The Coalition for Government Procurement

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March 11, 2010

Federal Docket Management Systems Office
1160 Defense Pentagon
Washington, DC 20301-1160

Attn: Admiral Thomas McGinnis, TRICARE Management Activity

Re: Department of Defense Office of the Secretary, CHAMPUS/TRICARE, Reconsideration of Final Rule and Request for Comments, Docket No. DoD-2008-HA-0029; 0720-AB22 (75 Fed. Reg. 6335-6, February 9, 2010)

Dear Admiral McGinnis:

The Coalition for Government Procurement ("CGP") appreciates the opportunity to submit additional comments on the Department of Defense ("DoD") Final Rule on CHAMPUS/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals (Docket No. DoD-2008-HA-0029; 0720-AB22) published in the Federal Register on March 17, 2009 ("Final Rule") in response to DoD's Notice of Reconsideration and Request for Comments (75 Fed. Reg. 6335-6, February 9, 2009.)

The CGP is a multi-industry association representing over 300 member companies that sell commercial products and services to the Federal government, including pharmaceutical manufacturers subject to the Final Rule.

The Final Rule implements Section 703 of the National Defense Authorization Act for Fiscal Year 2008 ("NDAA"), codified at 10 U.S.C. 1074g(f), which directed DoD to devise a means, by regulation, for applying the procurement pricing standards specified in section 603 of the Veterans Health Care Act ("VHCA"), 38 U.S.C. 8126, to prescription drug purchases made by TRICARE beneficiaries from retail pharmacies and paid by DoD. Pursuant to the VHCA, if manufacturers of covered drugs have entered into an agreement with the Department of Veterans Affairs ("VA") to cap prices charged DoD under certain types of supply contracts, when DoD procures covered drugs

from the manufacturers under those contracts for use by its Military Treatment Facilities and TRICARE Mail Order Pharmacy, the contract price cannot exceed the statutory price, referred to as the Federal Ceiling Price ("FCP").

The Proposed Rule, published on July 25, 2008 (73 Fed. Reg. 43394-97), applied FCP to retail pharmacy prescription sales by creating a powerful incentive for manufacturers of covered drugs to agree to rebate to DoD a specified portion of the prescription price DoD paid pharmacies, using the VHCA pricing standards to compute the rebate amount. Under the Proposed Rule, DoD's entitlement to receive a rebate from manufacturers flowed from the voluntary agreements, just as DoD's entitlement to a purchase price under a procurement contract flows from manufacturers' voluntary agreements. By contrast, the Final Rule (74 Fed. Reg. 11279-11293, March 17, 2009) purports to compel the payment of prescription rebates, regardless of whether the drug manufacturer had entered into a written agreement with DoD.

The CGP challenged the Final Rule in the U.S. District Court for the District of Columbia, and, on November 30, 2009, the court concluded that the Final Rule was materially defective because the NDAA did not create a statutory manufacturer refund obligation. The Final Rule was remanded to DoD for corrective action without vacatur.

Request for Comment on Alternative Approaches

The Notice of Reconsideration and Request for Comments states that DoD is soliciting comments on whether to readopt the Retail Pharmacy Benefit Program in the Final Rule as a matter of agency discretion or to adopt some other approach in light of the Court's November 30, 2009 decision. However, the Notice of Reconsideration, which does not specify any alternatives, does not provide adequate notice for comment, and as a consequence we cannot comment on an alternative approach that DoD has not proposed.

Comments on Issues Decided by the Lawsuit

Two issues concerning the scope of DoD's statutory authority to promulgate the Final Rule were decided by the Court in its November 30, 2009 decision. Those issues are still the subject of proceedings in the United States District Court for the District of Columbia and are pending appeal before the United States Court of Appeals for the District of Columbia Circuit. Since the Court has already decided the issues, and its decision is binding on DoD, the issues are not before DoD to decide in its action on remand. Accordingly, there is no reason for, and the CGP declines to submit the same issues in the litigation as "additional comments" on the Final Rule.

Other Comments on the Final Rule

If DoD is intending to readopt the Final Rule (or a modified Final Rule that is a logical outgrowth of the original Final Rule) and impose substantive obligations on drug manufacturers by regulation as a discretionary decision, and DoD's statutory authority to promulgate the Final Rule is affirmed on appeal, the CGP has the following comments on specific provisions in the original Final Rule that should either be retained or modified.

1. DoD Should Implement the Rule through Voluntary Agreements

Whether DoD purchases drugs directly and dispenses them itself, or pays pharmacies in the private sector for drugs they dispense to its beneficiaries, it is doing business in the commercial marketplace. We believe when DoD is engaging in commerce, as a policy matter, it should use its purchasing power to leverage consent to its terms for doing business, particularly the price it pays for commercial items, rather than impose liability for a price without an agreement through use of its sovereign power. As the Notice of Reconsideration recognizes, Congress did not hold manufacturers liable for the price paid to pharmacies by DoD for prescriptions, and DoD is not entitled by statute to refunds on the purchase price paid the pharmacies. If, in the exercise of its discretion, DoD readopts the Final Rule and burdens manufacturers with responsibility for DoD's purchase price, DoD should treat manufacturers the same as TRICARE network pharmacies participating in the retail pharmacy program and obtain their agreement to the transaction price.

Reliance on manufacturer agreements to make prices available to DoD is also consistent with the Veterans Health Care Act. Pursuant to that statutory scheme, DoD is not entitled to enforce the Federal Ceiling Price against a manufacturer who has not agreed to charge DoD that price. A regulatory scheme that mimics the Veterans Health Care Act should similarly rely on agreements as the source of a manufacturer's obligation to guarantee a purchase price and DoD's entitlement to enforce that obligation. Moreover, according to the Notice, 99% of prescriptions subject to the Final Rule are currently covered by pricing agreements. Thus, a program predicated on voluntary pricing agreements would present no administrative problems.

2. The Final Rule Should Apply on a Drug-by-Drug Basis

DoD should continue to apply the Final Rule on a drug-by-drug basis because the Uniform Formulary is a restricted formulary and formulary decisions are made on a drug-by-drug basis. Further, applying the Final Rule in this manner provides manufacturers with more flexibility in assessing the financial impact of the Rule and whether it makes economic sense to do business with TRICARE.