Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs.

FDC date	State	City	Airport	FDC No.	Subject
02/20/09	SC	NEWBERRY	NEWBERRY COUNTY	9/6480	NDB RWY 22, AMDT 6.
02/23/09	MD	FREDERICK	FREDERICK MUNI	9/6582	ILS OR LOC RWY 23, AMDT 5B.
02/27/09	NY	BATAVIA	GENESEE COUNTY	9/7308	ILS OR LOC RWY 28, AMDT 6.
03/03/09	ID	CALDWELL	CALDWELL INDUSTRIAL	9/7641	NDB RWY 30, AMDT 1.
03/03/09	ID	CALDWELL	CALDWELL INDUSTRIAL	9/7642	RNAV (GPS) RWY 30, AMDT 1.
03/03/09	ID	CALDWELL	CALDWELL INDUSTRIAL	9/7643	RNAV (GPS) RWY 12, AMDT 1.
03/03/09	CA	MODESTO	MODESTO CITY-CO-HARRY SHAM FLD.	9/7694	ILS OR LOC/DME RWY 28R, AMDT 14.
03/03/09	KS	WICHITA	BEECH FACTORY	9/7696	VOR/DME RNAV RWY 36, ORIG.
03/03/09	KS	WICHITA	BEECH FACTORY	9/7697	VOR/DME RNAV RWY 18, ORIG.

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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: Final 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 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 final rule is to implement section 703 of the NDAA–08.

DATES: *Effective Date:* This final rule is effective May 26, 2009.

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 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 TRICARE Retail Pharmacy Program 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 final rule and also, consistent with 10 U.S.C. 1073, consulted with the Departments of Health and Human Services and Homeland Security.

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 TRICARE Retail Pharmacy program 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. There are approximately 60,000 retail pharmacies in the Retail Pharmacy Network. Section 1074g requires DoD to establish a Uniform Formulary of pharmaceutical agents, selected based on clinical and cost effectiveness, as evaluated by the DoD Pharmacy and Therapeutics (P&T) Committee, reviewed by the Beneficiary Advisory Panel, and decided by the Director, TRICARE Management Activity (TMA). The Uniform Formulary has three tiers: Tier 1 contains generic drugs; Tier 2 brand name Uniform Formulary drugs; and Tier 3 non-Formulary drugs. Drugs in all three tiers are covered by the TRICARE Pharmacy Benefits Program, but cost sharing and other program differences encourage the use of generic drugs and Uniform Formulary brand name drugs.

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 Federal Ceiling Price 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 final regulation.

B. Provisions of the Proposed Rule

The proposed rule, published for public comment July 25, 2008, proposed to add a new paragraph (q) to 32 CFR 199.21. Paragraph (q)(1) repeated the new statutory requirement. Paragraph (q)(2) provided 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 stated that a drug not under such an agreement would require preauthorization to be provided through the Retail Pharmacy Network. In addition, it indicated 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 proposed 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 solicited 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 was 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.

Proposed paragraph (q)(3) established 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 proposed rule provided that a refund due under the statute is subject to the overpayment recovery procedures of § 199.11 of the TRICARE regulation.

Finally, proposed paragraph (q)(4) stated 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. Public Comments

The proposed rule was published in the **Federal Register** July 25, 2008, for a 60-day comment period. DoD received 16 public comments. Most of these were from or on behalf of the pharmaceutical industry. Several were from or on behalf of the retail pharmacy sector. Significant comments are discussed below.

1. Statutory Requirement (Paragraph (q)(1))

a. Statutory Interpretation

Comments: A number of comments by or on behalf of the pharmaceutical industry expressed the view that 10 U.S.C. 1074g(f), which was added by section 703(a) of NDAA–08, does not require that prescriptions filled in the TRICARE Retail Pharmacy Network are subject to Federal Ceiling Prices. Rather, they say, it authorizes DoD to use procedures of the TRICARE Pharmacy Benefits Program to encourage drug manufacturers to enter into agreements to apply FCPs to Retail Pharmacy Network prescriptions. Some commenters said the statute only establishes a general ''goal'' of applying FCPs and that the references in the preamble to the proposed rule to voluntary agreements with manufacturers should be taken to signal that the statute has no effect absent a manufacturer's agreement. On the other hand, commenters representing retail pharmacies strongly supported the interpretation that FCPs now apply equally in all three TRICARE Pharmacy Benefits Program venues.

Response: DoD does not agree with the interpretation of the statute recommended by the pharmaceutical industry representatives. 10 U.S.C 1074g(f) provides:

> (f) *Procurement of pharmaceuticals by TRICARE retail pharmacy program.* 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 Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary 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 such section 8126.

Setting aside the start date issue, which will be discussed below, DoD interprets the statute as follows. First, DoD interprets the phrase, ''the pricing standards in such section 8126'' to mean Federal Ceiling Prices. This is based on the text of 38 U.S.C. 8126(a) and (b), which provide that ''[e]ach manufacturer of covered drugs shall enter into a master agreement with the Secretary [of Veterans Affairs] under which'' ''with respect to each covered drug of the manufacturer procured by'' the Department of Veterans Affairs, the Department of Defense, the Public Health Service, or the Coast Guard, ''that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered into and has in effect a pharmaceutical pricing agreement with the Secretary * * * under which the price charged * * * may not exceed 76 percent of the non-Federal average manufacturer price.'' The end result of the pricing calculations required by section 8126 is referred to as the Federal Ceiling Price.

Second, DoD interprets the phrase ''treated as an element of the Department of Defense for purposes of

the procurement of drugs by Federal agencies under section 8126'' to mean treated the same as a covered drug directly procured by DoD. The phrase does not require that the retail pharmacy actually was involved in a procurement by a Federal agency under section 8126 or that the retail pharmacy was acting as an agent of a Federal agency. An interpretation that would require such an actual procurement by DoD is unsupportable because the words ''shall be treated as'' would be rendered meaningless, as would the entire section since any such actual procurement was undisputedly already covered within section 8126. In addition, DoD interprets this phrase as precluding an interpretation of the statute that would apply FCPs to what the retail pharmacy may be paid by DoD. In referring to the procurement of drugs by Federal agencies under section 8126, the statute is addressing manufacturers' prices, which are the focus of section 8126. Retail pharmacies are specifically excluded from the definition of ''manufacturer'' in 38 U.S.C. 8126(h)(4).

Third, DoD interprets the phrase ''pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section'' to mean pharmaceuticals paid for through the TRICARE Retail Pharmacy Program. More specifically, DoD interprets the provision as limited to the TRICARE Retail Pharmacy Network because prescriptions filled by non-network retail pharmacies are not subject to the pre-screening and authorization process incorporated into the information systems referred to in 10 U.S.C. 1074g and relied upon by DoD to document DoD payment for the specific prescriptions covered and because of legislative history on this point, specifically, a Conference Report statement (discussed below).

Fourth, DoD interprets ''any prescription filled'' to mean all prescriptions filled, regardless of whether the drugs are on the TRICARE Uniform Formulary or are non-formulary drugs. Provisions of the rule making a manufacturer's agreement to honor Federal Ceiling Prices in the Retail Pharmacy Network a condition for Uniform Formulary status in no way suggests that the statutory provision has such a limited scope.

Taken together, DoD interprets 10 U.S.C. 1074g(f) to mean that all TRICARE Retail Pharmacy Network prescriptions shall be treated the same as drugs procured directly by DoD for purposes of the Federal Ceiling Price program to the extent necessary to ensure that pharmaceuticals provided under those prescriptions are subject to Federal Ceiling Prices. Stated even more simply, DoD interprets 10 U.S.C. 1074g(f) to mean that all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices.

This interpretation is almost a verbatim restatement of the primary statement of legislative history concerning 10 U.S.C. 1074g(f). The Conference Report accompanying the legislation described it as a provision ''that would require that any prescription filled * * * through the TRICARE retail pharmacy network will be covered by the federal pricing limits applicable to covered drugs under section 8126 of title 38, United States Code.'' H. Conf. Rept. 110–477, p. 938. This simplified restatement of the statutory requirement has been added to paragraph (q)(1).

Comment: Some commenters representing the pharmaceutical industry recommended that instead of establishing regulatory requirements for benchmark pricing, DoD should pursue voluntary negotiations with manufacturers to reduce costs. Some commenters said that applying Federal Ceiling Prices in the Retail Pharmacy Program would hurt millions of other Americans because drug companies will raise prices to make up their reduced profits from DoD sales, and that retail refunds will cause DoD to push patients to retail pharmacies where their co-payments are higher. On the other hand, comments from the retail pharmacy sector expressed approval for equalizing ingredient costs across all TRICARE Pharmacy Benefits Program venues.

