

effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

#### *National Environmental Policy Act*

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

#### *Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### *Regulatory Flexibility Act*

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

#### *Small Business Regulatory Enforcement Fairness Act*

This rule is not a major rule under 5 U.S.C. 804(2), of the Small Business Regulatory Enforcement Fairness Act. This rule:

- a. Does not have an annual effect on the economy of \$100 million.
- b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

#### *Unfunded Mandates*

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

#### **List of Subjects in 30 CFR Part 950**

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 28, 2009.

**James F. Fulton,**

*Acting Regional Director, Western Region.*

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**BILLING CODE 4310-05-P**

## **DEPARTMENT OF DEFENSE**

### **Office of the Secretary**

[DoD-2008-HA-0029; 0720-AB22]

### **32 CFR Part 199**

#### **Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals**

**AGENCY:** Office of the Secretary, Department of Defense.

**ACTION:** Reconsideration and request for comments.

**SUMMARY:** This is notification of an additional opportunity to comment on the final rule of March 17, 2009, implementing provisions of section 703 of the National Defense Authorization Act (NDAA) for Fiscal Year 2008. This statute extended pharmaceutical Federal Ceiling Prices (FCPs) to TRICARE Retail Pharmacy Program prescriptions. The Department of Defense (DoD) issued a final rule on March 17, 2009, implementing the law. On November 30, 2009, the U.S. District Court for the District of Columbia "ordered that the final rule is remanded without vacatur for the Defense Department to consider in its discretion whether to readopt the current iteration of the rule or adopt another approach to implement 10 U.S.C. 1074g(f)." As part of DoD's reconsideration, DoD solicits public comments on the implementation of the statute, DoD's resulting regulations, and the matters addressed for DoD's consideration in the Court's Memorandum Opinion.

**DATES:** Written comments received at the address indicated below by March 11, 2010 will be considered and addressed in the final rule.

**ADDRESSES:** You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

Follow the instructions for submitting comments.

- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

*Instructions:* All submissions received must include the agency name and docket number or RIN for this FR document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Rear Admiral Thomas McGinnis, Chief, Pharmacy Operations Directorate, TRICARE Management Activity, telephone (703) 681-2890.

#### **SUPPLEMENTARY INFORMATION:**

##### **A. Background**

Section 703 of NDAA-08 enacted 10 U.S.C. 1074g(f). It provides that with respect to any prescription filled on or after the date of enactment (January 28, 2008), the TRICARE Retail Pharmacy Program shall be treated as an element of DoD for purposes of the 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 FCPs. This 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 proposed rule July 25, 2008 (73 FR 43394-97). It featured voluntary agreements with manufacturers, tied to preferred Uniform Formulary status, to pay DoD refunds for drugs entered into the normal commercial chain of transactions that end up as prescriptions given to TRICARE beneficiaries and paid for by DoD, the refund amount being the portion of the price of the drug sold by the manufacturer that exceeds the FCPs. The proposed rule also

solicited comment regarding any other appropriate and legally permissible implementation approach.

DoD issued a final rule March 17, 2009 (74 FR 11279–93), which was similar to the proposed rule. The preamble to the final rule discussed DoD's effort, particularly in the use of voluntary agreements tied to formulary status, to find "common ground" with the drug industry, which opposes FCPs. The preamble also stated that DoD interpreted the statute as automatically capping the price manufacturers may charge for those drugs that enter into the commercial chain of transactions that end up as TRICARE-paid 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. After the final rule became effective, May 26, 2009, drug companies signed voluntary agreements covering approximately 99 percent of TRICARE retail prescriptions.

However, at the same time, there was a litigation challenge to the validity of the final rule in a case called *Coalition for Common Sense in Government Procurement v. U.S.*, U.S. District Court for the District of Columbia, Civ. No. 08–996 (JDB), 2009 U.S. Dist. LEXIS 110746. The Court issued a decision November 30, 2009. This decision had four major points:

- Although 10 U.S.C. 1074g(f) requires that FCPs shall apply, the statute does not specify *how* they will apply. DoD incorrectly interpreted the statute as *requiring* manufacturer refunds, to the exclusion of other possible approaches. DoD must reconsider the implementation of the statute as a function of its discretionary judgment, rather than only as a legal interpretation. For example, DoD should exercise its discretion to consider "which of the five parties that participate in the retail pharmacy program—manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries—must bear any costs associated with imposing the Federal Ceiling Prices."

- While DoD considers whether to readopt the final rule as it currently stands or to change it, the final rule will remain in effect, as will the manufacturer agreements that cover approximately 99 percent of TRICARE retail prescriptions. (This is the effect of the Court's Order that the final rule is "remanded without vacatur.")

- DoD correctly interpreted the statute as applying FCPs to all prescriptions filled on or after January 28, 2008.

- The Court ordered that DoD file a status report with the Court by not later than March 1, 2010, "documenting its consideration on remand."

#### B. Invitation of Additional Public Comments

Although the Court did not specifically require more public comments, DoD invites public comments on the final rule issued March 17, 2009, as well as additional comments regarding any other appropriate and legally permissible implementation approach. DoD recommends that interested parties focus their comments on those matters that the Court addressed as requiring DoD reconsideration on the remand of the final rule. In considering alternative approaches, DoD intends to use at least the following three criteria (and welcomes comment on other suggested criteria): (1) Harmony with the statute and legislative history; (2) consistency with best business practice; and (3) practicability of administration. In addition to the citations noted above, to assist interested parties, the final rule and the Court's Order and Memorandum Opinion are posted on the TRICARE Pharmacy Program Web site at: [http://www.tricare.mil/pharm\\_mfg/default.cfm](http://www.tricare.mil/pharm_mfg/default.cfm).

Dated: February 3, 2010.

**Patricia L. Toppings,**  
OSD Federal Register Liaison Officer,  
Department of Defense.

[FR Doc. 2010–2666 Filed 2–8–10; 8:45 am]

BILLING CODE 5001–06–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R03–OAR–2009–0706; FRL–9111–6]

#### Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Removal of NO<sub>x</sub> SIP Call Rules

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of West Virginia that removes West Virginia's nitrogen oxides (NO<sub>x</sub>) SIP Call rules. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse

comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received in writing by March 11, 2010.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA–R03–OAR–2009–0706 by one of the following methods:

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:*  
[fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov).

C. *Mail:* EPA–R03–OAR–2009–0706, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA–R03–OAR–2009–0706. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your