was published in the **Federal Register** (January 10, 2011) was appropriate.

On July 13, 2010, the Investment Company Institute ("ICI") [11] submitted a letter stating that it will be difficult for its members to comply with the Recordkeeping and Travel Rule by January 10, 2011. Due to unique industry end-of-year systems issues,[12] as well as systems changes necessitated by other new regulatory requirements,[13] the ICI has requested a three month extension of the date by which mutual funds are required to comply with the requirements of the Recordkeeping and Travel Rule.

II. Extension of Compliance Date for the Recordkeeping and Travel Rule

FinCEN believes that it is appropriate to extend the date by which mutual funds must comply with the Recordkeeping and Travel Rule. Therefore, mutual funds now will have until April 10, 2011 to comply with 31 CFR 103.33. We do not anticipate granting a further extension beyond April 10, 2011 and expect that mutual funds thereafter will have adequate processes in place to comply with the Recordkeeping and Travel Rule.

[11] The ICI is an association of U.S. investment companies, including mutual funds, closed-end funds, exchange-traded funds (ETFs), and unit investment trusts (UITs). Members of ICI manage total assets of $11.42 trillion and serve 90 million shareholders.

[12] According to the ICI, most mutual funds and transfer agents refrain from implementing material modifications or enhancements to their transaction processing and recordkeeping systems for varying periods beginning in early December (generally referred to as a "freeze") to ensure that the systems are capable of handling the large number of end-of-year fund and shareholder transactions, as well as the preparation of year-end account statements and tax reporting information. Because the January 10, 2011 compliance date falls within the period when mutual fund transaction processing and recordkeeping systems are frozen, mutual funds will need to come into compliance with the Recordkeeping and Travel Rule by the middle of November 2010—before the systems are frozen. A three-month extension of the compliance date would allow mutual funds sufficient time to come into compliance with the Recordkeeping and Travel Rule without disrupting the year-end operations and reporting functions.

[13] According to the ICI, mutual fund transfer agents are currently redesigning their systems in order to comply with new cost basis reporting requirements, which entail significant operational and technological changes to allow funds to capture, report, and transfer required tax information, such as when shareholders transfer their accounts (*see* Basis Reporting by Securities Brokers and Basis Determination for Stock, 74 FR 67010 (Dec. 17, 2009)). In addition, mutual funds and their transfer agents are updating their systems to comply with a new requirement that money market mutual funds and their transfer agents be able to process purchases and redemptions electronically at a price other than $1.00 per share (*see* Money Market Fund Reform, SEC Release No. IC–29132 (Jan. 27, 2010)).

III. Proposed Location in Chapter X

As discussed in a previous **Federal Register** Notice, 73 FR 66414, Nov. 7, 2008, FinCEN is separately proposing to remove Part 103 of Chapter I of Title 31, Code of Federal Regulations, and add Parts 1000 to 1099 (Chapter X). If the notice of proposed rulemaking for Chapter X is finalized, the changes in the present rule would be reorganized according to the proposed Chapter X. The planned reorganization will have no substantive effect on the regulatory changes herein. The regulatory changes of this specific rulemaking would be renumbered according to the proposed Chapter X as follows: § 103.33 would be moved to § 1010.410.

IV. Notice and Comment Under the Administrative Procedure Act

FinCEN for good cause finds that, for the reasons cited above, including the brief length of the extension we are granting, notice and solicitation of comment regarding the extension of the compliance date are impracticable, unnecessary and contrary to the public interest. In this regard, FinCEN notes that mutual funds need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation processes accordingly.[14]

Dated: October 6, 2010.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2010–25886 Filed 10–14–10; 8:45 am]

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[14] *See* 5 U.S.C. 553(b)(3)(B) (an agency may dispense without prior notice and comment when it finds, for good cause, that notice and comment are "impracticable, unnecessary, and contrary to the public interest"). The change to the compliance date is effective upon publication in the **Federal Register.** The Administrative Procedure Act allows effective dates less than 30 days after publication in the **Federal Register** for "a substantive rule which grants or recognizes an exemption or relieves a restriction." *See* 5 U.S.C. 553(d)(1).

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2008–HA–0029]

RIN 0720–AB45

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

DATES: This final rule is effective December 27, 2010.

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 (January 28, 2008), the TRICARE Retail Pharmacy Program shall be treated as an element of DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. 8126 to the extent necessary to ensure pharmaceuticals paid for by DoD that are provided by network retail pharmacies to TRICARE beneficiaries are subject to Federal Ceiling Prices (FCPs). This section 8126 established FCPs for covered drugs (requiring a minimum 24% discount) procured by DoD and three other agencies from manufacturers. The NDAA required implementing regulations.

DoD issued a proposed rule July 25, 2008 (73 FR 43394–97) and a final rule March 17, 2009 (74 FR 11279–93). Among other things, the preamble to the final rule stated that DoD interpreted the statute as automatically capping the price manufacturers may get paid for

those covered drugs that enter into the commercial chain of transactions that end up as TRICARE-paid retail prescriptions, resulting in the conclusion that the amount above the FCP was an overpayment by DoD, which in turn required a refund of the overpayment. Ruling on a litigation challenge to the final rule in a case called *Coalition for Common Sense in Government Procurement* v. *U.S.,* the U.S. District Court for the District of Columbia decided on November 30, 2009, that although 10 U.S.C. 1074g(f) requires that FCPs shall apply, the statute does not specify *how* they will apply. The Court ruled that DoD incorrectly interpreted the statute as requiring manufacturer refunds, to the exclusion of other possible approaches, and ordered DoD to reconsider the implementation of the statute as a function of its discretionary judgment, rather than only as a legal interpretation. The Court also ruled that while DoD considers whether to readopt the final rule as it currently stands or to change it, the final rule and the manufacturer agreements will remain in effect. Finally, the Court held that DoD correctly interpreted the statute as applying Federal Ceiling Prices to all prescriptions filled on or after January 28, 2008.

To help DoD carry out the reconsideration ordered by the Court, on February 8, 2010, DoD published a notice in the **Federal Register** inviting additional public comments on the 2009 final rule, as well as additional comments regarding any other appropriate and legally permissible implementation approach. DoD recommended that interested parties focus their comments on those matters addressed by the Court. The Notice further advised that in considering alternative approaches to implementing the statute, DoD intended to use at least the following three criteria (and welcomed comment on these and other suggested criteria): (1) Harmony with the statute and legislative history; (2) consistency with best business practice; and (3) practicability of administration.