Response: While there are many policy arguments for and against various potential strategies for reducing the dramatically increasing costs of the TRICARE Pharmacy Program, the issue in this rule making is implementing the statutory requirement of section 703, under which all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. DoD will continue voluntary negotiations concerning prices, but does not have the authority to agree to prices above Federal Ceiling Prices. It may be noteworthy that over the past 20 years, Congress has enacted and DoD has implemented through regulations (32 CFR 199.14) a long series of payment reforms for TRICARE, including payment limits for acute care hospitals, psychiatric hospitals, hospital outpatient services, partial hospitalization programs, substance abuse treatment programs, ambulatory surgery centers, skilled nursing facilities, residential treatment centers, hospice programs, home health agencies, physicians and other individual health care professionals, durable medical equipment, and military treatment facility and mail order program pharmaceuticals. The last significant segment of the TRICARE program to be covered by payment reform is the $4.5 Billion Retail Pharmacy Network program.

b. Relationship Between 10 U.S.C. 1074g(f) and the Master Agreements Under 38 U.S.C. 8126

Comment: A number of comments from or on behalf of the pharmaceutical industry expressed the view that section 1074g(f) has no relationship to the VA Master Agreements under 38 U.S.C. 8126 and that therefore the final rule would also have no relationship. Some of these commenters also stated that under section 8126(g), their Master Agreement rights and obligations were frozen as of November 4, 1992, and cannot be enlarged by any subsequent enactment, including 10 U.S.C. 1074g(f).

Response: DoD does not agree with this opinion, but has endeavored to construct a rule that could stand on common ground between the view that the Master Agreements encompass the TRICARE Retail Pharmacy Network and the view that they utterly do not. This disagreement has some history. As noted above, section 8126 includes ''depot contracting systems'' within the scope of Federal Ceiling Price coverage. The term ''depot'' is defined in section 8126(h)(3) to include ''a centralized commodity management system through which covered drugs procured by an agency'' are ''delivered directly from the commercial source to the entity using such covered drugs.'' Pharmacy Benefits Program reforms adopted by DoD in response to 10 U.S.C. 1074g included restructured management of the Retail Pharmacy Program, including the establishment of a Retail Pharmacy Network of pharmacies linked to DoD through the Pharmacy Data Transaction Service required by section 1074g(e). This led to: A 2002 determination by the Secretary of Veterans Affairs that the restructuring, when completed, would make drugs provided by the Retail Pharmacy Network subject to Federal Ceiling Prices; a 2004 Dear Manufacturer letter from the Department of Veterans Affairs requiring manufacturers to refund to DoD costs above the FCPs; and a legal challenge in a case called *Coalition for Common Sense in Government Procurement* v. *Secretary of Veterans Affairs*, 464 F. 3d 1306 (Fed.Cir. 2006). In that case, the Federal Circuit Court of

Appeals set aside the VA's action on the grounds that it should have been taken through notice and comment rulemaking; the Court did not reach the merits of the Secretary's interpretation of the ''depot'' definition as covering the TRICARE Retail Pharmacy Network.

Fifteen days after the Court decision, the Conference Report on the National Defense Authorization Act for Fiscal Year 2007 (NDAA–07) explained that the House-Senate Conference Committee considered but did not adopt a Senate-passed provision, which was quite similar to section 703 of NDAA–08, to ''clarify'' the underlying issue of the Secretary's interpretation of section 8126: ''The conferees concluded that there is no need for additional legislation at this time because prescriptions dispensed by the Department of Defense Retail Pharmacy Program qualify for discounted prices under section 8126.'' H. Conf. Rept. 109–702, p. 772. In other words, the conferees on NDAA–07 agreed with the determination of the Secretary of Veterans Affairs. It is a reasonable inference that the comparable conferees for NDAA–08, in again considering a Senate-passed provision, decided to enact into law an affirmation of the determination of the Secretary of Veterans Affairs and the full Congress agreed.

With respect to the section 8126(g) argument, DoD understands the VA view to be that section 8126 already encompassed coverage of a depot contracting system such as the TRICARE Retail Pharmacy Network program, and that therefore it is not limited by section 8126(g), and DoD agrees with that view. Thus, there is a basis to conclude that Congress affirmed the determination of the Secretary of Veterans Affairs that the TRICARE Retail Pharmacy Network program was already covered by 38 U.S.C. 8126, and required that determination to be implemented as of the date of enactment of NDAA–08. This issue, however, remains a matter of controversy. The determination of the Secretary of Veterans Affairs, with which DoD has always strongly agreed, has never been withdrawn, nor has it been further acted upon, and there was no judicial resolution.

Based on this history, DoD decided to propose a rule that would allow the agencies and pharmaceutical companies to ''agree to disagree'' on that issue and seek common ground on a regulation centered on incentives within the TRICARE Pharmacy Benefits Program and encouraging voluntary, separate agreements between manufacturers and DoD, independent of the Master Agreements, under which manufacturers would agree to make TRICARE Retail Pharmacy Network prescriptions subject to Federal Ceiling Prices. That DoD considers these to be voluntary agreements does not indicate that DoD believes there is no legal obligation in the background. It means that, as with most laws, voluntary action consistent with the law is far preferable to reliance on enforcement action. It also means that, if there is voluntary agreement, whatever uncertainties there are about the existence or scope of potential enforcement actions can be set aside as moot. DoD contacts with pharmaceutical companies led DoD to believe that most companies might find this approach acceptable. Therefore, both the proposed and final rule focus primarily on DoD program elements and DoD market share for implementing the requirement that covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. The only reference in the rule to any matter outside the scope of the TRICARE program is the reservation by DoD of rights to pursue as a remedy (paragraph (q)(4)) ''any other action authorized by law.'' The scope of any such other actions is a matter that need not and, because it potentially involves agencies other than DoD, cannot be settled in this rule making.

c. Relationship Between the FCP Statutory Requirement and Other Statutory Requirements of 10 U.S.C. 1074g

Comment: Several commenters addressed the relationship between the new subsection (f) of section 1074g, which established the requirement that covered Retail Pharmacy Network prescriptions shall be subject to FCPs, and other provisions of the statute, such as the requirement (in subsection (a)(2)(A)) that the Uniform Formulary shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes and the requirement (in subsection (a)(2)(D)) that no pharmaceutical agent may be excluded from the Uniform Formulary except upon the recommendation of the Pharmacy and Therapeutics Committee. Some commenters argued that there are limitations on the applicability of FCPs. Several comments from representatives of retail pharmacies expressed agreement with the policy of the statute and the proposed rule in making Retail Pharmacy Network prescriptions subject to FCPs, noting that this would equalize ingredient prices between retail pharmacies and the TRICARE Mail Order Pharmacy program, and thus eliminate any need for TRICARE policies that encourage use of TMOP over retail pharmacies. Another commenter noted a prior statute that referred to ''best business practices of the private sector'' and suggested this limited the applicability of Federal Ceiling Prices.

Response: DoD interprets the interaction of section 1074g(f) and these provisions of 1074g(a) to be that cost-effectiveness determinations of the P&T Committee are now based on both a relative standard and a fixed standard. The relative standard is the cost-effectiveness of the drug relative to other drugs in the class. The fixed standard is that a drug cannot be considered cost effective if its price exceeds the maximum price allowed by law, the FCP. Thus, the P&T Committee will recommend Tier 3 (non-Formulary) status for any drug not covered by a manufacturer's agreement to honor FCPs for Retail Pharmacy Network prescriptions. However, there is a potential conflict with the requirement to ensure that all pharmacy classes are represented on the Uniform Formulary in the event that no drug in a class is covered by a manufacturer's agreement to honor FCPs. To deal with that possibility, even though remote, DoD has added a subparagraph to this part of the final rule to state that the requirement for Tier 2 status to be conditioned on a manufacturer's agreement to honor FCPs for Retail Pharmacy Network prescriptions may, upon the recommendation of the P&T Committee, be waived to ensure that at least one drug in the drug class is included on the Uniform Formulary (Tier 1 or Tier 2). It must be understood, however, that any such waiver does not waive the statutory requirement that Retail Network Pharmacy prescriptions are subject to FCPs, only the usual regulatory requirement of exclusion from the Uniform Formulary of drugs not covered by agreements.

