July 15, 2004

Via UPS Overnight and Facsimile

Honorable Robert A. Burton
Acting Director
Office of Federal Procurement Policy
725 17th Street, N.W.
Room NEOB 6025
Washington, DC 20503

Re: Modification of FSS Contract Clauses to Implement the TRICARE Retail Pharmacy Program to Require the Payment of Refunds by Pharmaceutical Manufacturers

Dear Mr. Burton:

On behalf of the Section of Public Contract Law of the American Bar Association (the “Section”), including its Health Care Contracting Committee, I am submitting comments on the above-referenced matter.¹ The Section consists of attorneys and associated professionals in private practice, industry and Government service. The Section’s governing Council and substantive committees have members representing these three segments, to ensure that all points of view are considered. By presenting their consensus view, the Section seeks to improve the process of public contracting for needed supplies, services, and public works.

¹ The Honorable Mary Ellen Coster Williams, Daniel I. Gordon, and Robert A. Burton, Council members of the Public Contract Law Section, did not participate in the Section’s consideration of these comments, and they abstained from the voting to approve this letter.
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.

The Section’s comments address a recent development in the Department of Defense’s (“DOD”) proposed implementation of the TRICARE Retail Pharmacy Benefit (“TRRx”) Program. The Section’s comments specifically address an announcement at a May 11, 2004, DOD-sponsored meeting, entitled “Federal Pricing in the TRICARE Retail Pharmacy Program,” that the Department of Veterans Affairs (“VA”) intends to modify existing clauses in the Federal Supply Schedule solicitation for pharmaceuticals (“FSS Solicitation”) to require a pharmaceutical manufacturer to periodically pay DOD a “refund” based on the volume of that manufacturer’s drugs dispensed by commercial retail pharmacies to TRICARE beneficiaries.

As you may know, on January 28, 2004, the Section submitted comments to the Assistant Secretary of Defense for Health Affairs regarding the TRRx program (the “January Comments”) (Attachment 1). A detailed description of the TRRx program is set forth in the Section’s January Comments. As described in the January Comments, DOD drafted the TRRx program as a mechanism to obtain, among other things, the benefit of certain discounted pharmaceutical prices that are made available to DOD purchasers as required under the Veterans Health Care Act of 1992 (“VHCA”). As outlined in the January Comments, the discounts available under the VHCA apply only in the context of a federal procurement.

For that reason, the Section in its January Comments disagreed with DOD’s position that a federal procurement occurs when a commercial retail pharmacy dispenses a covered drug to a TRICARE beneficiary with a subsequent reimbursement to that commercial pharmacy by a Pharmacy Benefit Manager (“PBM”) performing under a contract with DOD and using DOD appropriated funds. As explained in the Section’s January 2004 comments, the transaction occurring between a TRICARE beneficiary and a retail pharmacy is not a federal procurement notwithstanding DOD’s recent description of such a transaction as a “virtual” procurement. In the end, the Section believes that DOD’s contracted PBM will be nothing more than a third-party claims processor, which simply will reimburse a commercial pharmacy for covered drugs that the pharmacy itself previously purchased through the normal commercial distribution chain without any federal agency direction, involvement, or control.

We understand that the VA intends to seek or is in the process of seeking a deviation under the Federal Acquisition Regulation (“FAR”) to modify existing
General Services Administration ("GSA") clauses in the FSS Solicitation to implement the TRRx program. As described by a VA official at the May 11, 2004 program, the VA would amend existing clauses to require that manufacturers performing under FSS contracts pay a refund to DOD on each unit of product dispensed by a retail pharmacy to a TRICARE beneficiary such that the net reimbursement and refund associated with each unit would approximate the statutory discount available to DOD under the VHCA. We understand that the VA intends to insert the amended clauses in the FSS pharmaceutical contracts once it has obtained GSA approval of the VA’s proposed deviation language.

