scheduling of a substance expire at the end of one year from the date of issuance of the order. However, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance may be extended for up to six months. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of Health and Human Services, or on the petition of any interested party. Such proceedings regarding AMT and 5-MeO-DIPT have been initiated by the Acting Deputy Administrator of the DEA.

The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse and the relative potential for abuse for AMT and 5-MeO-DIPT. The Acting Deputy Administrator has submitted these data to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the Acting Deputy Administrator has also requested a scientific and medical evaluation and a scheduling recommendation for AMT and 5-MeO-DIPT from the Assistant Secretary for Health. Therefore, the temporary scheduling of AMT and 5-MeO-DIPT which is due to expire on April 3, 2004, may be extended until October 3, 2004, or until proceedings initiated in accordance with 21 U.S.C. 811(a) are completed, whichever occurs first.

Pursuant to 21 U.S.C. 811(h)(2), the Acting Deputy Administrator hereby orders that the temporary scheduling of AMT and 5-MeO-DIPT be extended until October 3, 2004, or until the proceedings initiated in accordance with 21 U.S.C. 811(a) are completed, whichever occurs first.

Regulatory Certifications

The Acting Deputy Administrator of the DEA hereby certifies that extension of the temporary placement of AMT and 5-MeO-DIPT in Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the extension of temporary control of substances with no currently accepted medical use in the United States.

The six month extension of AMT and 5-MeO-DIPT in Schedule I of the CSA is not a significant regulatory action for the purposes of Executive Order (E.O.) 12866 of September 30, 1993. Drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12866, section 3(d)(1). This action responds to an emergency situation posing an imminent hazard to the public safety and is essential to the criminal law enforcement function of the United States.

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132 and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: March 25, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04–7219 Filed 3–31–04; 8:45 am]

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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: Final rule.

SUMMARY: This final rule implements section 701 of the National Defense Authorization Act for Fiscal Year 2000. The rule establishes procedures for the inclusion of pharmaceutical agents on a uniform formulary based upon relative clinical effectiveness and cost effectiveness; establishes the cost-sharing requirements including a tiered co-payment structure for pharmaceutical agents based on their designation as a generic, formulary or non-formulary pharmaceutical agent; establishes procedures to assure the availability of pharmaceutical agents not included on the uniform formulary to eligible beneficiaries at the non-formulary 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&TC) and a uniform formulary Beneficiary Advisory Panel. Other administrative amendments are also made to clarify specific policies that relate to the program.

DATES: This final rule is effective May 3, 2004.

ADDRESSES: Pharmacy Benefits Division, TRICARE Management Activity, Skyline Five, 5111 Leesburg Pike, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: COLONEL William Davies, Director, Pharmacy Benefits Division, TRICARE Management Activity, Office of the Assistant Secretary of Defense (Health Affairs), telephone (703) 681–0039.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Changes

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's prescription (acting within the scope of their license) that has been ordered or prescribed by them. The pharmacy benefits program does not include prescription drugs which are used in medical treatments or

procedures that are expressly excluded from the TRICARE benefit by statute or regulation.

II. Scope of the Program

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 that therapeutic class, it may be classified as a non-formulary agent.

The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Its geographical applicability is 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), the 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 Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the pharmacy benefits program rules as may be appropriate to the areas involved.

III. Public Comments

The proposed rule was published in the **Federal Register** on Friday, April 12, 2002, (67 FR 17948) in which DoD proposed to implement its pharmacy benefits program and uniform formulary. Interested persons were invited to submit comments on DoD's proposed rule by June 11, 2002. We received more than 3,000 public comments with the majority concentrated in five general areas: the proposed non-formulary co-payment of $22; assurance that the uniform formulary will include a broad range of medications most often prescribed in each therapeutic class; procedures for documenting and approving clinical necessity for doctors should be streamlined; "grandfathering'' at current co-payments for patients already receiving a medication that may become non-formulary; and ensuring that providers have adequate educational materials and access to formulary lists.

In addition, other comments were received from organizations representing various medical fields or corporate entities regarding specific aspects of the proposed rule. A discussion of the more significant comments concerning DoD's proposed rule, and our responses to these comments, are set forth below.

A. Point of Clarification Concerning Availability of Non-Formulary Drugs

Public comments revealed the perception that "non-formulary'' drugs would not be available under the uniform formulary. That perception is incorrect. As stated in the proposed rule and as required by 10 U.S.C. 1074g(a)(5), we emphasize that drugs categorized as "non-formulary'' must be made available through at least one of our pharmaceutical venues. DoD will make non-formulary drugs available through the TRICARE Mail Order Pharmacy and retail pharmacies at the non-formulary co-payment.

B. Co-Payments

The most frequent public comment concerned the proposed $22 co-payment for the non-formulary tier of the uniform formulary. It was generally stated that "the jump from $9 to $22 for non-formulary drugs is excessively high and presents an undue financial burden upon all classes of beneficiaries.''

DoD was directed by 10 U.S.C. 1074g to establish an effective, efficient, and integrated pharmacy benefits program, to include a uniform formulary of pharmaceutical agents based upon relative clinical and cost effectiveness. DoD is authorized under 10 U.S.C. 1074g(a)(6) to establish cost-sharing requirements for generic, formulary, and non-formulary agents. The latitude given DoD in establishing non-formulary co-payments is limited by this section which states in pertinent part, "For non-formulary agents, cost-sharing *shall* be consistent with common industry practice and not in excess of amounts generally comparable to 20 percent for beneficiaries covered by section 1079 of this title or 25 percent for beneficiaries covered by section 1086 of this title.'' (emphasis added). Common industry practice is to either deny payment completely for non-formulary agents, or as in multi-tiered plans, have a difference in the cost-share between formulary and non-formulary agents that is enough to influence beneficiaries to select equally effective, less expensive medications. At the time the proposed rule was drafted, common industry practice was to establish a $12 to $15 differential between the non-formulary and formulary cost-shares. The proposed $22 co-payment creates a $13 differential and is within the 20% maximum cost-share limit established by law, based upon the average aggregate cost to the government for pharmaceutical agents that may be designated as non-formulary. The $22 co-payment is also significantly lower than commercial non-formulary co-payments that average $29 in retail pharmacies, and $34 to $57 in mail order pharmacies. (Source: Novartis Pharmacy Benefit Report: 2001 Facts and Figures). Within the TRICARE Mail Order Pharmacy, the proposed $22 co-payment for a 90 day supply of a non-formulary medication is even less than the formulary rate in the retail pharmacy network for a comparable 90 day supply (3 prescriptions at a $9 cost-share per prescription=$27 total) and is intended to influence beneficiary choice for mail order. Thus, the $22 non-formulary co-payment is in line with the commercial best practice business model, influencing beneficiary choice, while maintaining access to a broad range of pharmaceutical agents.

C. Formulary Range

The second most frequent comment concerned reassurance that the uniform formulary will include a broad range of frequently prescribed medications that offer a spectrum of choices within each therapeutic class, recognizing that the "lowest common denominator'' drug is not adequate to meet the health care needs of numerous beneficiaries. The Department is directed by 10 U.S.C. 1074g(a)(2)(A) to establish a "uniform formulary, which shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes.'' The selection for inclusion on the uniform formulary of particular pharmaceutical agents in each therapeutic class shall be based on the relative clinical and cost effectiveness of the agents in such class. In considering the relative clinical effectiveness of pharmaceutical agents, the Director, TRICARE Management Activity, is required by 10 U.S.C. 1074g(a)(2)(B) to presume inclusion in a therapeutic class of a pharmaceutical agent, unless the DoD 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 drugs included on the uniform formulary. The DoD Pharmacy and Therapeutics Committee, comprised of physicians and pharmacists with clinical expertise, will conduct in-depth clinical and cost-effective analysis of medications within a therapeutic class. The DoD Pharmacy and Therapeutics Committee will recommend that an agent have a non-formulary status based on clinical effectiveness, only if the agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other drugs included on the uniform formulary. The Committee's recommendations shall be commented upon by the Beneficiary Advisory Panel, and the final decision will be made by the Director, TRICARE Management Activity (TMA). Those medications designated non-formulary will still be accessible through the mail order pharmacy and retail pharmacies at the non-formulary cost-share, and at the formulary cost-share for conditions of medical necessity.