Based on these interpretations of the statute, the TMA will ask manufacturers to sign agreements to honor FCPs in Retail Pharmacy Network prescriptions. On or soon after the effective date of the final rule, separate from the usual practice of individual drug class reviews of both clinical and cost effectiveness, the P&T Committee will determine whether drugs are or are not covered by such agreements. A drug that is on the Uniform Formulary and is covered by such an agreement will be continued on the Uniform Formulary for the time being, pending the next review of the drug class. A drug that is on the Uniform Formulary (Tier 2) but not covered by such an agreement will be recommended for Tier 3, subject to the requirement for maintaining

representation on Tiers 1 or 2 for all drug classes. A drug that is on Tier 3 that is covered by such an agreement will be subject to review at a later time to determine if it should be changed to Tier 2.

Regarding the issue of preserving incentives for use of TMOP, as permitted by 10 U.S.C. 1074g, copayment amounts are currently lower in TMOP than in retail pharmacies for the purpose of encouraging TMOP use. Possible future changes to this are outside the scope of this rule making process. With respect to the comment about the prior statute that referred to ''best business practices of the private sector,'' this reference was in section 703 of the National Defense Authorization Act for Fiscal Year 1999, Public Law 104–261. The reference was in the context of a requirement for DoD to submit a plan to Congress for redesign of the military pharmacy system. This predates the primary statute that now governs the TRICARE Pharmacy Benefits Program, 10 U.S.C. 1074g, as well as the 2008 amendment on Federal Ceiling Prices. Whatever might be associated with the general notion of best business practices of the private sector, it does not limit the applicability of the later enacted statutory specification that all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices.

d. Start Date for FCP Coverage of Prescriptions Filled

Comments: All commenters representing the pharmaceutical industry argued that the final rule should state that only prescriptions filled on or after the effective date of the final rule are subject to FCPs, and that prescriptions filled on or after the effective date of the statute (January 28, 2008) and prior to the effective date of the final rule should not be subject to FCPs. In support of this position, these commenters cited legal precedents generally disfavoring retroactive application of regulations unless there is very clear legal requirement for retroactive application, including *Bowen* v. *Georgetown Univ. Hosp.,* 488 U.S. 204, 208 (1988). They argued that the fact that the statute required regulations to be issued supports the view that implementation of the statute was conditioned on the regulations; the fact that they could not be issued instantaneously, as Congress seemed to expect, does not obviate the need for regulations before the statutory requirement could apply. They further argued that because 10 U.S.C. 1074g(f) does not expressly address refunds, a refund requirement can only be established by regulation and by a contract or agreement, which cannot be retroactive. Also in response to the request in the proposed rule for legal justification, including under section 703 of NDAA–08, for any alternative implementation dates commenters may propose, a number of commenters argued that the statutory phrase, ''[w]ith respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008,'' should be construed as precluding any applicability to prescriptions filled prior to that date, not as requiring applicability as of that date. On the other hand, comments from representatives of retail pharmacies strongly supported the provision of the proposed rule incorporating the statutory date of applicability of FCPs in the retail network of January 28, 2008.

Response: The legal standard applicable to a question regarding impermissible retroactivity of a regulation is well summarized in *National Mining Ass'n* v. *Dept. of Labor,* 292 F.3d 849, 859 (D.C. Cir. 2002):

> The general legal principles governing retroactivity are relatively easy to state, although not as easy to apply. An agency may not promulgate retroactive rules absent express congressional authority. *Bowen* v. *Georgetown Univ. Hosp.,* 488 U.S. 204, 208 (1988). A provision operates retroactively when it ''impairs rights a party possessed when he acted, increases a party's liability for past conduct, or imposes new duties with respect to transactions already completed.'' *Landgraf* v. *USI Film Prods.,* 511 U.S. 244, 280, (1994). In the administrative context, a rule is retroactive if it '''takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already past.''' *Nat'l Mining Ass'n* v. *United States Dep't of Interior,* 177 F.3d 1, 8 (D.C. Cir. 1999) (quoting *Ass'n of Accredited Cosmetology Sch.* v. *Alexander,* 979 F.2d 859, 864 (D.C. Cir. 1992)). The critical question is whether a challenged rule establishes an interpretation that ''changes the legal landscape.'' Id. (quoting *Health Ins. Ass'n of Am., Inc.* v. *Shalala,* 23 F.3d 412, 423 (D.C. Cir. 1994)).

The rule does not create any retroactive obligation on drug companies. Paragraph (q)(1) simply restates the statute. The statute applies according to its terms and the regulation cannot modify those terms. The major provision of the regulation that ''changes the legal landscape'' is paragraph (q)(2). It requires an agreement from manufacturers to honor the statute as a condition of DoD Uniform Formulary status and unrestricted availability through the TRICARE Retail Pharmacy Network. This paragraph is prospective; a refusal to agree will not affect a drug's formulary status prior to the effective date of the final rule. If a drug company does not want to maintain formulary status and refuses to sign an agreement to honor the statute, the regulation does not say anything that would affect the legal rights and obligations of the parties—i.e., ''change the legal landscape''—with respect to prescriptions filled between the dates of January 28, 2008, and the effective date of the final rule.

The question of ''retroactivity'' of the regulation should not be confused with the effective date of the statute. The statute commands that ''[w]ith respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008,'' which was 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 under'' 38 U.S.C. 8126 ''to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program * * * are subject to the pricing standards in such section 8126.'' The statute changed the legal landscape, and did so prospectively. The fact that the statute also requires implementing regulations does not mean that the statute has no legal effect until implementing regulations are issued. On the contrary, the statute by its express terms requires that all prescriptions filled on or after the date of enactment ''shall'' be treated so as to ''ensure'' that they are subject to Federal Ceiling Prices. The Conference Report accompanying the proposed legislation reinforces that express statutory requirement:

> Inclusion of TRICARE retail pharmacy program in federal procurement of pharmaceuticals (sec. 703)
>
> * * * * *
>
> The Senate amendment contained a provision (sec. 701) that would require that any prescription filled on or after October 1, 2007 through the TRICARE retail pharmacy network will be covered by the federal pricing limits applicable to covered drugs under section 8126 of title 38, United States Code.
>
> The House recedes with an amendment that would change the implementation date from October 1, 2007 to the date of enactment of this Act.

H. Conf. Rept. 110–477, p. 938. The date of enactment is clearly established as the ''implementation date'' of the statutory requirement. The fact that conforming regulatory modifications are also required by section 703(b) does not

alter the fact that the statutory command to apply Federal Ceiling Prices to all covered drugs in Retail Pharmacy Network prescriptions filled on or after January 28, 2008 applies according to its explicit terms.

Therefore, with respect to prescriptions filled on or after January 28, 2008, drug companies had a right to payment at the Federal Ceiling Price and no more. The transaction of pharmaceuticals moving from manufacturer to patient, if not completed through the filling of a prescription before January 28, became subject to a new obligation: the transaction ''shall be treated'' as a DoD purchase under 38 U.S.C. 8126 ''to the extent necessary to ensure'' that the Federal Ceiling Price applies. With respect to the applicability of FCPs. the rule does not change that legal landscape, nor does it add to or subtract from that obligation. Under the statute, with respect to any covered TRICARE Retail Pharmacy Network prescriptions filled on or after January 28, 2008, if a manufacturer received more than the Federal Ceiling Price, the transaction produced an overpayment and an overpayment requires a refund.

The fact of the overpayment is purely a function of the statutory effective date, and has nothing to do with the date the Department of Defense asks for the refund of the overpayment or of the Uniform Formulary status of the drug. Separate from mandating the applicability of Federal Ceiling Prices to all prescriptions filled on or after January 28, the statute also commanded the Secretary of Defense to ''modify the regulations under'' the TRICARE Pharmacy Benefits Program ''to implement the requirements of'' the new subsection 1074g(f). The rule, when it becomes effective, will implement the requirements through means including agreements between manufacturers and DoD. Those agreements will call on manufacturers to honor the statute. Honoring the statute includes refunding any overpayments that accrued on or after January 28. Nothing in the rule and nothing in the agreements will operate to change the legal landscape that was created, effective January 28, by the statute.

