HTSUS	Tariff shift and/or other requirements
	(2) If the good does not consist of two or more component parts, a change to heading 6210 through 6211 from any heading outside that group, except from heading 5007, 5111 through 5113, 5208 through 5212, 5309 through 5311, 5407 through 5408, 5512 through 5516, 5602 through 5603, 5801 through 5806, 5809 through 5811, 5903, 5906 through 5907, 6001 through 6006, and 6217, and subheading 6307.90, and provided that the change is the result of a fabric-making process.
6212	(1) If the good is not knit to shape and consists of two or more component parts, a change to an assembled good of heading 6212 from unassembled components, provided that the change is the result of the good being wholly assembled in a single country, territory, or insular possession. (2) If the good is not knit to shape and does not consist of two or more component parts, a change to heading 6212 from any other heading, except from heading 5007, 5111 through 5113, 5208 through 5212, 5309 through 5311, 5407 through 5408, 5512 through 5516, 5602 through 5603, 5801 through 5806, 5809 through 5811, 5903, 5906 through 5907, 6001 through 6006, and 6217, and subheading 6307.90, and provided that the change is the result of a fabric-making process. (3) If the good is knit to shape, a change to heading 6212 from any other heading, provided that the knit to shape components are knit in a single country, territory, or insular possession.
* * * * * * *	

PART 134—COUNTRY OF ORIGIN MARKING

22. The authority citation for part 134 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1304, 1624.

23. Section 134.1 is amended by revising paragraphs (b), (d)(1) and (d)(2) to read as follows:

§ 134.1 Definitions.

* * * * *

(b) *Country of origin.* ''Country of origin'' means the country of manufacture, production, or growth of any article of foreign origin entering the United States as determined under §§ 102.1 through 102.21 of this chapter.

* * * * *

(d) * * *

(1) If an imported article will be further processed in the United States, the processor will be the ''ultimate purchaser'' if the country of origin of the processed good is determined to be the United States under §§ 102.1 through 102.21 of this chapter.

(2) If the country of origin of the processed good is not determined to be the United States under §§ 102.1 through 102.21 of this chapter, the consumer or user of the article, who obtains the article after the processing, will be regarded as the ''ultimate purchaser.''

* * * * *

24. Section 134.35 is revised to read as follows:

§ 134.35 Articles effecting a change in country of origin.

If an imported article will be used in further processing in the United States, the processor will be considered the ultimate purchaser if the processed good is determined to be a good of the United States under §§ 102.1 through 102.21 of this chapter. In such a case, the imported article is excepted from individual marking pursuant to 19 U.S.C. 1304(a)(3)(D) and § 134.32(d) of this part, provided the outermost container in which it is imported will reasonably indicate the country of origin of the article to the ultimate purchaser.

PART 177–ADMINISTRATIVE RULINGS

25. The authority citation for part 177 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1502, 1624, 1625.

26. Section 177.22 is amended by revising paragraph (a) to read as follows:

§ 177.22 Definitions.

(a) *Country of origin.* (1) For purposes of this subpart, an article is a product of a country or instrumentality only if:

(i) It is wholly the growth, product, or manufacture of that country or instrumentality; or

(ii) In the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce.

(2) The term ''instrumentality'' will not be construed to include any agency or division of the government of a country, but may be construed to include such arrangements as the European Economic Community. For purposes of this section, the expression ''wholly the growth, product, or manufacture'' refers to articles wholly obtained or produced within the meaning of § 102.1(g) of this chapter, and a substantial transformation into a ''new and different article of commerce'' occurs when the country of origin of an article which is produced in a country or instrumentality from foreign materials is determined to be that country or instrumentality under §§ 102.1 through 102.21 of this chapter.

* * * * *

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

Approved: July 21, 2008.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E8–17025 Filed 7–24–08; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD–2008–HA–0029; 0720–AB22]

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 (DoD).

ACTION: Proposed rule.

SUMMARY: Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA–08) states with respect to any prescription filled on or after the date of enactment of the NDAA, the TRICARE retail pharmacy program (TRRx) shall be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.), to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by network retail pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in such section 8126. NDAA–08 was enacted on January 28, 2008. The statute requires implementing regulations. This

proposed rule is to implement section 703 of the NDAA 2008.