D. Streamlining Medical Necessity Procedures

The third most frequent comment concerned assurances that procedures for documenting and determining "clinical necessity'' will be streamlined, without imposing unnecessary administrative procedures upon providers, patients, and pharmacists. Under both the TRICARE Mail Order Pharmacy program and the Request for Proposals for the TRICARE Retail Pharmacy contract, we have established streamlined processes that efficiently and accurately identify instances where it is clinically necessary for a beneficiary to use a non-formulary drug. We re-emphasized that beneficiaries may obtain non-formulary drugs without delay because the clinical necessity determination will, in most cases, be a retrospective review completed after the medication is dispensed. Under the TRICARE Mail Order Pharmacy Program, beneficiaries have the option of submitting evidence to support clinical necessity concurrently with their prescriptions. Under the pharmacy benefits program, clinical necessity establishes only the co-payment of a non-formulary medication for a beneficiary and does not impact access to medications.

E. Grandfathering Co-Payments

The fourth most frequent comment concerned the concept of "grandfathering'' co-pays at current levels for patients already receiving maintenance medications which subsequently may be designated as non-formulary when the uniform formulary is implemented.

Under 10 U.S.C. 1074g(a)(8), the"Secretary shall ensure that en eligible covered beneficiary may continue to receive coverage for any maintenance pharmaceutical that is not on the uniform formulary and that was prescribed for the beneficiary before'' October 5, 1999 [the date of enactment of section 1074g] "and stabilized the medical condition of the beneficiary.'' Compliance with this directive is achieved in that access to pharmaceuticals designated as "non-formulary'' is preserved under this rule, though at the non-formulary tier. Where there is clinical necessity for the use of a non-formulary agent that is not otherwise excluded as a covered benefit, the drug or medicine will be provided at the same co-payment as a formulary agent. Clinical necessity for use of a non-formulary agent is established when: Use of the formulary agent is contraindicated; the patient is likely to experience or has experienced 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 formulary agent.

The government will apply the commercial business practice of establishing a transition period during which the formulary co-payment will apply to pharmaceuticals that were prescribed for a beneficiary prior to that pharmaceutical agent being designated as "non-formulary''. Transition periods shall be determined by the DoD Pharmacy and Therapeutics Committee and included with any recommendation of a pharmaceutical for "non-formulary'' status. The intent of this transition period is to allow sufficient time for education and communication of this formulary status change, enabling coordination between beneficiaries and providers on whether to submit documentation of clinical necessity, continue therapy at the non-formulary tier, or modify therapy. With these considerations, transition periods may vary by drug; however, will not be longer than 180 days from the final decision date but may be less.

F. Provider Education and Formulary Access

The fifth most frequent public comments stated that DoD must ensure doctors have educational materials on the program, uncomplicated and immediate access to formulary lists, and the ability to identify and fulfill clinical necessity documentation requirements in real time via the Internet. The Department will incorporate the communication of formulary information into TMA's extensive marketing and education program that employs both electronic and print media. Dissemination of information to beneficiaries, beneficiary advisory groups, providers, and TRICARE contractors will be coordinated through TMA's Communications and Customer Services Directorate.

G. Financial Responsibility

A managed care support contractor of the TRICARE program inquired as to the status of the requirement under 10 U.S.C. 1074g(d) that in the operation of the pharmacy benefits program the Secretary of Defense assure through management and new contractual arrangements that financial resources are aligned such that the cost of prescriptions is borne by the organization that is financially responsible for the health care of the eligible covered beneficiary.

TRICARE, in its next generation of contracts, has announced that it is carving out from the managed care support contracts the requirement to provide retail pharmacy services. Managed care support contractors have had no requirement to provide mail order pharmacy services. Mail order pharmacy services were provided under a single, separate contract, the TRICARE National Mail Order Pharmacy Program, and are being provided now under a similar arrangement with the TRICARE Mail Order Pharmacy Program. The TRICARE Retail Pharmacy solicitation is structured so that the Government, with overall fiscal responsibility for the health care of eligible beneficiaries, bears its share of the cost of prescriptions as a Federal procurement.

H. Clinical Effectiveness and Cost Effectiveness

As explained in the preamble to the proposed rule, 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 collective professional judgment by considering pertinent information from a variety of sources. The 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. Information considered by the Committee 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.

A pharmaceutical company stated its belief that the broadly drafted definition of a "therapeutic class'' in the rule would make it difficult for beneficiaries to obtain access to their varied pharmaceutical needs because the uniform formulary may cover a limited number of drugs per therapeutic class. Therapeutic class is defined as a group of drugs that are similar in chemical structure, pharmacological effect, or clinical use. The pharmaceutical company suggested the following definition: "a group of covered outpatient drugs used to treat the same spectrum of disorders with similar patient outcomes, similar effects on all relevant drug receptors or other biological targets, and similar tolerability throughout their clinically accepted dosing ranges across all relevant patient populations.'' The narrow definition proposed by the pharmaceutical company would result in an extremely large number of therapeutic classes. Many of the classes would contain a single drug, or at most, very few drugs. This definition would obviously minimize the number of drugs that could possibly be designated as non-formulary. The definition in the rule is consistent with commonly accepted definitions of a therapeutic class. We are confident that, given the definition of a therapeutic class in the rule, the uniform formulary will include a sufficient number of pharmaceuticals to meet the clinical needs of DoD beneficiaries.

A pharmacy association suggested adding "and/or clinical use'' to the definition of therapeutic class. We concur with that recommendation and have made that change.

Comments were received from a pharmaceutical manufacturer concerning the date that new drugs approved by the Food and Drug Administration (FDA) will become available to beneficiaries under the pharmacy benefits program. The manufacturer recommended all new drugs be automatically included on the uniform formulary if it is in a therapeutic class that has not been reviewed; or if a new drug is in a class that has already been reviewed, the new agent shall be evaluated within six months of the market date. Currently, new drugs approved by the FDA are available immediately to our beneficiaries in retail pharmacies. Their availability in the TRICARE Mail Order Program is contingent upon a decision by the DoD Pharmacy and Therapeutics Committee. Their availability in military medical treatment facilities (MTFs) is contingent upon either the individual MTF placing them on its formulary or the DoD Pharmacy and Therapeutics Committee placing them on the Basic Core Formulary, thus mandating their inclusion on every MTF formulary.

Under 10 U.S.C. 1074g, DoD has the option of making a new drug available immediately in retail pharmacies at the formulary cost-share tier, or delay its availability until it is evaluated by the Pharmacy and Therapeutics Committee for placement in either the formulary or non-formulary cost-share tier. However, for any drugs newly approved by the Food and Drug Administration, the Pharmacy and Therapeutics Committee is required under 10 U.S.C. 1074g(b)(2) to consider their inclusion on the uniform formulary. Under 10 U.S.C. 1074g(a)(2)(B), 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 significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other pharmaceutical agents included on the uniform formulary. The department will continue with its current policy, and except for drugs for excluded benefits, new drugs approved by the FDA will automatically be included on the uniform formulary at the formulary cost-share tier. Newly approved FDA drugs will normally by reviewed at the next scheduled Pharmacy and Therapeutics Committee meeting for evaluation of the drug's clinical and cost effectiveness in comparison to other drugs in the therapeutic class.