DoD received eleven public comments. Five were from representatives of the pharmaceutical manufacturing industry, two from representatives of the retail pharmacy industry, two from specialty providers participating in the Department of Health and Human Services' 340B program, one from a representative of pharmaceutical wholesalers, and one from a pharmacy benefits manager.

Before discussing the major issues for reconsideration and the public comments received, Figure 1 is provided to assist in understanding the operation of the TRICARE Retail Pharmacy Program as it currently operates.

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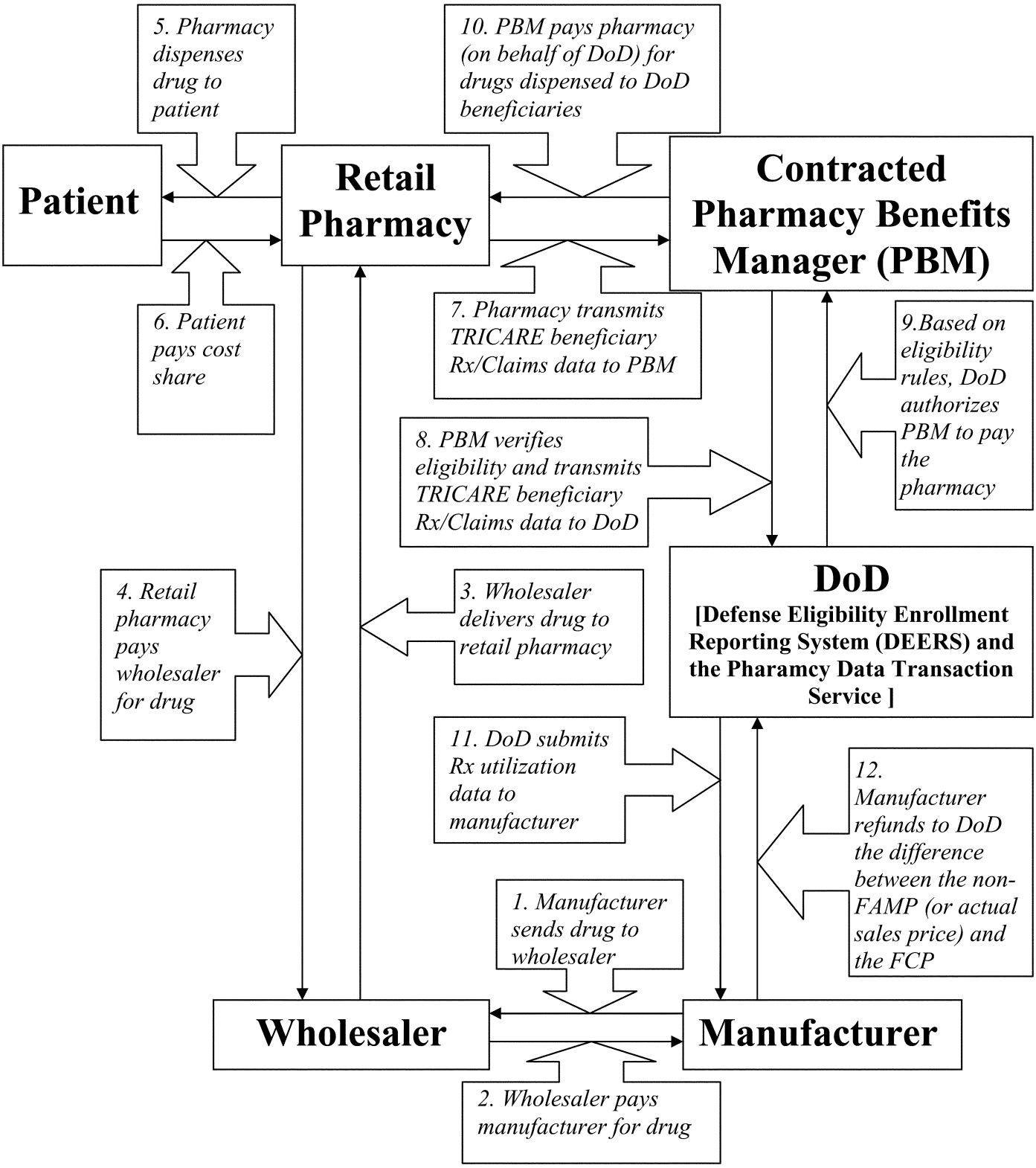
Figure 1: Steps in TRICARE Retail Pharmacy Program Transactions



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B. Major Issues for Reconsideration

There are four major issues for reconsideration: (1) *Who* bears the burden of applying FCPs? (2) *How* will FCPs be applied? (3) *When* do FCPs apply? (4) *To what* do FCPs apply? The first two of these issues are the ones that the Court specifically ordered DoD to reconsider as a matter of DoD's discretionary judgment. The last two were not covered by that specific Court order to DoD but were addressed by the Court and by commenters. These four major issues will be addressed in turn.

1. Who bears the burden of applying FCPs?

The Court framed this issue, stating that DoD should exercise its discretion to consider "which of the five parties that participate in the retail pharmacy program—manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries—must bear any costs associated with imposing the Federal Ceiling Prices."

For purposes of this regulation, DoD has considered the five options identified by the Court (DoD recognizes that a comprehensive analysis of distributional effects would involve a detailed market analysis). Representatives of retail pharmacies, wholesalers, and pharmacy benefits managers argued strongly that FCPs are *manufacturer* ceiling prices under 38 U.S.C. 8126 and that the economic burden necessarily falls on manufacturers. Pharmaceutical industry representatives that submitted comments did not contest this point, propose any of the four alternative options, or otherwise comment on this issue.

(a) *Assessment of options for harmony with the statute and legislative history concerning who bears the burden of FCPs.*

Section 1074g(f) provides that "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 * * * are subject to the pricing standards in such section 8126." Section 8126 provides that "[e]ach manufacturer of covered drugs shall enter into a master agreement with the Secretary under which * * * with respect to each covered drug of the manufacturer procured by [DoD and certain other agencies] 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" of Veterans Affairs "under which the price charged * * * may not exceed 76 percent of the non-Federal average manufacturer price [non-FAMP]. * * *" Section 8126 goes on to define "manufacturer" as excluding "a wholesale distributor of drugs or a retail pharmacy."