DATES: Written comments received at the address indicated below by September 23, 2008 will be considered and addressed in the final rule.

ADDRESSES: You may submit comments, identified by docket number and/or 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 Regulatory Information Number (RIN) for this **Federal Register** 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: Captain William Blanche, TRICARE Management Activity, telephone (703) 681–2890.

SUPPLEMENTARY INFORMATION:

A. Background

Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA–08) (Pub. L. 110–181) enacted 10 U.S.C. 1074g(f). It provides that with respect to any prescription filled on or after the date of enactment of the NDAA, the TRRx shall be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.), to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by network retail pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in such section 8126. NDAA–08 was enacted on January 28, 2008. The statute requires implementing regulations.

The Veterans Health Care Act (VHCA) of 1992, codified at 38 U.S.C. 8126, established Federal Ceiling Prices (FCPs) of covered pharmaceuticals (requiring a minimum 24% discount off non-Federal average manufacturing prices—''non-FAMP'') procured by the four designated agencies covered in the Act: Department of Veterans Affairs (VA), DoD, Coast Guard, and the Public Health Service/Indian Health Service. The non-FAMP is the average price paid to the manufacturer by wholesalers (or, if there are insufficient wholesale sales, others who purchase directly from the manufacturer) for drugs distributed to non-federal purchasers, taking into account any cash discounts or similar reductions given to those purchasers. The VA administers the VHCA discount program on behalf of the four specified agencies. The DoD consulted closely with the VA in the development of this proposed rule.

The TRICARE Pharmacy Benefits Program operates under the authority of 10 U.S.C. 1074g. It provides outpatient drugs to TRICARE beneficiaries through Military Treatment Facility (MTF) pharmacies, the TRICARE mail order pharmacy program (TMOP), and a TRRx consisting of TRICARE Retail Pharmacy Network and retail non-network pharmacies. As implemented, the new statutory requirement will only apply to pharmaceuticals paid for by DoD and provided to eligible beneficiaries through the TRICARE Retail Pharmacy Network.

The TRICARE Retail Pharmacy Network is managed under a single Pharmacy Benefits Manager contract, linked to the DoD Pharmacy Benefits Office, and enabled by a management information system to verify beneficiary eligibility, check for potential drug interactions, and authorize payment for the pharmaceuticals used to fill the beneficiary's prescription. The management information system also records data on all prescriptions filled through the Retail Pharmacy Network, permitting an accurate accounting of all retail network pharmaceuticals paid for by DoD under the TRICARE Pharmacy Benefits Program. Since the beginning of the FCP program, outpatient pharmaceuticals provided by DoD through MTF pharmacies have been subject to FCPs, as have those under the TMOP program since it began. Implementation of similar applicability to the TRICARE Retail Pharmacy Network component of the Program is the subject of this proposed regulation.

B. Provisions of the Rule

The proposed rule would add a new paragraph (q) to § 199.21. Paragraph (q)(1) repeats the new statutory requirement. Paragraph (q)(2) provides that an agreement by a manufacturer to honor the FCPs in the Retail Pharmacy Network component of the Pharmacy Benefits Program is a condition of inclusion of a drug on the uniform formulary. Further, it states that a drug not under such an agreement requires preauthorization to be provided through the Retail Pharmacy Network. In addition, it indicates that drugs covered by this requirement are TRICARE Retail Pharmacy Network provided drugs that are covered by the VA's FCP program, except any prescription for which the TRICARE Pharmacy Benefits Program is the second payer. While DoD proposes in this rulemaking to enter into voluntary agreements with manufacturers that would make prescriptions filled on or after the date of enactment of NDAA–08 subject to FCPs, the Department solicits comment regarding any other appropriate and legally permissible implementation approach and/or date from which to begin making prescriptions filled in the Retail Pharmacy Network subject to FCPs. DoD is specifically interested in the legal justification, including under section 703 of NDAA–08, for any alternative implementation approaches and/or dates that commenters may propose.

Paragraph (q)(3) establishes refund procedures to, in the words of the statute, ''ensure that pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards'' of the FCP program. The refund procedures will, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of submission by TMA to the manufacturer (initially expected to be on a quarterly basis) of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-FAMP (reported to VA) and the FCP or, in the discretion of the manufacturer, the difference between FCP and direct commercial contract sales prices specifically attributable to TRICARE paid pharmaceuticals, determined for each applicable National Drug Code (NDC) listing. Further, this paragraph of the rule provides that a refund due under the statute is subject to the overpayment recovery procedures of § 199.11 of the TRICARE regulation.