The Section does not believe that the VA is authorized to proceed with the amended clauses for the following reasons. First, as outlined in the January Comments, the Section does not believe the transactions at the retail pharmacy level constitute a federal procurement. The VA and GSA FSS contracting authority as set forth under the Federal Property and Administrative Services Act, as amended, extends only to the procurement of supplies and services for the direct benefit and use by the federal government. See 40 U.S.C. § 501(b). Such authority does not extend to reimbursement schemes under federal benefits programs as described above. The attempt to amend the FSS Solicitation to address such a reimbursement scheme is unauthorized and contrary to procurement law.

Second, the VA may not amend the clauses to address the TRRx program without going through required Federal Register notice and comment procedures, as required under the FAR. FAR Subpart 1.4 requires federal agencies to follow set procedures to effect FAR clause deviations, and contemplates FAR revisions for class deviations that are intended to effect permanent revisions to more than one contract action. Moreover, under FAR 1.501-2, all “significant revisions” to the FAR system are subject to a set notice and comment requirement requiring “a minimum of 30 days and, normally, at least 60 days,” regardless of whether the revision applies to a class of contract actions or an individual procurement. Significant revisions are defined as those “revisions that alter the substantive meaning of any coverage in the FAR System having significant cost or administrative impact on contractors or offerors, or a significant effect beyond the internal operating procedures of the issuing agency.” FAR 1.501-1. The implementation of the TRRx program would obligate contractors (1) to refund significant sums to the government and (2) to develop new systems to track and reconcile retail pharmacy sales and calculate applicable refunds. It is hard to imagine how revisions to standard GSA FSS contract clauses to implement the TRRx program would not be considered significant.

Accordingly, the Section provides these comments and analysis to encourage the Office of Federal Procurement Policy to review the actions of the
Honorable Robert A. Burton  
Acting Director  
Office of Federal Procurement Policy  
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VA and GSA and advise them that commercial pharmacy reimbursements by a DOD PBM contractor under the TRRx program do not constitute federal procurements and, as such, the VA is not authorized to include clauses in the FSS Solicitation to implement the TRRx refund program. Additionally, the Section requests a determination that appropriate notice and comment procedures be followed prior to use of the amended FSS clauses that would implement the TRRx program. Such a notice and comment period is designed to provide the various stakeholders an opportunity to raise concerns such as those expressed by the Section herein.

Sincerely,

[Signature]

Hubert J. Bell, Jr.  
Chair, Section of Public Contract Law

Enclosure

cc: Patricia H. Wittie  
Robert L. Schaefer  
Michael A. Hordell  
Patricia A. Meagher  
Mary Ellen Coster Williams  
Norman R. Thorpe  
Council Members  
Co-Chairs and Vice Chairs of  
the Health Care Contracting Committee  
David Kasanow
ATTACHMENT 1
January 28, 2004

Via UPS Overnight and Facsimile

William Winkenwerder, Jr., MD
Assistant Secretary of Defense for Health Affairs
1200 Defense Pentagon
Room 3E1082
Washington, DC 20301-1200

Re: Procurement Of Covered Drugs Under The TRICARE Retail Pharmacy Benefit Program

Dear Dr. Winkenwerder:

On behalf of the Section of Public Contract Law of the American Bar Association (the “Section”), including its Health Care Contracting Committee, 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 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.

I. Summary

The Section’s comments address the Department of Defense’s (“DOD”) proposed TRICARE Retail Pharmacy Benefit Program (“TPBP”), as detailed in an
August 6, 2003 letter (enclosed) from you to a trade association (the “DOD Letter”). Among other things, the DOD letter outlines the legal basis for requiring pharmaceutical manufacturers (“manufacturers”) to pay rebates to the DOD for purchases of covered drugs by DOD beneficiaries from retail pharmacies. The Section understands that DOD and Department of Veteran’s Affairs (“VA”) personnel have been discussing this topic in various forums, including a VA presentation made last fall at a seminar on the Veterans Health Care Act sponsored by the Section’s Health Care Contracting Committee. Although the DOD Letter was not addressed to the Section, the letter articulates the agency’s position in detail and therefore serves as a useful vehicle for the Section to express its views on certain procurement issues.

