents), those maximum amounts will be calculated based on the average government cost of all prescriptions, other than prescriptions for generic drugs, in the following four groups:

(*1*) Retail prescriptions for active duty dependents;

(*2*) Retail prescriptions for beneficiaries covered by 10 U.S.C. 1086;

(*3*) Mail order prescriptions for active duty dependents;

(*4*) Mail order prescriptions for beneficiaries covered by 10 U.S.C. 1086.

* * * * *

(j) * * *

(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.

* * * * *

Dated: June 20, 2012.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–15507 Filed 6–25–12; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 2011–2 CRB NCEB II]

Determination of Reasonable Rates and Terms for Noncommercial Broadcasting

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges are publishing for comment proposed rates and terms for the performance of musical compositions by Public Broadcasting Service (''PBS''), National Public Radio (''NPR'') and other public broadcasting entities and for the use of published pictorial, graphic and sculptural works by public broadcasting entities pursuant to the statutory license under section 118 of the Copyright Act for the period 2013–2017.

DATES: Comments and objections, if any, are due no later than July 26, 2012.

ADDRESSES: Comments and objections may be sent electronically to *crb@loc.gov.* In the alternative, send an original, five copies and an electronic copy on a CD either by mail or by hand delivery. Please do not use multiple