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Life Sciences Health Industry Alert

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# TRICARE Retail Pharmacy Program Subject To Federal Ceiling Prices Under New DoD Rule

On March 17, 2009, the Department of Defense (DoD) issued a final rule to implement a provision of the 2008 National Defense Authorization Act (NDAA).[1] In the final rule, the DoD takes the position that the NDAA requires pharmaceutical manufacturers to provide discounted drug prices based on the Veterans Health Care Act's (VHCA's) Federal Ceiling Price (FCP), for covered drugs sold by retail pharmacies to TRICARE beneficiaries on or after Jan. 28, 2008 (the date of enactment of the NDAA). DoD further establishes a process whereby manufacturers' satisfaction of this obligation will be a condition to a product's continued Tier 2 status on the TRICARE uniform formulary. Finally, however, DoD indicates that it will consider, pursuant to its authority under the Federal Debt Collection Act, proposals to settle outstanding "refund" claims for periods prior to the effective date of the rule.

### *Background*

Under the VHCA, pharmaceutical manufacturers must enter into "master agreements" with the Department of Veterans Affairs (VA) as a condition to federal spending on their products by the Medicaid program, the VA, the DoD, the Public Health Service (PHS), or certain other "covered entities." The master agreement in turn requires that the manufacturer may not charge the VA, DoD, or PHS more than the FCP. The FCP is equal to 76 percent of the non-federal average manufacturer price of the product, less an "additional discount," to the extent that a product's price increases faster than inflation on a year-to-year basis.

Traditionally, the VHCA and the FCP have applied solely in "pure" procurement contexts, i.e., where the manufacturer would "sell" physical inventory to an eligible government purchaser that would take possession of the product and dispense it in federal installations. By contrast, the government did not seek rebates or price concessions with respect to products sold to non-government retail pharmacies and dispensed to eligible government patients through managed care and similar arrangements.

In particular, the government did not historically seek to apply the VHCA or FCP in the context of products dispensed through private retail pharmacies to military beneficiaries under the TRICARE program. In 2004, the VA issued a "Dear Manufacturer" letter purporting to require FCP-based rebates for TRICARE retail utilization, but the United States Court of Appeals for the Federal Circuit held that the letter constituted a substantive rule that was not validly promulgated.[2]

### *The NDAA and Additional Litigation*

Following the decision of the Federal Circuit, Congress enacted the NDAA. Under the NDAA, on or after the enactment date of the NDAA, the "TRICARE Retail Pharmacy Program shall be treated as an element of the Department of Defense…to the extent necessary to ensure that pharmaceuticals paid for the by DoD" are subject to Federal Ceiling Prices.[3] The NDAA further required DoD to promulgate regulations to implement the requirements of the statute no later than Dec. 31, 2007.

Following the enactment of the NDAA, DoD issued its own "Dear Manufacturer" letter announcing that it would use its own pre-existing "voluntary" rebate program mechanism to implement the NDAA; industry participants challenged this letter, again on the ground that it purported to implement the NDAA without proper notice-and-comment rulemaking. DoD then proposed regulations July 25, 2008.[4] On Sept. 19, 2008, the United States District Court for the District of Columbia denied a request for preliminary injunction based on the industry's ability to demonstrate irreparable harm, although it indicated that the industry had shown a likelihood of success on the merits and noted that DoD had stated in its proposed rule that NDAA "requires implementing regulations."[5]

### *The Final Rule and Additional Agency Guidance*

The final rule issued by the DoD first reiterates the basic NDAA standard that on or after Jan. 28, 2008, the TRICARE Retail Pharmacy Program shall be treated as an element of the DoD for purposes of procurement of drugs by federal agencies to ensure that pharmaceuticals paid for by network retail pharmacies under the program to eligible beneficiaries are subject to FCP standards.[6] In doing so, however, DoD emphasized that it construed the statute as being self-executing—i.e., that it created a legal obligation for manufacturers to provide the FCP for TRICARE retail prescriptions as of that date without regard to whether regulations were first promulgated, and without regard to the VHCA or its implementing master agreements.[7] Further, the final rule specifies that DoD reserves its rights to take any action authorized by law to enforce the regulatory requirement.[8]

With respect to the scope and implementation of this new obligation, DoD clarified that FCPs are not applicable to products provided under Section 340B of the Public Health Service Act, and that the requirement will be implemented through a "refund" mechanism similar to traditional managed care rebate processes. The amount of the refund will be the difference between the Non-Federal Average Manufacturer Price and the FCP, and shall be due at least 70 days following the submission of utilization data to the manufacturer.[9] Rebates will not be due with respect to disputed utilization until the dispute is resolved.[10]

Second, the final rule creates an additional (and somewhat controversial) enforcement "hook" based on the TRICARE uniform formulary process. Under the TRICARE program, DoD has established a three-tier uniform formulary with variations in cost sharing and other benefit management techniques administered through a pharmacy benefits manager. The final rule requires manufacturers to enter into a written agreement confirming that they will honor the FCPs, as a condition to a product's inclusion on "Tier 2" of the uniform formulary, and also to avoid prior authorization requirements for the drug in connection with drugs dispensed through the retail pharmacy network.[11]

DoD has already issued informal guidance to manufacturers concerning the implications of these agreements.[12] For example, the agency has stated:

- Drugs currently on Tier 2 will be placed on Tier 3 if their manufacturers do not sign the agreements
- Drugs currently on Tier 3 will not automatically be placed on Tier 2 if their manufacturers do sign the agreements, but will be eligible for Tier 2 status upon the next regular formulary class review
- Agreements will not be required if the DoD determines that the product is necessary, because it is the only one of its class.