The DOD Letter included a diagram of the proposed structure of the TPBP, which is also enclosed. Although the proposed structure of the TPBP may raise other legal issues, the Section’s comments respond only to DOD’s position that the purchase of the covered drugs by DOD beneficiaries from a retail pharmacy constitutes the acquisition of supplies from the manufacturers under federal procurement laws and regulations. For the reasons explained herein, the Section respectfully disagrees.

The Veterans Health Care Act of 1992 (“VHCA”) requires the “acquisition” or “procurement” of covered drugs in order for DOD or another authorized federal agency to gain the benefit of the statutory discount available under the VHCA. An acquisition or procurement of covered drugs by a federal agency requires a contract under which title to the supplies passes to a federal agency. No such contract exists between DOD and a manufacturer. In addition, according to the diagram attached to the DOD Letter, no privity of contract exists between the manufacturer and DOD in connection with sales of covered drugs through retail pharmacies. Moreover, neither the Federal Supply Schedule (“FSS”) contracts nor the Master Agreement between the VA and each manufacturer includes provisions addressing sales of covered drugs through retail pharmacies as contemplated under the TPBP. We also understand that not all payments to the retail pharmacies involve appropriated funds as required under a federal procurement contract. In sum, the Section does not believe the VHCA changed the legal requirements and fundamental norms characterizing a federal procurement. The Section encourages DOD to reconsider its position that the sale of covered drugs through retail pharmacies constitutes a procurement of supplies by a federal agency under applicable procurement laws and regulations, including the VHCA and to investigate alternate means to achieve its ends.
II. Background

The VHCA authorizes certain agencies, including the DOD and the VA, to receive certain statutory discounts when procuring covered drugs. Under the VHCA, manufacturers enter into a “Master Agreement” with the VA under which a manufacturer agrees to make available its covered drugs at the discounted price (called the Federal Ceiling Price or “FCP”) for procurement under a FSS contract or that are “purchased under depot contracting systems . . .” 38 U.S.C. § 8126(a)(2). The VHCA defines the term “depot” as follows:

The term “depot” means a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are—

(A) received, stored, and delivered through—

(i) a federally owned and operated warehouse system,
or
(ii) a commercial entity operating under contract with such agency; or

(B) delivered directly from the commercial source to the entity using such covered drugs.

38 U.S.C. § 8126(h)(3). We understand that DOD relies on the alternative definition of depot in part (B) of this definition to support its position that DOD is procuring covered drugs when such drugs are purchased by DOD beneficiaries directly from retail pharmacies.

According to the DOD Letter, the TPBP will be implemented “through a centralized commodity management system (PBO) through which covered drugs will be procured by DOD using appropriated funds for use of its beneficiaries and delivered directly from the commercial source.” The term “PBO” refers to DOD’s Pharmacy Benefits Office that will be established to manage the TPBP with the assistance of a contracted commercial Pharmacy Benefits Manager (“PBM”). The PBM will provide its network of contracted retail pharmacies to dispense drugs to the TRICARE beneficiaries as shown in the attachment to the DOD Letter.
According to the diagram attached to the DOD Letter, retail pharmacies acquire covered drugs through the normal commercial sales channel. The manufacturer sells its covered drugs to a wholesaler, which in turn sells the covered drugs to one of the retail pharmacies participating in the PBM’s network of contracted pharmacies. Beneficiaries under DOD’s TRICARE program will purchase covered drugs directly from these retail pharmacies. The retail pharmacy will transmit pharmacy claims data to the PBM, which in turn pays the claim and transmits consolidated claims data to the PBO. The consolidated claims data will, generally speaking, indicate the volume of covered drugs purchased by DOD beneficiaries. The PBO will use this utilization data to request a rebate from the manufacturer that reflects DOD’s alleged entitlement to the lower of the FCP or the FSS price for such utilization.

