June 13, 2005

Via E-Mail and First Class Mail

General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, NW, Room 4035
ATTN: Ms. Laurieann Duarte
Washington, DC 20405

Re: General Services Acquisition Regulation; Federal Agency Retail Pharmacy Program; 70 Fed. Reg. 19045 (April 12, 2005); GSAR Case 2005-G501

Dear Ms. Duarte:

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 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.

The Section is authorized to submit comments on acquisition regulations 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.¹

I. INTRODUCTION

These comments are provided in response to the Proposed Rule entitled “Federal Agency Retail Pharmacy Program,” issued by the General Services Administration (“GSA”) on April 12, 2005. The rule includes a proposed contract clause that would be inserted in the Federal Supply Schedule (“FSS”) contracts of manufacturers of pharmaceutical products listed on Schedule 65, Part I, Section B of the FSS. The proposed clause would allow certain government agencies to access Federal contract prices for pharmaceuticals through “refunds” on prescriptions filled by network retail pharmacies for government agency beneficiaries.² The proposed clause would be added to the General Services Acquisition Regulations (“GSAR”).

Pursuant to the Veterans Health Care Act of 1992 (“VHCA”), the prices for covered drugs procured by the Federal agencies specified in the statute — that is, the Department of Defense (“DOD”), the Department of Veterans Affairs (“VA”), the Public Health Service (“PHS”) and the Coast Guard — under “depot contracting systems or . . . Federal Supply Schedule [“FSS”] contracts may not exceed the statutorily calculated Federal Ceiling Price (“FCP”). 38 U.S.C. §8126 (a)(2). Under the Proposed Rule, the government would be authorized to insert a clause into the FSS contracts of these particular contractors that would require them to “deem” orders for prescriptions, for pharmaceuticals purchased by Federal Agency Retail Pharmacy Program beneficiaries through participating retail pharmacies to be contract orders subject to the contract price, whether negotiated below FCP or capped at FCP. It specifically provides that a federal agency’s “instruction to its contractor or subcontracted retail pharmacy to fill a prescription for a health care beneficiary of the agency . . . shall be deemed an order placed against [the FSS] contract.”³

To qualify as a Federal Agency Retail Pharmacy Program, the program must be modeled after the TRICARE Retail Pharmacy (“TRRx”) Program, a DOD entitlement program. The federal agency must be authorized to provide insurance

¹This letter is available in pdf format at http://www.abanet.org/contract/Federal/regscommv/home.html under the topic “Health Care.”

²As you are aware, this issue does not relate to prices paid by Tri-Care beneficiaries and the Section does not take a position on any policy issue relating to prices paid by Tri-Care beneficiaries.

type pharmacy benefits to individuals by reimbursing private sector pharmacies for prescriptions provided to the beneficiaries. In addition, the agency must enter into a contract with a fiscal intermediary called a pharmacy benefits manager ("PBM") under which the PBM agrees to provide a network of retail pharmacies with which they have payment agreements. Under the TRRx model, the PBM is paid a fee to administer the benefit (coverage, deductibles, cost shares) and, on behalf of the agency, reimburse the network retail pharmacies the agency’s cost share of the pharmacies’ prescription price with government funds (including non-appropriated Medicare funds) for all pharmacy sales of “covered drugs” dispensed to agency beneficiaries. The PBM is not a supplier and does not acquire or deliver any product. Accordingly, the parties to the prescription transaction are the beneficiary ordering the medication prescribed, the retail pharmacy providing the medication to the beneficiary, and the PBM acting as a government fiduciary and third party payer.

The Proposed Rule does not contemplate that the provider network pharmacy would be authorized to order contract line items under FSS contracts on behalf of an agency and invoice the agency or its fiscal intermediary at the FSS contract price. Rather, it contemplates that the units of drugs sold to the government beneficiaries would be taken from the retail pharmacy’s commercial stock acquired from its usual commercial sources, rather than from government-owned property, and sold to the beneficiary at the commercial network price negotiated between the PBM and the pharmacy. The Proposed Rule also does not contemplate that the manufacturer have an agreement with the retail pharmacy authorizing it to distribute its products to the government or patients covered by a federal pharmacy benefit program. Consequently, in the reimbursement system covered by the Proposed Rule, there is no contract between the agency and the retail pharmacy authorizing it to act as a purchasing agent, nor is there a contract between the manufacturer and the retail pharmacy authorizing the pharmacy to take prescription orders under the manufacturer’s FSS contract and sell prescriptions on its behalf.4

According to the Proposed Rule, the prescription units of covered drugs ordered through a retail pharmacy program would be “deemed” to be ordered by the federal agency from the manufacturer under an FSS contract through the retail pharmacy, thereby invoking FSS and FCP prices for these orders. The manufacturer would be required to refund to the federal agency the difference between a “benchmark” commercial price and the FSS contract price (FCP or the

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4 Only licensed pharmacies may fill prescription orders.
negotiated FSS price for the drug, whichever is lower). The required contractor payment would not refund the difference between the FSS contract price and the price the pharmacy charged for the prescription or the share of the price the agency actually paid. The proposed clause would require manufacturers to treat retail pharmacy sales to beneficiaries as manufacturer sales and include them in their quarterly sales reports to VA and to pay the Industrial Funding Fee ("IFF") on those sales.

As explained in detail below, we believe that GSA has exceeded its rulemaking authority in undertaking the instant rulemaking. Specifically:

- The Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b), does not confer authority on GSA to deem commercial orders as orders by an executive agency under an FSS contract;

- The VHCA does not confer rulemaking authority on GSA;

- The Federal Agency Retail Pharmacy Program extends beyond the statutory mandate of the VHCA.