A pharmaceutical company stated its belief that the rule should require the Pharmacy and Therapeutics Committee to consider certain acknowledged sources of reliable clinical information when evaluating drugs within a therapeutic class (*e.g.,* clinical studies used for FDA approval, drug compendia information and peer-reviewed literature). The pharmaceutical company also stated that the rule should require the Committee to consult with independent medical specialists. The rule allows the Committee to consider all the sources of clinical information—including independent medical specialists—suggested by the pharmaceutical company. Rather than having the rule dictate the specific information sources that must be used in all circumstances, we believe it is more appropriate, as well as consistent with the statute and industry practice, to rely on the collective professional judgment of the Committee members to determine which information sources need to be used in order to most effectively evaluate the clinical and cost effectiveness.

A pharmaceutical company noted that the rule does not make any reference to the impact on quality of life when making formulary decisions. A pharmaceutical manufacturer

association stated its opinion that in determining clinical effectiveness, the Secretary must add "quality of life'' and "compliance'' as factors to consider when determining the therapeutic advantage of one drug over another. In 32 CFR 199.21(e)(1)(iii) it states that the 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. In 32 CFR 199.21(e)(1)(iv) it goes on to list various factors that the Committee may consider, but is not limited to considering. Clinical effectiveness is a composite of many factors. It is not our intent to include in the rule an exhaustive list of all factors that could potentially affect the clinical effectiveness of pharmaceutical agents. Although quality of life and compliance are not explicitly identified in the rule, the rule does not preclude or require the Committee to consider such information in evaluating the relative clinical effectiveness of pharmaceutical agents in a therapeutic class. We will rely on the collective professional judgment of the Committee to determine if relevant information on quality of life and compliance are available and useful for evaluating the relative clinical effectiveness of particular pharmaceutical agents.

A pharmaceutical manufacturer association stated that in determining "cost effectiveness'' the rule must include detailed information as to how the Pharmacy and Therapeutics Committee will factor in the value of saved lives and improved quality of life. In 32 CFR 199.21(e)(2)(ii) it lists information the Committee may consider, but is not limited to considering in evaluating the relative cost effectiveness of drugs in a therapeutic class. Although the value of saved lives and improved quality of life are not explicitly identified in the rule, the rule does not preclude the Committee from considering such information in evaluating the relative cost effectiveness of pharmaceutical agents in a therapeutic class. We will rely on the collective professional judgment of the Committee to determine if relevant information on the value of lives saved and improved quality of life are available and useful for evaluating the relative cost effectiveness of pharmaceutical agents. However, significant differences in clinical outcomes will obviously be a major focus of the Committee's actions.

A pharmaceutical company questioned how relative price is weighed against relative effectiveness. The rule states that the Committee will evaluate the costs of pharmaceutical agents in relation to the safety, effectiveness, and clinical outcomes of the agents in the therapeutic class.

A pharmaceutical company commented that the rule should be clarified to allow for cost effectiveness consideration only after the Pharmacy and Therapeutics Committee has determined clinical effectiveness is firmly established. Under 10 U.S.C. 1074g(a)(2)(A), the selection for inclusion on the uniform formulary of particular pharmaceutical agents in each therapeutic class shall be based on the relative clinical and cost effectiveness of the agents in such class. Like the statute, (10 U.S.C. 1074g(a)(2)(B) for clinical effectiveness and 1074g(a)(2)C) for cost effectiveness), the rule (32 CFR 199.21(a)(3)(ii)) specifies a two-step process that will evaluate clinical effectiveness first, then cost effectiveness second, and base a formulary status recommendation based upon both. Before making a recommendation that a therapeutic agent be classified as a non-formulary agent, both clinical effectiveness and cost effectiveness will be evaluated. However, in making the recommendation, a determination that an agent is either not as clinically effective or not as cost effective as other agents in the class, will be sufficient to support the recommendation that the agent will not be added to the uniform formulary.

A professional organization stated an opinion that § 199.21(a)(3)(ii) of the proposed rule, setting forth the standard for designating a pharmaceutical agent as non-formulary is unclear and potentially inconsistent with section 1074g(a)(2)(A) of the governing statute, which provides that the decision as to whether an agent in a particular therapeutic class is included on the uniform formulary will be based on "the relative clinical and cost effectiveness of the agents in the class.'' We disagree that the standard in the rule is either unclear or inconsistent with the statute. We concur with the commenter that the statutory provision envisions a test that takes into account both clinical effectiveness and cost. In 32 CFR 199.21(a)(3)(ii), it states: "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 Therapeutic 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.'' The rule is simply stating, in accordance with section 1074g(a)(2)(A) that "selection for inclusion on the uniform formulary . . . shall be based on the relative clinical and cost effectiveness of the agents in such [therapeutic] class.'' If it is either not relatively as clinically effective or cost effective as other agents in such class, the agent will not be considered as clinically effective and cost effective as other agents in such class.

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

As explained in the proposed rule, the DoD Pharmacy and Therapeutics Committee will periodically evaluate or re-evaluate individual drugs and/or drug classes for determinations regarding inclusion or continuation on the uniform formulary. Evaluation or re-evaluation 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.

A pharmaceutical company questioned how new Food and Drug Administration (FDA) approved drugs will be evaluated. Under 10 U.S.C. 1074g(b)(2), the Committee is required to meet quarterly to consider for inclusion on the uniform formulary any new drugs newly approved by the FDA. The Committee will evaluate the clinical effectiveness and cost effectiveness as outlined in the rule. Comments were received from pharmaceutical manufacturers and pharmaceutical associations on evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary. Evaluation or revaluations 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; shift 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.

J. Uniform Formulary at Military Treatment Facilities (MTFs)

As discussed in the proposed rule, pharmaceutical agents included on the uniform formulary shall be available through medical 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-payments or cost-shares for any beneficiaries utilizing MTF pharmacies.

A pharmaceutical association comments on the importance of standardizing the formulary process within the military treatment facilities (MTFs). Under 10 U.S.C. 1074g(a)(2)(E)(i), pharmaceutical agents included on the uniform formulary shall be available to eligible covered beneficiaries through facilities of the uniformed services, consistent with the scope of health care services offered in such facilities. Although the formulary process in the MTF Pharmacy and Therapeutics Committees is similar to the process outlined in the statute and the rule for the DoD Pharmacy and Therapeutics Committee, neither govern the procedures of the MTF Pharmacy and Therapeutics Committees. Each MTF must evaluate the scope of practice of the facility and determine which drugs in addition to those on the Basic Core Formulary, which is required for all MTFs, should be on that MTF's formulary.

The same association commented that the rule does not outline the steps an MTF must take to determine clinical necessity for non-formulary items. There are three issues associated with this comment. First, not all points of service or venues are required to have non-formulary pharmaceutical agents available to beneficiaries. Under 10 U.S.C. 1074g(a)(5), non-formulary agents are required to be available only through one of the venues described in 10 U.S.C. 1074g(a)(2)(E), specifically, MTFs, retail pharmacies, or the TRICARE Mail Order Pharmacy program. A higher cost-share is authorized for non-formulary pharmaceutical agents in the venue where they are offered. DoD has elected to make non-formulary pharmaceutical agents available at the non-formulary tier cost-shares described in this rule in all venues, except for the MTFs. Second, in those points of service or venues where non-formulary tier pharmaceutical agents are offered, under 10 U.S.C. 1074g(a)(7), DoD is required to establish procedures for beneficiaries to receive pharmaceutical agents at the formulary tier cost-share that are not included on the uniform formulary (*i.e.,* non-formulary), if the beneficiary establishes that the non-formulary pharmaceutical agent, as opposed to the formulary tier pharmaceutical agent, is clinically necessary for the beneficiary. Procedures for establishing clinical necessity for prescriptions presented at retail pharmacies and the TRICARE Mail Order Program are described in 32 CFR 199.21(h)(3). If clinical necessity is established, non-formulary tier pharmaceutical agents are provided to the beneficiary at the formulary tier cost-share. Third, non-formulary tier pharmaceutical agents will not be routinely available in the MTFs like they are in the other venues. These agents can be obtained in all other venues with payment of the non-formulary tier cost-share, whereas if available in the MTFs, they would be obtained without payment of the higher cost-share, because no cost-shares are charged at the MTFs. Although these agents will not routinely be available in the MTFs, DoD has decided to make non-formulary tier pharmaceutical agents available in the MTFs when medical necessity for the agent is established. Under 32 CFR 199.21(h)(3)(ii) we now state, "Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries for prescriptions approved through the non-formulary special order process of the MTFs that validates the medical necessity for the use of the non-formulary pharmaceutical agent.''

