June 11, 2002

VIA U.P.S. OVERNIGHT DELIVERY
AND ELECTRONIC MAIL

Mr. Michael Kottyan
Medical Benefits and Reimbursement System
TRICARE Management Activity
Office of the Assistant Secretary of Defense (Health Affairs)
16401 East Centretech Parkway
Aurora, Colorado  80011-9066

Re:  Proposed Rule:  Civilian Health and Medical
Program of the Uniformed Services (CHAMPUS)/
TRICARE; Implementation of the Pharmacy

Dear Mr. Kottyan:

On behalf of the Section of Public Contract Law of the American Bar
Association (“the Section”), I am submitting comments on the above-referenced
matter. The Section consists of attorneys and associated professionals in private
practice, industry, and Government service. The Section’s governing Council and
substantive committees contain members representing these three segments to ensure
that all points of view are considered. In this manner, the Section seeks to improve the
process of public contracting for needed supplies, services, and public works.

The Section is authorized to submit comments under special authority granted
by the Association’s Board of Governors. The views expressed herein have not been
approved by the House of Delegates or the Board of Governors of the American Bar
Association and, therefore, should not be construed as representing the policy of the
American Bar Association.
INTRODUCTION

The proposed rule on implementation of the Pharmacy Benefits Program (“the Proposed Rule”) addresses Section 701 of the National Defense Authorization Act for Fiscal Year 2000 (the “governing statute”), which requires the Secretary of Defense to establish a pharmacy benefits management program that includes a uniform formulary of pharmaceutical agents.¹ The Section’s comments on the Proposed Rule focus on a number of issues of concern to our members. First, the comments recommend that the Proposed Rule be revised to address the ethical and non-disclosure restrictions that will govern the conduct of the private sector members of the Pharmacy and Therapeutics (“P&T”) Committee. Next, the comments request clarification regarding several aspects of the Proposed Rule, including: (1) whether the P&T Committee will function as an advisory committee under the Federal Advisory Committee Act, (2) the procedures the P&T Committee will use to obtain full information about the cost of pharmaceutical agents, and (3) the applicable standard for designating a pharmaceutical agent as “non-formulary.” Finally, the Section recommends that the provisions concerning generic substitution be revised for internal consistency and to provide that mandatory substitution be waived when the Director of the TRICARE Management Activity determines that price incentives make a branded product more economically attractive than a generic version of that product.

SPECIFIC COMMENTS

A. The Proposed Rule Should Identify the Standards of Conduct and Other Restrictions Placed on Private-Sector Members of the P&T Committee.

Under the governing statute and the Proposed Rule, the P&T Committee will include representatives from the contractors responsible for the National Mail Order Pharmacy program, contractors responsible for the TRICARE retail pharmacy program, and TRICARE network providers.² The P&T Committee will make recommendations to the Director of the TRICARE Management Activity regarding which pharmaceutical agents should be considered “formulary” and “non-formulary” drugs based on the relative clinical effectiveness and cost effectiveness of the


² 10 U.S.C. § 1074g(b)(1); 67 Fed. Reg. at 17951.
pharmaceutical agents in a therapeutic class. In this regard, the P&T Committee’s recommendations are similar to the recommendations made by a source selection evaluation board under the Federal Acquisition Regulation (“FAR”).

Numerous laws and regulations govern the conduct of the government employees serving as members of the P&T Committee. For example, rules promulgated by the Office of Government Ethics restrict the government employees from accepting gifts from prohibited sources, misusing their positions, or having conflicting outside interests; these rules also require impartiality in performing their official duties. In addition, depending on the type of information it considers, the P&T Committee members may be reviewing “source selection information” or “contractor bid and proposal information” (as those terms are defined in the FAR), the disclosure of which is prohibited by statute and regulation. The government employees serving on the P&T Committee also may be subject to sanctions imposed under the Trade Secrets Act for releasing confidential commercial or financial information submitted by pharmaceutical manufacturers for review by the P&T Committee.

The Proposed Rule does not discuss or identify whether any of the above restrictions will apply to the private-sector members of the P&T Committee to the same extent that they apply to the government members of the Committee. For example, the Proposed Rule provides that the Executive Council, which is comprised of all government personnel, will review and analyze, among other things, “procurement sensitive information,” but the Proposed Rule does not explain whether the P&T Committee members (government and non-government) will be excluded from such information. The Section recommends that the Proposed Rule address the ethical and non-disclosure restrictions that will govern the conduct of the private-sector members. The Section believes that it is important to identify these restrictions to

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4 See 48 C.F.R. § 3.104-3 (2002) (defining the term “source selection evaluation board” as “any board, team, council, or other group that evaluates bids or proposals”).


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protect the integrity of the formulary decision-making process and to provide notice to both the private-sector members and the affected pharmaceutical manufacturers of the restrictions that will govern the conduct of those members and, in turn, the remedies available for any violations.

