Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA63

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE; Implementation of the Pharmacy Benefits Program

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule is designed to implement section 701 of the National Defense Authorization Act for Fiscal Year 2000. This proposed rule establishes procedures for the inclusion of pharmaceutical agents on a Uniform Formulary based upon relative clinical effectiveness and cost effectiveness; establishes cost-sharing requirements, including a tiered co-payment structure, for generic, formulary and non-formulary pharmaceutical agents; establishes procedures to assure the availability of pharmaceutical agents not included on the Uniform Formulary to eligible beneficiaries at the non-formulary cost-share tier; establishes procedures to receive pharmaceutical agents not included on the Uniform Formulary, but considered clinically necessary, under the same terms and conditions as an agent on the Uniform Formulary; establishes procedures to assure the availability of clinically appropriate non-formulary pharmaceutical agents to members of the uniformed services; establishes procedures for prior authorization when required; and establishes a Department of Defense Pharmacy and Therapeutics Committee (DoD P&T Committee) and a Uniform Formulary Beneficiary Advisory Panel. Other administrative amendments are also made to clarify specific policies that relate to the program. Public comments are invited and will be considered for possible revisions to the final rule.

DATES: Written comments will be accepted until June 11, 2002.

ADDRESSES: Medical Benefits and Reimbursement Systems, TRICARE Management Activity, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Michael Kottyan, Medical Benefits and Reimbursement System, TRICARE Management Activity, Office of the Assistant Secretary of Defense (Health Affairs), telephone 303–676–3520.

SUPPLEMENTARY INFORMATION:

A. Overview of the Rule

Section 701 of the National Defense Authorization Act for Fiscal Year 2000 (Public Law 106–65), codified at Title 10, United States Code, Section 1074g, directs the Department to establish an effective, efficient, integrated Pharmacy Benefits Program. The current prescription drug benefit under TRICARE includes the U.S. Food and Drug Administration (FDA) approved drugs and medicines that by United States law require a physician's or other authorized individual professional provider prescription (acting within the scope of their license) that has been ordered or prescribed by them. The benefit does not include prescription drugs for medical conditions that are expressly excluded from the TRICARE benefit by statute or regulation.

The Pharmacy Benefits Program will include a Uniform Formulary of pharmaceutical agents that will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized under the current TRICARE prescription drug benefit. A therapeutic class is defined as a group of drugs that are similar in chemical structure, pharmacological effect, or clinical use. Pharmaceutical agents in each therapeutic class shall be 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 not to have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome compared to other drugs included on the Uniform Formulary, it may be classified as a non-formulary agent. If a pharmaceutical agent in a therapeutic class is not cost effective relative to other pharmaceutical agents in a therapeutic class, it may be classified as a non-formulary agent. Pharmaceutical agents used exclusively for medical conditions that are expressly excluded from the TRICARE benefit by statute or regulation will not be considered for inclusion on the Uniform Formulary.

B. Clinical Effectiveness and Cost Effectiveness

It is presumed that pharmaceutical agents 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 other pharmaceutical agents included on the uniform formulary. The DoD Pharmacy and Therapeutics Committee will exercise their collective professional judgement by considering pertinent information from a variety of sources.

The DoD Pharmacy and Therapeutics Committee has sole discretion in determining what sources should be reviewed in evaluating the clinical effectiveness of a pharmaceutical agent in a therapeutic class. The DoD Pharmacy and Therapeutics Committee may designate Government agents to research pertinent sources of information and report the results to the full committee. The DoD Pharmacy and Therapeutics Committee or their designated agents will exercise their professional judgement in determining what sources of information to review. Sources of information may include, but are not limited to: medical and pharmaceutical textbooks and reference books; clinical literature; the U.S. Food and Drug Administration; pharmaceutical companies; clinical practice guidelines; and expert opinion.