We respectfully maintain that the Proposed Rule is an improper exercise of GSA’s authority. Moreover, even if GSA were authorized to proceed with this rule, it would be necessary to revise the Proposed Rule to clarify certain implementation and operational aspects of the rebate program it seeks to create. For the reasons explained below, we urge GSA not to proceed with the Proposed Rule.

II. THE PROPOSED RULE EXCEEDS GSA’S AUTHORITY

To undertake a rulemaking, an agency must have authority to do so.\(^5\) It is "a fundamental principle of administrative law that agencies may not self-levitate their power to promulgate regulations – they must rather find any such power in a source conferred by Congress."\(^6\) In other words, there must be a “nexus between

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\(^6\) *Respect Inc. v. Comm. on Status of Women*, 815 F. Supp. 1112, 1123 (N.D. Ill. 1993) (court determined that the Department of Health and Human Services did not have authority to promulgate a regulation because the regulation in question was not within the contemplation of any existing statute).
the regulation[ ] and some delegation of the requisite legislative authority by Congress.”7 To determine if the required nexus exists, we must “reasonably be able to conclude that [a] grant of authority [by Congress] contemplates the regulations issued.”8

The “Introduction” and “Background” sections of the Proposed Rule point to two principal statutory bases of authority:


- Veterans Health Care Act, 38 U.S.C. § 8126

As discussed below, these statutes do not contemplate that GSA (or any other agency) has the authority to “deem” an instruction by an agency, through a fiscal intermediary, to a retail pharmacy to dispense covered drugs to an agency beneficiary, to constitute an order by the agency under an FSS contract. Moreover, the Proposed Rule is inconsistent with the FAR.

A. The Federal Agency Retail Pharmacy Program Is Inconsistent With the Fundamental Elements of a Procurement

As discussed below, both statutes referenced in the Proposed Rule as possible sources of authority apply to federal procurements. Nevertheless, the relationships and transactions covered by the Proposed Rule do not involve a procurement by a federal agency as that term is used in federal jurisprudence. The meaning of the term “procurement” is well-established. A procurement is a transaction involving the acquisition of items or services for the use and benefit of the government.9 Moreover, a fundamental principle of contract law requires privity of contract between the seller and the entity procuring the goods or services.10 Another critical factor that separates procurements from other types of

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9 See, e.g., 31 U.S.C. § 6303; FAR § 2.101 (defining acquisition as purchase or lease “the acquiring by contract . . . by and for the use of the Federal Government,” and stating that “[a]cquisition begins at the point when agency needs are established . . .”).
10 See Etchey v. United States, 15 Cl. Ct. 152, 154 (1988) (defining privity of contract as “that connection or relationship which [sic] exists between two or more contracting parties”).
transactions is that title must pass from the seller to the buyer.\textsuperscript{11}

Not all Federal payments for goods and services are procurements. Federal agencies do have inherent power to procure supplies such as pharmaceuticals for their own use in carrying out government functions, although that inherent power may be limited by procurement laws and regulations. By statute, and as discussed below, GSA has special authority to procure supplies for the use of other agencies. By contrast, agencies have no inherent power to use tax dollars for the assistance of non-governmental entities (including members of the public as such beneficiaries), whether directly or by paying for supplies provided to beneficiaries. These assistance expenditures must be specifically authorized by Congress\textsuperscript{12}. Where the purpose of the transaction is to transfer something of value to a recipient in order to carry out a public purpose of support or stimulation authorized by a law of the United States, the vehicle is a grant -- which requires specific legislative authorization -- and not a contract.\textsuperscript{13} Under the Federal Agency Retail Pharmacy Programs described in the Proposed Rule, the purpose of the federal payments to retail pharmacies for prescribed medication is to provide assistance to members of the public, i.e., to ensure that medication is provided to federal beneficiaries. These payments are not made in order to obtain supplies of drugs for the direct use and benefit of DOD. Accordingly, these transactions are not procurements and GSA may not treat them as federal agency orders under the FSS contracts.

A Federal Agency Retail Pharmacy Program, as described in the Proposed Rule, involves a third-party reimbursement system through which a contracted fiscal intermediary (the PBM) reimburses retail pharmacies for prescriptions provided to beneficiaries. Commercial packages of drugs are purchased by retail pharmacies through commercial distribution channels without any federal agency direction, involvement, or control. The only involvement by the government in these transactions is to approve the eligibility of the federal health plan beneficiary, thereby authorizing its PBM contractor to reimburse the pharmacy the government’s cost-share for the dispensed medication with federal funds. There is no contract between the manufacturer and the government providing any particular price – FCP, FSS, or otherwise – for the federal reimbursements provided to the retail pharmacies. Moreover, as noted, the orders are placed by, and for the use of,

\textsuperscript{11} See, e.g., Uniform Commercial Code § 2-106(1) (defining a sale as “passing of title from the seller to a buyer for a price . . . .”).

\textsuperscript{12} General Accounting Office, Principles of Federal Appropriations Law, 10-11 (2d ed. 1992)

\textsuperscript{13} 31 U.S.C. 6303-6305
the beneficiaries. In short, the government payments to the retail pharmacies are insurance benefit payments in the form of cost-sharing subsidies. Laws and regulations governing federal procurement distinguish such transactions as “nonprocurement transactions.” See, e.g., FAR 9.403 (examples of non-procurement transactions include grants, cooperative agreements, subsidies, insurance, and payments for specified use).

