

MEETING WITH OFFICE OF MANAGEMENT AND BUDGET  
TRICARE FINAL RULE  
March 4, 2009

SUBMISSION OF THE COALITION FOR GOVERNMENT PROCUREMENT

Background

- The Coalition for Government Procurement and member representatives met with OMB last year concerning DoD's planned implementation of Sec. 703 of the National Defense Authorization Act for FY 2008. Sec. 703 requires application of federal price controls established by the Veterans Health Care Act (38 USC 8126) to the TRICARE retail pharmacy program, which shares the cost of prescriptions provided in the private sector. It did not amend the VHCA.
- The VHCA legislated the maximum amount that certain agencies (including DoD) could pay for drugs procured for their own use in providing health care. It did not order drug manufacturers to sell at the statutory price, but required their agreement to the price as a condition of inclusion on the Medicaid formulary. DoD's entitlement to procure drugs at federal ceiling prices is based entirely on executed agreements between manufacturers and the VA, which did not cover purchases of prescriptions from retail pharmacies.
- Initially, DoD intended to implement Sec. 703 through a regulation that would unilaterally alter manufacturers' obligations under their existing agreements with the VA. At our first meeting with OMB, our concerns focused on whether such a regulation would breach those agreements.
- The TRICARE Retail Pharmacy Benefits Program Proposed Rule adopted an entirely different approach - it proposed to establish a retail pharmacy rebate program in which DoD would leverage competition for inclusion in its restricted formulary to obtain voluntary rebate agreements based on the ceiling price set forth in the VHCA.
- Unlike commercial managed care practices, the proposed TRICARE rebate agreement terms are uniform and non-negotiable. For a drug to be included on the Uniform Formulary, its manufacturer must execute a standard rebate agreement covering the drug and agreeing to pay a mandatory rebate amount. Although we believe specifying an acceptable rebate amount by regulation is bad policy because it artificially manipulates the market, we support the competition-based voluntary approach in the Proposed Rule as more consistent with a commercial managed care model than across the board price controls, which discourage investment in innovation and may ultimately lead to costlier drugs.
- In November, we met with OMB seeking two clarifications to the Proposed Rule.

## Need for Clarification on Scope

- The language of the Proposed Rule indicates 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”). This is consistent with DoD’s past actions and intent to continue reviewing classes and excluding drugs from the Uniform Formulary based on clinical and cost effectiveness. We support this approach.
- Given the restrictive nature of the TRICARE formulary, the statutory and regulatory requirements for both formulary selection and beneficiary access to prescription medication, and the significant number of executed rebate agreements that cannot be terminated in less than six months, any other method for implementing rebate agreements under the regulation would be unworkable. Further, requiring the agreement to cover a company’s entire portfolio of products would be contrary to the program’s voluntary underpinning and would be a huge disincentive for participation in the program.
- Problem: The Proposed Rule contemplates that formulary status 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, *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, and makes participation in the program risky.
- Solution: Encourage participation in the program by adding 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 Agreements to Apply Prospectively

- Sec. 703 of the NDAA directed DoD to promulgate a regulation that would subject TRICARE prescription purchases to procurement price ceilings. The Proposed Rule would accomplish this goal through voluntary rebate agreements specified by the regulation, and sought comments as to whether the statute required such agreements be effective retroactively.

- Problem: Applying agreements prescribed by regulation to transactions preceding the effective date of the regulation is not mandated by statute, and is presumptively prohibited in the absence of express statutory authorization. Requiring the terms of voluntary agreements to apply retroactively would also be an arbitrary and abusive use of regulatory authority, would create undue burden, and would breach existing rebate agreements.

### Congress Did Not Authorize Agreements With Retroactive Effective Dates

- Sec. 703 of the NDAA did not require application of the implementing regulation to prescriptions dispensed on and after the date of enactment, but required prescription purchases be subject to procurement prices “on or after” that date. This important distinction acknowledged that DoD needed time to promulgate an implementing regulation with a later effective date than the statute.
- The District Court for the District of Columbia already rejected DoD’s argument that the NDAA mandated voluntary rebate agreements apply federal pricing to prescriptions in advance of a regulation. Since then, DoD agreed to accept lesser rebates. If the statute allows DoD to pay more than FCP until it finalizes its implementing regulation, the statute could not mandate retroactive application of agreements prescribed by the regulation during that same period.
- Although the NDAA did not specify a TRICARE drug rebate program, the Medicaid drug rebate program is instructive in understanding programs implemented through prescribed rebate agreements: the effective date of the requirement for an agreement is separate from the effective date of the agreement itself. The Medicaid rebate statute (42 USC 1396r-8) induces manufacturers to enter into a prescription rebate agreement with HHS by making it a requirement for inclusion on the Medicaid formulary. This requirement applies to drugs dispensed “on or after” January 1, 1991, just like Sec. 703 of the NDAA applies to prescriptions “on or after” the date of enactment.
- The Medicaid statute gave HHS three months to develop a national rebate agreement that met the statutory requirements, but did not require retroactive application of agreements entered into with HHS more than three months after the statute’s effective date. Although the statutory requirement to have an agreement went into effect on or after January 1, 1991, the agreements themselves - and the obligation to pay rebates - became effective “the first day of the calendar quarter that began 60 days after the date the agreement is entered into.”
- Given that agreements to pay rebates normally apply prospectively, in the absence of express intent by Congress to the contrary, there is no basis for making rebate agreements prescribed by regulation instead of statute effective before the regulation is promulgated and the agreements are executed.

- DoD was required to issue a regulation by December 31, 2007, three months after the anticipated effective date of the statute (October 1, 2007). The timetable contemplated 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.

#### Requiring Application of Agreements to Prior Transactions Is Arbitrary and Burdensome and Would Breach Existing Rebate Agreements

- In the absence of a rebate agreement, manufacturers had no legal obligation to pay DoD rebates on drugs they sold commercially. A new 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.
- Applying the rebate program to prior transactions will necessitate reclassifying those transactions as DoD procurements, recalculating all Non-FAMPs and ceiling prices incorporated in manufacturers' procurement contracts, and adjusting all invoices based upon those prices.
- Picking October 1, 2008 or some other arbitrary date as the effective date for subsequent agreements has no rational basis in the statute.
- If rebates are lagged discounts, a requirement to pay quarterly rebates on purchases preceding the quarter in which the rebate terms are agreed to conflicts with commercial practices and HHS regulations governing the treatment of rebates as discounts in the context of other federal health care programs.
- A mandatory retroactive start date for rebate payments conflicts with the concept of voluntary rebate agreements, could result in litigation and delay, and could deter participation. For example, if a manufacturer opts to add a drug to the agreement in the future, a requirement to pay rebates on prescriptions back to the program start date could be a powerful disincentive.
- Mandatory payment of prescribed rebates in exchange for formulary position will breach existing agreements in which DoD agreed to accept lesser rebates on the same transactions for the same consideration. Until these agreements are terminated, the drugs covered by them must be exempt from the requirement to have a different rebate agreement in order to keep these drugs on the formulary.
- Solution: The Final Rule should clarify that voluntary agreements to pay rebates on prescription purchases by TRICARE are effective on the date the agreements are executed by DoD.