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. Information considered by the committee may include but is not limited to: FDA approved and other studied indications; pharmacology; pharmacokinetics; contraindications; warnings/precautions; incidence and severity of adverse effects; drug to drug,

drug to food, and drug to disease interactions; availability, dosing, and method of administration; epidemiology and relevant risk factors for diseases/conditions in which the drugs are used; and concomitant therapies; results of safety and efficacy studies; results of effectiveness/clinical outcomes studies; and results of meta-analyses.

In considering the relative cost effectiveness of pharmaceutical agents in a therapeutic class authorized under the TRICARE pharmacy benefit, the DoD Pharmacy and Therapeutics Committee shall evaluate the costs of the agent in relation to the safety, effectiveness, and clinical outcomes of other agents in the class. The DoD Pharmacy and Therapeutics Committee may designate Government agents to conduct the evaluation and report the results for the Committee's consideration and decision. Information considered by the committee or its designated agents concerning the relative cost effectiveness of the pharmaceutical agent may include but is not limited to: cost of the drug to the Government; impact on overall medical resource utilization and costs, cost-efficacy studies; cost-effectiveness studies; cross-sectional or retrospective economic evaluations; pharmacoeconomic models; patent expiration dates; clinical practice guideline recommendations; and existence of existing blanket purchase agreements, incentive price agreements, or contracts.

Based on its assessment of the relative clinical and cost effectiveness of agents within a therapeutic class, the DoD Pharmacy and Therapeutics Committee will recommend that an agent either be included on the Uniform Formulary or designated as non-formulary. The DoD Pharmacy and Therapeutics Committee's recommendation will be determined by a majority vote.

C. Evaluation of Pharmaceutical Agents for Determinations Regarding Inclusion on the Uniform Formulary

The DoD Pharmacy and Therapeutics Committee will periodically evaluate or reevaluate individual drugs and/or drug classes for determinations regarding inclusion or continuation on the Uniform Formulary. Evaluation or reevaluation of individual drugs or drug classes may be prompted by a variety of circumstances that may include but are not limited to: approval of a new drug by the FDA; approval of a new indication for an existing drug; changes in the clinical use of existing drugs; new information concerning the safety, effectiveness or clinical outcomes of existing drugs; price changes; shifts in market share; scheduled review of a therapeutic class; and requests from Pharmacy and Therapeutics Committee members, military treatment facilities, or other Military Health System officials.

D. Uniform Formulary at Military Treatment Facilities (MTFs)

Pharmaceutical agents included on the Uniform Formulary shall be available through military treatment facilities of the uniformed services, consistent with the scope of health care services offered in such facilities. The Basic Core Formulary (BCF) is a subset of the Uniform Formulary and is a mandatory component of all MTF pharmacy formularies. The BCF contains the minimum set of drugs that each MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Additions to individual MTF formularies are determined by local Pharmacy and Therapeutics Committees based upon the scope of health care services provided. However, pharmaceutical agents that are designated as non-formulary on the Uniform Formulary shall not be included on an MTF pharmacy formulary. All drugs on the MTF formulary must be available to all beneficiaries. There are no co-pays or cost-shares for any beneficiaries utilizing MTF pharmacies.

E. Prior Authorizations

Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness. The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of agents within a therapeutic class. 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 a given agent.

F. Cost-Sharing Requirements

Active duty members do not pay a cost-share. Cost-sharing requirements for all other beneficiaries will be based upon the pharmaceutical agent's classification on the uniform formulary, that is, generic, formulary, or non-formulary and the point of service, that is, MTF, retail network pharmacy, retail non-network pharmacy, or the National Mail Order Pharmacy (NMOP), from which the agent is acquired. TRICARE Prime point of service charges will still apply.

There is no co-pay for pharmaceutical agents obtained from a military treatment facility.

For pharmaceutical agents obtained from a retail network pharmacy there is a $9.00 co-pay per prescription for up to a 30-day supply of a formulary agent, a $3.00 co-pay per prescription for up to a 30-day supply of a generic agent, and a $22.00 co-pay per prescription for up to a 30-day supply of a non-formulary agent.

