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.

3. 340B Prescriptions Should Be Excluded

DoD should continue to exclude prescriptions dispensed by providers participating in the 340B program created by Section 602 of the VHCA, because manufacturers sell drugs to those providers at deep discounts pursuant to a pharmaceutical pricing agreement with the Government, and refunds on those prescriptions would subject manufacturers to duplicate discounts under different pricing agreements with separate agencies.

4. The Final Rule Conflicts with Authorized Use of Coverage Preauthorization

Pursuant to 10 U.S.C. §1074g(a)(4), preauthorization of a drug for benefit coverage may be required only to assure use of the drug is clinically appropriate. Drugs that are subject to preauthorization and not authorized are not covered by TRICARE. DoD should avoid the conflict between the provisions for mandatory preauthorization of drugs not covered by a pricing agreement (§199.21(q)(2)(ii)) and existing law that requires a clinical assessment and establishment of preauthorization criteria as a prerequisite to imposition of such a restriction on beneficiary access to a drug.

The Final Rule should clarify that a drug cannot be subject to a preauthorization requirement until the Pharmacy and Therapeutics Committee performs a clinical assessment and establishes the criteria for that drug. It is important to provide an emergency supply of drugs in the retail point of service so that a patient will not be denied access to necessary medication. An exception for maintenance drugs to prevent problems that could occur from the necessity to switch a patient's therapy should also be provided. As noted in our prior comments, these are fairly standard managed care practices, although the number of days for which an emergency supply is available varies from plan to plan.

5. Generic Drugs Should Be Treated Consistently

The TRICARE pharmacy benefit regulation, 32 C.F.R. §199.21(j), follows commercial best practices in designating drugs as generics based on whether they are listed with an "A" rating in the FDA's Orange Book, and generally mandates substitution of an "A" rated generic equivalent for the reference brand. Classification of generic drugs by the FDA does not depend on the regulatory path by which the FDA approved the marketing and sale of the drug. Hence drugs are rated as generic in the Orange Book regardless of whether they are approved under a New Drug Application or an Abbreviated New Drug Application. The Final Rule, however, differentiates between generic drugs on this basis, and requires refunds on generic drugs approved by the FDA under an original New Drug Application as a condition of inclusion

on the Uniform Formulary because DoD erroneously believed the statute required refunds on these drugs.

As manufacturers of generic drugs are not statutorily required to pay refunds, DoD may and should, as a discretionary matter, exclude from the Final Rule all prescriptions filled with "A" rated generic drugs, regardless of how they were approved by the FDA for marketing and sale. First, commercial managed care practices do not differentiate among generic drugs based on their regulatory approval pathway and frequently reduce prescription costs by paying lower reimbursement rates for all generics in recognition of the pharmacy's low acquisition cost. Failure to adopt this practice would not conform with the Rule's intent to follow commercial best practices. Second, all generic drugs are price-driven, low-margin commodities, and an additional 24% discount to DoD on top of the heavily discounted price to the pharmacy can result in a below-cost sale for the manufacturer, so that there is an economic disincentive to paying prescription refunds to TRICARE. Third, as an administrative matter, it is not practicable to treat generic drugs the same as brands under the TRICARE pharmacy benefit regulation. If a generic drug were subject to the refund rule but was not covered by a pricing agreement, a prescription for that drug would be simultaneously subject to the generic co-payment and mandatory substitution rule and the formulary exclusion and preauthorization rule. If the drug were the only generic version listed in the Orange Book, beneficiaries would be forced to pay the higher co-pay for the non-formulary brand, despite the rule entitling them toa $3.00 co-pay for generics, because the generic would be excluded from the formulary in all points of service. Further, if the brand was covered by a pricing agreement and thus was not subject to preauthorization, but the generic version was subject to preauthorization, the lower cost alternative would be unavailable at a retail pharmacy, which is counter-productive and illogical.

