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## TRICARE Final Rule Establishes New Manufacturer Rebate Liability

### *Manufacturers of Branded Drugs Face Retroactive Refunds, Additional Formulary Hurdles*

On March 17, 2009, the Department of Defense (DoD) published the final rule implementing Section 703 of the National Defense Authorization Act for Fiscal Year 2008.<sup>1</sup> Under the law, drugs dispensed by the TRICARE Retail Pharmacy Program are eligible for the Federal Ceiling Prices (FCP) available to the other “Big Four” federal purchasers.

The final rule imposes retroactive rebate liability on all sales of branded pharmaceuticals made through the TRICARE Retail Pharmacy Program since January 28, 2008—whether the products were covered by an agreement with TRICARE or not.

The final rule largely adopted provisions in the proposed rule, but clarified many aspects of the voluntary rebate agreement and the rebate mechanics.<sup>2</sup> It also added provisions allowing manufacturers to petition DoD for adjustment or waiver of rebate liabilities and expanded DoD’s authority to place products not covered by an agreement on the preferred formulary.

#### *Voluntary Rebate Agreements*

The final rule maintained DoD’s request that manufacturers of single source and innovator multiple source drugs enter into voluntary rebate agreements with the TRICARE Management Activity (TMA). Failure to subject drug products to this agreement will prevent, except in narrow circumstances, a product from obtaining a preferred position on the military’s Uniform Formulary, which is necessary to avoid prior authorization and higher co-payments. Manufacturers may specify, on a product-by-product basis, which drugs will be subject to an agreement; the agency will not condition inclusion of drugs on the preferred formulary on a

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manufacturer's willingness to subject all of its marketed products to a voluntary agreement.

In general, products not covered by an agreement will still be included in the Uniform Formulary, but in a disfavored tier. However, DoD added language to the final rule that grants the formulary's P&T Committee authority to waive the agreement requirement if it is necessary to ensure that at least one drug in the applicable drug class is in the preferred tier. The final rule also included a beneficiary transition provision that allows, in certain circumstances, the TMA Director to treat products removed from the preferred formulary tier as if they were still subject to an agreement.

Irrespective of formulary status, manufacturers must pay the full TRICARE rebate on all products purchased through the Retail Pharmacy Program, even if they are not subject to a voluntary rebate agreement.

### *Rebate Mechanics*

As under the proposed rule, the required rebate is calculated as the difference between the most recent annual non-Federal average manufacturer price (Non-FAMP) and the FCP or, at the manufacturer's discretion, the difference between the FCP and the "direct commercial contract sales price" specifically attributable to TRICARE paid pharmaceuticals (manufacturers electing this option should maintain auditable records). DoD will furnish manufacturers with utilization data quarterly and manufacturers will have 70 days to prepare and submit rebate payments.

In the final rule, DoD acknowledged the potential for duplicate discounts on TRICARE prescriptions dispensed by 340B pharmacies and conceded that manufacturers need not pay these. Accordingly, DoD will exclude 340B sales from the utilization data it submits to manufacturers. Also, no rebates will be requested on drugs dispensed by out-of-network pharmacies, the TRICARE mail-order pharmacy, or military treatment facilities and rebates will not be required where TRICARE is the secondary payer.

### *Implementation Date and Requests for Waiver*

DoD determined that all TRICARE retail pharmacy prescriptions filled on or after January 28, 2008 are eligible for FCP pricing and that manufacturers must refund any overpayments that have accrued since then. Although the final rule contained significant discussion justifying this position, it included a new provision that allows manufacturers to seek a compromise or waiver of any refund. This provision may be used to request modification of rebate liabilities associated with sales since January 28, 2008 or, in future cases, to adjust rebate liabilities where a manufacturer opts to voluntarily remove its products from the preferred formulary tier. Also, during the pendency of any request to modify or waive liability, there will be no need to pay any associated rebates and the product associated with the request will be deemed outside of any voluntary agreement.



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*Dispute Resolution and Penalties*

New language in the final rule specified that where a manufacturer disputes the accuracy of the utilization data, its rebate obligation will be deferred pending good faith efforts to resolve the dispute. If the dispute is not resolved within 60 days, the TMA will issue an initial administrative decision and provide the manufacturer an opportunity to request reconsideration.

As in the proposed rule, instances of non-compliance may be subject to any actions authorized by law.

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*This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.*

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<sup>1</sup> Final Rule, 74 *Fed. Reg.* 11,279, 11,293 (March 17, 2009).

<sup>2</sup> Proposed Rule, 73 *Fed. Reg.* 43,394, 43,397 (July 25, 2008).