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

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

For pharmaceutical agents obtained under the NMOP program there is a $9.00 co-pay per prescription for up to a 90–day supply of a formulary agent, a $3.00 co-pay per prescription for up to a 90-day supply of a generic agent, and a $22.00 co-pay per prescription for up to a 90-day supply of a non-formulary agent.

Section 1074g(a)(6) provides that for non-formulary agents, cost sharing shall be consistent with common industry practice and not in excess of amounts generally comparable to 20% for dependents of active duty service members or 25% for retirees and their dependents. The proposed non-formulary cost share of $22 (or in the case of non-formulary agents provided by non-network providers, the greater of $22 or 20%) complies with this statutory requirement. An analysis of categories of agents for which the selection of formulary and non-formulary agents is anticipated indicated that the average prescription cost and dispensing fee of potential non-formulary agents will, in the aggregate, be in excess of $110. Thus, the non-formulary co-payment will not be in excess of amounts generally comparable to the statutory maximums. In addition, these co-payment provisions are based upon common industry practice. Common industry practice typically has a $12 to $15 differential in the cost share between formulary and non-formulary pharmaceutical agents. The $22.00 per prescription co-pay for non-formulary agents is subject to annual adjustment by the Assistant Secretary of Defense (Health Affairs), upon advice of

the Pharmacy and Therapeutics Committee, based on experience with the Uniform Formulary, changes in economic circumstances, and other relevant factors. Any adjustments will remain consistent with the statutory co-pay maximum.

A point of service cost-share of 50 percent applies in lieu of the 20 percent co-pay for TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies.

Except as provided below, for prescription drugs 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.

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.

The TRICARE catastrophic loss limits apply to pharmacy benefits. For dependents of active duty members, the maximum family liability is $1,000 for cost-shares and deductibles based on allowable charges for TRICARE Basic Program services and supplies received in a fiscal year. For all other categories of beneficiary families, the maximum family liability is $3,000 in a fiscal year.

G. Determination of Generic Drug Classification Under the Pharmacy Benefits Program

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. In considering the relative cost effectiveness of pharmaceutical agents in a therapeutic class, the Pharmacy and Therapeutics Committee may consider the existence of blanket purchase agreements, incentive price agreements, or contracts. The existence of these agreements or contracts may result in situations where a brand drug is the most cost effective pharmaceutical agent for the Government to purchase, even more cost effective than generic agents. When this circumstance occurs, the Pharmacy and Therapeutics Committee may designate that the branded drug cost share be the same as the lower generic drug cost share when the branded drug is selected as the preferred agent over generic drugs because it is more cost effective for the Government. This will assure that the beneficiary is not penalized when brand products are competed and selected as the formulary pharmaceutical agent over generic products following a contracting initiative.

H. 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. MTFs shall establish procedures to evaluate the clinical appropriateness 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 appropriate, the MTF will provide the pharmaceutical agent to the member. TRICARE will conduct an evaluation for clinical appropriateness when a member presents a prescription for a non-formulary pharmaceutical agent to a network or non-network pharmacy or the NMOP.

I. Availability of Non-Formulary Pharmaceutical Agents to Eligible Covered Beneficiaries

Non-formulary pharmaceutical agents will be available to eligible beneficiaries through the retail network pharmacies and the NMOP at the non-formulary co-pay tier of $22.00 per prescription.

Non-formulary pharmaceutical agents will be available to eligible beneficiaries through the retail non-network pharmacies at the non-formulary co-pay tier of 20 percent or $22.00, whichever is greater, per prescription.

Non-formulary pharmaceutical agents will be available to eligible covered beneficiaries through the MTF pharmacies only for prescriptions written by MTF providers and approved through the non-formulary special order process that validates the clinical necessity for use of the non-formulary pharmaceutical agent.

J. Reduction of Co-Pay for Cases of Clinical Necessity

Non-formulary pharmaceutical agents will be available to eligible covered beneficiaries through the retail network and non-network pharmacies at the same co-pay as a formulary pharmaceutical agent in situations of documented clinical necessity. A clinical necessity to use a non-formulary drug may exist when either: the use of formulary agents is contraindicated; the patient experiences significant adverse effects from formulary agents; formulary agents result in therapeutic failure; the patient previously responded to a non-formulary agent and changing to a formulary agent would incur unacceptable clinical risk; or there is no alternative agent on the formulary.