In January 2004, the Section submitted comments to Dr. William Winkenwerder Jr., Assistant Secretary of Defense, Health Affairs, expressing the Section’s view that TRRrx transactions between retail pharmacies and TRICARE beneficiaries do not constitute the acquisition of supplies under Federal procurement laws and regulations. Because the Section’s comments are enclosed, detailed discussion of those points is unnecessary. In summary, the Section’s conclusion was based on the following rationale:

1. Title to dispensed covered drugs will never pass to the federal government, as required by the FAR and by the Uniform Commercial Code for a sale and purchase to occur;

2. Not all payments received by the retail pharmacies for the covered drugs dispensed to TRICARE beneficiaries will involve appropriated funds, as is required for a federal procurement;

3. The covered drugs dispensed by a retail pharmacy to the TRICARE beneficiaries will not necessarily match any package size listed as a line item in FSS contracts (e.g., SKU or NDC);

4. The covered drugs dispensed by a retail pharmacy to the TRICARE beneficiary will not be traceable to any order issued by a contracting officer; and

5. The retail pharmacies are not acting as the agent of the Federal government when purchasing the covered drugs from commercial wholesalers.

Because the Proposed Rule applies to commercial transactions occurring between federal agency beneficiaries and a retail pharmacy, the Section’s January 2004 comments outlined above also apply to the Proposed Rule.

The Proposed Rule describes this instruction by the federal agency to fill a beneficiary’s prescription as a “deemed order” under the FSS that would generate a refund. Calling these instructions “deemed orders,” however, cannot transform
them into government orders under the FSS contract in view of the fact that the
drugs actually are procured by retail pharmacies. In fact, the Proposed Rule
concedes that a federal agency will never place an order for the drugs dispensed by
a retail pharmacy to a TRICARE beneficiary directly or by the retail pharmacy
acting as an authorized purchasing agent. To overcome the lack of privity of
contract, the Proposed Rule provides that “[t]he drugs will be deemed to have been
ordered by the Federal agency through the FSS contract, for the purposes of
establishing price, delivery, and scope of coverage . . . .”\textsuperscript{14} The Proposed Rule
resorts to “deemed” orders because there are no actual orders by a federal agency
under a Federal Agency Retail Pharmacy Program.

Further, the Proposed Rule does not identify any statutory or other basis for
authorizing non-governmental entities to place FSS orders on behalf of the
government in the absence of a contract establishing that agency relationship. Nor
does it attempt to rely on FAR Part 51,\textsuperscript{15} which describes the mechanism for
authorizing cost-reimbursement contractors to access FSS contracts. This is not
surprising given that retail pharmacies – regardless of their participation within a
commercial PBM network – and federal health care plan beneficiaries are not cost
reimbursement contractors of the federal government. Because the retail
pharmacies through which the agencies are ostensibly procuring the dispensed
drugs are not authorized to order drugs on behalf of the government directly under
the manufacturers’ FSS contracts, the manufacturers cannot by rule be “deemed”
responsible for refunding a portion of the government’s expenditure on these
transactions.

Likewise, the proposed method of invoicing and paying manufacturers for
these drugs further exemplifies how the Proposed Rule departs from fundamental
procurement norms. One of the standard aspects of a procurement relationship is
that the contracting officer will be privy to the payment terms of the contract.
Under the Proposed Rule, “[t]he time and method of payments to the Contractor for
FSS items . . . will be determined in accordance to commercial agreements
between the FSS Contractor and such pharmacies or their authorized
Pharmaceutical prime vendor.”\textsuperscript{16} Therefore, because the Proposed Rule

\textsuperscript{14} 552.238-XX(b); 70 Fed. Reg. 19050 (2005) (emphasis added).

\textsuperscript{15} Generally, FAR Part 51 provides that “Before issuing an authorization to a contractor to use
Government supply sources . . . , the contracting officer shall place in the contract file a written
finding supporting issuance of the authorization.” FAR 51.102(a).

\textsuperscript{16} 552.238-XX(d); 70 Fed. Reg. 19050 (2005) (emphasis added).
acknowledges that transactions actually occur pursuant to private commercial contracts rather than pursuant to orders placed under FSS contracts, the provisions containing the time and method of payment under those private commercial contracts appear to be incorporated by reference into the FSS contracts. A federal contracting officer will never review, approve, or know the substance of such payment terms. Moreover, some of the transactions targeted by the Proposed Rule may involve multiple contractual relationships reflecting a chain of wholesalers, distributors, or other resellers, some of which will not have direct contracts with the FSS contractor.

In sum, the transactions required under Federal Agency Pharmacy Programs described in the Proposed Rule reflect the payment of subsidies to reimburse commercial health care providers for drugs obtained through normal commercial distribution channels without any privity of contract with the federal government. Due to the missing contractual link between the government and the manufacturer and the absence of a procurement action, there is no price agreement between those parties. In addition, the Proposed Rule requires rebates (referred to as “refunds”) applied to the price ultimately paid (through its PBM contractor) to reduce the net benefit outlay, but payment of these rebates by the FSS contractors never results in the actual FSS contract price. The procurement gymnastics required to make this clause functional demonstrate that the Proposed Rule is outside the bounds of GSA’s statutory authority.