B. The Proposed Rule Should Clarify Whether the P&T Committee Will Function as an Advisory Committee Under the Federal Advisory Committee Act.

The Proposed Rule provides that the Beneficiary Advisory Panel “will function in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2).”

In comparison, the Proposed Rule provides that the P&T Committee “will function consistent with the Federal Advisory Committee Act (5 U.S.C. App. 2).” These two statements may be intended to mean the same thing – i.e., that both the Beneficiary Advisory Panel and the P&T Committee are advisory committees under the Federal Advisory Committee Act (“FACA”) and, therefore, are subject to the procedural requirements for advisory committees under existing regulations. On the other hand, if the difference in these statements is intended to mean that the P&T Committee is not subject to FACA, but will closely follow FACA’s requirements, the Proposed Rule should clarify that point and identify which FACA procedures the Proposed Rule would require the P&T Committee to follow. In making this recommendation, the Section takes no position on whether FACA applies to the P&T Committee.

C. The Regulation Should be Clarified to Specify Procedures for Obtaining Current and Accurate Information About the Cost of Pharmaceutical Agents to the Government.

The Section recommends that the Proposed Rule be revised, as discussed below, to specify procedures for obtaining current and accurate information about the cost of pharmaceutical agents to the Government. In making these recommendations, the Section takes no position on whether the process of selecting a pharmaceutical

8 67 Fed. Reg. at 17952 (to be codified at 32 C.F.R. § 199.21(c)).

9 Id.


agent for inclusion on the uniform formulary is a “procurement” for purposes of the Competition in Contracting Act. Notwithstanding this question, we believe that the process of determining cost effectiveness will benefit from ground rules aimed at providing accurate and complete information in a manner that is fair to the participants.

Proposed section 199.21(d)(2)(ii) lists nine categories of information the P&T Committee “may” consider in determining cost effectiveness. The list does not exclude the P&T Committee from considering other information beyond these nine categories.

The first category, “cost to the Government,” should be treated separately from the others. It would not seem possible to determine cost effectiveness without considering the cost to the Government of the pharmaceutical agent in question. Therefore, this category should not be optional. Instead, the Proposed Rule should make clear that “cost to the Government” shall be considered in every determination of cost effectiveness.

In most cases, “cost to the Government” will consist of two components: the cost of pharmaceutical agents the Government purchases directly, and the cost of those that others -- such as Managed Care Support (“MCS”) contractors -- purchase and pass along to the Government either directly or by inclusion in a price charged. In this regard, we also note that the last of the nine categories, “[t]he existence of existing blanket purchase agreements, incentive price agreements, or contracts,” is a subset of “cost to the Government.”

The Section recommends that the Proposed Rule be amended to include procedures for obtaining complete and accurate information about costs in a manner that is fair to all parties. This would involve:

12 10 U.S.C. § 2301 et seq.


14 The governing statute makes clear that formulary determinations must be based on both clinical and cost effectiveness. 10 U.S.C. § 1074g(a)(2)(A).

15 67 Fed. Reg. 17952 (to be codified at 32 C.F.R. § 199.21(d)(2)(ii)(I)).
1. Notifying the manufacturer that its pharmaceutical agent is being considered for inclusion on the uniform formulary.

2. Permitting the manufacturer to provide salient information with regard to clinical and cost effectiveness.

3. Inviting the manufacturer to submit better pricing with respect to contracts, blanket purchase agreements, incentive price arrangements, or the prices charged to MCS contractors.16

4. Making clear that better pricing may (or may not) be contingent on the inclusion of the pharmaceutical agent on the uniform formulary.

5. If more than one pharmaceutical agent in a therapeutic class is being considered, providing a common cut-off date for the submission of information, including price proposals.

6. Making clear whether offers of better pricing will be maintained as confidential during the process or, if they will be disclosed, to whom and under what circumstances.

In addition, the Section recommends that pharmaceutical manufacturers be informed, as much as possible, of the various factors that will be used to determine inclusion on or exclusion from the uniform formulary. This can be done in the final rule, in an accompanying policy statement, or in the notice provided to manufacturers that their pharmaceutical agent is being considered for inclusion.

Finally, with respect to the second component of “cost to the Government,” involving the cost of pharmaceutical agents purchased by MCS contractors, the Proposed Rule does not require the consideration of information from MCS contractors about their cost of pharmaceutical agents, and the effect of inclusion or exclusion on the price the Government pays under the MCS contract. In this regard, the statute being implemented requires that these contracts be modified to account for, among other things, “military activities and policies that affect costs of pharmacy

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16 By referring to “existing” agreements and contracts (§ 199.21(d)(2)(ii)(I)), the Proposed Rule suggests that special pricing arrangements will not be considered. Nevertheless, manufacturers may be willing to propose better pricing to obtain a place on the formulary.
These modifications would affect, and indeed determine, that part of the “cost to the Government” that flows through the MCS contracts. Accordingly, the Section would submit that they are critical in determining the effect on cost of a formulary determination. The Proposed Rule should recognize this process and require the P&T Committee to gather and evaluate salient information from the MCS contractors as part of determining “cost to the Government.”