For prescriptions submitted to the NMOP, information to justify the clinical necessity for use of a non-formulary agent should be submitted with the prescription. The beneficiary may also submit information to justify the clinical necessity for use of a non-formulary agent to the NMOP after the prescription has been filled. If clinical necessity for use of a non-formulary agent is validated, then the patient will receive a refund for the co-pay differential. For prescriptions submitted to a retail network pharmacy, the beneficiary will submit information to justify the clinical necessity for use of a non-formulary agent to the servicing TRICARE contractor and request a refund for the difference in the cost between the formulary and non-formulary pharmaceutical agent. Determinations of the clinical necessity for use of a non-formulary agent will undergo a peer review.

If the request for the difference is denied, either the beneficiary or provider may appeal the decision under section 199.10 of this Part.

K. Department of Defense Pharmacy and Therapeutics Committee

The Department of Defense Pharmacy and Therapeutics Committee will develop the uniform formulary of pharmaceutical agents. The committee will review the formulary on a periodic basis, and make additional recommendations regarding the formulary as the committee determines necessary and appropriate to the Director, TRICARE Management Activity. The committee shall include representatives of pharmacies of the uniformed service treatment facilities, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the national mail order pharmacy program, providers in facilities of the uniformed services, and TRICARE network providers. 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.

The committee will identify therapeutic classes of pharmaceutical agents. The committee will consider the clinical and cost effectiveness of pharmaceutical agents relative to other agents in the class, following the guidelines contained in this regulation. Therapeutic drug class reviews will be

conducted on a scheduled, periodic basis, as determined by the committee.

L. Uniform Formulary Beneficiary Advisory Panel

A Uniform Formulary Beneficiary Advisory Panel will be established to review and comment on the development of the uniform formulary. 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.

M. Mandatory Generic Substitution

Mandatory substitution of generic drugs listed with an ''A'' rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (or any successor) published by the Food and Drug Administration and generic equivalents of grandfather or Drug Efficacy Study Implementation (DESI) category drugs is required for brand name drugs.

Brand name drugs will be available at the non-formulary co-pay when dispensed in lieu of a generic equivalent if selection of the branded product is based solely on the personal preference of the provider or beneficiary. Section J of this preamble describes the process for obtaining non-formulary drugs at the formulary co-pay in situations of clinical necessity.

N. Regulatory Procedures

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. 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 rule is not an economically significant regulatory action. Cost-shares for generic and formulary pharmaceutical agents were addressed in the implementation of the TRICARE Senior Pharmacy benefit earlier this year. Approximately 1.5 million persons are potential beneficiaries of this program, and expected benefits per person are approximately $2,000 per year. This rule includes the addition of a third tier to the formulary cost-share structure by adding non-formulary pharmaceutical agents, which will have an impact of less than $100 million. The rule, although not economically significant under Executive Order 12866, is significant under Executive Order 12866, and has been reviewed by the Office of Management and Budget.

This rule is not a major rule under the Congressional Review Act. This rule does not require a regulatory flexibility analysis as it would have no significant economic impact on a substantial number of small entities.

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511).

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 199.2(b) is amended by adding a sentence at the end of the current definition of Prescription drugs and medicines to read as follows:

§ 199.2 Definitions.

* * * * *

(b) *Prescription drugs and medicines.* * * * Prescription drugs and medicines may also be referred to as ''pharmaceutical agents''.

* * * * *

3. Revises § 199.21 to read as follows:

§ 199.21 Pharmacy Benefits Program.

(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) *Uniform Formulary.* The Pharmacy Benefits Program features a Uniform Formulary of pharmaceutical agents.

(i) The Uniform Formulary will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized as basic program benefits. Pharmaceutical agents are prescription drugs and medicines as defined in § 199.2. A therapeutic class is defined as a group of drugs that are similar in chemical structure, pharmacological effect, or clinical use.