**B. The Federal Property And Administrative Services Act Does Not Confer Authority On GSA To Deem Commercial Orders As Orders By An Executive Agency Under An FSS Contract**

The Introduction to the Proposed Rule incorrectly cites to FPASA as authority for the rulemaking action being taken by GSA. FPASA sets forth procedures relating to GSA’s procurement of goods and services for executive agency use. As discussed above, procurement contracts authorized by FPASA may not be used as a vehicle for non-procurement transactions in order that beneficiaries may obtain drugs subsidized with federal dollars at federal contract prices. Further, FPASA does not authorize, or even contemplate, a scheme where the items being procured are not acquired from a government source of supply (such as an FSS contract or depot) as a procurement. Because the “covered drugs” dispensed through a Federal Agency Retail Pharmacy Program would be acquired through commercial agreements to which the government is not a party, FPASA does not
authorize GSA to impose the Proposed Rule.\textsuperscript{17}

1. **FPASA Does Not Authorize Procurements Through Commercial Third Parties**

   Section 201(a) of FPASA, 40 U.S.C. § 501, authorizes GSA to “procure and supply personal property and nonpersonal services for executive agencies to use in the proper discharge of their responsibilities.”\textsuperscript{18} The purpose of FPASA is “to provide the Federal government with an economical and efficient system for . . . procuring and supplying property and nonpersonal services.”\textsuperscript{19} Specifically, Congress intended to empower GSA “to regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services.”\textsuperscript{20} FPASA defines the term “procurement” to mean “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.”\textsuperscript{21}

   Section 309 of FPASA, 41 U.S.C. § 259(b), the other FPASA provision cited in the Proposed Rule, includes procedures established by GSA for the award of multiple award schedule contracts within the definition of “competitive procedures” under the statute if participation in the multiple award program is “open to all responsible sources” and contracts awarded through the GSA procedures result in “the lowest cost alternative to meet the needs of the Government.”\textsuperscript{22} Section 259(b) is a definitional provision. It provides that “competitive procedures” are those procedures under which an “executive agency” enters into a contract pursuant to full and open competition, and may include

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\textsuperscript{17} The proposed GSAR clause also fails to meet FAR 1.302(b) because it would not further the needs of GSA (the agency promulgating the regulation). Instead, by its terms, the clause would benefit only the VA, DOD, PHS, and Coast Guard by entitling them to recover refunds on third party transactions. See Service Employees Int’l Union v. Gen’l Servs. Admin., 830 F. Supp. 5, 9-10 (D.D.C. 1993) (GSA supplemental regulation held improper because it was contrary to a FAR clause and did not address a specific GSA need).


\textsuperscript{19} 40 U.S.C. § 471.


\textsuperscript{21} 41 U.S.C. § 403.

\textsuperscript{22} 41 U.S.C. § 259(b).
procedures relating to the award of multiple award schedule contracts. 23

Neither of the two cited FPASA provisions (nor any other FPASA provision) allows the addition/modification to the FSS contracts described in Proposed Rule. For example, neither provision contemplates the establishment of procedures under which a purely commercial enterprise, which is not party to a procurement contract with the government, such as the retail pharmacies in the Proposed Rule, may be deemed to have ordered property or services from an FSS contractor on behalf of the government for purposes of accessing the pricing, ordering, and delivery terms of an FSS contract. As noted, FPASA authorizes GSA to establish procedures that govern the actual procurement of property and services for use by executive agencies. FPASA does not support a scheme whereby an instruction from a federal agency to a retail pharmacy authorizing payment for a beneficiary prescription order could serve as a substitute for an order by an authorized entity under the FSS contract.

2. A “Deemed Order” Is Not Contemplated by FPASA

Consistent with the limitations of its authority under FPASA and other statutes, GSA issued GSA Order ADM 4800.2E (“GSA Order”) that identifies those entities and organizations that are eligible to order supplies and services from FSS contracts. In the GSA Order, GSA notes that FPASA authorizes it to “procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government.” 24

As discussed, in the scheme contemplated by the Proposed Rule, the drugs are ordered by the beneficiaries. That is, prescription doses of the drugs are ordered from the retail pharmacy by the beneficiary, based on the beneficiary’s prescription received from its physician, and payment of the agency’s cost share is authorized by the agency’s fiscal intermediary at the point of sale. The drugs that are dispensed are procured by commercial retail pharmacies through commercial transactions to which the government is not a party. The drugs themselves are not ordered by any executive agency from the FSS contracts, but rather are ordered by a beneficiary and filled from the retail pharmacy’s commercial inventory.

24 GSA Order ¶ 3.
The limits of the GSA Order are consistent with our conclusion that GSA lacks authority to “deem” prescription orders to be agency orders under the FSS contracts. The GSA Order specifically limits the entities that may order from the FSS contracts to executive agencies and other organizations that have explicit statutory or regulatory authority to access government sources of supply. Moreover, although contractors that have cost reimbursement contracts are permitted in certain circumstances to access FSS contracts, manufacturers are not required to accept all such orders. The Proposed Rule conflicts with the GSA Order because it would allow drugs that are procured by entities other than an executive agency to be deemed “ordered” by an executive agency under FSS contracts. There is no statutory authority to issue a regulation of such expansive scope.

Finally, the introduction of the “deemed order” concept could have unintended and significant consequences to the GSA schedule program. FSS contracts were intended to provide an efficient means for executive agencies to procure products and services for their own use. Permitting deemed orders such as those contemplated in the Proposed Rule would expand the FSS contracts far beyond their intended scope. It also could set a broad precedent for purely commercial orders to be deemed orders under other FSS contracts. Such a precedent could undermine the economics and integrity of the FSS contracting system, and discourage contractor participation in the program.