A retiree association comments that beneficiaries should be notified regarding changes to the MTFs' Basic Core Formulary. We will include all formulary changes in the marketing/education efforts described previously.

A retiree association commented that the rule should include a statement regarding quantities of medications available from MTFs, just as it does concerning the quantities available from the retail networks and mail order pharmacy. Quantity limits in retail pharmacies and the TRICARE Mail Order Program are discussed in § 199.21(i)(2) under the heading of "Cost-sharing amounts.'' The purpose of this subsection is to describe the cost-share required in each venue, and the maximum quantity of a prescribed drug that may be obtained for that cost-share. The rule clearly states that there is no cost-share for pharmaceutical agents obtained from an MTF. Because there is no cost-share in the MTF, regardless of the quantity dispensed, it is unnecessary to describe the quantity limit that may apply at a MTF. Omitting any reference to quantity limits at the MTF also allows appropriate flexibility to change policies as necessary to meet operational requirements in the MTFs, without having to revise the Code of Federal Regulations.

A beneficiary advocacy organization requested assurance that the Basic Core Formulary at MTFs will be as robust as possible to provide a cost-effective distribution channel for beneficiaries. MTF pharmacies are the least costly point of service for the beneficiary. The Basic Core Formulary as stated in 199.21(h)(2)(ii) "contains the minimum set of drugs that each MTF pharmacy must have on its formulary to support the primary care scope of practice for the Primary Care Manager enrollment sites.'' To the extent appropriate based on the scope of practice at each MTF, the actual formulary in use at the MTF will reflect the needs of the MTF's patients. We believe the result will be reasonable access through MTF pharmacies to drugs needed by MTF patients.

K. Prior Authorizations

As noted in the proposed rule, 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.

A medical association stated its opinion that the rule should state the time frame to turn around a prior authorization denial and that the reasons for the denial must be documented. Similar to other sections of Part 199, the rule specifies that the Director, TRICARE Management Activity, may issue policies, procedures, instructions, guidelines, standards and/or criteria to implement this requirement. Our goal is to efficiently, accurately, and promptly process prior authorization requests. Our mail order and retail pharmacy services contracts are structured to meet these goals and ensure that beneficiaries are advised of their right to appeal.

A medical association stated the opinion that pharmaceutical agents can not be subject to prior authorization criteria that apply in all circumstances. We disagree. There are similarities but also differences between prior authorization and clinical necessity. Prior authorization may be required under § 199.21(k) when considering the relative clinical and cost effectiveness of agents within a therapeutic class, and will require the establishment of prior authorization criteria. For example, some drugs should not be used as the first line of therapy. In those circumstances, it may be appropriate to require prior authorization to ensure medically appropriate care is being given by use of the first line therapy before the second line is used.

A TRICARE managed care support contractor asked if a pharmaceutical agent did not previously require prior authorization, but the DoD Pharmacy and Therapeutics Committee makes a decision that it should, will affected beneficiaries be notified in writing of the new requirement? Also, will affected beneficiaries be ''grandfathered'' long enough for them to obtain a letter of medical necessity from the prescribing physician? We intend to apply the commercial business practice of providing an implementation time period that applies to pharmaceuticals that were prescribed prior to that agent requiring a prior authorization. Transition periods will be recommended by the DoD Pharmacy and Therapeutics Committee and will be included with any recommendation that a pharmaceutical require prior authorization. The intent of the transition period is to allow sufficient time for education and communication of this change enabling coordination between beneficiaries and providers on whether to continue the therapy or modify the therapy. We will use the same methods of education and communication previously discussed.

A pharmaceutical company stated that the rule does not identify the prior authorization criteria that will be established. The government will rely on the collective professional judgment of the DoD Pharmacy and Therapeutics Committee to identify both the pharmaceutical agents that require prior authorization and the criteria that apply to any particular agent.

L. Cost-Sharing Requirements

The proposed rule explained that active duty members do not pay a cost-share for prescription drugs. 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 TRICARE Mail Order Pharmacy (TMOP), from which the agent is acquired. TRICARE Prime point of service charges still apply to the pharmacy benefits program.

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 TMOP 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.

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.

A comment was received from a pharmaceutical association stating it does not support incentives to encourage populations to obtain their pharmacy services from mail order over retail pharmacy, and that there is little evidence to suggest mail order saves money. The DoD co-payment structure is established to encourage use of the most economical venue to the Department. Prescriptions filled under the TRICARE Mail Order Pharmacy Program are currently a more cost effective venue then a retail pharmacy for the Department. As the Department implements the national retail pharmacy contract, the Department may re-evaluate this policy.

A comment was received from a commercial group recommending that the enrollment year deductible for outpatient claims of $300 per individual; $600 per family under TRICARE Prime be included with the statement that ''a point of service cost-share of 50 percent (50%) applies in lieu of the 20 percent (20%) co-payment for TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies.'' This clarification of deductibles under TRICARE Prime has been included in the final rule.

A question was received from a commercial group regarding pharmaceutical agents obtained under the TMOP program where there is a: ''$22.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent.'' The question was that in the event the Government has a contract for a preferred agent within the therapeutic class, will the non-preferred agent be designated as

non-formulary and would it be available from the TMOP with the $22.00 co-pay for up to a 90-day supply? Whether the non-contracted, non-preferred agent is designated as a formulary or non-formulary agent will be based upon the relative clinical and cost effectiveness of the agent in comparison to other agents in the class. Non-formulary agents will be available through the TRICARE Mail Order Pharmacy Program at the $22.00 co-payment for up to a 90 day supply.

A question was received from a commercial group asking to which tier will compounded prescriptions be assigned. Compounded prescriptions will be subject to the same process of evaluation as other pharmaceutical agents under the uniform formulary. They will fall under the non-formulary tier only as determined by the DoD Pharmacy and Therapeutics Committee.

A military association submitted a comment stating that until a national retail pharmacy contract is implemented, beneficiaries who are under the age of 65 and who need to purchase drugs while traveling out of their region must pay non-network prices even when using a retail network pharmacy. The association asserted that procedures need to be in place between the implementation of the uniform formulary and the implementation of the new retail pharmacy contract that will allow beneficiaries obtaining prescriptions out of region to be able to pay network prices when using a network pharmacy. The national retail pharmacy contract will assure portability, in that a network pharmacy will be a part of a national, as opposed to regional, pharmacy network. Implementation of the uniform formulary has nothing to do with portability of the pharmacy benefit.

A comment was received from a military association stating provisions should be spelled out to allow nursing home patients to pay retail network rates even when the nursing home's pharmaceutical supplier is not a network provider. Beneficiary cost-shares are based on point of service and formulary status of the pharmaceutical agent, and not on unique categories of beneficiaries of their residence. The Department has not made any changes based on this comment.

A foundation stated its opinion that brand names should be in the lowest co-payment tier. A primary objective of tiered co-pays is to encourage beneficiaries to use the most cost-effective pharmaceutical agents that will satisfy their clinical needs. Generic drugs are placed in the lowest co-pay tier because they are generally much less expensive than brand name drugs. It would be contrary to the underlying premise of a three tier formulary to place more expensive brand name drugs in the lowest co-pay tier.