Taken together, the texts of the two statutes support the view that Federal Ceiling Prices refer to manufacturer prices, not to wholesalers' prices or retail pharmacies' prices; that FCPs are the ceiling prices that manufacturers may charge or be paid by the covered Federal agencies, which may not exceed 76 percent of the average manufacturer price applicable to non-Federal purchasers; that these maximum manufacturer prices apply to covered drugs procured by the agencies, including DoD; and that the TRICARE Retail Pharmacy Program shall be treated as part of DoD for purposes of this procurement to the extent necessary to ensure that these maximum manufacturer prices apply to covered drugs paid for by DoD through this Program.

The other two participants in the TRICARE Retail Pharmacy Program are the pharmacy benefits manager, which is a company that functions essentially as a management agent for DoD, and the beneficiary. The pharmacy benefits manager is not mentioned in section 1074g or section 8126. The financial responsibility of TRICARE beneficiaries under the Pharmacy Benefits Program is specifically addressed in section 1074g(a)(6), which provides explicit maximums on beneficiary costs.

Based on these statutory provisions, the option that manufacturers bear the burden of FCPs is in harmony with the statutes, which establish FCPs as a ceiling on manufacturer prices. The option that retail pharmacies bear the burden is not in harmony because section 8126 specifically excludes retail pharmacies from the definition of manufacturer for purposes of identifying entities covered by FCPs. The same is true of the option that wholesalers bear the burden of FCPs. The option that beneficiaries bear the burden of FCPs is not in harmony with section 1074g, which separately specifically establishes maximum limits on beneficiary costs. The option that pharmacy benefits managers bear the burden of FCPs is not addressed by the statutory texts.

In addition to the statutory texts, the legislative history of section 1074g(f) is noteworthy. As previously addressed, section 1074g(f) was enacted as part of NDAA–08. A very similar provision was included in the Senate-passed version of the proposed National Defense Authorization Act for Fiscal Year 2007 (NDAA–07), but was not enacted in the final version. That provision, like the NDAA–08 provision eventually enacted, said 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 section 8126 of title 38." The Senate Armed Services Committee explained that the purpose of the provision was to "affirm a decision made by the Secretary of Veterans Affairs * * * that drugs purchased by the TRICARE retail pharmacy network are subject to the same federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program." (S. Rept. 109–254, 109th Cong. 2d Sess., May 9, 2006, pp. 342–343.) The Secretary of Veterans Affairs decision that the Senate proposed to affirm through language quite similar to that eventually enacted placed the burden of FCPs on manufacturers, not on retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries. Similarly, the Federal pricing limits that have long applied to military facility pharmacies and the mail order program, which the Senate proposal sought also to apply to drugs provided through the retail network, place the financial burden on manufacturers, not on any other participants in those transactions, such as the pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries.

The legislative history of 38 U.S.C. 8126 is also notable. That section was enacted by section 603 of the Veterans Health Care Act of 1992. The Senate Committee Report described the provision as one intended to ensure "reasonable prices" from manufacturers and explained that the 24 percent discount from non-FAMP was based on "the Congressional Budget Office's estimate of the median percentage discount received" through the Medicaid manufacturer rebate program, which in turn is based on the "best price" manufacturers charge customers. (S. Rept. No. 102–401, 102d Cong., 2d. Sess., September 15, 1992, pp. 68–70, reprinted in 1992 U.S. Code Congressional and Administrative News, pp. 4158–60.)

Therefore, the option of manufacturers bearing the financial burden of FCPs under section 1074g(f) is in harmony with the legislative history of both 10 U.S.C. 1074g(f) and 38

U.S.C. 8126. None of the other options is in harmony with the legislative history. Further, there is no legislative history hinting that the financial burden of FCPs, which § 8126 places on manufacturers, was intended by § 1074g(f) to be shifted to retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries, or that § 1074g(f) was intended to regulate the financial activities of retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries.

(b) *Assessment of options for consistency with best business practice concerning who bears the burden of FCPs.*

Assuming that the only requirement of the statute applies to the amount paid by DoD in the retail pharmacy program and that DoD can implement that requirement by allocating financial burden on any of the five identified participants, the issue here is to assess what allocation is consistent with best business practice. As a matter of business management, the TRICARE Pharmacy Benefits Program provides outpatient pharmaceuticals through three venues: Military facility pharmacies, the mail order pharmacy, and retail pharmacies. All three venues involve four categories of costs: Manufacturing costs, distribution costs, management costs, and prescription filling costs; and all three have potential cost sharing with beneficiaries. In military facility pharmacies, manufacturing costs for covered drugs are subject to FCPs under 38 U.S.C. 8126, and potentially larger discounts through competitive market procedures. Distribution costs are paid to wholesalers under prime vendor contracts based on competitive processes. Management costs are incurred through direct costs of the Defense Logistics Agency, a component of the Department of Defense. Prescription filling costs are incurred through direct costs of military and civilian personnel, expenses, and operations of outpatient pharmacies in military hospitals and clinics. Cost sharing by beneficiaries is subject to some policy discretion by DoD; there are no beneficiary co-payments for outpatient services in military facilities.

In the mail order pharmacy program, as in military facility pharmacies, manufacturing costs for covered drugs are subject to FCPs under 38 U.S.C. 8126, and potentially larger discounts through competitive market procedures. Distribution costs are paid by DoD to wholesalers under prime vendor contracts. Management and prescription filling costs are incurred by the mail order pharmacy program contractor and paid by DoD based on prices set in the competitive contracting process. Cost sharing by beneficiaries is set by DoD regulation, subject to specifications in 10 U.S.C. 1074g and based on a policy structure aimed at encouraging use of the mail order venue and more cost-effective drugs.

The retail pharmacy system in the United States is part of the American health care system, of which the DoD health system is a relatively small part. In the normal commercial chain, manufacturers sell their pharmaceuticals to wholesalers. Wholesalers add to the manufacturing costs (*i.e.,* the costs incurred in purchasing the drugs from the manufacturers) an amount that covers distribution expenses and profit (possibly including in these calculations prompt payment discounts or other incentives) and charge this price to retail pharmacies. Retail pharmacies take the manufacturing costs and the distribution costs and add an amount to cover the retail pharmacies' expenses in salaries and operations and a profit (possibly factoring in incentives in exchange for network agreements with pharmacy benefit managers), and arrive at a price reflecting manufacturing, distribution, and prescription costs. This amount is typically billed to a pharmacy benefits manager, functioning as an administrative agent for a health plan sponsor, after collecting a limited portion of the amount as the beneficiary's co-payment. The plan sponsor ultimately pays the roll-up of the manufacturing, distribution, prescription, and management costs.