Concerning the argument that the ''with respect to any prescription filled on or after the date of the enactment'' clause of the statute should be construed as only precluding any applicability to prescriptions filled prior to that date, not as requiring applicability as of that date, DoD does not believe that is a credible interpretation. Had Congress intended that FCPs would apply only ''with respect to any prescription filled on or after the date of promulgation of regulations under section 703(b) of the National Defense Authorization Act for Fiscal Year 2008,'' Congress would have said that. The words chosen by Congress are quite different and cannot be dismissed as imprecise drafting. Further, as noted above, the legislative history, in the form of the Conference Report, unequivocally refers to the date of enactment of the statute as the ''implementation date'' for ensuring that prescriptions filled through the TRICARE Retail Pharmacy Network shall be subject to Federal Ceiling Prices.

DoD interprets section 703 as precluding any start date for applying FCPs to covered Retail Pharmacy Network prescriptions filled other than the date of enactment, January 28, 2008. The only legal authority DoD has found that would allow it to disregard the overpayment and/or waive the refund is the Federal Debt Collection Act and related statutes. In an effort to find an acceptable resolution, DoD has added to the final rule provisions to address requests for compromise or waiver of overpayment refunds under those authorities. These provisions are discussed below.

Comment: In addition to the legal arguments, a number of commenters advanced several practical arguments and what they considered to be fairness arguments. One was the need to recalculate non-FAMPs if manufacturers' commercial sales into retail distribution between the statutory enactment date and the regulatory effective date have to be reclassified as DoD sales. Another practical problem was that if refunds are required for prescriptions filled throughout 2008, by the time refund demands are made, manufacturers will be forced to review and evaluate stale utilization data to determine the accuracy of the data. Another concern expressed was that companies already accounted for 2008 sales as commercial sales and reported profits based on regular commercial prices, and should not have to redo financial statements and accounting and profit reports, which would be costly and burdensome, especially for small companies. Commenters also cited a contemporaneous statement in the Congressional Record from Senator Nelson which they said was to the effect that section 703 was not intended to modify any existing agreements with drug companies, and that existing Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs) for amounts higher than FCPs, or other agreements pertaining to drugs dispensed in military hospitals and through TMOP, would be breached by a demand for an additional refund under the statute. In relation to this breach of contract argument, some commenters cited *Winstar Corp.* v. *United States,* 518 U.S. 839 (1996), for the proposition that the government's contract obligations cannot be reduced by subsequent legislation. Further, commenters argued that in the case of a drug that had previously been moved to Tier 3 because the manufacturer refused to offer a refund, it would be unfair to now require a refund for a time period for which the drug was on Tier 3.

Response: DoD does not agree with all of these arguments, but believes some may have merit in relation to particular drugs. First, with respect to recalculating non-FAMPs, DoD understands that the Department of Veterans Affairs has addressed that concern, as it relates to the 2008 annual non-FAMP reports, by advising manufacturers that there is no need for reclassification of 2008 sales data to redesignate commercial sales as DoD sales because of section 1074g(f). Second, DoD believes all drug manufacturers were promptly aware of the enactment of section 703 and were thus on notice regarding the statutory date for applying FCPs to prescriptions filled. This situation is not like the *Winstar* case. In that case, the legislation purported to reduce the government's contract obligation after the contractors had already performed their part of the bargain. In this case, the statute changed nothing regarding transactions completed before January 28, 2008. And the companies were on notice as of that date that covered prescriptions filled on or after that date in the TRICARE Retail Pharmacy Network were subject to FCPs. Third, with respect to Senator Nelson's statement, what he said was that with respect to the ''section of the bill that would require that prescriptions dispensed through the TRICARE retail pharmacy program be procured at or below Federal ceiling prices,'' ''it is the intent of the language and the intent of the conferees not to modify the current master agreements.'' (153 Cong. Rec. S–15,613–14, Dec. 14, 2007.) DoD's consistent position, both prior to and since the enactment of section 703, has been that the law does not require an amendment to the master agreements between the VA and drug manufacturers. But DoD does not believe there is any legislative history, including Senator Nelson's statement, suggesting a statutory implementation

date other than January 28, 2008, or making any point regarding UF–VARRs.

However, DoD agrees there may be merit to some of the other concerns that in particular circumstances concerning stale utilization data, prior incentive pricing agreements between DoD and drug manufacturers, and other situations, there may be a reasonable basis to waive or compromise a refund for prescriptions filled between January 28, 2008 and the effective date of the final rule. The proposed rule included a paragraph ((q)(3)) stating that a refund due under paragraph (q) is subject to section 199.11 of the TRICARE regulation, which is the section of the regulation addressing overpayments recovery, including administration of procedures under the Federal Debt Collection Act and related laws for compromise or waiver of overpayment refunds. DoD has revised this provision of paragraph (q) to address specifically a request for waiver or compromise of a refund amount in the context of section 1074g(f) and the new 32 CFR 199.21(q). It provides that a manufacturer may request waiver or compromise of a refund amount and that during the pendency of any request for waiver or compromise, a manufacturer's written agreement to honor FCPs for covered Retail Pharmacy Network prescriptions shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to make or honor an agreement for purposes of the remedies paragraph of the regulation. In other words, a manufacturer can request a waiver or compromise of a refund DoD believes is owing on any grounds the manufacturer believes appropriate, and the matter that is the subject of the request will not be considered noncompliance with any provision of the regulation while the request is pending. This provision for waiver or compromise is available at any time, but DoD intends that it especially be available to address and resolve in a reasonable way issues arising from the period between the date of enactment of the statute and the effective date of the regulation.

Thus, to give one possible example, a company might propose that if it agrees that for all of its covered drugs, all TRICARE retail pharmacy network prescriptions will prospectively be priced at or below Federal Ceiling Prices, it might further propose to compromise refunds for prescriptions filled during the period beginning January 28, 2008, and ending on the date this final rule becomes effective. One formulation for such a compromise could be to propose a date that is in between January 28, 2008, and the effective date of the final rule, proposing that DoD waive collection of refunds for prescriptions filled prior to that date, and for the company promptly to pay refunds for prescriptions filled on or after that date. (This example is merely illustrative and does not commit the Department of Defense to any response.)

Comment: One commenter said that DoD's failure to meet the statutory deadline for issuing implementing regulations, which was December 31, 2007, did not give DoD the right to make drug manufacturers bear the cost of DoD's delay.

Response: Nothing in the final rule requires manufacturers to bear the cost of DoD's delay in issuing final regulations. As noted above, section 1074g(f) requires that all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices, beginning with prescriptions filled on or after the date of enactment. Drug manufacturers were aware of the law and were on notice of their obligations. It is not clear how they were somehow prejudiced by the delay in issuing regulations. In some ways they benefited by the delay because it deferred the due date of the refund necessary to resolve the statutory overpayment. Nonetheless, the final rule provides any company that believes it has been prejudiced in some way to apply for a waiver or compromise of the refund necessary for prescriptions filled between the date of enactment and the effective date of the regulation to be subject to FCPs. DoD will consider all such applications and their supporting rationale.

Comment: One commenter said there are constitutional limitations on laws that alter rights under existing contracts, and that this reinforced the need for not applying FCPs to prescriptions filled before the effective date of the regulation.

Response: The existing contract rights referred to by this commenter are not identified. If the commenter is referring to the Master Agreements with VA, DoD does not believe they are altered by section 703. If the commenter means existing UF–VARRs, DoD does not believe section 1074g(f) is dependent on such an agreement. DoD is unaware of any constitutional or legal right of a vendor to sell its goods or services to the Federal government at a price dictated by the vendor. The law set a ceiling price for covered prescriptions filled in the TRICARE Retail Pharmacy Network, beginning on the date of enactment. A company that thought the statute breached an existing contract had the ability to mitigate the alleged contract damages by canceling the agreement. Even now, a company that does not wish to provide its drugs to the TRICARE Pharmacy Benefits Program is not forced to do so. If a company believes it has incurred some contract damages based on the enactment of section 1074g(f), it can take action to mitigate those damages and apply to DoD to waive or compromise any refund required by that law.

Comment: Several commenters argued that applicability of Federal Ceiling Prices to prescriptions filled on or after the date of enactment but before the effective date of regulations and agreements would violate Health and Human Services regulations as 42 CFR 1001.952(h)(4), which require that in order to be within a safe harbor from anti-kickback rules, a ''rebate'' must be ''disclosed in writing to the buyer at the time of sale of the initial purchase to which the discount applies,'' and that this can only be achieved after regulations and agreements are in effect. Some commenters also said applicability of Federal Ceiling Prices to prescriptions filled on or after the date of enactment but before the effective date of regulations and agreements would be contrary to the Sarbanes-Oxley Act of 2002 and accounting principles for recording anticipated payment liabilities.

