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April 3, 2009

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

The Honorable Ike Skelton
Chairman
The Honorable John M. McHugh
Ranking Minority 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-AB22). We received the rule on March 19, 2009. It was published in the *Federal Register* as a final rule on March 17, 2009. 74 Fed. Reg. 11,279.

The final rule implements section 703 of the National Defense Authorization Act for Fiscal Year 2008, and provides 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 the procurement of drugs by federal agencies under section 8126 of title 38, United States Code. The rule seeks to ensure that pharmaceuticals paid for by DoD that are provided by network retail pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in section 8126. The final rule is effective on May 26, 2009.

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-AB22)

(i) Cost-benefit analysis

According to DoD, the economic impact of applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network as this rule does takes the form of reducing the prices of drugs paid for by DoD in the retail pharmacy component of the TRICARE Pharmacy Benefits Program, making them comparable to the prices paid by DoD in the Military Treatment Facility and Mail Order Pharmacy components of the program. DoD ultimately determined that applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network will reduce DoD spending on pharmaceuticals by more than $100 million per year.

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

DoD concluded that the final rule will not have a significant impact on a substantial number of small entities. DoD noted that drugs newly subject to implementation of Federal Ceiling Prices under the final rule represent less than 2 percent of manufacturers' prescription drug sales.

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

DoD concluded that the final rule does not contain a federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year. The economic impact of this rule is in the form of reduced federal expenditures.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. § 553. DoD published a Notice of Proposed Rulemaking in the *Federal Register* on July 25, 2008. 73 Fed. Reg. 4339. DoD received 16 public comments, most of which were from or on behalf of the pharmaceutical industry. DoD responds to the comments in the final rule.

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

The final rule contains information collection requirements subject to the Act. This information collection has been approved by the Office of Management and Budget (OMB) and assigned OMB Control Number 0720-0032.

Statutory authorization for the rule

The final rule implements section 703 of the National Defense Authorization Act for Fiscal Year 2008 (Pub. L. No. 110-181, 122 Stat. 3, 188 (2008)), which enacted 10 U.S.C. § 1074g(f).

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

DoD determined that the final rule was an economically significant regulatory action under the Executive Order.

Executive Order No. 13,132 (Federalism)

DoD concluded 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. DoD therefore concluded that the final rule does not have federalism implications.