3. **The GSAR Impermissibly Conflicts with the FAR**

The GSAR may supplement, but not conflict with, the Federal Acquisition Regulation. The “deemed order” concept of the Proposed Rule, however, conflicts directly with the ordering requirements set forth in FAR 8.406-1 (“Order Placement”), which provides that an “ordering activity shall place an order directly with the contractor in accordance with the terms and conditions of the pricelists” and specifies the terms that must be included in the order. (Emphasis added.) Under the Proposed Rule, no order is placed “directly” with the contractor, either by the agency or by an ordering agent under contract with the agency. Because the proposed GSAR clause conflicts with the FAR (and no deviation from the FAR is being sought), the proposed clause is an invalid exercise of agency authority. In addition, the GSAR conflicts with FAR 8.402, which requires the pricing and terms and conditions for contract items ordered from the schedule contractor. The deemed orders are for prescription unit doses, not the package units (and related

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prices) listed on the FSS contract. Finally, the Proposed Rule conflicts with FAR 12.301(b) and 52.212-4(n), which govern the terms and conditions in contracts for commercial items (including FSS Schedule 65) and specifically require title to items furnished under the contract to pass to the government. Under the Proposed Rule, title for drugs furnished under the contract ostensibly through retail pharmacies pursuant to “deemed” orders would never pass to the agency deemed to be ordering the contract items. For all these reasons, the GSAR is an invalid exercise of GSA authority.

C. The Veterans Health Care Act Does Not Authorize the Proposed Rule

In addition to the references to the FPASA in the “Introduction” to the Proposed Rule as providing authority for the rulemaking, there are a number of references to Section 603 of the Veterans Health Care Act of 1992 (“the VHCA”), 38 U.S.C. § 8126, in the “Background” section of the Proposed Rule. These references, which were included to demonstrate that the VHCA provides independent statutory authority for the Proposed Rule, cannot and do not serve this purpose. As discussed below, the VHCA establishes a pricing program that places upper limits on the prices of drugs procured by certain federal agencies under FSS and depot contracts. It does not entitle federal agencies to refunds based on retail sales that are reimbursed through federal health insurance programs.

1. The VHCA is a Pricing Statute Administered by the VA

The VHCA establishes a federal pricing program administered by the VA. Participation in the program is required in order for a company’s products to be paid for with federal funds in several contexts – including the Medicaid program. To participate, a manufacturer must execute a Master Agreement and Pharmaceutical Pricing Agreement with the VA in which it commits to make its “covered drugs” available on FSS contracts. The manufacturer further agrees that prices charged certain federal agencies, including DOD, VA, PHS, and the Coast Guard (the “Big 4”) on FSS contracts and depot contracts cannot exceed Federal Ceiling Prices (FCPs).

As is evident from the basic terms of the statute, the only impact that the

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27 Id. See 38 U.S.C. § 8126(e)(3).
VHCA can have on FSS contracts is to create caps on prices offered on these contracts. 38 U.S.C. § 8126(a)(2). Accordingly, the VHCA cannot properly be considered to authorize efforts to modify non-price terms of FSS contracts such as the ordering provisions by requiring contractors to treat “deemed orders” by retail pharmacies as purchases under the contract.

Moreover, in view of the fact that the VA is the sole agency empowered to interpret and apply the requirements of the VHCA, it would be inappropriate for GSA to rely on the statute as authority for its Proposed Rule. Recognizing this delineation of authority, DOD has posted the following question and answer on its TRICARE web site:

...Is there a letter from GSA approving [the TRRx] program?

Response: No, GSA does not have jurisdiction over TRICARE or the application of Federal ceiling prices to TRRx under P.L. 102-585, Sect. 603.28

Accordingly, GSA may not rely on the VHCA as providing a statutory basis for the Proposed Rule.

2. VHCA Federal Ceiling Prices Only Apply To “Procurements”

The VHCA places upper limits on the prices that may be charged under two types of federal procurement contracts: FSS contracts and depot contracts. In the Proposed Rule, GSA indicates that the new FSS clause would apply “for those Federal Agency Retail Pharmacy Programs... determined by the VA Secretary to qualify as [VHCA] ‘depot’ contracting system[s]...”.29 As provided below, however, the Federal Agency Retail Pharmacy Programs described in the Proposed Rule simply do not meet the VHCA’s definition of “depot.”

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29 69 Fed. Reg. at 19406 (the Proposed Rule provides that the clause should be added to FSS contracts as set forth in 38 U.S.C. 8126). The VA previously made such determination regarding the TRICARE Retail Pharmacy Program (TRRx) in a form letter to manufacturers of covered drugs. See Dear Manufacturer Letter, dated October 14, 2004 (http://www1.va.gov/oamm/nac/fss/files/20041014DearManufacturer.pdf).
The term “depot” is defined under the VHCA 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.

Following enactment of the VHCA, the VA elaborated on its understanding of the term depot, describing it as a “centralized commodity management system[] through which covered drugs are: (A) received, stored and delivered to a listed Federal agency through a Federally-owned warehouse system or a commercial warehouse system operating under contract with the procuring Federal agency; or (B) delivered directly from the manufacturer or its agent to a listed Federal agency’s ordering activity at its purchasing address.”

As is clear from the statutory definition and the VA’s own interpretation of the term, for a commodity management system to qualify as a depot under the VHCA, the government must necessarily “procure” drugs from a manufacturer.