In this system, prevailing business practice for a plan sponsor is to get the best value that is feasible at each step of the commercial chain. The plan sponsor negotiates and contracts directly with the pharmacy benefits manager, seeking the best value in the management costs incurred in return for the success of the pharmacy benefits manager in meeting overall plan objectives for beneficiary services and cost-effectiveness. The plan sponsor also sets beneficiary co-payment amounts based on applicable dynamics that may include collective bargain agreements, employer policy, and the like, as well as management objectives in influencing market share toward more cost-effective drugs and points of service. Either the plan sponsor or the pharmacy benefits manager will seek best value regarding manufacturing costs, distribution costs, and prescription costs through whatever tools are feasible in dealing with manufacturers, wholesalers, and retail pharmacies respectively.

In this system, best business practice for the TRICARE Pharmacy Benefits Program is to seek to achieve best value with respect to each of the four categories of cost and with respect to the matter of beneficiary cost sharing. For purposes of this assessment of retail program options, the assumption is that the final cost to DoD must somehow reflect the implementation of FCPs somewhere in the system, whether in relation to manufacturing costs, distribution costs, prescription costs, management costs, or beneficiary cost sharing, or some combination of these. The most obvious option is to apply FCPs to manufacturing costs in the retail program because FCPs apply to manufacturing costs in the military facility and the mail order components of the program. Alternatively, DoD could permit higher manufacturing costs for the retail program than are legal in the military facility or mail order programs, and somehow offset that higher cost by lowering distribution, prescriptions, or management costs or increasing beneficiary co-payments. Neither DoD nor DoD's pharmacy benefits manager has much practical ability to have wholesalers pass on to retail pharmacies less than their normal amounts in order to offset DoD's ultimate manufacturing costs that exceed the FCPs.

Although drug manufacturers argue that retail pharmacies enjoy a mark-up over what they pay wholesalers, the DoD's pharmacy benefits manager already negotiates network agreements with retail pharmacies that seek best value, consistent with DoD policy objectives on maintaining a very large retail pharmacy network, currently more than 60,000 pharmacies. In theory, DoD could limit payments to retail pharmacies so as to offset the absence of the FCP 24% discount in manufacturing costs, but the predictable effect of this would be that most or all retail pharmacies would drop out of the network, resulting in an inability of DoD to extend the benefits of the network system to many military families. DoD policy favors a very large pharmacy network because military families, which include spouses and children of deployed military members and also include Reserve Component families, are in communities all over the United States. Retail pharmacy industry commenters stated they had no economic ability to absorb such reductions, and that is consistent with DoD's understanding.

The other two participants in the retail pharmacy enterprise are the pharmacy benefits manager and the beneficiary. With respect to the

pharmacy benefits manager, DoD's management costs are the product of the competitive selection of a pharmacy benefits manager contractor under the Competition in Contracting Act. Manufacturing costs are pass-through costs under this contract, so there is no opportunity for the pharmacy benefits manager contractor to absorb the higher manufacturing costs that would result from not applying FCPs to manufacturing costs. Finally, beneficiary co-payments are the means to encourage beneficiaries to favor more cost-effective drugs and service venues, and must conform to a set of statutory specifications. There is little or no room to accommodate these requirements and objectives and also to offset the absence of a 24% discount in manufacturing costs.

A recent Congressional Budget Office report, "Prescription Drug Pricing in the Private Sector," January 2007, used available private sector economic data to construct a hypothetical example of payments for a single-source prescription. In this example, the plan sponsor paid a total of $88 for a prescription, of which $74 went to the manufacturer (manufacturing cost), $3 to the wholesaler (distribution cost), $5 to the retail pharmacy (prescription fill cost), and $6 to the pharmacy benefits manager (management cost). The economics reflected in the relative amounts in this example support the view that best business practice is to treat FCPs as applicable to manufacturing costs, and therefore the manufacturer prices. Further, pharmaceutical industry representatives have never asserted that they do not make a profit at the Federal Ceiling Price or that the economics could support assessing the burden of FCPs on any other participant.

Based on all of these factors, best business practice is for DoD to deal with management costs through the best value competitive selection of a pharmacy benefits manager; prescription fill costs through the pharmacy benefits manager's network pharmacy negotiations, consistent with overall health program objectives; beneficiary co-payments based on incentives for cost-effective utilization, consistent with statutory specifications; distribution costs, to the extent there is any feasibility, indirectly through retail network negotiations; and manufacturing costs by applying FCPs in a manner comparable to the application of FCPs to manufacturing costs in the military facility and mail order programs. Therefore, based on the criteria of best business practice, DoD has concluded that the financial burden of FCPs is properly assigned to drug manufacturers.

(c) *Assessment of options for practicability of administration concerning who bears the burden of FCPs.*

Again assuming that the only requirement of the statute applies to the amount paid by DoD in the retail pharmacy program and that DoD can implement that requirement by allocating financial burden on any of the five identified participants, the issue here is to assess what allocation is consistent with practicability of administration. The allocation of the financial burden of FCPs to manufacturers in the context of a retail pharmacy program can be administered through a rebate/refund apparatus, possibly among other options (which will be discussed below). A rebate system is common practice in the industry and was used by the TRICARE Retail Pharmacy Program prior to the enactment of NDAA–08 to implement a program of formulary-based manufacturer discounts.

Allocating the financial burden to wholesalers is not practicable because, like most plan sponsors, DoD has no relationship with wholesalers in the distribution mechanisms of the retail pharmacy system in the United States. Further, as pointed out by a commenter, it is not clear how DoD could identify from prescription claims data the identity of the wholesaler that sold the drugs to the retail pharmacy since there is nothing comparable to a National Drug Code (NDC) number, which identifies the manufacturer. An administrative system for imposing FCPs on retail pharmacies could presumably be created that would limit payments to FCPs plus a reasonable prescription filling fee, but this would not avoid the retail pharmacy losing money on each transaction. Under the current pharmacy benefit manager relationship, there is no practicable way to allocate the financial burden of FCPs to the TRICARE pharmacy benefits manager because manufacturing costs are a pass-through to DoD and there is no basis to subtract an amount equal to 24% of total manufacturing costs from the management fee DoD pays the pharmacy benefits manager, that total fee being a far lesser amount. An administrative system for allocating the financial burden of FCPs to beneficiaries in the form of co-payments increased by an amount equal to 24% of manufacturing costs would be feasible to design but not to implement because it would far exceed the maximum co-payment amounts allowed by 10 U.S.C. § 1074g. Thus, all things considered, DoD has concluded that allocating the financial burden of FCPs to manufacturers is the most practicable of administration.