Third, the preamble to the final rule and additional DoD guidance provide insight concerning the application of the refund requirement to periods between the effective date of the NDAA and the effective date of the final rule. While DoD has informally noted on its websites that refunds for these periods will be due May 26, 2009, it has also emphasized that these obligations are subject to the Federal Debt Collection Act, and therefore DoD has the discretion to waive or compromise its claims for these amounts upon a request from the manufacturer "on any grounds the manufacturer believes appropriate."[13] In fact, the preamble seems to invite proposals designed to simply "clean up the books" for the periods prior to the rule, noting that a manufacturer might agree to pay refunds on all products prospectively while compromising refunds for particular periods or products in the retrospective period.[14]

### *Discussion and Commentary*

The final rule is an unusual document in two senses. First (and perhaps understandably in light of the litigation history), DoD spends much of its preamble outlining its legal argument in support of the program. Second, after taking a seemingly inflexible legal position that the NDAA imposed statutory discount obligations effective for prescriptions dispensed through TRICARE retail pharmacies on or after Jan. 28, 2008, the agency then opened the doors to negotiation of these obligations. This latter "invitation" may be a simple function of pragmatism. Specifically, given that the final rule has now been issued, the agency may believe that it is on firm legal footing with respect to refunds prospectively, and that the negotiation process may be the most efficient mechanism for resolving claims in the interim period between the NDAA and the effective date of the rule.

While manufacturers can of course simply pay any refund amounts and enter into the agreements contemplated by DoD, we believe that there are a number of key issues to consider in responding to the rule:

- As a threshold matter, given the continuing pendency of the industry litigation against the DoD, manufacturers should consider whether the rule is in fact appropriate even prospectively (e.g., Did the NDAA actually create a refund mandate? Can the NDAA override the VHCA without amending it or the implementing master agreements?).
- Perhaps the most critical unanswered question is whether DoD contemplates that the waiver and compromise process will be implemented flexibly in order to "put the past behind them" and avoid further legal disputes relating to the effective date of refund obligations, or instead interpreted more rigidly as an "exception" process based on actual disputes relating to data. Manufacturers may wish to discuss these matters informally with DoD.
- If a manufacturer elects to explore a compromise, it should promptly review and evaluate its specific products, the potential outstanding amounts, and the products' status (both retrospectively and prospectively) on the TRICARE uniform formulary. There may be many variables that could be taken into account when crafting a compromise proposal, including, but not limited to, the products for which refunds will be paid, the periods in which refunds will be paid, and the percentage of claims or claims dollars that can be paid.
- In the event that a manufacturer's products are in the middle of a formulary review (but the TRICARE formulary final decision has not yet been made), manufacturers may wish to contact DoD to seek a delay in any final decision so that the manufacturer's compliance or compromise position may be taken into account.
- Manufacturers could also consider proposing settlements that would unwind if the regulation was subsequently invalidated, although it is difficult to imagine what incentive the DoD would have for compromise on that basis.
- Manufacturers should evaluate any existing voluntary rebate agreements with the agency to assure that they wish to continue them, in light of the potential for increased aggregate liability under the final rule.

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1 74 Fed. Reg. 11279 (Mar. 17, 2009).

2 *Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs,* 464 F.3d 1306 (Fed. Cir. 2006).

3 10 U.S.C. § 1074g(f) (2008).

4 73 Fed. Reg. 43394 (July 25, 2008).

5 Complaint of Plaintiff, *Coalition for Common Sense in Government Procurement v. United States,* No. 1:08-cv-00996 (D.D.C. June 10, 2008).

6 32 C.F.R. § 199.21(q)(1) (2009).

7 74 Fed. Reg. 11,279, 11,280-84 (Mar 17, 2009).

8 32 C.F.R. § 199.21(q)(4) (2009).

9 The draft agreement also provides an alternative basis for calculating the refund, but the final rule fails to provide a clear explanation as to what the DoD means with respect to an alternative basis.

10 *See id.* § 199.21(q)(3) (2009).

11 *See id.* § 199.21(q)(2) (2009).

12 *See generally* http://www.tricare.mil/pharm_mfg/default.cfm. The TRICARE website also includes a sample form of agreement that DoD has prepared to implement the regulation.

13 74 Fed. Reg. 11,279, 11,285 (Mar 17, 2009).

14 *Id.*

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Manufacturers seeking additional information or assistance concerning the DoD TRICARE final rule may contact Joseph W. Metro (jmetro@reedsmith.com) or Lorraine Campos (lcampos@reedsmith.com), or other Reed Smith attorneys with whom you regularly work.

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