Response: DoD disagrees. Under section 1074g(f), DoD is the buyer in a sales transaction that occurs when the prescription is filled for a covered beneficiary by a retail network pharmacy. As of the date of enactment, DoD and the manufacturer both had written notice that Federal Ceiling Prices apply. Further, the statute clearly indicated that FCPs applied to prescriptions filled on or after the effective date, giving companies and their accountants notice of the anticipated payment liability. Nevertheless, if there were a case in which a manufacturer is charged with an illegal kickback or some other violation as a result of a refund under section 1074g(f), DoD would welcome a request to waive or compromise the refund under paragraph (q)(3)(iii) of the regulation.

Comment: Some commenters went further than arguing that FCPs only start to apply when the final rule becomes effective, and argued that they only start to apply when an agreement between DoD and the manufacturer becomes effective. In support of this position they stated that because the statute says

''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,'' some agreement in the nature of a procurement contract has to be made before the statute has any effect.

Response: DoD disagrees. As noted previously, DoD interprets 10 U.S.C. 1074g(f) to mean that for all covered drugs, TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. DoD interprets the statutory phrase ''treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by'' DoD in the Retail Pharmacy Network ''are subject to'' FCPs to mean treated the same as a covered drug directly procured by DoD vis-à-vis the applicability of FCPs; the phrase does not require that there be some other transaction comparable to a direct procurement by a Federal agency under section 8126. The transaction of a covered drug prescription filled in the Retail Pharmacy Network is all that is required. Further, as previously noted, DoD interprets the phrase, ''[w]ith respect to any prescription filled on or after the date of the enactment'' to mean that FCPs apply with respect to any prescription filled on or after the date of the enactment.

2. Manufacturer Written Agreement (Paragraph (q)(2))

a. Agreement in General

Comment: Some commenters expressed the view that an agreement between DoD and a manufacturer is necessary for the manufacturer to have any requirement to pay refunds to DoD for amounts received for drugs dispensed under prescriptions filled in the TRICARE Retail Pharmacy Network. These commenters said a manufacturer's agreement to pay refunds must be met with contractual consideration from DoD in the form of Uniform Formulary status or something similar, comparable to the current Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs). They also argued that if a drug is not included on Tier 2, the manufacturer would have no obligation to refund to DoD any amount it received above the FCP for that drug dispensed under prescriptions filled in the TRICARE Retail Pharmacy Network.

Response: DoD does not agree with this view. As noted above, DoD interprets 10 U.S.C. 1074g(f) to mean that all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. This means that if a manufacturer was paid more than the FCP for a covered drug that was provided through the TRICARE Retail Pharmacy Network, the transaction resulted in an overpayment in what DoD paid the pharmacy and in what the manufacturer received from the pharmacy (directly or through an intermediary). To resolve the overpayment, the manufacturer must pay DoD a refund of the amount above the FCP. If the amount above the FCP was the difference between FCP and the average commercial price for the drug sold to buyers other than the Federal government—represented by the non-Federal Average Manufacturer's Price (non-FAMP)—then the refund amount is the difference between the non-FAMP and FCP. DoD interprets the statute as establishing the fact of an overpayment and the need for a refund. These things are not dependent on the agreement to exist; they exist by operation of law under the statute. The purpose of the agreement, therefore, is simply to acknowledge the existence of the obligation and promise to meet it. This is a change from the UF–VARRs, which are not premised on a statutory requirement that prescriptions filled in the Retail Pharmacy Network are subject to FCPs.

However, as noted above, DoD wishes to emphasize voluntary compliance by manufacturers. To this end, DoD has included in the new regulatory provision for waiver or compromise of refunds, discussed above, a waiver criteria (subparagraph (q)(3)(iii)(C)) premised on a written request by the manufacturer for voluntary removal of a drug from coverage in the TRICARE Pharmacy Benefits Program. Thus if there were ever a case in which a manufacturer was really involuntarily involved with DoD in relation to drugs sold into the normal commercial market, the manufacturer could request voluntary exclusion of a drug from coverage in the TRICARE Pharmacy Benefits Program and waiver of the refund obligation. This reinforces the voluntariness of drug manufacturers' participation in the commercial transaction covered by section 1074g(f), a transaction that features sales by the company and payment by DoD through the TRICARE Retail Pharmacy Network.

b. Product-by-Product Review

Comment: A number of pharmaceutical industry commenters agreed with the proposed rule's approach of product-by-product review of drugs for compliance with Federal Ceiling Prices, rather than requiring a manufacturer to agree to provide all covered drugs produced by the manufacturer as a condition for any of the manufacturer's drugs to be included on the Uniform Formulary.

Response: This is another area where DoD is seeking an accommodation with drug companies. DoD believes it has statutory authority to require a manufacturer to agree to provide all covered drugs produced by the manufacturer as a condition for any of the manufacturer's drugs to be included on the Uniform Formulary because the statute applies to all covered drugs. However, DoD chooses in this rule at this time to follow a product-by-product approach for Uniform Formulary status. DoD urges pharmaceutical companies to honor Federal Ceiling Prices for all covered drugs and thereby preserve eligibility for each drug for the Uniform Formulary, as well as show their compliance with the law.

c. Relationship Between Federal Ceiling Prices and Uniform Formulary Status

Comment: A number of pharmaceutical industry representatives recommended that because non-compliance with Federal Ceiling Prices generally disqualifies a covered drug for Uniform Formulary status, compliance with Federal Ceiling Prices should automatically qualify a covered drug for Uniform Formulary status. These comments indicated that Uniform Formulary status is a necessary quid-pro-quo for a company's agreement to honor FCPs.

Response: DoD does not agree. Under 10 U.S.C. 1074g(a), Uniform Formulary (Tier 2) status is based on the relative clinical and cost effectiveness of drugs within a drug class. Under section 1074g(f), all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. Both requirements apply. A company's obligation to honor FCPs is not dependent on Uniform Formulary placement. Further, there are drugs that at their particular Federal Ceiling Prices are not cost-effective within their respective drug classes. Subject to the judgment of the Pharmacy and Therapeutics Committee and the other steps in the statutory and regulatory process, such drugs are likely to be classified as non-Formulary drugs. However, during the initial period of implementation of this final rule, DoD anticipates that drugs currently on the Uniform Formulary that become covered by manufacturer agreements to honor FCPs in the Retail Pharmacy Network will remain on the Uniform Formulary in Tier 2, pending the next

periodic review of the drug class involved.

Comment: A number of commenters asked how the requirement for an agreement to honor FCPs would affect drugs previously placed on the Uniform Formulary or in non-Formulary status, as well as newly approved drugs.

Response: For covered drugs, continuation on the Uniform Formulary is conditioned on the manufacturer signing an agreement to honor Federal Ceiling Prices for that drug. If there is currently in effect a UF–VARR at a price above the FCP, that agreement fails to achieve the statutory requirement; DoD anticipates canceling it. For a drug previously placed in Tier 3, if the manufacturer signs an agreement to honor FCPs, it will be eligible for reclassification to Tier 2 upon the next review by the P&T Committee of the drug class involved. That will not necessarily occur when the initial adjustments to the Uniform Formulary are made upon the final rule becoming effective. For newly approved drugs, DoD will continue its current practice of scheduling P&T Committee review at the next practicable quarterly meeting.

Comment: A number of commenters suggested that the requirement for a manufacturer's agreement to honor FCPs for TRICARE Retail Pharmacy Network prescriptions as a condition for Tier 2 status should be waived by DoD if a drug is more cost-effective, or if a weighted average of prices in all three venues is no higher than the FCP, or if otherwise in the best interests of beneficiaries. Also, some commenters suggested that the Uniform Formulary process should not be changed to leverage drug manufacturers to agree to honor FCPs in the retail network, and that the process of P&T Committee and Beneficiary Advisory Panel review by drug class should not be usurped and should continue unchanged. These commenters said the beneficiaries should not have to pay higher copays or bother with preauthorization because the drug company does not comply with the law.

Response: DoD has modified the final rule to provide for a waiver if necessary to ensure that each drug class is represented on the Uniform Formulary. Beyond this, DoD does not see a need for further waiver. As noted above, DoD interprets the statute as now establishing for determining cost-effectiveness a relative standard and a fixed standard and the fixed standard must be met, except as noted. With respect to protecting beneficiary interests, preauthorization procedures ensure that beneficiaries will continue to have access to whatever drugs they need. Also, the P&T Committee and Beneficiary Advisory Panel will continue to be involved in the process.