III. The Proposed Depot Contracting System Does Not Result In A Procurement Of Covered Drugs By A Federal Agency

The DOD Letter characterizes the TPBP mechanism described above as a procurement by DOD so as to trigger the VHCA. Specifically, DOD maintains that covered drugs will be “procured” through a “centralized commodity management system” using “appropriated funds for use of its beneficiaries and delivered directly from the commercial source.” DOD Letter at 3.

There appears to be no dispute that a procurement of covered drugs must occur for DOD to be entitled to the statutory discounts under the VHCA. The VHCA expressly refers to the procurement of covered drugs when discussing the two delivery mechanisms, specifically the FSS contracts and a depot contracting system. The VHCA provides that “the manufacturer of covered drugs shall make available for procurement on the Federal Supply Schedule of the General Services Administration each covered drug of the manufacturer.” 38 U.S.C. § 8126(a)(1) (emphasis added). Similarly, the VHCA definition of a “depot” includes a requirement that “covered drugs [be] procured by an agency of the Federal Government . . .” 38 U.S.C. § 8126(h)(3) (emphasis added).

The DOD Letter acknowledges that the “laws and regulations relating to the acquisition authority of DOD generally refer to procurement or acquisition as the acquiring of supplies or services by contract with appropriated funds by and for the use of the Federal Government.” DOD Letter at 3. For the reasons below, however, the purchase of covered drugs by a beneficiary from a retail pharmacy
does not meet the definition of a procurement or acquisition under these laws and regulations.

A. No Contract Exists Between The Manufacturer And DOD For Sales Of Covered Drugs Through Retail Pharmacies

First, a procurement or acquisition requires a contract between the federal agency and the seller, which in this case is the manufacturer. The Office of Federal Procurement Policy Act defines the term “procurement” as including “all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout.” 41 U.S.C. § 403(2) (emphasis added). Likewise, the Federal Acquisition Regulation (“FAR”) defines the term “acquisition” as meaning “the acquiring by contract . . . of supplies or services . . .” FAR 2.101(2)(emphasis added). A fundamental norm underlying contract law is that a buyer and seller of goods share privity of contract. As the diagram attached to the DOD Letter shows, there is no privity of contract between DOD and the manufacturer as the seller of the covered drugs. At least five separate transactions of money and product occurs under DOD’s proposed scheme. None of these transactions involves a contractual agreement between the manufacturer and DOD. In the absence of the requisite privity of contract between DOD (or its authorized agent) and the manufacturer (or its authorized agent), there is no procurement from the manufacturer to which the provisions of the VHCA can attach.2

The proposed arrangement stands in contrast to the commercial practice with managed care companies that DOD apparently desires to replicate. In those

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1 See, e.g., Etchey v. United States, 15 Cl. Ct. 152, 154 (1988) (defining privity of contract as “that connection or relationship which exists between two or more contracting parties”).

2 See United States v. Johnson Controls, Inc., 713 F.2d 1541, 1550 (Fed. Cir. 1983). An exception to the general subcontractor privity rule exists if the prime contractor is acting as merely a government agent, thereby establishing a relationship between a subcontractor and the government. Id. The exception does not apply in this case. To establish an agency relationship one needs to prove that the prime contractor: (1) is acting as a purchasing agent for the government; (2) the agency relationship between the government and prime contractor was established by clear and contractual consent; (3) the contract stated that the government would be directly liable to vendors for the purchase price. Id. at 1551. Under the current structure of the TPBP, the manufacturer did not consent to providing FCP/FSS prices for the TRICARE beneficiaries. Also, the PBM will make payments on DOD’s behalf, but the Government will not be directly liable to pay a purchase price to the pharmacy’s supplier.
situations, the manufacturers often pay chargebacks and rebates for drugs indirectly purchased by a managed care company or PBM through a wholesaler. In those cases, however, a contractual agreement exists between the manufacturers and a managed care company or PBM that establishes the terms and conditions associated with those forms of discounting practices. Likewise, a contractual agreement exists between the manufacturer and the wholesaler for the latter to submit a chargeback to the manufacturer if the wholesaler sold the drug to a managed care company or PBM at a lower price than the wholesaler paid to the manufacturer. In contrast, the two contracts implementing the VHCA — the Master Agreement and FSS contracts — do not contain any term or condition authorizing indirect sales through retail pharmacies or the payment of rebates. DOD appears to authorize such indirect sales and payments and does not cite any existing provision in either of these agreements to support its position.