Finally, paragraph (q)(4) states that in the case of the failure of a manufacturer of a covered drug to make or honor an agreement to ensure that DoD pays no more than the FCP for covered drugs provided through the TRICARE Retail Pharmacy Network component of the program, the Director, TMA, in addition

to other actions referred to in the rule, may take any other action authorized by law.

C. Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review''

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of $100 million or more in any one year. The DoD has examined the economic, legal, and policy implications of this proposed rule and has concluded that it is an economically significant regulatory action under section 3(f)(1) of the EO. The economic impact of applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network is in 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.

A recent Government Accountability Office Report, ''DoD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies,'' April 2008 (GAO–08–327), 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. The principal economic impact of this proposed rule is to moderate somewhat the rate of growth in the retail pharmacy component of the program.

DoD has estimated the reduced spending associated applying Federal Ceiling Prices 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. DoD estimated cost reductions from applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network in Fiscal Years 2009 through 2011 are:

	Millions
FY–2009 DHP Reduced Spending	$352
FY–2009 MERHCF Reduced Spending	367
FY–2010 DHP Reduced Spending	388
FY–2010 MERHCF Reduced Spending	404
FY–2011 DHP Reduced Spending	427
FY–2011 MERHCF Reduced Spending	444

As a frame of reference, total TRICARE Pharmacy Benefits Program spending (incorporating these spending reductions) is estimated to be $8 billion in FY–2009, $8.4 billion in FY–2010, and $9.3 billion in FY–2011.

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This proposed rule is a major rule under the Congressional Review Act. As noted above, applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network will reduce DoD spending on pharmaceuticals by more than $100 million per year.

Sec. 202, Pub. L. 104–4, ''Unfunded Mandates Reform Act''

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribunal governments, in aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. 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 proposed rule. In addition, drugs newly subject to implementation of Federal Ceiling Prices under the proposed rule represent less than 2% of manufacturers' prescription drug sales. Therefore, this proposed rule is not expected to result in significant impacts on a substantial number of small entities.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This proposed rule contains information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3511). This consists of responding to the periodic TMA report of the TRICARE prescription utilization data needed to calculate the refund. This information collection has been approved with OMB Control Number 0720–0032. No person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

Executive Order 13132, ''Federalism''

This proposed rule does not have federalism implications, as set forth in Executive Order 13132. This 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.

Public Comments Invited

This is a proposed rule. DoD invites public comments on all of its provisions.

List of Subjects in 32 CFR Part 199

Claims, Health care, Health insurance, Military personnel, Pharmacy benefits.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.21 is amended by adding a new paragraph (q), to read as follows:

§ 199.21. Pharmacy Benefits Program.

* * * * *

(q) *Pricing standards for retail pharmacy program.*—(1) *Statutory requirement.*—As required by 10 U.S.C. 1074g(f), with respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the

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 the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

(2) *Manufacturer written agreement.* (i) A written agreement by a manufacturer to honor the pricing standards required by 10 U.S.C. 1074g(f) and referred to in paragraph (q)(1) of this section for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for:

(A) Inclusion of that drug on the uniform formulary under this section; and

(B) Availability of that drug through retail network pharmacies without preauthorization under paragraph (k) of this section.

(ii) A covered drug not under an agreement under paragraph (q)(2)(i) of this section requires preauthorization under paragraph (k) of this section to be provided through a retail network pharmacy under the Pharmacy Benefits Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug does not include:

(A) A drug that is not a covered drug under 38 U.S.C. 8126;

(B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);

(C) A drug that is not provided through a retail network pharmacy under this section;

(D) Any pharmaceutical for which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section; and

(E) Any other exception, consistent with law, established by the Director, TMA.

(3) *Refund procedures.* (i) The agreement referred to in paragraph (q)(2) of this section shall include refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing.

(iii) A refund due under this paragraph (q) is subject to § 199.11 of this part.

(4) *Remedies.* In the case of the failure of a manufacturer of a covered drug to make or honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

* * * * *

Dated: July 18, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–17024 Filed 7–24–08; 8:45 am]

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