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

As explained in the proposed rule, 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 formula pharmaceutical agent over generic products following a contracting initiative.

Retiree groups commented that beneficiaries should be notified if a brand-name drug is the "preferred agent'' even when a generic exists and the brand-name can be obtained at the lower $3 co-payment. The Department will incorporate the communication of formulary and co-pay information into TMA's extensive marketing and education program that employs both electronic and print media. Dissemination of information to beneficiaries, beneficiary advisory groups, providers, and TRICARE contractors will be coordinated through TMA's Communications and Customer Services Directorate.

Comments received from a current managed care support contractor recommended that brand-name products made available at the generic co-payment rate apply only to TMOP since government pricing is available at TMOP. Likewise, the contractor commented that currently the government is not at risk for the retail benefit and should not make decisions based on prices that do not apply in the retail sector. This comment is counter to the government's intent to implement a uniform, consistent, and equitable benefit. Overall cost effectiveness evaluations will include price considerations for all venues, since the Government if financially responsible for the retail benefit with the carve-out of the TRICARE retail pharmacy benefit from the managed care support contracts.

A comment was received asking for confirmation that "all multi-source'' brand prescription drugs that have a generic equivalent will be classified as non-formulary with a $22 co-payment. This final rule re-instates the mandatory generic substitution policy in situations where a generic equivalent is available. Therefore, in the situation described above, the branded product would not be covered unless medical necessity is validated, and then the formulary cost-share would apply. Additionally, as stated in § 199.21(j)(3), the Pharmacy and Therapeutics Committee may consider the existence of blanket purchase agreements, incentive price agreements, or contracts when considering the relative cost effectiveness of pharmaceutical agents. 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 equivalents. When this circumstance occurs, the Pharmacy and Therapeutics Committee may designate that the brand drug cost-share be the same as the lower generic cost-share. This will assure that the beneficiary is not penalized when brand products are competed and selected as the formulary pharmaceutical agent over generic products.

A managed care support contractor of the TRICARE program asked for confirmation that all 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 (with the exception of prescription drugs for medical conditions that are expressly excluded from the TRICARE benefit by statute or regulation) are included in the uniform formulary and subject to the $3.00 co-payment per prescription for up to a 30-day supply from retail network pharmacies and $3.00 co-payment per prescription for up to a 90-day supply from the TMOP (except active duty members of the uniformed services do not pay cost-shares for TRICARE covered pharmaceutical

agents). Under the proposed rule it is presumed that pharmaceutical agents should be included on the uniform formulary unless the Pharmacy and Therapeutics Committee determines that an 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. This is consistent with 10 U.S.C. 1074g(a)(2)(D) which states: ''no pharmaceutical agent may be excluded from the uniform formulary except upon the recommendation of the Pharmacy and Therapeutics Committee.'' Generic pharmaceutical agents that are included on the uniform formulary will be subject to the $3.00 co-payment. Generic agents that are categorized as ''non-formulary'' would be subject to the $22 non-formulary co-payment.

N. Availability of Clinically Appropriate Non-Formulary Pharmaceutical Agents to Members of the Uniformed Services

The proposed rule noted that 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 TMOP.

A commerical group recommended the statement that ''TRICARE will conduct an evaluation for clincal appropriateness when a member presents a prescription for a non-formulary pharmaceutical agent to a network or non-network pharmacy'' be changed to read: ''The TRICARE contractor (or servicing TRICARE contractor) will conduct an evaluation for clinical appropriateness when a member presents a perscription for a non-formulary pharmaceutical agent to a network or non-network pharmacy.'' Under 10 U.S.C. 1074g(a)(7), the Department bears the responsibility for establishing procedures for beneficiaries to receive pharmaceutical agents that are not included on the uniform formulary (i.e., non-formulary agents), when clinical necessity is established. The rule reflects this fact, and although the Department may choose to implement this through the use of a contractor, the rule should not require the Department to use one. Therefore, the Department does not concur with the suggestion.

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

As explained in the proposed rule, non-formulary pharmaceutical agents will be available to eligible beneficiaries through the retail network pharmacies and the TMOP at the non-formulary co-payment 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-payment 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 approved through the non-formulary special order process that validates the clinical necessity for use of the non-formulary pharmaceutical agent.

Comments from pharmaceutical industry members and a current managed care contractor asked for clarification concerning ''grandfathering'' certain medications. Where there is clinical necessity for the use of a non-formulary agent that is not otherwise excluded as a covered benefit, the drug or medicine will be provided at the same co-payment as a formulary agent. clinical necessity for use of a non-formulary agent is established when: Use of the formulary agent is contraindicated; the patient experiences or is likely to experience 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 formulary agent. As previously discussed, the rule requires a specific transition period be recommended by the DoD Pharmacy and Therapeutics Committee for any pharmaceutical agent (including maintenance medications) that was previously a formulary, as opposed to non-formulary drug.

P. Reduction of Co-Payment for Cases of Clinical Necessity

As explained in the proposed rule, non-formulary pharmaceutical agents will be available to eligible covered beneficiaries through the retail network and non-network pharmacies at the same co-payment as a formulary pharmaceutical agent in situations of documented clinical necessity. In the proposed rule it stated 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. A voluntary organization for a specific disease proposed that § 199.21(i)(3)(ii)(B) be amended as follows: ''The patient experiences or is likely to experience significant adverse effects from formulary agents. This would expressly allow the view and professional judgment of the prescribing clinician to be considered.'' The commenter also propose § 199.21(i)(3)(ii)(C) be amended to read, ''Formulary agents result in therapeutic failure or in the reasonable judgment of the clinician would be expected to result in therapeutic failure.'' We concur that the likelihood of adverse events or therapeutic failure, with appropriate documentation, could be considered when establishing medical necessity. Although we have not used the exact wording suggested by the voluntary organization, the rule has been modified to convey the intent.

For prescriptions submitted to the TMOP, 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 TMOP 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-payment 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 co-payment 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 to the extent allowed and consistent with the procedures under § 199.10.

A pharmaceutical manufacturer association suggested incorporation of a sixth prong that would allow beneficiaries to demonstrate clinical necessity by showing that ''a non-formulary agent is expected to have a therapeutic advantage'' for a particular patient. Under 32 CFR 199.21(i)(3)(ii)(A)–(E) we list five circumstances that would demonstrate a clinical necessity to use a non-formulary agent. For an agent to become a non-formulary agent, the decision would have already been made under 10 U.S.C. 1074g(a)(2)(B) that the agent ''does not have a significant, clinically meaningful therapeutic advantage'' over formulary agents. Based on this, a clinical opinion that a non-formulary agent is ''expected'' to offer a therapeutic advantage, without any showing of a probable problem with the formulary agent, is not sufficient to establish clinical necessity. There has to be a showing that use of a formulary agent in the therapeutic class is problematic in some objective manner before clinical necessity for purposes of obtaining the drug at the formulary cost-share is established. If the suggested circumstance for establishing clinical necessity were incorporated into the rule, a prescriber could simply state such an expectation about any non-formulary drug, which would essentially render the non-formulary category meaningless. We do not believe this would be consistent with the statutory charge that DoD ''establish an effective, efficient, integrated pharmacy benefits program.''

A pharmaceutical company suggested that the rule should state that a beneficiary or provider be able to demonstrate the need for a non-formulary drug without having to demonstrate a prior failure of a formulary drug, *i.e.* should not have to have a ''fail first'' before using a non-formulary drug. Therapeutic failure on a formulary drug is but one of the five circumstances listed in the rule that may demonstrate clinical necessity to use a non-formulary drug, and is not required for any of the other four conditions to apply.