(ii) As required by 10 U.S.C 1074g(a)(2) and implemented under the procedures established by paragraphs (d) and (e) 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 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, it may be classified as a non-formulary agent. In addition, if the evaluation of the Pharmacy and Therapeutics Committee concludes that a pharmaceutical agent in a therapeutic class is not cost effective relative to other pharmaceutical agents in a therapeutic class, considering costs, safety, effectiveness, and clinical outcomes, it may be classified as a non-formulary agent.

(iii) Pharmaceutical agents that are used exclusively for medical conditions that are expressly excluded from the TRICARE benefit by statute or regulation will not be considered for inclusion on the Uniform Formulary.

(b) *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. The Committee will function consistent with the Federal Advisory Committee Act (5 U.S.C. App. 2).

(2) *Composition.* As required by 10 U.S.C. 1074g(b), the committee includes representatives of pharmacies of the uniformed service treatment facilities, contractor(s) responsible for the TRICARE retail pharmacy program, contractor(s) responsible for the National Mail Order Pharmacy (NMOP) program, providers in facilities of the uniformed services, and TRICARE network providers. 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 has an Executive Council, composed of those voting and non-voting members of the Committee who are military members 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.

(c) *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. 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 Federal Advisory Committee Act (5 U.S.C. App. 2).

(d) *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 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.

(F) Expert opinion.

(iii) The DoD Pharmacy and Therapeutics Committee will evaluate the relative clinical effectiveness of drugs 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 drugs are used.

(J) Concomitant therapies.

(K) Results of safety and efficacy studies.

(L) Results of effectiveness/clinical outcomes studies.

(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 drug 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.

(I) Existence of existing blanket purchase agreements, incentive price agreements, or contracts.

(e) *Evaluation of pharmaceutical agents for determinations regarding inclusion on the Uniform Formulary.* The DoD Pharmacy and Therapeutics Committee will periodically evaluate or reevaluate individual drugs and drug classes for determinations regarding inclusion or continuation on the Uniform Formulary. Evaluation or reevaluation of individual drugs or drug classes may be prompted by a variety of circumstances including, but not limited to:

(1) Approval of a new drug by the U.S. Food and Drug Administration;

(2) Approval of a new indication for an existing drug;

(3) Changes in the clinical use of existing drugs;

(4) New information concerning the safety, effectiveness or clinical outcomes of existing drugs;

(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.

(f) *Administrative procedures for establishing and maintaining the Uniform Formulary.* (1) Determinations of the Pharmacy and Therapeutics Committee are 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. The minutes will include a record of the number of members voting for and against the Committee's action.

(2) 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) 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.

(g) *Obtaining pharmacy services under the Pharmacy Benefits Program.*—(1) *Points of service.* There are four outpatient pharmacy points of service: Military Treatment Facilities (MTFs), retail network pharmacies, retail non-network pharmacies, and the National Mail Order Pharmacy (NMOP). Retail network pharmacies are those non-MTF pharmacies that are a part of the network established for TRICARE Prime under § 199.17. Retail non-network pharmacies are those non-MTF pharmacies that are not part of such a network.

(2) *Availability of formulary drugs.*—(i) *General.* Subject to paragraph (g)(2)(ii) of this section, formulary drugs are available under the Pharmacy Benefits Program from all of the points of service identified in paragraph (g)(1) of this section.

(ii) *Availability of formulary drugs at military treatment facilities.* Pharmaceutical agents included on the Uniform Formulary are available through MTFs, consistent with the scope of health care services offered in such facilities. The Basic Core Formulary (BCF) is a subset of the Uniform Formulary and is a mandatory component of all MTF pharmacy formularies. The BCF contains the minimum set of drugs that each MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Additions to individual MTF formularies are determined by local Pharmacy and Therapeutics Committees based on the scope of health care services provided at the respective MTFs. All drugs on the local MTF formulary must be available to all categories of beneficiaries.

