January 12, 2005

VIA UPS OVERNIGHT AND FACSIMILE

Honorable David Safavian
Director
Office of Federal Procurement Policy
725 17th Street, N.W.
Room NEOB 6025
Washington, DC 20503

Re: Implementation of TRICARE Retail Pharmacy Program to Require the Payment of Refunds by Pharmaceutical Manufacturers

Dear Mr. Safavian:

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 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."

Prior Approach to TRRx Implementation: As you may recall, the Section submitted comments to your office dated July 15, 2004, that addressed an announcement that the Department of Veterans Affairs (“VA”) intended to modify existing clauses in the Federal Supply Schedule (“FSS”) solicitation for pharmaceuticals to require pharmaceutical manufacturers to periodically pay the Department of Defense (“DOD”) “refunds” based on the volume of the manufacturer’s drugs dispensed by commercial retail pharmacies to TRICARE beneficiaries. In those comments, the Section disagreed with the VA and DOD position that the DOD TRICARE Retail Pharmacy Program (“TRRx”) was authorized under the terms of the Veterans Health Care Act of 1992 (“VHCA”). The Section also noted that such FSS contract modifications would impose new obligations and could have a significant cost impact on pharmaceutical contractors, thus requiring notice and comment rulemaking. We understand that the VA and DOD now agree that a rulemaking is required in order to implement TRRx through the FSS program, and that the VA is considering this approach in parallel with the new approach described below.

New Approach to TRRx Implementation: Despite its acknowledgment that rulemaking is required to implement TRRx through the FSS program, DOD has fashioned another approach to implement the TRRx refund program. DOD has made numerous presentations to industry laying out the structure of the TRRx program. DOD apparently has concluded that no contract modification is required to implement the TRRx program, and thus no rulemaking is necessary. We understand that DOD takes the position that the refund program constitutes a “depot contracting system” -- one of the two contracting systems under which Federal Ceiling Prices apply under the VHCA -- and that refunds are due to DOD whenever DOD funds are expended on covered drugs under the program, because DOD is “procuring” such drugs from a commercial source under a “virtual” depot contracting system. In the VA’s view, however, DOD need not acquire the drugs under a procurement contract with the commercial source. The VA has issued a “Dear Manufacturer” letter dated October 14, 2004, affirming the permissibility of this approach and that no further action is required by DOD to begin requiring refunds under the program. Our understanding is that DOD will be seeking refunds.

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1 This letter is available in pdf format at http://www.abanet.org/contract/federal/regscomm/home.html under the topic “Healthcare.”
based on TRRx utilization -- i.e., prescriptions dispensed to TRICARE beneficiaries -- as of October 1, 2004.2

As noted in the Section’s earlier comments, the VA’s position with respect to drugs procured under a depot contracting system, and DOD’s new approach to TRRx implementation -- like its initial FSS approach -- will have a significant cost impact on pharmaceutical contractors and, thus, also may not be implemented without a formal rulemaking process. See 41 U.S.C. § 418b (requiring rulemaking for procurement policy or procedure with significant cost impact on contractors). The TRRx program will require manufacturers to pay substantial rebates and to develop complex new systems to accurately process DOD data, track and calculate rebates, and resolve disputes. Manufacturers also will be required to factor these rebates into other federal price calculations administered by other federal agencies. Accordingly, it appears that this alternate approach to TRRx implementation should not be exempted from notice and comment rulemaking.

Moreover, as we explained in earlier correspondence to your office and in letters to DOD, the TRRx program does not constitute a depot contracting system because, as a matter of law, it does not involve a procurement of covered drugs, a foundational requirement for a contracting system to come within the definition of depot under the VHCA. See Master Agreement, entered into between the VA and pharmaceutical manufacturers to implement VHCA pricing. TRRx involves a third-party claim reimbursement system through which a contracted pharmacy benefits manager reimburses retail pharmacies for prescription services provided to beneficiaries, including an amount for drugs used to fill the prescriptions. These drugs are purchased by the pharmacy providers through the commercial distribution chain without any federal agency direction, involvement, or control. Given that the program involves reimbursement of commercial health care providers, and not purchase of drugs for the benefit of DOD, we do not see the basis for the assumption that TRRx involves any procurement of covered drugs. See e.g., 31 U.S.C. § 6304 et seq. DoD is not purchasing or taking title to the drugs at issue.3

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

3 Even if the TRRx were not a “procurement,” a rulemaking would still be required because a significant agency program is being developed. Outside the procurement context, the Administrative Procedure Act (“APA”) requires a rulemaking where an agency takes actions that constitute a “substantive” rule. See, e.g., State v. U.S. Dep’t of Health and Human Servs., 2004 WL (continued...
Accordingly, the Section recommends that appropriate notice and comment procedures be followed prior to implementation of the TRRx program, in order to provide the various stakeholders an opportunity to raise concerns such as those expressed by the Section herein.

Sincerely,

Patricia H. Wittie
Chair, Section of Public Contract Law

cc: Robert L. Schaefer
    Michael A. Hordell
    Patricia A. Meagher
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    Hubert J. Bell, Jr.
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    Council Members
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    the Health Care Contracting Committee
    David Kasanow

(...continued)

2203843 (D.C.C.) (agency transmittals concerning cost allocations considered rules created in violation of APA requirements).