A military association stated its opinion that the term ''significant adverse effects'' must be better defined in the rule since adverse side effects from a preferred drug can be a reason for obtaining a non-formulary drug at a formulary price. The determination that an adverse effect experienced by a particular patient is ''significant enough'' to justify the clinical necessity to use a non-formulary drug is a medical judgment based on the specific circumstances for a specific patient. It is impossible to spell out a definition or set of criteria in a regulation that will lead to such a determination.

A professional association expressed pleasure that DoD proposed adoption of a three tiered cost-share design to make the patient and the provider aware of the cost implications of their choice in drugs. The association questions whether it is a wise move for DoD to allow beneficiaries to obtain non-formulary tier drugs at the formulary tier drug cost-share when clinical necessity has been established. DoD is required by 10 U.S.C. 1074g(a)(7) to establish procedures for allowing beneficiaries to receive agents that are not included on the uniform formulary but that are considered clinically necessary. When clinical justification is established, ''the pharmaceutical agent shall be provided under the same terms and conditions as an agent on the uniform formulary.''

A pharmaceutical professional association notes that 10 U.S.C. 1074g(a)(7) requires procedures for beneficiaries to receive pharmaceutical agents that are not included on the uniform formulary under the same terms and conditions as an agent on the uniform formulary if those agents are considered clinically necessary for the beneficiary. Section 1074g(a)(7) says in pertinent part, ''Such procedures shall include peer review procedures'' under which the determination of clinical necessity is made. The commenter presumes that the peer review provisions of § 199.15 will apply, and requests that these provisions be applied to the Military Treatment Facilities as well.

The rule has been modified to reflect that peer review provisions comparable to those of § 199.15 apply to clinical necessity determinations for prescriptions submitted to the TMOP or retail pharmacies. Although the time periods for peer review under § 199.15 applicable to the pharmacy benefits program have not been specifically modified in the rule, the retail pharmacy benefits program have not been specifically modified in the rule, the retail pharmacy Request for Proposals has a requirement that the goal is to complete 95% of the medical necessity reviews within two days, and 100% within 5 days. In initial determinations are subject to reconsideration, which are subject to appeal, with the contract directing shorter time periods than allowed under the Quality and Utilization Review Peer Review Organization (PRO) Program provisions of § 199.15. Information on clinical necessity may be provided by beneficiaries, providers, and pharmacies. The peer review provisions of § 199.15 do not apply to the Military Treatment Facilities, where there is no beneficiary entitlement to non-formulary drugs. The Military Treatment Facilities, however, will have procedures for evaluation of clinical necessity determinations.

A professional association commented that the rule does not explain patient appeal rights. The association recommended that the rule should explicitly incorporate the existing appeal process found at § 199.10 for all beneficiaries asserting they are entitled to a non-formulary agent at the formulary cost-share because of clinical necessity. An expeditious appeal process is required under 10 U.S.C. 1074g(a)(7). The rule has been modified to state that policies and procedures comparable to those for appealing decisions under § 199.15 and § 199.10 shall apply to requests that non-formulary agents be dispensed by retail pharmacies or TMOP at the formulary co-pay tier. Appealable issues include medical or clinical necessity denials, and denials based on factual coverage issues. Although the rule has not been specifically modified with respect to appeal timeframes, the retail pharmacy Request for Proposals has a requirement that 75% of requests for reconsideration shall be processed to completion within 10 working days after the date of receipt by the contractor, and 100% within 25 working days.

A medical association submitted a comment recommending prescribing decisions be made exclusively by a specialist provider who must be able to override any formulary restriction. Under the uniform formulary the medical necessity process allows medical providers to provide documentation to justify provision of a non-formulary pharmaceutical agent at the formulary cost-share. If clinical necessity is not established, the pharmaceutical agents within the TRICARE pharmacy benefit are still available to the beneficiary in both the TMOP and retail pharmacies, but at the non-formulary cost-share.

A manufacturer's association notes that the process in the rule for requesting a non-formulary prescription at the formulary cost-sharing amount requires the beneficiary or his or her provider to submit documentation supporting the claim of clinical necessity. The association appreciates that the rule does not delay dispensing the prescription pending a determination of clinical necessity, however expresses an opinion that Congress did not intend the beneficiary to incur a financial burden of paying the

non-formulary cost-share pending a decision on clinical necessity. The association recommends the rule be changed so that whenever a prescription for a non-formulary agent is accompanied by a request for a finding of clinical necessity, that the prescription be dispensed at the formulary cost-share. Instead of a beneficiary receiving a refund when clinical necessity has been established by the beneficiary, the government would have to attempt to collect the difference in cost-shares if either the beneficiary was unsuccessful in supporting his assertion of medical necessity, or the beneficiary submits no information in support at all. In establishing a process to implement the statutory policy, we have adopted a process that accomplishes the legislative intent with minimal transaction costs. The process suggested by this comment would have greater transaction costs, with a need for a separate billing, accounting, and collection system, not commensurate with any benefit associated with beneficiaries potentially parting temporarily with the $13 co-pay differential per prescription.

Q. Department of Defense Pharmacy and Therapeutics Committee

In the proposed rule we explained that 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. 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.

A professional association asked what procedures will be used by the Committee to obtain full information about the cost of pharmaceutical agents. The Committee will obtain information on existing process from the Federal Supply Schedule (FSS), temporary FSS price reductions, national pharmaceutical contracts, blanket purchase agreements, and incentive price agreements. The Committee will also obtain information on prices that pharmaceutical companies may offer in proposed blanket purchase agreements, proposed temporary FSS price reductions, and proposed incentive agreements.

A pharmacy association stated that the approach used to make formulary decisions is the antithesis of the approach used in the private sector and recommends DoD follow that approach. The association stated the private sector requires the value of a drug in terms of clinical and/or cost effectiveness must be established before it is added to the formulary, rather than having a presumption that a drug is a formulary drug. This approach is unavailable to DoD because under 10 U.S.C. 1074g(a)(2)(B), ''the Secretary shall presume inclusion in a therapeutic class of a pharmaceutical agent * * * 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 drugs included on the uniform formulary.''

A pharmacy association stated that the proposed rule does not assure confidentiality regarding proprietary data considered by the Pharmacy and Therapeutics Committee. Proprietary information submitted is protected under the Freedom of Information Act, specifically 5 U.S.C. 552(b)(4), which protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential.

Comments were received from a pharmaceutical association and medical associations stating the proposed rule does not clearly define the types of professionals that will be on the DoD Pharmacy and Therapeutics Committee. Additional comments were received from a medical association, and a pharmaceutical manufacturer recommending specific types of physician membership on the Pharmacy and Therapeutics committee. In § 199.21(b)(2) we describe the composition of the committee. 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. When such expertise is not available within the committee regarding the review of specific pharmaceuticals or therapeutic classes, the committee may request assistance from consultants with expertise in those areas. The rule is consistent with the statute regarding committee membership.

A comment was received by a medical association stating that Pharmacy and Therapeutics Committee decisions must be well documented and shared publicly with all concerned parties. The recommendations of the Pharmacy and Therapeutics Committee, the comments of the Beneficiary Advisory Panel, and the decisions of the Director, TRICARE Management Activity will be made public through the TRICARE Communications and Customer Service Directorate information systems previously described, excluding those materials proprietary in nature.

Several questions were received from professional associations and drug manufacturer's concerning the ethical and conflict of interest restrictions, including non-disclosure restrictions that will apply to members of the DoD Pharmacy and Therapeutics Committee, and whether the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, applies.