B. Title To The Covered Drugs Sold Through Retail Pharmacies Does Not Pass To The Government

Second, another fundamental procurement norm is that title to the supplies must pass from the seller to the buyer when supplies are being purchased (as opposed to being leased, for example). Under the Uniform Commercial Code ("U.C.C."), a "sale" is defined as "passing of title from the seller to the buyer for a price . . . ." U.C.C. § 2-106(1). Similarly, the FAR contains a requirement to pass title to the government. For commercial items such as the covered drugs, the requirement for title to pass is reflected in FAR 52.212-4, which provides that "unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession." Under the proposed structure of the TPBP, DOD neither accepts nor takes physical possession of the covered drugs at any time.\(^3\) Stated otherwise, DOD's position violates the long-established

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3 The U.C.C. also requires that "title to goods cannot pass under a contract for sale prior to their identification to the contract (Section 2-501)." U.C.C. § 2-401(1). Under the proposed TPBP, the covered drugs are never identified to any contract between the Government and the manufacturer. If a "contract is for the sale of future goods," identification under the U.C.C. "occurs when the goods are shipped, marked or otherwise designated by the seller as goods to which the contract refers." U.C.C. § 2-501(1)(b). Under the proposed TPBP, the manufacturer never designates the covered drugs to be sold to DOD or any DOD beneficiary. Although the U.C.C. does not directly apply to federal procurements, its provisions regarding the sale of goods is instructive regarding when title passes to goods under FAR 52.212-5 for commercial items.
C. DOD Uses Non-Appropriated Funds

Third, procurements must involve the payment of appropriated funds. FAR 2.101(b)(2) ("[a]cquisition means the acquiring by contract with appropriated funds . . .") (emphasis added). We understand that non-appropriated funds in the Medicare Retiree Health Care Fund will be used to pay some of the claims submitted by TRICARE Retail Pharmacies.4

In addition, member and other third party payment will be involved in most if not all of these transactions due to coverage limitations, co-pays, coordination of benefits, etc. Therefore, appropriated funds will not be used to purchase the drugs. Instead, appropriated funds will only be used to reimburse a portion of the cost of the drugs based on the benefit structure provided under the health coverage and other third parties’ liability related to the beneficiary’s individual facts and circumstances (e.g., coordination of benefits). Finally, it is our understanding that if the guaranteed discount level is not achieved by the PBM, the excess price above the guaranteed discount will be deducted from the PBM’s administrative fee up to the full value of the PBM contract price. As a result, a portion of the price of the drug under the current structure could be paid by the PBM.

D. The Terms And Conditions Of The FSS Contract Do Not Correspond To The Manner Of Sale Under The TPBP

Fourth, assuming arguendo that retail sales of covered drugs occur under a FSS contract,5 the proposed TPBP does not involve reimbursement to retail pharmacies for items that are listed on the FSS contract. The FSS contract establishes prices for certain contracted line items known as stock keeping units ("SKUs"). Each SKU has a unique eleven-digit National Drug Code ("NDC") number. There may be multiple SKUs for the same product to reflect market demand for various package sizes. FCPs are calculated only for the same 11-digit

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5 We understand that DOD maintains that the covered drugs to be procured under the depot contracting system will be sold under FSS contracts. On that note, we further understand that the VA intends to collect an industrial funding fee on each covered drug sold through a retail pharmacy.
NDC contract line items. The entities that purchase from the wholesaler, *e.g.*, retail pharmacies, break the SKUs down into dispensing units for resale or for their own use. At the same time, retail pharmacies establish what price to charge for dispensed prescriptions based on numerous factors, including negotiated arrangements with health plans and dispensing fees. The units dispensed by retail pharmacies are not traceable to a particular SKU or NDC on the FSS contract and in many cases are not traceable to a particular wholesaler or commercial distribution channel. In fact, dispensed units could have been obtained through a number of sources, including unauthorized secondary markets, and at unknown prices. For these reasons, it would not be possible to determine a rebate amount for a dispensed unit of drug by reference to the FSS price for a contracted SKU.