(d) *Conclusion on who bears the burden of applying FCPs.*

Considering harmony with the statute and legislative history, best business practice, and practicability of administration, DoD has concluded that it is most appropriate that manufacturers bear the burden of applying FCPs to the TRICARE Retail Pharmacy Program. No commenter contested this conclusion or proposed a different option.

2. How are FCPs applied?

Accepting that for the reasons discussed above FCPs apply to manufacturer prices, the second issue is *how* FCPs will be applied to manufacturer prices. In the proposed and final rules, DoD applied FCPs to manufacturer prices through manufacturer refunds to DoD of amounts received by the manufacturers for covered prescriptions paid for by the TRICARE Retail Pharmacy Program. The Court's opinion of November 30, 2009, stated that "Congress did not speak to the 'precise question' of how the Department should implement the statute's requirements." The opinion continued:

Indeed, the Court can imagine several other regulatory schemes consistent with 10 U.S.C. 1074g(f) that the Department could have chosen. For example, instead of requiring pharmaceutical manufacturers to pay DoD the amounts in excess of the Federal Ceiling Prices, a rule could require manufacturers to reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. Or DoD arguably could have adjusted the retail pharmacy mark-ups or dispensing fees to ensure that the Department did not pay more than Federal Ceiling Prices. The Coalition suggests two additional possibilities: "DoD could have contracted with pharmacies to purchase TRICARE beneficiaries' drugs * * * at the Federal Ceiling Price," or "DoD could have procured drugs directly from manufacturers at the Federal Ceiling Price and then distributed the drugs to pharmacies."

The manufacturer refund method as well as the four alternative options noted in the Court's opinion have been considered. DoD also considered two other options that are used in other parts of the TRICARE Pharmacy Benefits Program—vendor charge-backs and replacement inventories. No other options on how to apply FCPs to

manufacturer prices were presented by commenters, including commenters representing pharmaceutical manufacturers, and no commenters recommended a method other than manufacturer rebates or refunds.

(a) *Assessment of options for harmony with the statute and legislative history concerning how FCPs are applied.*

10 U.S.C. 1074g(f) provides that "with respect to any prescription filled * * *, 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 * * * are subject to the pricing standards in such section 8126."

The manufacturer refund method of implementation is in harmony with the statute. In the case of Department of Defense procurement of drugs under § 8126, the drug manufacturer's price may not exceed the FCP and the manufacturer is not paid more than the FCP. Under § 1074g(f), a prescription filled in the TRICARE retail pharmacy program and paid for by DoD should produce the same outcome. The manufacturer refund method produces the same outcome because the manufacturer refunds to DoD the amount above the FCP that the manufacturer had been paid when the manufacturer began the chain of transactions that ended with the prescription being filled through the TRICARE retail pharmacy program. Thus, DoD's net manufacturing cost is at the FCP and the manufacturer's net price is at the FCP.

The first alternative option is that instead of requiring pharmaceutical manufacturers to refund to DoD the amounts in excess of the Federal Ceiling Prices, a rule could require manufacturers to reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. If a practicable way could be devised to identify prospectively the subset of drugs that will end up as TRICARE retail pharmacy program prescriptions out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler, this alternative could also be in harmony with the statute.

The second alternative option is that DoD could perhaps adjust the retail pharmacy mark-ups or dispensing fees to ensure that the Department did not pay more than Federal Ceiling Prices. If this occurs after the manufacturer has already been paid more than the FCP by the wholesaler (*e.g.,* been paid at the average manufacturer price) and the wholesaler passed that higher price on to the retail pharmacy, harmony with the statute and the resolution of issue number one (on who bears the burden of FCPs) would require some further transaction between the retail pharmacy and the manufacturer (such as a manufacturer rebate/refund to the retail pharmacy) so that the FCP pricing standard actually applies to the manufacturer. Were this accomplished, then the manufacturing cost portion of the amount the retail pharmacy charges DoD could be held down to the FCP, and the result would be in harmony with the statute.

The third alternative option is that DoD could contract with pharmacies to allow those pharmacies to purchase drugs for distribution to TRICARE beneficiaries at the Federal Ceiling Price. Were a practicable method devised for this approach, it would be in harmony with the statute because prescriptions filled in the TRICARE retail pharmacy program would be with drugs for which manufacturers were paid at the FCPs and the savings would be passed on the DoD through the arrangement between DoD and the retail pharmacies.

The fourth alternative option would be for DoD to procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies. Were a practicable method devised for this approach, it would also be in harmony with the statute because prescriptions filled in the TRICARE retail pharmacy program would be with drugs for which manufacturers were paid directly by DoD at the FCP.

The fifth alternative option is the vendor charge-back method, under which the wholesaler obtains a refund from the manufacturer for pharmaceuticals that the wholesaler passes down stream to retail pharmacies for TRICARE beneficiaries. This system is used in the military system for drugs sold by wholesalers to military facility pharmacies, the charge-back to the manufacturer being based on FCPs or lower contracted prices. Were a feasible method devised for managing the retail transactions for exclusive use for TRICARE beneficiaries, this approach would be in harmony with the statute.

The sixth alternative option is the replacement inventory approach, under which the pharmacy fills TRICARE prescriptions from its regular inventory of drugs, but is allowed to replace this inventory from DoD's prime vendor wholesaler, which then uses the vendor charge-back to the manufacturer. This system is used for the TRICARE Mail Order Program contractor. Were a feasible method developed for managing the transactions throughout the retail pharmacy network to limit replacement inventory to actual TRICARE prescriptions filled, this approach would be in harmony with the statute.

Thus, the manufacturer refund method is in harmony with the statute, as are the last four alternative options if they could be feasibly implemented. The other two alternatives, with sufficient other conditions met, could also be in harmony.