6. DoD Should Not Promulgate a Regulation that Breaches Its Contracts

Prior to enactment of the NDAA, DoD entered into contracts with manufacturers in which it promised to place certain of their products in a preferred position (Tier Two) on the Uniform Formulary in exchange for payment of rebates on prescription units of the drug, which reduced DoD's net expenditure for the prescription for the duration of the contract term. If the deal were terminated by either party, the terms remained in effect for 120 days. Accordingly, manufacturers were entitled to the benefit of their bargain for six months even if DoD terminated the contract. In the Final Rule, DoD required manufacturers to pay a greater amount to DoD in order to *retain* the benefit of their bargain, thereby reneging on its promise and breaching the contracts, because DoD mistakenly believed Congress gave it no choice. If DoD desires to impose a regulatory requirement for larger prescription rebates than it bargained for, it must do so in accordance with the contract terms. In considering whether to exercise discretion in requiring refunds measured by

FCP as a condition of a drug's placement in Tier Two of the Uniform Formulary, DoD should exclude prescriptions covered by pre-NDAA contracts from the Final Rule to avoid intentionally breaching them. It is our understanding that such an exclusion would affect very few drugs and thus would have no material impact on achievement of the statutory goals.

7. The Final Rule Must Provide an Opportunity for Manufacturers to Avoid Refund Liability Created by Regulation

The Final Rule published on March 17, 2009, purported to implement a manufacturer refund obligation mandated by statute; however, as the Notice recognizes, manufacturers had no such statutory obligation to pay refunds to DoD. Accordingly, the provisions in the Final Rule for manufacturers to opt out of participation in the TRICARE pharmacy benefit program in order to avoid liability for statutorily mandated refunds could not apply to refunds that they were not required by law to pay. If DoD decides to compel payment of manufacturer refunds on drugs that are purchased from retail pharmacies, but are not covered by a voluntary pricing agreement, manufacturers must be given a reasonable opportunity to avoid transactional liability established by regulatory action before the effective date of the regulation. Additionally, if manufacturers who do not wish to participate in the retail pharmacy program with respect to a particular drug must affirmatively opt out of participation in the pharmacy benefit program by removing the drug from the Uniform Formulary, the Final Rule must clarify what constitutes adequate notice to DoD to avoid liability for refunds on retail pharmacy sales of that drug under the Final Rule. This is particularly important because manufacturers cannot control decisions made by DoD with respect to the makeup of the Uniform Formulary and DoD's management of its pharmacy benefit.

8. The Final Rule Does Not Comply with the Unfunded Mandates Reform Act

The Final Rule states in reference to Section 202 of Public Law 104-4, "Unfunded Mandates Reform Act," that it does not contain a Federal mandate that may result in the expenditure by the private sector of $100 million or more (adjusted for inflation) in any one year. That statute imposes on DoD certain requirements if a provision in a final regulation will cause the private sector to spend, in the aggregate, $100 million in order to comply with the regulation. Assuming DoD mandates by regulation that drug manufacturers assume responsibility for prices paid pharmacies by DoD (instead of establishing a voluntary program), the pharmaceutical industry will spend well in excess of $100 million annually in mandatory refunds as a result of the regulation. In fact, DoD states in the Final Rule that the amount of refunds collected annually that will offset its own expenditures at pharmacies is ten times that amount. The Final Rule states that the economic impact of the regulation is not in the form of a "mandated expenditure" by the private

sector. That is clearly not true if provision of a benefit under the TRICARE retail pharmacy program (i.e., payment for a prescription) triggers a mandatory refund payment by pharmaceutical manufacturers. Unless DoD is relying on voluntary agreements to achieve its cost savings, it must follow the requirements of the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, 109 Stat. 48, or explain why the Final Rule does not contain a Federal mandated expenditure by the pharmaceutical industry.

We appreciate your consideration of these comments in taking corrective action with respect to the Final Rule on the TRICARE retail pharmacy benefit program.

Sincerely,

Larry Allen
President