With respect to the argument that beneficiaries should not be inconvenienced by the refusal of drug companies to honor FCPs as required by law, DoD believes this will very much be the exception to the norm. To minimize inconvenience to beneficiaries, DoD has added a new paragraph (q)(5) to provide beneficiary transition provisions. It provides that in cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

d. Preauthorization for Retail Pharmacy Network Prescriptions for Drugs for Which the Manufacturer Refuses To Agree To Honor Federal Ceiling Prices

Comment: A number of commenters argued that DoD should delete the provisions of the proposed rule that made a manufacturer's agreement to honor FCPs in the Retail Pharmacy Network a precondition for the availability of that drug through retail network pharmacies without preauthorization under section 199.21(k) of the current regulation. They argued that this preauthorization requirement conflicts with 10 U.S.C. 1074g and the current scope of the preauthorization provisions of paragraph (k) of the regulation, which are intended to promote broad beneficiary access to clinically appropriate drugs. These comments noted that under the current regulation, non-formulary drugs are generally available in retail pharmacies, and the only statutory reference to preauthorization (in 10 U.S.C. 1074g(a)(4)) is to assure clinical appropriateness. They also argued that the preauthorization requirement would delay beneficiary access to needed pharmaceutical agents, and should have exceptions for emergencies and other clinical needs.

Response: These comments misunderstand the current statute and regulation as they apply to preauthorization. First, the statute does not require that non-Formulary (Tier 3) drugs be provided in the Retail Pharmacy Network. It requires (in paragraph (a)(5) of section 1074g) only that non-Formulary drugs are available through one of the three pharmacy venues. Non-Formulary drugs are and will remain available in the TRICARE Mail Order Pharmacy Program (TMOP). Second, the current paragraph (k) of the regulation is not limited to preauthorization for medical necessity, but rather provides that: ''Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness.'' The new requirement for preauthorization for non-Formulary drugs for which manufacturers refuse to honor FCPs as required by law is entirely consistent with the current law and regulation, as well as with the policy of assuring beneficiary access to needed pharmaceutical agents.

In the case of a beneficiary presenting a prescription in a retail network pharmacy for a drug that is on Tier 3 because of the refusal of the manufacturer to honor Federal Ceiling Prices, there are several possible outcomes. First, the pharmacist may consult with the prescribing physician and the physician may change the prescription to a Uniform Formulary drug, which can be provided immediately at the Tier 2 co-payment. Second, if the beneficiary has a valid clinical need for that non-Formulary drug without delay, preauthorization will be granted. This will take care of emergency needs for pharmaceuticals and other cases of immediate clinical need. However, depending on the circumstances, the beneficiary may be advised that any refills will need to be obtained from TMOP. Third, if there is no urgency, the beneficiary may be advised to submit the prescription to TMOP. This approach is consistent with the statutory requirement that non-Formulary agents be made available in at least one venue, and also with the statutory requirement that all covered Retail Pharmacy Network prescriptions are subject to FCPs. Moreover, it continues DoD policy of meeting beneficiary needs, even in cases in which drug manufacturers fail to honor the law—a circumstance DoD expects to be very rare. The concern expressed by manufacturers for unencumbered beneficiary access to needed pharmaceuticals is admirable, and it should provide sufficient motivation for the manufacturers to accept the ceiling price set by law.

Comment: Commenters on behalf of retail pharmacies argued forcefully that preauthorization requirements for drugs not covered by manufacturer agreements to honor FCPs apply equally to prescriptions in the Retail Pharmacy

Network and TMOP. The rationale for this is to increase the incentive on pharmaceutical manufacturers to honor FCPs and to avoid the shifting of prescriptions from retail pharmacies to TMOP. These commenters believe retail pharmacies better meet beneficiary needs and that to require preauthorization in retail pharmacies but not in TMOP would be unfair and contrary to the ''uniform formulary'' requirement of law. They argued that rather than adopt a procedure disadvantageous to retail pharmacies, DoD should make sure pharmaceutical companies comply with the legal requirement to honor Federal Ceiling Prices in the Retail Pharmacy Network.

Response: DoD's focus is on assuring that beneficiaries receive the pharmaceuticals they need and that the requirements of the law are faithfully executed. While there is some merit to this suggestion, DoD believes the best approach for now is to preserve the option of referring some prescriptions to TMOP when that is the most direct means to both provide the pharmaceuticals needed by the beneficiary and assure the applicability of FCPs. DoD believes it is not unfair or contrary to the uniform formulary provisions of 10 U.S.C. 1074g to have differences in co-payments or preauthorization requirements among the three venues while maintaining the same formulary listing of drugs in all three venues. These differences are all consistent with statutory purposes. DoD agrees with retail pharmacy representative commenters that the right outcome is for all manufacturers to comply with the obligation to honor FCPs in the Retail Pharmacy Network. DoD's expectation is that there will not be many drugs that will be subject to this preauthorization requirement.

e. Covered Drugs

Comment: A number of commenters recommended that DoD exclude from the regulation drugs covered by section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals. The rationale for this comment is that these prescriptions should not be covered by double discounts. A number of commenters also requested clarification on how DoD would report utilization data involving 340B sales or whether DoD would exclude all pharmacies eligible for the 340B program.

Response: DoD agrees and has revised the rule accordingly in paragraph (q)(2)(iii)(E). With respect to pharmacies that dispense only prescriptions covered by the 340B program, those pharmacies will be excluded from DoD's utilization data reported to manufacturers. Regarding other pharmacies that are eligible to participate in the 340B program but also fill other prescriptions, DoD will incorporate into the process appropriate procedures to identify and exclude 340B covered prescriptions.

Comment: A number of commenters requested clarification that a covered drug for purposes of this regulation is a covered drug under 38 U.S.C. 8126.

Response: The final rule includes clarifying language to this effect.

Comment: A number of commenters recommended expansion of the exceptions for covered drugs to allow a broad process for drug manufacturers to obtain exemptions for particular drugs.

Response: DoD does not agree. The statute commands that all covered TRICARE Retail Pharmacy Network prescriptions are subject to FCPs. DoD has established a limited waiver of the condition for Uniform Formulary placement when necessary to preserve representation of all drug classes on the Uniform Formulary, and has established a process under section 199.11 for waiver or compromise of refunds in appropriate circumstances. There is also an authority for any other exception, consistent with law, established by the Director, TMA. This is intended for special circumstances, analogous to the 340B program. DoD does not see a need for another procedure for individual drug products to avoid FCPs.

3. Refund Procedures (Paragraph (q)(3))

a. Refund Procedures in General

Comment: A number of commenters requested further information and/or specification in the regulation regarding the details of the refund procedures referred to in the rule. They argued that much more detail needed to be included in the rule for manufacturers to be expected to decide whether they wanted to sign agreements. Another comment urged that all refund procedures be published in the **Federal Register** for public comment under 41 U.S.C. 418b.

Response: The only definite requirement in the regulation for a manufacturer's agreement to be a condition for Uniform Formulary placement and Retail Pharmacy Network availability without preauthorization is a simple agreement to honor Federal Ceiling Prices in the Retail Pharmacy Network. DoD prefers to also include in the agreement refund procedures, but has revised the final rule (in paragraph (q)(3)(i)) to clarify that these things need not be in the same document. Thus, if there are issues that need to be resolved with respect to refund procedure details, these need not interfere with a manufacturer's ability to agree to follow the law and thereby maintain eligibility for Uniform Formulary status. Again, as noted above, DoD does not interpret 10 U.S.C. 1074g(f) as making the applicability of FCPs or the collection of refunds for amounts above FCPs subject to the existence or terms of an agreement between DoD and the manufacturer. Therefore, any disputes or problems regarding refund procedure details can be resolved appropriately without disturbing rights or obligations under the law. Moreover, such details can best be addressed outside the formalities of the rulemaking process. DoD will continue to provide means to answer specific manufacturers' questions regarding refund procedures, Uniform Formulary procedures, and the like. Such means include the following Web site: *http://tricare.mil/tma/Pharmacy.aspx.* DoD supports incorporating into the manufacturer written agreements effective refund procedures consistent with best commercial practice. Absent such agreement, the standard collection procedures of the existing TRICARE Regulation (section 199.11) are available.