All members of the DoD Pharmacy and Therapeutics Committee are governed by the DoD Standards of Conduct regulations. The Standards of conduct cross-references are published in 32 CFR Part 40, hence, are not repeated in the rule. DoD employees are governed by the Office of Government Ethics (OGE) regulation, Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635, and the Department of Defense regulation, DoD 5500.7–R, that supplements the OGE regulation. With respect to the Federal Advisory Committee Act (FACA), its applicability is dependent upon whether any members are not federal employees. The National Defense Authorization Act for Fiscal Year 2004, (Pub. L. 108–136), section 725, transferred certain members of the Pharmacy and Therapeutics Committee to the Beneficiary Advisory Panel. The result is that there will be no members of the Pharmacy and Therapeutics Committee who are not federal employees, therefore the requirements of FACA do not apply to this committee.

A professional organization suggests that TRICARE consider having cost effectiveness recommendations made by a contracting officer, as opposed to the DoD Pharmacy and Therapeutics Committee. Recommendations concerning the cost effectiveness of pharmaceutical agents are required to be made by the Pharmacy and Therapeutics Committee under 10 U.S.C. 1074g(a)(2)(C) which states: ''In considering the relative cost

effectiveness of agents under subparagraph (A), the Secretary shall rely on the evaluation by the Pharmacy and Therapeutics Committee of the costs of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of such agents.''

A drug manufacturer commented that DoD should require the Pharmacy and Therapeutics Committee to document the rationale (*e.g.*, the clinical evidence) behind a decision to include or not include a drug on the formulary. The Pharmacy and Therapeutics Committee will document its rationale and recommendations, which will be forwarded to the Beneficiary Advisory Panel. The Committee will apply the relevant criteria listed in the regulation for determining clinical effectiveness.

A drug manufacturer commented that the preamble to the proposed rule provided that the decisions of the Pharmacy and Therapeutics Committee will occur by majority vote, but the text of the rule is silent on this issue. The commenter also recommends that a ''decision to exclude a drug from the uniform formulary'' include a requirement for two-thirds of the members concurring in the recommendation. The rule has been amended to include in the text of the rule that recommendations of the Committee will be by majority vote. DoD does not believe that two-thirds of the members need to concur in a recommendation that a particular pharmaceutical agent be a non-formulary agent. First, the Committee makes a recommendation, and not a final decision on the formulary classification of a pharmaceutical agent. Second, any decision by the Director, TRICARE Management Activity to classify an agent as non-formulary does not ''exclude'' the agent from the list of allowable pharmaceutical agents. Non-formulary agents will continue to be available in retail pharmacies and the TMOP, only with a higher cost-share. The lower formulary cost-share will be applied if it is determined that it is clinically necessary for the beneficiary to have that particular agent, rather than a formulary agent.

The rule states that 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. A pharmaceutical industry association expressed a belief that this is contrary to the requirements of 10 U.S.C. 1074g(a)(2)(D) that ''no pharmaceutical agent may be excluded from the uniform formulary except upon the recommendation of the Pharmacy and Therapeutics Committee'' and 10 U.S.C. 1074g(b)(2) that the committee consider for inclusion ''any drugs newly approved by the Food and Drug Administration.'' The quotation of this language from the statute must be read in the context of 10 U.S.C. 1074g(a)(1), which requires the establishment of ''an effective, efficient, integrated pharmacy benefits program under this chapter'' (emphasis added). This ''chapter'' is chapter 55 of title 10, which established some boundaries on the DoD health program. Under 10 U.S.C. 1079(a)(13), CHAMPUS/TRICARE does not cover ''any service or supply which is not medically or psychologically necessary to prevent, diagnose, or treat a mental or physical illness, injury or bodily malfunction.'' Additionally, certain therapies and treatments are expressly prohibited under chapter 55. For example, under 10 U.S.C. 1079(a)(10), therapy or counseling for sexual dysfunctions or sexual inadequacies may not be provided, and under 10 U.S.C. 1079(a)(11) treatment of obesity may not be provided if obesity is the sole or major condition treated. Only in these very limited types of circumstances will the Committee not consider for inclusion on the uniform formulary a new FDA approved drug. Except for these types of limited circumstances, which are required by other statutes under chapter 55 of title 10, United States Code, the Committee shall review at each quarterly meeting ''drugs newly approved by the Food and Drug Administration.'' No pharmaceutical agent on the uniform formulary shall become a non-formulary agent unless recommended by the Committee, referred to the Beneficiary Advisory Panel for comment, and acted upon by the Director, TRICARE Management Activity.

A commercial group recommended that we make clear that excluded pharmaceutical agents shall not be available as non-formulary agents, nor will they be cost-shared under the TRICARE Pharmacy program. We concur with that recommendation and have modified the rule.

R. Uniform Formulary Beneficiary Advisory Panel

The proposed rule stated that 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.

Comments were received from a pharmaceutical association and pharmaceutical manufacturer recommending the Beneficiary Advisory Panel have a member on the DoD Pharmacy and Therapeutics Committee, and the Beneficiary Advisory Panel should meet before the Pharmacy and Therapeutics Committee meets to provide input to the Pharmacy and Therapeutics Committee. The Department non-concurs on both suggestions because they would be contrary to the statute. The rule as written is consistent with 10 U.S.C. 1074g(c) on both the authorized membership of the DoD Pharmacy and Therapeutics Committee and the role of the Beneficiary Advisory Panel. Under 10 U.S.C. 1074g(b)(1), Congress has defined the membership of the Pharmacy and Therapeutics Committee, and we are in compliance with that statute. The purpose of the Beneficiary Advisory Panel is to ''review and comment on development of the uniform formulary'', while the role of the Pharmacy and Therapeutics committee is to actually develop the formulary.

A comment was received from a military association recommending a higher DoD authority than the Director, TRICARE Management Activity, should have the responsibility of reviewing the Beneficiary Advisory Panel concerns. Additionally, the association proposed that the rule should direct the Beneficiary Advisory Panel when submitting comments that are contrary to the recommendation of the Pharmacy and Therapeutics Committee, to submit the comments to the Assistant Secretary of Defense for Health Affairs, with a copy to the Under Secretary of Defense for Personnel and Readiness, and the Assistant Secretary of Defense for Health Affairs, or his designee, should be responsible for responding to the panel's comments in writing prior to the next meeting of the panel. The Department non-concurs with these suggestions. The responsibilities and functions of the Assistant Secretary of Defense for Health Affairs are described in DoD Directive 5136.1, and the responsibilities and functions of the Director, TRICARE Management Activity are described in DoD Directive 5136.12. Operational issues are the responsibility of the Director, TRICARE Management Activity. The Director, TRICARE Management Activity is responsible for serving as the program

manager for TRICARE health and medical resources, and supervising and administering TRICARE programs. A recent reorganization of the TRICARE Management Activity has the Assistant Secretary of Defense for Health Affairs also serving in the role of Director, TRICARE Management Activity. Feedback to the Beneficiary Advisory Panel will occur without the need for a regulatory specification in the rule.

A drug manufacturer association suggested that the rule require the Director, TRICARE Management Activity to respond to the comments and recommendations of the Beneficiary Advisory Panel in writing to enable the public to understand the reasoning and motivation that support his decisions.

This suggestion is neither required by the statute nor consistent with Department management. The TMA Director is accountable to senior DoD leadership, as well as to Congressional oversight and for compliance with all legal requirements. An advisory panel provides input to the decision process, but is not the accountable entity for the Department's decisions. Information on Department decisions and the rationale for them will be a matter of public record, without the need for regulatory specifications in the rule.

S. Mandatory Generic Substitution

As discussed in the proposed rule, 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 tier 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 P, "Reduction of Co-Payment for Cases of Clinical Necessity'' of this preamble describes the process for obtaining non-formulary drugs at the formulary tier in situations of clinical necessity.

A medical association commented that mandatory substitution of one product for another should be prohibited. Mandatory generic substitution is a cost-effective method of providing FDA approved equivalent pharmaceutical products to DoD beneficiaries. In those rare situations when the brand name version of a generically available product is needed to meet the unique clinical needs of a patient, it will be available at the formulary tier with documented clinical necessity.