(b) *Assessment of options for consistency with best business practice concerning how FCPs are applied.*

The mechanism of manufacturer refunds is the established industry practice in the retail pharmacy system in the United States for manufacturers to provide price discounts—*i.e.,* reductions below the average manufacturer price applicable to sales to wholesalers—to health plan sponsors. No commenter contested this point. The manufacturer refund method of implementation is consistent with best business practice.

The first alternative option is that instead of requiring pharmaceutical manufacturers to refund or rebate to DoD the amounts in excess of the Federal Ceiling Prices, manufacturers could reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. This option does not fit normal industry practice, which cannot identify the subset of drugs that will end up as prescriptions paid for by a particular health plan sponsor out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler. No commenter recommended this alternative option.

The second alternative option—that the plan sponsor reduce payments to retail pharmacies by an amount corresponding to a manufacturing cost discount of 24% below the non-Federal average manufacturer price, expecting other arrangements among retail pharmacies, wholesalers, and manufacturers to accommodate those participants' commercial viability—is also outside the realm of established business practice in the retail pharmacy system in the United States. No commenter recommended this alternative option.

The third alternative option is that pharmacies purchase drugs from manufacturers earmarked for particular health plan beneficiaries so as to achieve different ultimate health plan costs for different health plans,

depending on the degree of discount the manufacturer intends for the particular plan sponsor. With so many different plan sponsors and so many thousands of retail pharmacies, this is not a system that is in use in the industry. No commenter recommended such a system for implementing FCPs for the TRICARE Retail Pharmacy Program.

The fourth alternative option—that the plan sponsor procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies for use in filling prescriptions to beneficiaries of the plan sponsor—is not an established system in the retail prescription drug system in the United States. It would require multiple product distribution and vast inventory management systems wholly different from those currently in use. No commenter recommended such a system.

The fifth alternative option, the vendor charge-back by the wholesaler to the manufacturer, is not a prevailing method for very large retail networks. It is in use in restricted pharmacy systems, like military facility pharmacies, where all beneficiaries are eligible for prescriptions filled with the drugs covered by the discounted price so that the vendor charge back can be applied to all drugs moving from the wholesaler to the retailer. In the large, non-restricted retail pharmacy network context, only a relatively small fraction of prescription drug customers of those pharmacies are TRICARE beneficiaries and only this fraction of prescriptions is covered by the discounted price. In such a context, a business process between manufacturers and wholesalers does not accommodate the manufacturer's desire to restrict the discount to a small subset of eventual retail customers.

The sixth alternative option, the replacement inventory approach, is also not a prevailing method for very large retail networks because of a need to track and audit the retail transactions to prevent diversion of discounted drugs to customers not eligible for the discounts. DoD uses this method with its mail order contractor, which is a single pharmacy, rather than a network of more than 60,000 pharmacies.

Thus, the manufacturer refund method is most consistent with established business practice in the retail prescription drug pharmacy system in the United States, and no commenter recommended an approach other than manufacturer rebates or refunds to apply FCPs to the TRICARE Retail Pharmacy Program.

(c) *Assessment of options for practicability of administration concerning how FCPs are applied.*

The manufacturer refund method of implementation is practicable administratively. Before the enactment of NDAA–08, the TRICARE Retail Pharmacy Program implemented a system of Voluntary Agreements for Retail Rebates (VARRs), which utilized the same apparatus as the refund program under the 2009 final rule. That apparatus includes an accounting through the data systems of prescriptions provided to TRICARE beneficiaries, submission of these data to manufacturers on a quarterly basis, procedures to reconcile any differences or disagreements between the manufacturer's data and DoD's data, and rebate/refund payments by the manufacturer to DoD of the amount in excess of the target price. Under the VARRs system the target price was that established in the agreement, which could be above or below the FCP. Under the final rule, the target price may be no higher than the FCP, but may be lower. The administrative apparatus, however, is the same. It is well established and works effectively.

The first alternative option is that instead of pharmaceutical manufacturers refunding to DoD the amounts in excess of the Federal Ceiling Prices, manufacturers could reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. This option is not practicable to administer because there is no existing apparatus to identify the very small (relatively) subset of drugs that will end up as prescriptions paid for by TRICARE out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler. No commenter suggested that such a system would be practicable.

The second alternative option—that TRICARE reduce payments to retail pharmacies by an amount corresponding to a manufacturing cost discount of 24% below the non-Federal average manufacturer price, expecting other arrangements among retail pharmacies, wholesalers, and manufacturers to accommodate those participants' commercial viability—is also not practicable. DoD has no way to manage the implementation of such other arrangements. It is not practicable to expect retail pharmacies to absorb an economic loss in order the remain in the TRICARE Retail Pharmacy Network. No commenter suggested that this alternative option is administratively practicable.

The third alternative option is that DoD authorize pharmacies to purchase drugs directly from manufacturers earmarked for TRICARE beneficiaries and to do so at the FCP. For example, the retail pharmacy could be authorized to order off the Federal Supply Schedule. This is not practicable because the retail pharmacies would then have to have a separate inventory management system to ensure that those drugs are used only for prescriptions provided to TRICARE beneficiaries, and not diverted to individuals covered by other health plans for whom the manufacturer is not required to provide drugs at the FCP. DoD has no administrative apparatus to ensure that 60,000 network pharmacies strictly maintain such a separate inventory management system, especially considering that TRICARE covered prescriptions are generally a very small fraction of the retail pharmacy's total prescription drug business. No commenter commented that this option would be administratively practicable.

The fourth alternative option—that DoD procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies for use in filling prescriptions to beneficiaries of the plan sponsor—is not practicable because DoD would need to establish a separate distribution system to deliver drugs to more than 60,000 retail pharmacies. Further, such pharmacies would then have to have a separate inventory management system to ensure that these drugs are not provided to non-TRICARE eligible people. It is not practicable for DoD to create separate distribution and inventory management systems for the vast prescription drug retail pharmacy industry, particularly because TRICARE beneficiaries make up a very small portion of the United States population served by that industry. No commenter commented that this alternative option is administratively practicable.

The fifth alternative, the vendor charge-back approach, is not practicable in a very large retail pharmacy network because there is no practicable system for DoD to ensure that the earmarked drugs from the wholesaler would be handled by many thousands of retail pharmacies for the exclusive benefit of TRICARE beneficiaries. No commenter recommended this approach as administratively practicable.