Regarding the 41 U.S.C. 418b argument, DoD believes that although section 1074g(f) requires that the TRICARE Retail Pharmacy Network ''shall be treated as'' an element of the Department of Defense for purposes of the ''procurement of drugs by Federal agencies'' under 38 U.S.C. 8126 ''to the extent necessary to ensure that'' pharmaceuticals dispensed are subject to FCPs, this does not result in any legal requirement, or even an inference, to also treat the transaction as if it were a procurement for purposes of various procurement statutes. Thus, DoD does not view refund procedure agreements as falling within the scope of a ''procurement policy, regulation, procedure, or form'' subject to 41 U.S.C. 418b. In addition, especially while DoD seeks to work with manufacturers on implementing practical and smooth procedures for sharing utilization data, resolving issues and problems, facilitating Uniform Formulary placement consistent with the law and regulations, and facilitating a positive relationship, DoD does not see the advantage of chiseling into regulatory stone a detailed set of procedures which will then become too hard to adapt or improve.

b. Specific Refund Procedures

Comment: Specific refund procedure issues included whether the current Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs) template will be used; whether the non-FAMPs and FCPs that will be used for the refunds are those applicable to the year in which the prescription was filled or the year in which the refund is due or the year in which the agreement was signed; whether UF–VARRs currently in effect would be cancelled; whether transferred ownership would require a new agreement; whether DoD would change any VA determinations of non-FAMP or FCP; the guidance VA and the Centers for Medicare and Medicaid Services (CMS) would provide on reporting transactions covered by section 1074g(f) for purposes of non-FAMP, best price, and other calculations; whether DoD will maintain manufacturer pricing data in confidence; how DoD will deal with ''penny pricing'' on an FCP or various data anomalies in the VA's processes; whether drug companies will have the right to audit DoD utilization data; and whether in any quarterly utilization period there will be an exclusion of prescriptions filled significantly before that quarter.

Response: The rule has been clarified to specify that the FCPs that apply are those in effect in the year in which the prescription is filled. The non-FAMP that applies will be the one that gave rise to the applicable FCP. DoD believes the UF–VARR process has been effective and intends to use that as a base line for refund procedures under the regulation, but intends to continue to work with industry on refinements and improvements. Thus, these procedures are not part of this regulation. DoD anticipates that current UF–VARRs that do not meet the statutory requirement will be canceled, but they are not cancelled by this regulation. In cases of transferred ownership of a drug, DoD will look to the parties to advise DoD of the transfer and its effect on existing relationships. DoD will not change any VA determinations of non-FAMPs or FCPs; DoD will accept VA determinations. This includes deferring to VA determinations on penny pricing and the VA procedures for resolution of data anomalies and relief from unfair calculations. DoD is already under legal obligation to maintain manufacturer pricing data in confidence and will comply with that obligation. DoD cannot speak for VA and CMS but has consulted with those agencies and will do everything possible to facilitate responses to manufacturers' questions to those agencies. With respect to the audit question, the dispute resolution process provides the manufacturer the opportunity to dispute any utilization on which its data and DoD's data are in conflict. All pertinent pricing information is already in the hands of the manufacturer. Thus, DoD sees no need for routine manufacturer audits of DoD utilization data, other than what might be appropriate in a dispute resolution context. Other details will be worked out consistent to the extent practicable with common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors.

c. Dispute Resolution Procedures

Comment: Several commenters representing the pharmaceutical industry urged that in cases in which drug companies dispute DoD utilization reports, the companies are not required to pay refunds pending the outcome of the dispute resolution process. At the conclusion of the dispute resolution process, refund amounts would then include interest charges from the original payment due date. These commenters pointed out that this would be a change from the current DoD standard procedure under the Uniform Formulary Voluntary Agreement for Retail Refunds (UF–VARRs), but would be consistent with the current practice under Medicaid rebate agreements.

Response: DoD agrees to this proposal and has added a new paragraph (q)(3)(iv) to defer refund payments pending resolution of disputes over the accuracy of the utilization data.

d. Overpayments Recovery

Comment: A number of commenters questioned the portion of the proposed rule stating that a refund due under the new paragraph (q) is subject to section 199.11 of the TRICARE Regulation. That section governs overpayments recovery. These commenters recommended that refund procedures should be negotiated between DoD and manufacturers, rather than handled under section 199.11.

Response: As noted above, DoD interprets section 1074g(f) as requiring that all prescriptions for covered drugs in the Retail Pharmacy Network are subject to Federal Ceiling Prices. To the extent the ingredient costs for the prescriptions paid for in the Retail Pharmacy Network exceed the FCP, the prescription transaction produced an overpayment to the manufacturer, giving rise to a DoD right to a refund. There are existing statutes that govern refunds of government payments that exceed the legally authorized purposes, circumstances, or amounts. TRICARE's implementing regulations under these statutes are at section 199.11. This does not preclude mutually agreeable refund procedures, but section 199.11 is a necessary baseline of authority and procedures.

4. Remedies (Paragraph (q)(4))

Comment: A number of comments from or on behalf of the pharmaceutical industry urged revision to the proposed rule provision that in the case of the failure of a manufacturer of a covered drug ''to make or honor an agreement'' to honor FCPs in the Retail Pharmacy Network, the Director of TMA, in addition to other actions referred to in this paragraph (q), may take ''any other action authorized by law.'' These comments argued that agreements to honor FCPs in the retail network should be completely voluntary, so there should be no ''remedy'' or ''penalty'' for failure to make such an agreement. Some commenters described this provision as purporting to give the Director of TMA arbitrary power or unlimited discretion.

Response: As discussed above, while DoD wants to emphasize voluntary compliance, the statute unambiguously commands that all covered Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices. As a result, DoD has no reason to and expressly does not waive the right to pursue any action authorized by law. This in no way is arbitrary, unlimited, or unreasonable because it is strictly limited to authorities under the law.

Comment: A comment from the retail pharmacy sector urged DoD to revise the final rule to state that a failure of a manufacturer to honor FCPs in the Retail Pharmacy Program is a violation of 38 U.S.C. 8126 and bars the manufacturer from eligibility to sell pharmaceuticals to the referenced Federal agencies and in Medicaid.

Response: It is DoD's view that a failure of a manufacturer to comply with 10 U.S.C. 1074g(f) does also constitute a failure to comply with 38 U.S.C. 8126. However, as noted above, there are no judicial rulings on this point and the state of the law is not settled on it. In any event, it is outside any regulatory authority of the Department of Defense to make rules or issue legally controlling interpretations regarding 38 U.S.C. 8126. Thus, this matter is not addressed in this rule. This rule only addresses matters within the regulatory authority of the Department of Defense.

D. Provisions of the Final Rule

Like the proposed rule, the final rule adds to section 199.21 of the TRICARE regulation a new paragraph (q) regarding

pricing standards for the retail pharmacy program. Paragraph (1)(i) repeats the statutory requirement, virtually verbatim. Paragraph (1)(ii) has been added to state in simpler terms DoD's interpretation of the statute as requiring that all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126.

Paragraph (2) provides that a written agreement by a manufacturer to honor Federal Ceiling Prices in the retail pharmacy network as required by the statute is with respect to a particular covered drug a condition for inclusion of that drug on the Uniform Formulary (Tier 2) and for the availability of that drug through retail network pharmacies without preauthorization. A covered drug not under such an agreement requires preauthorization to be provided through a retail network pharmacy. This preauthorization requirement does not apply to other points of service. The final rule has been modified a bit to clarify that a covered drug for this purpose is a drug that is a covered drug under 38 U.S.C. 8126. A covered drug does not include a drug that is not a covered drug under 38 U.S.C. 8126; a drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f); a drug that is not provided through a TRICARE retail network pharmacy; any pharmaceutical for which the TRICARE Pharmacy Benefits Program is the second payer; and any other exception, consistent with law, established by the Director, TMA. The final rule adds to the list of non-covered drugs for this purpose any drug provided under a prescription and dispensed by a pharmacy under the Section 340B program.

The final rule adds a new paragraph (q)(2)(iv) stating that the requirement for a manufacturer's agreement to honor FCPs in the Retail Pharmacy Network as a precondition to Uniform Formulary (Tier 2) placement may, upon the recommendation of the P&T Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the applicable drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement that all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements.