D. The Proposed Rule Should be Clarified With Respect to the Applicable Standard for Designating a Pharmaceutical Agent as “Non-Formulary.”

Section 199.21(a)(2)(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 such class.” Although this statutory provision envisions a balancing test that takes into account both clinical effectiveness and cost, section 199.21(a)(2)(ii) of the Proposed Rule could be interpreted as setting forth two independent and alternative standards – one based solely on clinical effectiveness, and one based on cost effectiveness.

For example, interpreted literally, the second sentence in section 199.21(a)(2)(ii) would appear to permit the P&T Committee to designate as “non-formulary” an inexpensive but effective agent solely on the ground that it does not have a significant therapeutic advantage over a slightly more effective but much higher-priced agent. Such an interpretation would be inconsistent with the governing statute’s mandate that the selection of uniform formulary agents be based on both therapeutic effectiveness and cost effectiveness. The Section recommends that the standard for designating agents as “non-formulary” be clarified in the final rule so as to be consistent with the underlying statutory language.

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17 10 U.S.C. § 1074g(d)(2).

18 We also note that the Proposed Rule does not indicate how the therapeutic classes will be designated, or by whom. The Section recommends that the final rule clarify that the American Hospital Formulary Service classification system (or a similarly authoritative and recognized classification system) will be followed.
E. The Provisions Concerning Generic Substitution Should Be Revised For Internal Consistency and to Provide For a Waiver of Mandatory Substitution When Price Incentives Make a Branded Product More Economically Attractive Than a Generic Version of the Product.

The Section recommends that the Proposed Rule be revised to resolve an apparent conflict between two provisions of the Proposed Rule concerning generic substitution. Section 199.21(i) (2) provides that the Pharmacy Benefits Program generally requires mandatory substitution of generic drugs when available.\footnote{67 Fed. Reg. 17954 (to be codified at 32 C.F.R. § 199.21(i)(2)).} The designation of a drug as “generic” for cost-sharing purposes will be determined through use of standard pharmaceutical references as part of commercial, best-business practices; drugs will be designated as generics only if listed with an “A” rating in the Orange Book.\footnote{Id.} In the commercial insurance sector, the published price of a generic version of a drug must be at least 10% lower than the published price of the reference drug in order for the drug to qualify as a generic. Section M of the Overview of the Proposed Rule explains that, under the rule, mandatory substitution of “A” rated generic drugs is required for brand-name drugs.\footnote{Id. at 17951.}

In the Proposed Rule, cost-sharing requirements are based on the classification of a drug as formulary, non-formulary, or generic.\footnote{Id. at 17953 (to be codified at 32 C.F.R. § 199.21(h)).} Consistent with the mandatory generic-substitution policy, section 199.21(h)(2) provides a substantially lower co-pay for generic drugs, and section 199.21(i)(2) provides that the referenced brand-name drug will not be available to the beneficiary at the formulary co-pay unless there is a clinical justification for a brand-name drug in lieu of a generic equivalent under the specific standards set forth in section 199.21(h)(3).\footnote{Id. at 17953 (to be codified at 32 C.F.R. § 199.21(h)(3)).} At the same time, section 199.21(i)(3) provides that brand drugs with non-formulary status may be treated as generics for purposes of cost sharing if the brand-name drug is the most cost-effective
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drug for purchase by the Government through blanket purchase agreement, price incentive agreements, or other Government contract action.

The Section recommends that the Proposed Rule be modified to make the Government’s intent clear regarding the use of generics -- that is, that mandatory substitution is waived not only when there is clinical justification for dispensing the brand, but also when the Director of the TRICARE Management Activity determines that price incentives make the brand more economically attractive than the generic version. In addition, section 199.21(i) on designation of generic drugs for purposes of cost-sharing should be revised to remedy the conflicting provision in section 199.21(i)(3) by including language such as “except if accorded generic status in accordance with section (i)(3) below.” The Proposed Rule should also be revised to clarify that, like the cost ultimately borne by the Government of agents purchased by MCS contractors (discussed above), the effects of co-pays will be taken into account in the P&T Committee’s cost-effectiveness determination. The difference between a $3.00 co-pay for a generic and $22.00 for a non-formulary drug must be paid by the Government and should be considered in an economic value determination.

The Section appreciates the opportunity to provide these comments and is available to provide additional information or assistance as you may require.

Sincerely,

Norman R. Thorpe  
Chair, Section of Public Contract Law

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