The sixth alternative, the replacement inventory approach, is also not practicable in a very large retail pharmacy network because DoD has no system to audit the inventory replacement for many thousands of retail pharmacies. No commenter recommended this approach.

Thus, the manufacturer refund method is the most administratively practicable system for implementing

FCPs for the TRICARE Retail Pharmacy Program and no commenter suggested that any other system was administratively practicable. In fact, with the exception of arguments made in litigation, the pharmaceutical industry has consistently endorsed manufacturer rebates or refunds as the practicable method of administration, and no commenter recommended otherwise.

(d) *Conclusion on how FCPs are applied.*

DoD's conclusion on *how* FCPs should apply to the TRICARE Retail Pharmacy Program is that they should apply through a system of manufacturer refunds to DoD of the amount the manufacturer received above the FCP. That system is in harmony with the statute and legislative history, consistent with best business practice in the industry, and administratively practicable. None of the alternative options is comparable based on these criteria and no commenter suggested that any of them be adopted.

3. When do FCPs apply?

This was not one of the issues that the Court ordered DoD to reconsider as a matter of DoD's discretionary judgment. However, it was an issue addressed in the Court's ruling and it was the subject of several comments. This issue is: *When* do FCPs begin to apply to prescriptions filled in the TRICARE retail pharmacy program? The Court's order of November 30, 2009, granted judgment in favor of DoD "with respect to the Defense Department's conclusion that 10 U.S.C. 1074g(f) required that the Federal Ceiling Prices apply to any TRICARE retail pharmacy prescriptions filled on or after January 28, 2008." The Court's opinion stated "the precise question is whether the statute's requirement that TRICARE drug prescriptions are subject to the Federal Ceiling Prices—however implemented by the agency—is active on January 28, 2008, or only once DoD promulgates a rule to implement the statute." The Court answered the question by explaining that "the statutory language is clear: 'With respect to *any* prescription filled *on or after the date of the enactment of [NDAA–08],'* pharmaceuticals purchased through the retail pharmacy program are subject to the Federal Ceiling Prices." (Emphasis in the Court's opinion.) The opinion further concludes that "no retroactivity problem is presented" by the final rule because all parties "were aware on January 28, 2008, that 10 U.S.C. 1074g(f) applied the Federal Ceiling Prices to retail pharmacy program transactions as of that date."

DoD understands the Court's conclusion to be that the starting date for applying FCPs to TRICARE Retail Pharmacy Program prescriptions is established by statute and it is not a matter of DoD's discretion in the final rule to establish a different starting date. DoD agrees with this conclusion. However, commenters on behalf of the pharmaceutical industry argue that DoD can and should establish a starting date on or after the effective date of the final rule. Therefore, assuming for the sake of completeness of the rule making record that DoD has discretion to establish a starting date for applying FCPs as of the effective date of the final rule, rather than the effective date of the statute, DoD has considered that alternative option.

(a) *Assessment of options for harmony with the statute and legislative history concerning when FCPs apply.*

Under this criterion, DoD agrees with the Court that "the statutory language is clear." Moreover, the primary statement of legislative history of this section of NDAA–08, the accompanying Conference Report, expressly stated Congressional intent that "the implementation date" is "the date of enactment of this Act." (H.Conf. Rept. No. 110–477, page 938.) Thus, the option of a start date as of the date of enactment of NDAA–08 is in harmony with the statute and legislative history, and the alternative option of a starting date as of the effective date of the final rule is not.

(b) *Assessment of options for consistency with best business practice concerning when FCPs apply.*

Pharmaceutical industry commenters asserted that standard business practice requires that arrangements concerning price be adopted prospectively and that it is unfair to change those arrangements after the fact. However, DoD believes this standard was met with respect to NDAA–08 because everyone was on notice that FCPs applied as of the date of enactment. Further, DoD sent a "Dear Pharmaceutical Manufacturer" letter to each manufacturer three days after the date of enactment of the law, providing them with a copy of the applicable section as well as DoD's interpretation making clear that DoD believed the law to apply to manufacturer prices as of the date of statutory enactment. Moreover, the proposed rule also stated that FCPs apply to any prescription filled on or after the date of statutory enactment. It is also noteworthy that NDAA–08 followed a four year running debate between the government and the pharmaceutical industry over the issue of applying FCPs to the TRICARE Retail Pharmacy Program, a debate that included prior litigation and Congressional consideration. Thus, no one associated with the pharmaceutical industry could have been unaware. Finally on this point, DoD included in the final rule a procedure for waiver or compromise of refund amounts to permit consideration of any particular circumstances where implementation as of the statutory effective date would be insupportable. On this criterion, DoD concludes that the statutory effective date option is consistent with best business practice of establishing prospective terms for transactions.

(c) *Assessment of options for practicability of administration concerning when FCPs apply.*

Based on the data systems that have been in use and the pre-existing VARRs process for retail rebates, both options—the statutory effective date option and the final rule effective date option—are administratively practicable.

(d) *Conclusion on when FCPs apply.*

On this issue, DoD has concluded that the statutory effective date option is the right one to adopt because it is in harmony with the statute and legislative history, whereas the final rule effective date option is not; it is consistent with best business practice; and it is on par with the final rule effective date option regarding administrative practicability.

4. To what do FCPs apply?

This also is not an issue the Court ordered DoD to reconsider as a matter of DoD's discretion. However, commenters on behalf of the pharmaceutical industry recommended that DoD reconsider it. The industry recommendation is that DoD not apply FCPs to *all* covered prescriptions filled through the TRICARE Retail Pharmacy Program and paid for by DoD, but only those prescriptions covered by prospective procurement contracts between DoD and the manufacturer or comparable agreements having certain attributes they associate with procurement contracts. The Court's November 30, 2009, opinion rejected the argument that the statute required a procurement-type contract as a precondition to applying FCPs, but considered this option to be within the scope of DoD's discretionary judgment as to implementation method.

DoD has considered two options on the issue of what prescriptions are to be covered by manufacturer refunds: (1) All covered prescriptions; and 2) only those prescriptions covered by procurement-type contracts or agreements. The 2009 final rule applied to *all* covered drug prescriptions, subject to a voluntary opt-out and a waiver/compromise process. Covered

drugs for this purpose are drugs covered by 38 U.S.C. 8126, paid for by DoD, introduced by the manufacturer into the normal supply chain, and dispensed to a TRICARE beneficiary by a network retail pharmacy. The final rule excluded drugs not covered by § 8126, drugs for which TRICARE was not primary payer, drugs provided through the 340B program, and (based on legislative history and administrative practicability) non-network pharmacy dispensed drugs.