Paragraph (q)(3) addresses refund procedures. Paragraph (q)(3)(i) states that refund procedures to ensure that pharmaceuticals paid for by DoD that are provided by retail network pharmacies under the Pharmacy Benefits Program are subject to Federal Ceiling Prices shall be established. Such procedures may be established as part of the agreement referred to above, or in a separate agreement, or pursuant to section 199.11. This paragraph of the final rule has been revised somewhat from the proposed rule. The options for procedures to be addressed in a separate agreement between the manufacturer and DoD or to be adopted under the overpayment recovery rules of section 199.11 are added in the final rule to ensure that any problems regarding specific refund procedures need not get in the way of manufacturers agreeing to honor FCPs and thereby preserve eligibility for their drugs for Uniform Formulary Tier 2 placement. Paragraph (q)(3)(ii) provides that the refund procedures shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. The procedures will 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 corresponding 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. The current annual FCP and the non-FAMP on which it was based will be those applicable during the calendar year in which the prescription was filled.

As under the proposed rule, paragraph (q)(3)(iii) provides that a refund due under the law is subject to section 199.11 of the TRICARE regulation, the section that governs recovery of overpayments. The final rule provision has been revised to clarify that the refund amount will be treated, in the vernacular of section 199.11, as an erroneous payment. The final rule has also been revised to elaborate that the applicability of section 199.11 brings with it a procedure for a manufacturer to request waiver or compromise of a refund amount due under the statute. During the pendency of any request for such a waiver or compromise, a manufacturer's written agreement to honor FCPs shall be deemed to exclude the matter that is the subject of the request for waiver or compromise so that the agreement, if otherwise sufficient, will continue to be sufficient for purposes of satisfying the precondition to Uniform Formulary Tier 2 placement. Also, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of remedies for noncompliance. The final rule is further revised to state that a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program. This change further protects a manufacturer from involuntary involvement in the program.

One other change to the refund procedures paragraph is that a new paragraph (q)(3)(iv) has been added to state that in the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under the TRICARE regulation. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge consistent with the normal regulatory practice.

Paragraph (q)(4) provides that in the case of the failure of a manufacturer of a covered drug to make or honor an agreement under paragraph (q), the Director, TMA, in addition to other actions referred to in the paragraph, may take any other action authorized by law. This paragraph is unchanged from the proposed rule.

Finally, a new paragraph (q)(5) has been added. It provides that in cases in which a pharmaceutical is removed from the Uniform Formulary or designated for preauthorization, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the Uniform Formulary.

E. 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 final 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 final 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. The FY–2009 budget approved by the President and Congress incorporated savings of $352 million in the Defense Health Program appropriation. DoD estimated cost reductions from applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network in Fiscal Years 2010 through 2015 appear in the following table. It should be noted that these estimates have been updated from those available at the time the proposed rule was issued. The estimates included with the proposed rule were the standing out-year budget estimates developed several years ago from an FY–2003 utilization and cost baseline. New estimates are from an FY–2007 utilization and cost baseline. The significant increase in retail utilization and costs between 2003 and 2007 results in a significant increase in overall budget impact of implementing section 1074g(f). Finally, it should be noted that the budget estimates include amounts DoD would have expected to receive from voluntary refunds under the current Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs). In FY–2010, for example, even if FCPs were not required by the statute, DoD would have expected the UF–VARR program to produce Defense Health Program refunds of $100 million to $150 million of the projected $761 million in reduced spending.

MILLIONS OF DOLLARS

FY–2010 DHP Reduced Spending ..	761
FY–2010 MERHCF Reduced Spending	910
FY–2011 DHP Reduced Spending ..	842
FY–2011 MERHCF Reduced Spending	1,007
FY–2012 DHP Reduced Spending ..	919
FY–2012 MERHCF Reduced Spending	1,099
FY–2013 DHP Reduced Spending ..	993
FY–2013 MERHCF Reduced Spending	1,188
FY–2014 DHP Reduced Spending ..	1,072
FY–2014 MERHCF Reduced Spending	1,282
FY–2015 DHP Reduced Spending ..	1,177
FY–2015 MERHCF Reduced Spending	1,408

As a frame of reference, total TRICARE Pharmacy Benefits Program spending is estimated to be $8 billion in FY–2009.

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 final 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.

Section 202, Public Law 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. The economic impact of this regulation, described above, is not in the form of a mandated expenditure by a State, local, or tribal government or the private sector, but by reduced Federal expenditures.

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 final rule. In addition, drugs newly subject to implementation of Federal Ceiling Prices under the final rule represent less than 2% of manufacturers' prescription drug sales. Therefore, this final 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 final 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 final 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.

List of Subjects in 32 CFR Part 199

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

■ Accordingly, 32 CFR part 199 is 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.* (i) 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.

(ii) Under subparagraph (q)(1)(i) of this section, all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 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 is a drug that is a covered drug under 38 U.S.C. 8126, but 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) A drug provided under a prescription which the TRICARE Pharmacy Benefits

Program is the second payer under paragraph (m) of this section;

(E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or

(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) *Refund procedures.* (i) 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 shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to § 199.11.

(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 corresponding 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. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to section 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under § 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under subparagraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in § 199.11 of this section, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under § 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the

date payment of the amount was initially due, consistent with § 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.

(5) *Beneficiary transition provisions.* In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

Dated: March 10, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–5702 Filed 3–16–09; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG–2008–0155]

RIN 1625–AA01

Anchorage Regulations; Port of New York; Correction

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting the preamble to a final rule that appeared in the **Federal Register** of March 11, 2009 (74 FR 10484). The preamble incorrectly referred to Department of Homeland Security Management Directive 5100.1, instead of Department of Homeland Security Management Directive 0023.1.

DATES: Effective April 10, 2009.

FOR FURTHER INFORMATION CONTACT: LT Edward Munoz, Chief, Waterways Management Division, telephone 718–354–2353.

SUPPLEMENTARY INFORMATION: In FR Doc. E9–5095 appearing on page 10484 of the **Federal Register** of Wednesday, March 11, 2009, the following correction is made:

1. On page 10486, in the second column, correct the ''Environment'' section to read: ''We have analyzed this rule under Department of Homeland Security Directive 0023.1 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph 34(f), of the Instruction. This rule involves a regulation reducing the size of an anchorage ground.

Under figure 2–1, paragraph (34)(f), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.''

Dated: March 12, 2009.

Steve G. Venckus,

Chief, Office of Regulations and Administrative Law.

[FR Doc. E9–5757 Filed 3–16–09; 8:45 am]

BILLING CODE 4910–15–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2009–17 and CP2009–24; Order No. 187]

Domestic Mail Product

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding Express Mail & Priority Mail Contract 4 to the competitive product list. This action is consistent with changes in a recent law governing postal operations. Republication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

DATES: Effective March 17, 2009 and is applicable beginning March 10, 2009.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202–789–6820 and *stephen.sharfman@prc.gov.*

SUPPLEMENTARY INFORMATION: *Regulatory History,* 74 FR 9316 (March 2, 2009).

The Postal Service seeks to add a new product identified as Express Mail & Priority Mail Contract 4 to the Competitive Product List. For the reasons discussed below, the Commission approves the Request.

I. Background

On February 20, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Express Mail & Priority Mail Contract 4 to the Competitive Product List.[1] The Postal Service asserts that the Express Mail & Priority Mail Contract 4 product is a competitive product ''not of general applicability'' within the meaning of 39 U.S.C. 3632(b)(3). This Request has been assigned Docket No. MC2009–17.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2009–24.

In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors' Decision authorizing the new product which also includes an analysis of Express Mail & Priority Mail Contract 4 and certification of the Governors' vote;[2] (2) a redacted version of the contract which, among other things, provides that the contract will expire 3 years from the effective date, which is proposed to be 1 day after the Commission issues all regulatory approvals;[3] (3) requested changes in the Mail Classification Schedule product list;[4] (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;[5] and (5) certification of compliance with 39 U.S.C. 3633(a).[6]

In the Statement of Supporting Justification, Kim Parks, Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to coverage of institutional costs, and will increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. Request, Attachment D, at 1. W. Ashley Lyons, Manager, Corporate Financial Planning, Finance Department, certifies that the contract complies with 39 U.S.C. 3633(a). *See id.* Attachment E.

The Postal Service filed much of the supporting materials, including the unredacted Governors' Decision and the

[1] Request of the United States Postal Service to Add Express Mail & Priority Mail Contract 4 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, February 20, 2009 (Request).

[2] Attachment A to the Request. The analysis that accompanies the Governors' Decision notes, among other things, that the contract is not risk free, but concludes that the risks are manageable.

[3] Attachment B to the Request.

[4] Attachment C to the Request.

[5] Attachment D to the Request.

[6] Attachment E to the Request.