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30 Letter from P. Anderson, Assistant General Counsel of the VA, to R. Seaman, General Counsel of TRICARE Management Activity, dated November 1, 2001 (emphasis added) (discussing 1994 VA interpretation of the term depot).
a. A Separate VA Rulemaking is Required In Connection With Any Conclusion That a Pharmacy Program Constitutes a VHCA Depot

As an initial point, even if there were a legal basis for concluding that the Federal Agency Retail Pharmacy Programs described in the Proposed Rule could be considered a procurement and thus meet the VHCA depot definition, any such determination would have to result from a rulemaking process. Notice and comment rulemaking is required where an agency determination involves a substantive interpretation of a statute. A conclusion that a retail pharmacy program meets the VHCA definition of the term “depot” would necessarily require a substantive determination under the VHCA.

Thus far, the VA has deemed one Federal Agency Retail Pharmacy Program— the TRICARE Retail Pharmacy Program (“TRRx”)— to be a depot under the VHCA. Nevertheless, the VA has not engaged in notice and comment rulemaking in connection with this determination; rather, it has issued a “Dear Manufacturer Letter” to industry stating its conclusion that TRRx constitutes a VHCA depot. To the extent that GSA is relying on the VA determination published in the VA’s letter that TRRx is a depot for which rebates would be triggered under its new FSS clause, such reliance is misplaced given that the letter does not meet the standard notice and comment requirements. Moreover, given that GSA is not authorized to interpret the VHCA, the instant Proposed Rule cannot be considered to satisfy the rulemaking requirement with respect to whether any Federal Agency Retail Program meets the VHCA definition of depot. Rather, a separate VA rulemaking specifically addressing the depot determination would be required prior to the implementation of any requirement to pay refunds under the FSS clause in the Proposed Rule.

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32 Moreover, such determination would necessarily involve the interpretation of “procurement policy [or] procedure . . . relating to the expenditure of appropriated funds” that would have a significant cost impact on contractors. See 41 U.S.C. § 418b (emphasis added) (requiring rulemaking under such circumstances).

b. Federal Agency Retail Pharmacy Programs Cannot Be Considered VHCA Depots Because They Do Not Involve Procurements

The VHCA definition of “depot” involves a centralized commodity management system through which drugs are *procured* by a federal agency. As described above, Federal Agency Retail Pharmacy Programs as described in the Proposed Rule do not involve procurements by the government. Rather, they involve third-party reimbursement systems through which a contracted fiscal intermediary (the PBM) reimburses retail pharmacies for prescriptions provided to beneficiaries. These programs involve the purchase of drugs by pharmacies through commercial distribution channels. Later, when a prescription order is placed, the government determines the eligibility of the federal health plan beneficiary, and can authorize its PBM contractor to reimburse the pharmacy the government’s cost-share for the dispensed medication with federal funds. There is no contract between the manufacturer and the government providing any particular price – FCP, FSS, or otherwise – for these transactions. Prescription orders are placed by health plan beneficiaries when they submit their prescriptions. The drugs obtained clearly are for the use of these beneficiaries – and not the government. After the prescription is dispensed, the federal agency reimburses the retail pharmacy, as is the standard procedure under insurance benefit payment systems that involve cost-sharing between the insurer and the beneficiary.

In sum, the elaborate web of transactions among four distinct entities – the retail pharmacy, the federal health plan beneficiary, the PBM, and the federal agency – cannot be considered to “add up” to a federal procurement. As discussed above, a procurement is a transaction involving the acquisition of items or services for the use and benefit of the government. Procurements involve privity of contract between the seller and the buyer and the passing of title between these entities. They involve orders by the government and payment of contractor invoices by the government. None of these criteria that are fundamental to procurement transactions are present in Federal Agency Retail Pharmacy Programs.

c. Federal Agency Retail Pharmacy Programs are Not Centralized Commodity Management Systems

Moreover, apart from the fact that they do not involve federal procurements, Federal Agency Retail Pharmacy Programs as described in the Proposed Rule do not involve centralized commodity management systems, as is contemplated in the VHCA definition of depot. As provided above, a commodity management system involves a system where drugs are: “(A) received, stored and delivered to a listed
federal agency through a Federally-owned warehouse system or a commercial warehouse system operating under contract with the *procuring* Federal agency; or (B) delivered directly from the manufacturer or its agent to a listed Federal agency’s ordering activity at its purchasing address.”

These arrangements involve contractual relationships that establish a distribution chain through which drugs sold by a manufacturer are delivered through a third party to a federal purchaser. At a minimum, there is a purchase contract between the manufacturer selling product and the federal customer and a distribution agreement between the manufacturer and an intermediary that delivers the product to federal customers. One established example of such commodity management system that constitutes a VHCA depot is the VA’s prime vendor program, which involves a separate agreement between the VA and one or more wholesalers under which the wholesaler purchases, delivers, and invoices for orders under manufacturer’s FSS contracts. The prime vendor(s) provides these services on behalf of the government in connection with the established FSS contractors between manufacturers and the VA.

In an attempt to meet the VHCA depot definition, the Proposed Rule appears to rely on a fiction that retail pharmacies are procuring drugs as purchasing agents of the government. The Proposed Rule itself, however, does not identify any statutory or other basis for authorizing these commercial entities to place FSS orders on behalf of the government. Despite the proposed FSS clause’s reference to “a Federal agency’s directly contracted or indirectly subcontracted retail pharmacy” (see Rule at (e)(4)), there is no agreement between the government and any Federal Agency Retail Pharmacy Program network pharmacy that would create any contractual or subcontractual relationship between the two entities.