(3) *Availability of non-formulary drugs*—(i) *General.* Non-formulary pharmaceutical agents are generally available under the Pharmacy Benefits Program from retail network pharmacies, retail non-network pharmacies, and the National Mail Order Pharmacy (NMOP).

(ii) *Availability of non-formulary drugs at military treatment facilities.* Non-formulary pharmaceutical agents will be available to eligible covered beneficiaries through the MTF pharmacies only for prescriptions written by MTF providers and 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. MTFs shall establish procedures to evaluate the clinical appropriateness 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 appropriate, the MTF will provide the pharmaceutical agent to the member. TRICARE will conduct an evaluation for clinical appropriateness when a member presents a prescription for a non-formulary pharmaceutical agent to a retail pharmacy or the NMOP.

(h) *Cost-sharing under the Pharmacy Benefits Program*—(1) *General.* Under 10 U.S.C. 1074g(a)(6), cost-sharing requirements (independent of those established under other provisions of this Part) are established in this section for the Pharmacy Benefits Program. 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. 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-pay.

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

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

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

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

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

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

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

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

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

(vi) A point of service cost-share of 50 percent applies in lieu of the 20 percent co-pay for TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies.

(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.

(ix) The TRICARE catastrophic cap limits apply to Pharmacy Benefits Program cost-sharing.

(x) The $22 per prescription co-pay established in this paragraph (h)(2) of this section may be adjusted periodically (but no more frequently than annually unless necessary to comply with a statutory requirement) based on experience with the Uniform Formulary, changes in economic circumstances, and other appropriate factors. Any such adjustment must 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).

(3) *Special cost-sharing rule when there is a clinical necessity for use of a non-formulary drug.* (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 drug or medicine will be provided at the same co-pay as a formulary pharmaceutical agent can be obtained.

(ii) A clinical necessity for use of a non-formulary drug 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 agents is contraindicated;

(B) The patient experiences significant adverse effects from formulary agents;

(C) Formulary agents result in therapeutic failure;

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

(E) There is no alternative 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 pharmaceuticals 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 NMOP.

(vi) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may also be provided at a later date as an appeal to reduce the non-formulary co-pay to the same co-pay 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 can not be determined in a timely manner, the non-formulary pharmaceutical will be dispensed at the non-formulary co-pay and a refund provided to the beneficiary should clinical necessity be established.

(i) *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. Drugs 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 when available. Brand name drugs will be available at the non-formulary co-pay when dispensed in lieu of a generic equivalent if selection of the branded product is based solely on the personal preference of the provider or beneficiary. 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, or other Government contract action 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.

(j) *Preauthorization of certain pharmaceutical agents.* Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness. The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of agents within a therapeutic class. 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 agent.

(k) *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 § 199.3. The benefit under the TRICARE Senior Pharmacy Program applies to prescription drugs and medicines provided on or after April 1, 2001.

(l) *Effect of other health insurance.* The double coverage rules of § 199.8 are applicable to services provided under the Pharmacy Benefits Program. For this purpose, to the extent they provide a prescription drug benefit, Medicare supplemental insurance plans or Medicare HMO plans are double coverage plans and will be the primary payor.

(m) *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.

Dated: April 4, 2002.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 52, 96, and 97

[FRL–7170–9]

Interstate Ozone Transport: Response to Court Decisions on the NO_X SIP Call, NO_X SIP Call Technical Amendments, and Section 126 Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: Today, EPA is extending the closing date of the public comment period regarding EPA's notice of proposed rulemaking ''Interstate Ozone Transport: Response to Court Decisions on the NO_X SIP Call, NO_X SIP Call Technical Amendments, and Section 126 Rules,'' published February 22, 2002 at 67 FR 8395. The original comment period was to close on April 15, 2002. The new closing date will be April 29, 2002. The EPA received a request to extend the comment period due to the complexity of the issues surrounding the actions EPA is proposing to take. We find it appropriate to provide additional time for interested and affected parties to submit comments. All comments received by EPA on or prior to April 29, 2002 will be considered in the development of a final rule.

DATES: All comments regarding EPA's notice of proposed rulemaking issued on February 22, 2002 must be