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October 26, 2010

The Honorable Carl Levin
Chairman
The Honorable John McCain
Ranking Member
Committee on Armed Services
United States Senate

The Honorable Ike Skelton
Chairman
The Honorable Howard P. "Buck" McKeon
Ranking Member
Committee on Armed Services
House of Representatives

Subject: *Department of Defense, Office of the Secretary: Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Defense (DOD), Office of the Secretary, entitled "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals" (RIN: 0720-AB45). We received the rule on October 15, 2010. It was published in the *Federal Register* as a final rule on October 15, 2010, with an effective date of December 27, 2010. 75 Fed. Reg. 63,383.

The final rule implements section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA–08) which states that with respect to any prescription filled on or after the date of enactment, the TRICARE Retail Pharmacy Program shall be treated as an element of DOD for purposes of procurement of drugs by federal agencies under 38 U.S.C. § 8126, to the extent necessary to ensure pharmaceuticals paid for by DOD that are provided by network retail pharmacies to TRICARE beneficiaries are subject to Federal Ceiling Prices (FCPs). Section 8126 established FCPs for covered drugs (requiring a minimum 24 percent discount) procured by DOD and three other agencies from manufacturers. The NDAA required implementing regulations.

DOD issued a final rule on March 17, 2009, implementing the law. Ruling on a litigation challenge, on November 30, 2009, the U.S. District Court for the District of Columbia remanded the final rule to DOD (without vacating the rule) for DOD to reconsider the implementation of the statute and to consider in its discretion whether to readopt the current iteration of the rule or adopt another approach. This final rule is the product of that reconsideration. DOD is readopting the 2009 final rule, with some revision.

Enclosed is our assessment of DOD's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that DOD complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Patricia Toppings
OSD Federal Register Liaison Officer
Department of Defense

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF DEFENSE,
OFFICE OF THE SECRETARY
ENTITLED
"CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE
UNIFORMED SERVICES (CHAMPUS)/TRICARE:
INCLUSION OF TRICARE RETAIL PHARMACY PROGRAM
IN FEDERAL PROCUREMENT OF PHARMACEUTICALS"
(RIN: 0720-AB45)

(i) Cost-benefit analysis

DOD referenced a Government Accountability Office report, "DOD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies," April 2008 (GAO–08–327), which found that DOD's drug spending "more than tripled from $1.6 billion in fiscal year 2000 to $6.2 billion in fiscal year 2006" and that retail pharmacy spending "drove most of this increase, rising almost nine-fold from $455 million to $3.9 billion and growing from 29 percent of overall drug spending to 63 percent." DOD concurs in these findings and notes that the principal economic impact of this final rule is to moderate somewhat the rate of growth in spending in the retail pharmacy component of the program.

At various times since the enactment of NDAA–08, DOD estimated the reduced spending associated with applying FCPs to the Retail Pharmacy Network. DOD funds the Military Health System through two separate mechanisms. One is the Defense Health Program (DHP) appropriation, which pays for health care for all beneficiaries except those who are also eligible for Medicare. DOD-funded health care for DOD beneficiaries who are also eligible for Medicare is paid for by way of an accrual fund called the Medicare-Eligible Retiree Health Care Fund (MERHCF) under 10 U.S.C. chapter 56. Funds are paid into the MERHCF from military personnel appropriations and the general U.S. treasury. At the time of the 2008 proposed rule, for example, DOD estimated Fiscal Years (FY) 10 reduced spending of $388 million for the DHP and $404 for the MERHCF. At the time of the 2009 final rule, DOD used a different estimating model and estimated much larger savings, including for FY–10 for example, reduced spending of $761 million for the DHP and $910 for the MERHCF. Based on experience since issuance of the final rule and a refined estimating model, DOD now estimates that the reduced spending will be closer to the original, lower estimates. DOD's current estimated cost reductions from applying FCPs to the TRICARE Retail Pharmacy Network in Fiscal Years 2010 through 2015 ranges from $375 to $560 for DHP reduced spending and $474 to $707 for MERHCF reduced spending. FCP savings estimates will continue to be updated as actual refunds are received and estimating methodologies are refined. As a frame

of reference, total TRICARE Pharmacy Benefits Program spending is estimated to be $8.5 billion in FY 2010.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

DOD does not anticipate that this regulation will result in changes that would impact small entities, including retail pharmacies, whose reimbursements are not affected by the final rule. In addition, DOD explains that drugs newly subject to implementation of FCPs under the final rule represent less than 2 percent of manufacturers' prescription drug sales. Therefore, DOD believes that this final rule is not expected to result in significant impacts on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

DOD states that the final rule does not contain a federal mandate that may result in the expenditure by state, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

The final regulations were issued using the notice and comment procedures found at 5 U.S.C. § 553. DOD issued a proposed rule July 25, 2008 (73 Fed. Reg. 43,394) and a final rule March 17, 2009 (74 Fed. Reg. 11,279). Among other things, the preamble to the final rule stated that DOD interpreted the statute as automatically capping the price manufacturers may get paid for those covered drugs that enter into the commercial chain of transactions that end up as TRICARE-paid retail prescriptions, resulting in the conclusion that the amount above the FCP was an overpayment by DOD, which in turn required a refund of the overpayment. Ruling on a litigation challenge to the final rule in a case called *Coalition for Common Sense in Government Procurement* v. *U.S.,* the U.S. District Court for the District of Columbia decided on November 30, 2009, that although 10 U.S.C. § 1074g(f) requires that FCPs shall apply, the statute does not specify *how* they will apply. The Court ruled that DOD incorrectly interpreted the statute as requiring manufacturer refunds, to the exclusion of other possible approaches, and ordered DOD to reconsider the implementation of the statute as a function of its discretionary judgment, rather than only as a legal interpretation. The Court also ruled that while DOD considers whether to readopt the final rule as it currently stands or to change it, the final rule and the manufacturer agreements will remain in effect. Finally, the Court held that DOD correctly interpreted the statute as applying FCPs to all prescriptions filled on or after January 28, 2008. To help DOD carry out the reconsideration ordered by the Court, on February 8, 2010, DOD published a notice in the *Federal Register* inviting

additional public comments on the 2009 final rule, as well as additional comments regarding any other appropriate and legally permissible implementation approach. DOD received eleven public comments.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

DOD states that the final rule contains information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501-3511), which have been approved with OMB Control Number 0720-0032.

Statutory authorization for the rule

DOD states that the authority citations for the rule are 3 U.S.C. § 301 and 10 U.S.C. chapter 55.

Executive Order No. 12,866 (Regulatory Planning and Review)

DOD has examined the economic, legal, and policy implications of this final rule and has concluded that it is an economically significant regulatory action under section 3(f)(1) of the executive order.

Executive Order No. 13,132 (Federalism)

DOD states that the final rule does not have substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications as set forth in the Order.