It would seem that the agreements the government is referencing here are the network retail pharmacies’ arrangements with the Federal Agency Retail Pharmacy Program PBM. As noted above, the PBM serves under contract with the government as the fiscal intermediary under the Federal Agency Retail Pharmacy Program. The PBM’s function under the contract is to reimburse pharmacies that dispense drugs to federal beneficiaries; it is not a purchaser of drugs. The agreements between the PBM and its network retail pharmacies simply permit the PBM to provide the pharmacies a particular retail prescription reimbursement price for drug prescriptions dispensed to the PBM’s client’s plan members – here the

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34 Letter from P. Anderson, Assistant General Counsel of the VA, to R. Seaman, General Counsel of TRICARE Management Activity, dated November 1, 2001 (emphasis added) (discussing 1994 VA interpretation of the term depot).
client is the federal health plan – e.g., TRRx. Given that these agreements have no relationship to the actual retail pharmacy drug procurement transactions, they cannot be considered to create an agency relationship between the federal government and network retail pharmacies such that the retail pharmacies drug purchases would somehow be linked up with the a federal contract allowing the purchase of drugs from a manufacturer.

In addition, as noted above, given that the PBM’s network retail pharmacies are not contractually linked to the government in any way, and that the government is not procuring drugs under these Federal Agency Retail Pharmacy Programs, there is no basis for any assertion that the pharmacies could be authorized to access FSS contracts as cost reimbursement contractors of the government under FAR Part 51.35 As can be seen, contractual relationships that would be required in order to establish a commodity management system as contemplated under the VHCA definition of the term depot simply do not exist under the types of Federal Agency Retail Pharmacy Programs described in the Proposed Rule.

3. The VHCA Does Not Require A Manufacturer To Provide FSS Pricing under Depot Arrangements

As discussed above, the Federal Agency Retail Pharmacy Programs discussed in the Proposed Rule are health insurance reimbursement programs that cannot properly be considered depot contracts as that term is defined in the VHCA. Nevertheless, even if a Federal Agency Retail Program could meet the depot definition as described in the VHCA, the statute only places a cap on the pricing offered to the designated agencies, but does not authorize the VA, GSA, or any other agency to require manufacturers to offer FSS pricing on depot contracts.

As noted, the VHCA imposes price caps (FCPs) on two distinct types of contracts – FSS contracts and depot contracts. It does not, however, mandate the actual pricing on these contracts. Moreover, it does not mandate that the pricing on a manufacturer’s depot contract with the government be the same as its FSS contract pricing. Given that these two types of arrangements are separately negotiated and priced, it is quite possible that a manufacturer will provide pricing on its FSS contract that is different from that offered on its depot contract.

35 Generally, FAR Part 51 provides that “Before issuing an authorization to a contractor to use Government supply sources ..., the contracting officer shall place in the contract file a written finding supporting issuance of the authorization.” FAR 51.102(a).
For example, a manufacturer may negotiate pricing that is lower than applicable FCPs on its FSS contract, while it makes FCPs available on separate depot contracts. The reverse could also be the case, with subceiling pricing being made available on a depot contract and FCP-based pricing made available on a company’s FSS contract. Nevertheless, to the extent that a manufacturer chooses to make such sub-ceiling pricing available, it does so voluntarily and only on the terms specified under the particular contract. Thus, if a manufacturer offers sub-ceiling pricing on its FSS contract, it may not be required to provide that same sub-ceiling pricing on a depot contract that it might enter into with the government. The VA has recognizes that agreement by pharmaceutical companies is required before applying FSS contract pricing under depot arrangements. It is for this reason that the VA includes a clause in its FSS contracts permitting, but not requiring, participation in its prime vendor program (described above), which is considered a commodity management system that meets the depot definition. Without a manufacturer’s participation in the program, federal purchasers simply are not permitted to access FSS pricing through the prime vendor arrangements.

Yet, under the Proposed Rule, retail pharmacy programs that are determined to be VHCA depots would automatically be entitled access to FSS pricing. Conceptually, the Proposed Rule superimposes these “depots” onto different contract vehicles – FSS contracts – by considering dispensed units to be “deemed orders” under those contracts. Even if it were otherwise permissible to consider retail pharmacy reimbursement transactions as FSS contract orders, the VHCA simply does not authorize the government to require a contractor to merge its depot and FSS contract vehicles such that FSS pricing will be applied to their depot contracts. Unless a manufacturer voluntarily agrees to offer FSS pricing on a depot contract, it may not be forced to do so. Mandating FSS pricing on depot contracts runs afoul of basic contracting and procurement principles that require agreement on price by the contracting party and the government.

III. THE PROPOSED RULE SHOULD BE CLARIFIED

Even if, contrary to the legal principles discussed above, it were determined that the Proposed Rule does not exceed GSA’s authority, the Rule raises a number of additional procurement-related issues that require clarification, as discussed below.

36 See 70 Fed. Reg. at 19050 (acknowledging that the FSS price for a drug can be lower than the applicable FCP).
A. It Is Unclear How The Proposed Rule Will Be Implemented

The Proposed Rule provides in 538.XX02 that “the contracting officer shall insert the clause… in solicitation and schedule contracts for Schedule 65, Part I.” Although it is clear that the VA may insert the new clause in future FSS solicitations, the VA may not incorporate the clause into a current FSS contract that has already been executed. FAR 52.212-4(c) requires a bilateral written agreement for changes in the terms and conditions of a commercial item procurement, such as the FSS contract for pharmaceuticals. Accordingly, if the government unilaterally were to amend existing FSS contracts to incorporate the Federal Agency Retail Pharmacy Program clause without negotiating with the contractor and providing consideration for the modification, that action would constitute a breach of contract."37 GSA should modify the Proposed Rule to make clear that the clause will not be unilaterally added to existing FSS contracts.