Comments were received from commercial groups validating and encouraging the Department's use of generic pharmaceuticals in place of more costly brand-names whenever possible.

A comment challenged the proposed rule provision that brand name drugs will be available at the non-formulary tier when dispensed in lieu of a generic equivalent if based solely on the personal preference of the provider or beneficiary. The rule has been changed to modify mandatory generic substitution such that the formulary tier co-payment applies only when clinical necessity is established. A brand name drug that has a generic equivalent is not covered by TRICARE if clinical necessity is not established.

A TRICARE managed care support contractor stated the following in regard to § 199.21(i)(2), now designated in the rule as 199.21(j)(2), on mandatory generic substitution: "Currently, if a pharmacy enters a DAW2 on a MAC-list drug, a 100% beneficiary cost-share will be passed to the pharmacy. By changing the DAW indicator to a DAW1, a $9 brand co-pay results on the same medication. Today, different DAWs result in different co-pays/cost-shares. Is it correct to assume that, with the new program, how the DAW field of the claim is populated (*i.e.,* DAW 0, 1, 2, or 4) will have no bearing on the resulting co-pay?'' A DAW–1 (Dispense as Written 1—Medically necessary as indicated by the physician on the prescription) designation by itself is not sufficient to obtain coverage of a brand name drug at the formulary co-payment. For the brand name drug to be covered by TRICARE, clinical necessity must also be independently validated by TRICARE. Prescriptions designated as DAW–2 (Dispense as Written per patient request) and other DAW prescriptions are not covered.

A medical association stated its opinion that psychotropic drugs cannot be substituted for each other. A foundation stated its opinion that the formulary must include all anti-epileptic drugs regardless of brand name or generic status. A voluntary organization for a specific disease has requested that all drugs for treatment of this disease be included in the uniform formulary and that these drugs be exempted from the mandatory substitution requirements in the rule. We are not aware of any clinical reason why psychotropic drugs or anti-epileptic drugs or drugs for other specific diseases should be treated differently than products in other therapeutic categories. Our three-tiered approach and the generic substitution rule apply to all products.

IV. Preemption of State Laws

The rule was modified to clarify the preemption of State laws as applicable to the TRICARE Pharmacy Benefits Program.

V. Fraud, Abuse, and Conflict of Interest

The rule was modified to clarify the fraud, abuse, and conflict of interest requirements under the TRICARE pharmacy benefits program.

VI. 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. The 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 in 2001. Approximately 1.5 million persons are potential beneficiaries of this program, and expected benefits per person are approximately $2,000 per year. The rule includes the addition of a third tier to the uniform 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.

The rule is not a major rule under the Congressional Review Act.

The rule does not require a regulatory flexibility analysis as it would have no significant economic impact on a substantial number of small entities.

The 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 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. Amend § 199.2(b) by adding in alphabetical order a definition of "*Pharmaceutical Agent*'' and adding a sentence at the end of the current definition of "*Prescription drugs and medicines*'' to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Pharmaceutical Agent. Drugs, biological products, and medical devices under the regulatory authority of the Food and Drug Administration.

* * * * *

Prescription drugs and medicines * * * Prescription drugs and medicines may also be referred to as "pharmaceutical agents''.

* * * * *

■ 3. Revise § 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) *Pharmacy benefits program.* The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Its geographical applicability is 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), the TRICARE 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 Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the pharmacy benefits program rules as may be appropriate to the areas involved.

(3) *Uniform formulary.* The pharmacy benefits program features a uniform formulary of pharmaceutical agents as defined in § 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 seciton, 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 inculsion 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 § 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.

(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.

(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.

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

(i) Military Treatment Facilities (MTFs);

(ii) Retail network pharmacies: Those are non-MTF pharmacies that are a part of the network established for TRICARE retail pharmacy services;

(iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services, and

(iv) the TRICARE Mail Order Pharmacy (TMOP).

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

(ii) *Availability of formulary pharmaceutical agents at military treatment facilities.* 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 pharmaceutical agents 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 pharmaceutical agents on the local MTF formulary must be available to all categories of beneficiaries.

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

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities.* Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through the MTF pharmacies for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent.

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

(iv) *Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP.* Eligible beneficiaries will receive non-formulary pharmaceutical agents at the formulary cost-share when medical necessity has been established by the beneficiary and/or his/her provider. The peer review provisions of § 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.

(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. For other categories of beneficiaries, cost-sharing amounts are as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

(viii) Under TRICARE Standard, dependents of members of the uniformed services whose pay grade is E–4 or below are subject to the $50.00 per indiviudal 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 per prescription co-payments established in this paragraph (i)(2) of this section may be adjusted periodically based on experience with the uniform formulary, changes in economic circumstances, and other appropriate factors. Any such adjustment may be made upon the recommendation of the Pharmacy and Therapeutics Committee and approved by the Assistant Secretary of Defense (Health Affairs). Any such adjusted amount will maintain compliance with the requirements of 10 U.S.C. 1074g(a)(6).

(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 formualry 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 §§ 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 § 199.10(a)(7), the relevant amount is the difference between the cost shares of a formulary versus non-formulary drug. The amount for each of multiple prescriptions involving the same drug to treat the same medical condition and filled within a 12-month period may be combined to meet the required amount in dispute.

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

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

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

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

(2) The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of pharmaceutical agents within a therapeutic class. Pharmaceutical agents that require prior authorization will be identified by a majority vote of the Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee will establish the prior authorization criteria for the pharamaceutical 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 § 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 § 199.8 of this part 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. Beneficiaries who elect to use this 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 § 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.

Dated: March 25, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

32 CFR Part 2001

[Directive No. 1: Appendix A]

Publication of Revised Bylaws of the Interagency Security Classification Appeals Panel

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Final rule.

SUMMARY: The Information Security Oversight Office, National Archives and Records Administration, is publishing a revision of the bylaws of the Interagency Security Classification Appeals Panel (ISCAP). The bylaws are revised in accordance with section 5.3(c) of Executive Order 12958, as amended, ''Classified National Security Information.'' Under the terms of E.O. 12958, as amended, the Director of ISOO serves as Executive Secretary to the ISCAP.

EFFECTIVE DATE: April 1, 2004.

FOR FURTHER INFORMATION CONTACT: J. William Leonard, Executive Secretary, Interagency Security Classification Appeals Panel, 202–219–5250.

SUPPLEMENTARY INFORMATION: The Interagency Security Classification Appeals Panel (ISCAP) performs several critical functions in implementing several provisions of E.O. 12958, ''Classified National Security Information,'' as amended. These include: (a) Deciding appeals brought by authorized persons who have filed classification challenges under section 1.8 of the amended Order; (b) approving, denying, or amending agency exemptions from automatic declassification, as provided in section 3.3(d) of the amended Order; and (c) deciding on appeals by parties whose requests for declassification of information under section 3.5 of the amended Order have been denied.

These bylaws describe the procedures to be followed by individuals or organizations who wish to bring matters before the ISCAP, and the procedures that the ISCAP will follow to resolve these matters. The ISCAP first published its bylaws on March 15, 1996 (61 FR 10854).

The ISCAP has revised its bylaws to reflect the March 25, 2003, amendment of E.O. 12958. While intelligence sources and methods information remain subject to the jurisdiction of the ISCAP, section 5.3(f) of the amended Order recognizes the special authority and responsibility of the Director of Central Intelligence to protect such information. Of particular note, the revised ISCAP bylaws include a new article (*see* No. IX) which addresses section 5.3(f) of the amended Order.

The appendix was inadvertently removed when we revised part 2001 (*see* 68 FR 55168, September 22, 2003) and we are publishing an updated Appendix A.

These bylaws are being issued in final without prior notice of proposed rulemaking because they are not subject to the Administrative Procedure Act (APA), 5 U.S.C. 551, *et seq*, The ISCAP