Moreover, FSS contracts are indefinite quantity, indefinite-delivery contracts that require the issuance and acceptance of purchase or delivery orders to effectuate a transaction. No such orders occur under the proposed TPBP mechanism. In addition, we understand that the contracted retail pharmacies will not act as agents of DOD and do not have authority to purchase under the FSS contract. Likewise, neither the wholesaler or retail pharmacy are agents of the manufacturer selling FSS contracted products to authorized DOD users. There is no transaction contemplated in the proposed arrangement that would qualify as an order under an FSS contract. This is an essential requirement for an authorized user to obtain supplies under FSS contracts.

Based on the preceding discussion, DOD's proposed retail pharmacy program is not a procurement or acquisition of covered drugs by a federal agency, and DOD has no authority to seek rebates from pharmaceutical manufacturers in connection with purchases of covered drugs by DOD beneficiaries under this program.
IV. Conclusion

Notwithstanding the foregoing, there may be alternative ways to structure the TPBP so that the program falls within statutory requirements. To that end, as a Section comprised of procurement professionals in private practice, industry, and government service, we encourage the relevant stakeholders to work together to find such alternatives. Please consider the Section and its Health Care Contracting Committee as a potential resource in connection with such an effort. The Section's main concern is the potential unauthorized expansion of legally prescribed definitions of "procurement" and "acquisition." Acquisition of supplies and services by a third party not acting as an agent of the federal government is not a procurement as that term currently is defined under the law. The VHCA does not change this definition.

Sincerely,

[Signature]

Hubert J. Bell, Jr.
Chair, Section of Public Contract Law

Enclosure

cc: Patricia H. Wittie
    Robert L. Schaefer
    Michael A. Hordell
    Patricia A. Meagher
    Mary Ellen Coster Williams
    Norman R. Thorpe
    Council Members
    Co-Chairs and Vice Chairs of
    the Health Care Contracting Committee
    David Kasanow
Mr. Richard I. Smith  
Senior Vice President  
Strategic Communications & Policy  
Pharmaceutical Research and Manufacturers of America  
1100 Fifteenth Street, NW  
Washington, DC 20005  

Dear Mr. Smith:

This is in response to your recent letter on behalf of members of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the new TRICARE Retail Pharmacy Program and the current Department of Defense (DoD) solicitation for a TRICARE Retail Pharmacy contract. I understand that identical letters were also sent to Dr. Robert H. Roswell, Under Secretary for Health, Department of Veterans Affairs (VA), Ms. Phillipa L. Anderson, Assistant General Counsel, VA, and Mr. Robert Seaman, General Counsel, TRICARE Management Activity (TMA).

Your letter asserts that the TRICARE Retail Pharmacy Program involves a commercial reimbursement arrangement, and not a procurement by DoD, and as such is unlawful under current statutes. It appears that your concerns are based on a misunderstanding of the Department’s new TRICARE Pharmacy Benefits Program and DoD’s acquisition of drugs under the retail portion of that Program.

As noted in your letter, manufacturers are statutorily required under the Veterans Health Care Act of 1992 (VHCA) to make their covered drugs available at or below federal ceiling prices (FCPs) for procurement by the VA, DoD, the Public Health Service and the U.S. Coast Guard. Such procurements may be under Federal Supply Schedule (FSS) contracts or depot contracting systems administered by Federal agencies.

