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## Congress Requires Pharmaceutical Manufacturers to Provide Deeply Discounted Prices for Covered Drugs Purchased at TRICARE Retail Pharmacies

Effective immediately, under the recently enacted 2008 National Defense Authorization Act (“NDAA”), pharmaceutical manufacturers are required to offer deeply discounted prices for covered prescription drugs sold by retail pharmacies to TRICARE beneficiaries. On January 28, 2008, President Bush signed the NDAA into law. The NDAA seeks to add sales at retail pharmacies to TRICARE beneficiaries to the list of sales entitled to deeply discounted pricing under the Veterans Health Care Act of 1992 (“VHCA”). This statutory change is contemplated to result in very large cost savings for DoD in the purchase of prescription drugs, which will come as the result of the rebates paid by pharma companies related to their retail pharmacy TRICARE sales.

### Background

Under the VHCA, pharmaceutical manufacturers must offer a reduced price for innovator drugs and biologics to certain agencies including VA, DoD, and the Public Health Service in order to participate in Medicaid, Medicare Part B, and certain other federal funding programs. Through contractual agreements with the VA implementing the requirements of the VHCA, each manufacturer must offer its products on the VA Federal Supply Schedule at prices that are equal to or lower than the Federal Ceiling Price. The Federal Ceiling Price is determined through the use of a statutory formula that provides for a 24% discount off of the average price to wholesalers. Discounted prices are available to the qualifying agencies for all purchases off of the Federal Supply Schedule as well as “depot” contract sales. Up to now, these discounted prices have only been available where the Government agency was the direct purchaser, and previous attempts by DoD to obtain VHCA rebates on TRICARE retail pharmacy sales were unsuccessful.

TRICARE is DoD's health insurance program for over 9 million active duty service members, their dependants and retirees of the uniformed services. TRICARE beneficiaries have the option of obtaining their prescriptions from military treatment facilities, a mail order pharmacy, or at one of over 50,000 participating retail pharmacies. Prior to the NDAA, DoD would benefit from reduced VHCA pricing only when TRICARE beneficiaries filled prescriptions via mail order or at a military treatment facility as DoD purchases those drugs directly from the manufacturer. Sales to TRICARE beneficiaries via retail pharmacies were not considered “depot” sales, as retail pharmacies purchase the drugs through a normal commercial transaction and then seek reimbursement from DoD after filling a TRICARE prescription.

DoD has attempted to access VHCA discounted prices for retail pharmacy sales previously. In October 2004, VA issued a “Dear Manufacturer” letter that required drug manufacturers to refund DoD via rebate the difference between the drug's wholesale price and the discounted price for covered drugs purchased at TRICARE network retail pharmacies. The basis for claiming entitlement to such rebates was the characterization of TRICARE retail pharmacy sales (in which, as described above, a manufacturer sells directly to the pharmacy and the pharmacy is later reimbursed by DoD via a pharmacy benefits manager) as a “virtual depot.” This policy was challenged as a violation of the

Administrative Procedure Act and in September 2006, the United States Court of Appeals for the Federal Circuit held that the letter was invalid because it violated the APA's notice and comment procedures. Also, in April 2005, the GSA issued a proposed rule that attempted to extend Federal Ceiling Prices to drug purchases made at TRICARE retail pharmacies, but that agency has not taken any public action on the proposed rule since June 2005, when the comment period ended.

### New Legislation

Section 703 of the NDAA purports to give DoD the benefit of heavily discounted VHCA pricing for all covered drugs purchased by TRICARE beneficiaries at network retail pharmacies. The law provides that, as of January 28, 2008, "the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies . . . to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in [the VHCA]." Pub. L. 110-181, § 703(a), 122 Stat. 3 (2008). The statute requires DoD to modify its TRICARE regulations immediately to implement the new law.

The precise implications for pharmaceutical manufacturers will be known when DoD issues guidance and regulations. It is likely that DoD will seek compliance with the new pricing requirements through the payment of quarterly rebates (as it has in the past) to be paid as soon as the end of first quarter 2008 under current or new contractual agreements with manufacturers. Further, the statute and its implementing regulations may well be subject to legal challenge by interested industry groups (for instance, on the ground that the new law constitutes a legislated breach of preexisting contracts). This would leave manufacturers to navigate compliance obligations while the statute's legality remains in question.

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