



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of General Counsel**  
**PO Box 76**  
**Hines IL 60141**

October 14, 2004

Dear Manufacturer of Covered Drugs:

As you are aware, the Veterans Health Care Act of 1992 (VHCA), P.L. 102-585, Section 603 (38 U.S.C. 8126), and the Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) that your company signed with the Department of Veterans Affairs (VA), require that Federal ceiling prices (FCPs) must be applied to covered drugs purchased by the Department of Defense (DoD) through depot contracting systems. TRICARE Management Activity (TMA) is the DoD organization established to manage DoD's comprehensive health care program known as TRICARE, which includes an alternate health care system mandated by Congress for U.S. armed forces personnel, retirees, and dependents who do not reside near a military treatment facility. (See Chapter 55, Title 10, United States Code.) The TRICARE program involving health care furnished outside of military treatment facilities has traditionally been implemented through contracts with large civilian managed health care organizations, which, in the past, provided pharmaceuticals to DoD beneficiaries with no direct involvement by DoD officials. Under this prior approach, TRICARE regional contractors entered into their own agreements with providers of pharmaceuticals, and DoD did not directly or indirectly control payments for its TRICARE beneficiaries' drugs. Furthermore, DoD was not entitled to receive each dollar saved, had managed care contractors been permitted to buy drugs and prescriptions at Government discounts. Under these circumstances, VA determined that the VHCA requirement for a depot contracting system did not exist and TRICARE was not able to benefit from Federal covered drug pricing through its original managed care contracts. (See "Dear Manufacturer letter" of October 7, 1996.)

Effective May 3, 2004, TRICARE restructured its Pharmaceutical Benefit Program in response to congressional direction to redesign the military and contractor pharmacy system. It carved the benefit out of its regional contracts, set up a DoD Pharmacy Benefit Office to control payments for beneficiary scripts and hired a Pharmacy Benefits Manager (PBM) to handle most administration work involved in contracting with a large number of retail pharmacies (collectively, "the network") to fill TRICARE beneficiary scripts. TMA followed commercial models in devising its new plan, allowing network pharmacies to

2.

## Dear Manufacturer of Covered Drugs

obtain drugs in the usual fashion and then applying the Federal discount after scripts were filled, through refund claims submitted to manufacturers by the PBO itself. This approach eliminated the possibility that commercial contractors or subcontractors of DoD might profit from application of FCPs to TRICARE purchases.

TMA presented the restructuring plan to VA in 2002, with a request that VA approve application of FCPs to TMA purchases of covered drugs obtained by its beneficiaries from subcontracted retail pharmacies. On October 24, 2002, after consideration of the functional elements and the legal issues inherent in the plan, the Secretary of VA decided that TMA's Retail Pharmacy Benefit Plan (TRRx) was a centralized pharmaceutical commodity management system that met the definition of "depot" contracting system set forth in 38 U.S.C. 8126(h)(3). Consequently, covered drug prescription purchases under TRRx, authorized and paid for by TMA's Pharmacy Benefits Office, qualified for FCPs from commencement of the TRRx program on June 1, 2004. However, to avoid complicating and delaying manufacturers' 2004 annual non-FAMP reports, TMA has agreed not to demand refunds resulting from application of FCPs to retail network purchases until after September 30, 2004, the cut-off date for transactions included in the 2004 reports.

It is within the authority of the VA Secretary, in administration of the VHCA and as issuer of the MAs and PPAs, to determine whether one of the four VHCA Federal agencies has established a qualifying depot contracting system under which covered drugs may be purchased at a discount. (See 38 U.S.C. 8126(a), (e)(3) & (4), (f), (g), and (h)(5).) Once that determination is made, the Federal agency (in this case, DoD) is authorized to receive FCPs on covered drugs by operation of law and the express terms of the Master Agreement executed by VA and each drug manufacturer. No published notice or rulemaking is required to make effective the policy and requirements already established by statute and written agreements.

Because TMA's retail pharmacy network covered drug purchases will be made initially at commercial prices, TMA will obtain Federal ceiling pricing for these purchases by forwarding detailed purchase data to manufacturers each month and then requesting refunds on a quarterly basis to achieve Federal pricing. TMA's plan for transmitting data and collecting refunds is set forth at the TMA web site: [http://www.tricare.osd.mil/pharm\\_mfg/default.cfm](http://www.tricare.osd.mil/pharm_mfg/default.cfm),

In addition to calculating covered drug refunds using TMA's monthly purchase data feeds, manufacturers who sell and/or deliver their drugs to network pharmacies and others through wholesalers will need to adjust their

3.

Dear Manufacturer of Covered Drugs

sales data used in current non-FAMP computations in order to ensure that TMA purchases are properly reclassified as sales to the Government. Once TMA identifies aggregate purchases of NDC packages of covered drugs as Government purchases, manufacturers will have to remove these purchases from net wholesale sales in order to arrive at correct non-FAMP figures for each NDC of each drug. Manufacturers may assume that TMA's reported purchases occurred during the non-FAMP reporting period in which the TMA data was received. Except for adjusting the third-quarter 2004 non-FAMP in Nov. 2005, and except to correct fundamental computation errors in later quarters, there will be no requirement to re-open and adjust already filed non-FAMP reports to accommodate TMA data received after filing. Accounting methods for removing TMA purchases from wholesale sales may vary by company, depending on systems set-up. Please find attached to this letter some "Non-FAMP Calculation Considerations" and "Non-FAMP Impact Scenarios" to assist you with devising a method for removing TMA purchases from wholesale sales.

If you have any questions concerning the above policies, please telephone Mel Noel at (708) 786-5167.

Sincerely,

Steven Thomas  
Acting Executive Director  
VA National Acquisition Center

1 Enclosure