TRICARE Pharmacy Benefits Program (TPBP)

A new TPBP has been developed and will be implemented in lieu of the current retail pharmacy program operating under the current generation of TRICARE Managed Care Support Contracts. Section 703 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Public Law 105-261, required the Secretary of Defense to plan a “system-wide redesign of the military and contractor retail and mail-order pharmacy system of the Department of Defense by incorporating best business practices of the private sector.” Subsequently, section 701 of The National Defense Authorization Act for Fiscal Year 2000, Public Law 106-65, directed the Secretary of Defense to “establish an effective, efficient, integrated pharmacy benefits program ....” The re-engineered TPBP was developed consistent with these mandates and will include, among others, a uniform formulary, implementation of the Pharmacy
Data Transaction Service (PDTS), and a pharmaceutical and therapeutics committee. A final regulation implementing the TPBP will be published in the near future as title 32, Code of Federal Regulations, Section 199.21.

The new TPBP will be administered through a government office, preliminarily known as a Pharmacy Benefits Office (PBO), which will manage the TRICARE pharmacy benefit using the PDTS and a single TRICARE Retail Pharmacy contract for a Pharmacy Benefit Manager (PBM). The PBM will be paid a negotiated administrative (transaction) fee for performance of certain services under the contract; however, the fee will not be related, directly or indirectly, to DoD’s acquisition costs under federal pricing. Enclosed for your information is a diagram of the process as it will operate.

The PBM will be tasked with providing a retail pharmacy network and performing services as a fiscal intermediary by using DoD appropriated funds (either Defense Health Program funds or the accrual “Fund” established under chapter 56, title 10, United States Code) to pay for all TRICARE prescriptions once the PBO verifies the individual beneficiary’s eligibility and authorizes payment. Consistent with legislative mandate, administration of the TPBP will preserve best commercial practices by allowing a retail pharmacy to obtain its supply of drugs as it normally does in the commercial world. Retail pharmacies may purchase their supplies from a wholesaler, or in certain instances, directly from the manufacturer. This avoids DoD having to create unnecessary warehousing/distribution facilities and is consistent with current government procurement and inventory practices generally known as “just-in-time delivery.”

A network retail pharmacy will communicate directly with the PBM on each individual request to fill a prescription by a TRICARE beneficiary. The PBM will interface with the PBO for beneficiary eligibility, clinical adjudication, and application of TPBP rules—all in real time before the prescription is filled. The PBO will manage the TPBP through the PDTS to verify beneficiary eligibility, check for potential drug interactions, and authorize payment of each prescription. The PBM will authorize the network retail pharmacy to fill the prescription and receive appropriate co-payments from the patient. The PBM will then receive specific authorization to draw funds from an appropriate government account to issue payment to the network pharmacy based on a negotiated network rate (e.g., AWP pricing less a discount) less the patient’s co-payment and plus a dispensing fee.

Unlike the current retail pharmacy program under existing TRICARE Managed Care Support Contracts, DoD will work directly with the manufacturer to receive rebates based on federal pricing. The PBO will be able to ensure that every purchase made under the TPBP was for an eligible TRICARE beneficiary for a covered benefit and will give pharmaceutical manufacturers itemized information, using the PDTS, on drugs procured under TRICARE. In turn, the appropriate manufacturers would provide rebates directly to DoD for deposit into the TRICARE appropriations with assurance that the rebates based on FCPs (or FSS, whichever is lower) only apply to prescriptions filled for eligible DoD beneficiaries.
Department of Defense Procurement

Briefly, under the VHCA, FCPs are required by section 38 U.S.C. § 8126(a)(2) "... with respect to each covered drug of the manufacturer procured by [DoD] ... that is purchased under depot contracting systems ...." The statute, at § 8126(h)(3), defines "depot" as:

"... a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are —

(A) received, stored and delivered through —

(i) a federally owned and operated warehouse system, or
(ii) a commercial entity operating under contract with such agency; or

(B) delivered directly from the commercial source to the entity using such covered drugs."