B. Disputes

In 552.238-XX(h)(2), the Proposed Rule would require the parties, in the event of a dispute over the amount of a refund, to engage in “best good faith” negotiations for a 60 day period before the contractor may file a claim. Although the Contract Disputes Act (“CDA”) encourages alternative dispute resolution (“ADR”), the CDA does not permit mandatory negotiations and exhaustion requirements of this nature. Additionally, even if the CDA authorized a mandatory negotiation provision, the clause in subsection 552.238-XX(h)(3) does not provide any guidance to contractors in the event that the negotiations do not resolve the disagreement. The clause should be modified to require the contractor to redress any disputes through the Disputes Clause of the FSS contracts. Consistent with the CDA, the clause could be modified to add a voluntary negotiation or ADR process, but could not require the parties to pursue that process as a substitute for the process mandated by the CDA.

C. The IFF Payment Should Not Be Available for Deemed Orders

Subsection 552.238-XX(i) of the clause would require FSS contractors to remit the Industrial Funding Fee (“IFF”) for retail pharmacy sales in accordance with the timelines and procedures established in 552.238-74 (“Industrial Funding

37 FAR 52.212-4(c), FAR 43.103. See, e.g., United States v. Winstar Corp., 518 U.S. 839 (1996) (holding that government enactment of a statute that adversely affected a party’s contract rights constituted a breach of contract).
Fees and Sales Reporting (JUL 2003) (VARIATION)”). In our view, requiring FSS contractors to pay the Industrial Funding Fees on retail pharmacy sales (to which the FSS contractor is not a party) would be inappropriate. The purpose of an IFF payment is to fund VA’s administration of the FSS contract. For retail pharmacy sales, however, the FSS contracts are not implicated and VA has no administrative role. Accordingly, payment of the IFF for such “deemed orders” would be unrelated to any service that VA provides and thus would be unnecessary.

Moreover, the IFF and Sales Reporting clause provides that, in reporting sales, “the dollar value of the sale is the price paid by the Schedule user for products and services on a Schedule task or delivery order.” In the “deemed order” scheme that the Proposed Rule would establish, however, there would be no Schedule task or delivery order, and no dollar value to report, because there would be no order made under the FSS contract. The Proposed Rule would appear to require the contractor to derive the dollar value of the sale to report from a data file that the contractor would receive from the agency administering the retail pharmacy program. But the data file that the contractor would use to determine the amount of reportable sales would not be a list of orders from the FSS contracts by ordering agencies. Instead, the files would consist of agency beneficiary utilization data for each of the FSS contractor’s covered drugs. We are not aware of any statutory report allowing such beneficiary utilization data (that is, a beneficiary’s prescription order filled at a commercial retail pharmacy) to trigger an FSS contractor’s obligation to make an IFF payment under the FSS contract. We recommend that GSA delete subsection (i) of the clause.

IV. CONCLUSION

Based on the foregoing, the Section believes that GSA lacks authority to proceed with the Proposed Rule. In particular, the Section respectfully disagrees with the GSA’s conclusion that either FPASA and the VHCA, or both, authorize a federal agency to collect refunds on non-procurement transactions such as those contemplated by the Proposed Rule. For this reason, the Section recommends that GSA not proceed with the Proposed Rule.
The Section appreciates the opportunity to comment on the Proposed Rule and is available to provide any additional information or assistance as you may require.

Sincerely,

[Signature]

Patricia H. Wittie
Chair, Section of Public Contract Law

Enclosure

cc: Robert L. Schaefer
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    Carol N. Park-Conroy
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    Healthcare Contracting Committee
    David Kasanow
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 (“TRPB”), 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.1 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 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 "[u]nless 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 “[t]itle 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.
procurement norm that when purchasing supplies, the government must obtain title at some point in the transaction.

C. **DOD Uses Non- Appropriated Funds**

Third, procurements must involve the payment of appropriated funds. FAR 2.101(b)(2) ("aquisition 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.

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, 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

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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 letters assert 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 “reban” 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 rulemaking 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 “deport” 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,

William Winkenwerder, 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
TRICARE Retail Pharmacy

**Legend**
- ■ Flow of Funds
- ■ Flow of Drugs
- □ Flow of Data

**Flow of Drugs**
- **Patient**
  - Dispenses drug to patient
  - Pays Copay
  - Pays Wholesaler for drug

- **Retail Pharmacy**
  - Receives drug from Wholesaler
  - Delivers drug to pharmacy

- **Contracted PBMO**
  - Transmits DoD beneficiary Rx/Claims data
  - Authorizes contracted PBMO to pay the pharmacy

- **DoD PBMO/DSCP**
  - Transmits DoD beneficiary Rx/Claims data (Consolidated at PDTS)
  - Rebates to DoD the difference between wholesale acquisition cost and the lesser of the FCP/FS/contracted price

- **Wholesaler**
  - Sends drug to Wholesaler
  - Pays manufacturer for drug

- **Manufacturer**
  - Pays manufacturer for drug

**Acronyms**
- PBO = Pharmacy Benefits Office
- DSCP = Defense Supply Center Philadelphia

**Note**
- PROCUREMENT SENSITIVE