

MEETING WITH OFFICE OF MANAGEMENT AND BUDGET
TRICARE FINAL RULE
November 7, 2008

Introduction

- The Coalition for Government Procurement and member representatives met with OMB last April concerning the Department of Defense's planned implementation of Section 701 of the National Defense Authorization Act for FY 2008. At the time, DoD intended to promulgate a rule that would force drug manufacturers to pay DoD rebates on pharmacy prescriptions by mandating extension of procurement pricing provisions in existing agreements with the Department of Veterans Affairs to DoD retail pharmacy benefit payments.
- Our concerns focused on the impact of such a regulation on the VA agreements, and the confusion between the VA procurement program, through which DoD purchases drugs from manufacturers for use at its treatment facilities, and the TRICARE retail pharmacy benefit program, through which DoD pays pharmacies a retail prescription price on behalf of the pharmacies' TRICARE-covered customers.
- DoD's TRICARE Retail Pharmacy Benefits Program Proposed Rule adopted an entirely different approach than originally discussed - it proposed to establish a retail pharmacy rebate program and leverage competition for Uniform Formulary status to obtain voluntary rebate agreements from competing drugs within the same therapeutic class.
- TRICARE uses the commercial managed care technique of a restricted formulary to reduce program costs. By statute and regulation, selection of drugs for inclusion in the formulary is based on consideration of clinical and cost effectiveness. Because DoD's formulary determinations impact beneficiary access to drugs at military treatment facilities and their mail order and retail pharmacy prescription costs, which impacts the volume of manufacturers' business, the restrictive nature of the formulary promotes competition, and creates an opportunity for DoD to obtain prescription rebates from manufacturers.
- The current TRICARE regulation also provides for pre-authorization for certain drugs. The Proposed Rule would not alter the process for determining whether a drug will be subject to pre-authorization, although drugs not covered by a rebate agreement would have to undergo the clinical assessment required for a pre-authorization determination in the retail venue. We expect the Final Rule will likewise maintain the current regulation's limitations on imposition of pre-authorization requirements.

- The key difference between the proposed TRICARE rebate program and commercial managed care practices is that the TRICARE rebate agreement terms are uniform and non-negotiable. Participation in the rebate program requires execution of a standard rebate agreement covering participating drugs and payment of a mandatory rebate amount. We believe specifying an acceptable rebate amount by regulation is bad policy because it artificially manipulates the market, and may ultimately lead to costlier drugs. Nevertheless, we support the competition-based voluntary approach in the Proposed Rule as more consistent with a commercial model than across the board price controls, which discourage investment in innovation, subject to the following clarification on the scope and effect of the Final Rule.

Need for Clarification on Scope

- The language of the Proposed Rule indicated that DoD would apply the rebate program on a drug by drug basis through its existing formulary structure (“a written agreement... shall with respect to a particular covered drug be a condition for ...inclusion of that drug on the uniform formulary”), *i.e.*, manufacturers would decide where they want to compete for the TRICARE market. Given the restrictive nature of the TRICARE formulary, the statutory and regulatory requirements for formulary selection and beneficiary access to prescription medication, and the significant number of executed agreements that cannot be terminated in less than six months, any other method for implementing rebate agreements under the regulation would be unworkable.
- Problem: The Proposed Rule contemplates that formulary placement would be the Government’s consideration for manufacturer payment of rebates on a particular drug; however, the language of the rule lacks the clarity needed to prevent a different interpretation of the rule in the future, *i.e.*, the manufacturer cannot select the drugs on which it willingly pays rebates in exchange for formulary position, but must agree to pay rebates on all drugs even if individual drugs are excluded from the formulary. This lack of clarity on the scope of the rule and the potential for future exposure creates uncertainty, which impacts financial projections, and pricing decisions, particularly for manufacturers who invest heavily in bringing new agents to market.
- Solution: Add language in the Final Rule clarifying that the voluntary rebate agreement required for Uniform Formulary consideration applies on a drug-by-drug basis, and that any agreement to pay rebates on individual drugs under the regulation is contingent on the drug’s inclusion on the Uniform Formulary.

Need for Prospective Effect

- The Proposed Rule sought comments on whether the statute directing DoD to promulgate a regulation intended to subject TRICARE prescription purchases after the date of enactment to procurement price ceilings requires DoD's voluntary retail pharmacy rebate program to apply retroactively to purchases preceding establishment of the program.
- Problem: Retroactive application of a voluntary rebate program is not required, would be an arbitrary and abusive use of regulatory authority, and would breach existing rebate agreements.
- The NDAA did not require application of the implementing regulation to prescriptions dispensed on and after the date of enactment, but gave DoD discretion to treat prescriptions like procurements "on or after" that date. This important distinction acknowledged that DoD needed to promulgate a rule with a later effective date than the statute.
- DoD has already argued before the District Court for the District of that the statute mandated it execute voluntary rebate agreements measured by the federal procurement ceiling price in advance of a final rebate rule, and the court rejected that argument. Since then, DoD permitted companies to offer lesser rebates. If the statute allowed DoD to pay more than FCP until it finalized a rule, it would not require retroactive application of agreements executed after the effective date of the rule.
- Congress did not intend for DoD's regulation to apply to transactions occurring many months before finalization of the regulation. Originally, DoD was to promulgate a rule by December 31, 2007, three months after the effective date of the statute. The timetable contemplated that DoD would publish a proposed rule shortly after enactment. Slippage of the enactment date did not authorize DoD to delay the rulemaking process and then claim retroactive relief from those subject to the regulation.
- In the absence of a rebate program established by regulation, manufacturers had no legal obligation to pay DoD rebates on drugs they sold commercially. A requirement to pay retroactive rebates reduces the realization on these prior commercial sales, which means companies must re-evaluate their earnings and financial statements. For certain companies, the cumulative amount might have a material impact.
- Mandatory retroactive payment of rebates in exchange for formulary position would breach existing rebate agreements pursuant to which lesser rebates were paid to DoD on the same transactions for the same consideration.

- A mandatory retroactive start date for rebate payments conflicts with the concept of voluntary rebate agreements, and could deter future participation. For example, if a manufacturer opts to add a drug to the agreement when a competing product is launched, a requirement to pay rebates on prescriptions back to the program start date could be a powerful disincentive.
- A requirement to pay rebates on purchases preceding an agreement on the rebate terms conflicts with regulations governing the treatment of rebates as discounts in the context of other federal health care programs.
- The Proposed Rule is predicated on cost savings for the Defense Health Service budget beginning with FY 2009. If DoD requires by regulation that rebate agreements apply to prescriptions purchased before FY 2009, the savings contemplated by the rule would be grossly understated.
- Solution: The Final Rule should clarify that voluntary agreements to pay rebates on prescription purchases by TRICARE apply prospectively.