It is true that the Department of Veterans Affairs (VA) previously determined that the retail pharmacy program under the current generation of TRICARE Managed Care Support Contracts is not considered a DoD procurement of drugs. However, the new TPBP has been reviewed by VA, and VA has determined that the retail portion of the new TPBP qualifies for FCPs because such purchases will be a procurement by DoD under a depot contracting system as defined in 38 U.S.C. § 8126(h)(3).

The TPBP will be implemented in a manner meeting the specific words of the VHCA; i.e., through a centralized commodity management system (PBO) through which covered drugs will be procured by DoD using appropriated funds for use of its beneficiaries and delivered directly from the commercial source. The term "procured" is not defined in 38 U.S.C. § 8126; however, laws and regulations relating to the acquisition authority of DoD generally refer to procurement or acquisition as the acquiring of supplies or services by contract with appropriated funds by and for the use of the Federal Government.

In compliance with the above applicable definition and 38 U.S.C. § 2816, the TRICARE Pharmacy Benefits Program (TPBP) will involve DoD procurement of covered drugs "purchased under depot contracting systems ...." The VA specifically agrees that the TPBP is, in reality, a system for the acquisition, delivery, and distribution of prescriptions by DoD on behalf of its beneficiaries through the use of a DoD Pharmacy Benefits Office and a contracted PBM with a retail pharmacy network. The VA agrees that the TPBP method of acquisition meets the alternative definition of "depot" under 38 U.S.C. § 8126(h)(3)(B).

The VA also supports the DoD position that FSS contract prices are applicable to retail network TRICARE prescriptions under the new TPBP (where such prices are lower than FCPs) in that the FSS drugs are being procured by the DoD PBO, part of an executive Government agency entitled to access the FSS. Because the PBO, not the contracted PBM, is procuring
beneficiaries' drugs, there is no need for implementing procedures under FAR Part 51 to issue an authorizing letter to the PBM.

Policy Concerns

Your letter raises a concern with the complexities involved in implementing a "rebate" process under the TPBP. We recognize the concern and are willing to work with the manufacturers to address the complexities. If helpful, TMA is willing to provide current utilization data to assist your members and other pharmaceutical manufacturers in addressing their operational needs to ensure success of the program. I understand that representatives of TMA and VA intend to meet with representatives of manufacturers in the near future on this issue.

Your letter also expresses an opinion that this new TPBP represents an expansion of federal pricing beyond authorized users. It is DoD's position that this new TPBP does not represent an expansion of statutory authority, merely the expanded use by DoD of authority already given to DoD by statute. Maintaining the status quo whereby manufacturers have been the beneficiary of windfalls because DoD has not fully exercised its statutory entitlement to federal pricing is no barrier to DoD's expanded use of its existing authority.

Your letter also notes your concerns regarding implementation of the DoD Uniform Formulary and advises that the concerns were raised in comments in response to public rule making procedures. Those concerns will be appropriately addressed as part of publication of the final rule.

In summary, it is the opinion of DoD and VA that the TPBP is, in reality, a system for the acquisition, delivery, and distribution of prescriptions by DoD on behalf of its beneficiaries through the use of a DoD Pharmacy Benefits Office and a contracted PBM with a retail pharmacy network, and that the TPBP method of acquisition meets the alternative definition of "depot" under 38 U.S.C. § 8126(h)(3)(B). Further, FSS contract prices are applicable to retail network TRICARE prescriptions under the new TPBP (where such prices are lower than FCPs) in that the FSS drugs are being procured by the DoD PBO, part of an executive Government agency entitled to access the FSS. This response has been shared with VA officials, including the VA Office of General Counsel, and I understand that they have no objections to the content of this letter.

Sincerely,

[Signature]

William Winkler, Jr., MD
Enclosure:
TRICARE Retail Pharmacy Diagram

cc: w/enclosure
Dr. Robert H. Roswell
Under Secretary for Health
Department of Veterans Affairs

Ms. Phillipa L. Anderson
Assistant General Counsel
Department of Veterans Affairs

Mr. Robert D. Seaman
General Counsel
TRICARE Management Activity