The procurement-type contract option, as presented by commenters, would require a prospective written contract or agreement stating that in return for FCP-based refunds/rebates the manufacturer would receive favorable positioning on the uniform formulary, and that prescriptions filled in the TRICARE Retail Pharmacy Program for drugs not covered by such an agreement would be exempt from FCPs. (Some commenters asserted that the 2008 proposed rule was consistent with this option, but this is incorrect as both the 2008 proposed rule and the 2009 final rule required the application of FCPs to any prescription filled on or after the date of enactment and incorporated the regulatory overpayment recovery procedures of 32 CFR 199.11 for all such prescriptions.)

(a) *Assessment of options for harmony with the statute and legislative history concerning FCP applicability.*

As noted above, the statute provides:

> 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.

Section 8126 of title 38 is titled, "Limitation on prices of drugs procured by Department and certain other Federal agencies." The Department referred to is the Department of Veterans Affairs and the other agencies include DoD. The statute requires that as a condition of doing business under covered Federal programs, "[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 a [covered] Federal agency * * * the manufacturer has entered into and has in effect a pharmaceutical pricing agreement * * * under which the price charged * * * may not exceed 76 percent of the non-Federal average manufacturer price." The price referred to in this statute is the Federal Ceiling Price. The purpose and effect of section 8126, as applied to DoD, is that all covered drugs procured by DoD are subject to the Federal Ceiling Price.

Pharmaceutical industry commenters asserted that the "procurement of drugs" phrase in § 1074g(f) requires implementation through procurement-type contracts. They commented that this position is supported by the construct of § 8126, which requires an agreement and that the application of FCPs without such a contract would be to treat the TRICARE Retail Pharmacy Program better than other elements of DoD under § 8126. They further pointed to § 8126(g)(2), which they say freezes the statute's requirements in place as of the date of enactment, giving the resulting pharmaceutical pricing agreement precedence over later statutory enactments and their implementing regulations.

DoD does not agree that these views are in harmony with the statute and legislative history. The "procurement of drugs" phrase in § 1074g(f) is to identify the applicability of § 8126 and to establish the applicability of § 8126 as the purpose for which the TRICARE retail pharmacy program shall be treated as an element of DoD. That purpose is to bring it within the scope of the requirement of § 8126 "to the extent necessary to ensure that pharmaceuticals paid for by" DoD through the TRICARE retail pharmacy program "are subject to the" FCP "pricing standards." The "procurement of drugs" phrase does not in § 1074g(f) describe the *transaction* to which the FCP requirement attaches. Rather, the transaction to which the FCP requirement attaches is clearly established as a "prescription filled" for a drug "paid for by" DoD "provided by" a program pharmacy "to eligible covered beneficiaries." The procurement-type contract option requires that the phrase "procurement of drugs" in § 1074g(f) be treated as the TRICARE Retail Pharmacy Program *transaction* to which the FCP requirement attaches. This would treat the statute as if it read:

> With respect to any *procurement of drugs by the TRICARE retail pharmacy program* [rather than "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 *procured by the TRICARE retail pharmacy program* [rather than "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.

This is not in harmony with what Congress actually enacted. It would not cover "any prescription filled," but only some prescriptions filled. It would not "ensure that" pharmaceuticals paid for by DoD are subject to FCPs; it would exempt prescriptions paid for by DoD but not covered by a procurement-type contract. And it would not provide that the retail pharmacy program "shall" be treated as an element of DoD for purposes of FCP applicability, only that it may be so treated if that is provided for in a procurement-type contract.

The pharmaceutical industry's argument on § 8126(g)(2) also does not have weight. What this paragraph actually says is that a manufacturer meets its obligation under that law if it "establishes to the satisfaction of the Secretary" of Veterans Affairs that the manufacturer is complying with § 8126 as enacted, without regard to a future legislative change in that section. DoD has seen no evidence that the Secretary of Veterans Affairs has determined that anything in § 1074g(f) or the 2009 final rule is beyond the scope of § 8126. Rather, it is DoD's understanding that the position of the Secretary of Veterans Affairs continues to be that the TRICARE Retail Pharmacy Program is covered by § 8126. (In the preamble to the 2009 final rule, DoD suggested that DoD and the pharmaceutical industry should "agree to disagree" on whether the TRICARE Retail Pharmacy Program is covered directly by § 8126 since that issue was beyond the scope of the final rule and DoD authority, and it would be a moot point if manufacturers complied with the final rule.)

Nor is the procurement-type contract option in harmony with the legislative history of what Congress enacted. The Conference Report accompanying NDAA–08 described the applicable section 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.) In addition, a very similar provision that was passed by the Senate in its proposed version of NDAA–07 but not finally enacted at that

time ("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 section 8126 of title 38 * * *.") was described in the accompanying Senate Committee Report as a provision to "reaffirm a decision made by the Secretary of Veterans Affairs on October 24, 2002, * * * that drugs purchased by the Department of Defense through the TRICARE retail pharmacy network are subject to the same Federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program." (S. Rept. No. 109–254, pp. 342–43.) Thus, the all covered prescriptions option is in harmony with the statute and legislative history; the procurement-type contract option is not.

In addition to the pre-enactment legislative history, recent Congressional commentary reinforces this understanding of Congressional expectations. For example, the Senate Appropriations Committee report accompanying the Department of Defense Appropriations Bill, 2010, expressed concern that "the fiscal years 2008 and 2009 budgetary savings programmed by the Department of Defense and the Office of Management and Budget for manufacturer refunds for TRICARE retail pharmacy prescriptions under section 703 of the National Defense Authorization Act for Fiscal Year 2008 have not been realized," and asked for a report from DoD on implementation, "including an assessment of whether any additional legislation is needed to effectuate the purposes of section 703." (S. Rept. No. 111–74, p. 224.) (The resulting DoD report advised that no additional legislation is needed.) The House Appropriations Committee expressed similar concern, noting "the $1,000,000,000 in rebates that are currently owed." (H. Rept. No. 111–230, p. 307.)

(b) *Assessment of options for consistency with best business practice concerning FCP applicability.*

Commenters on behalf of the pharmaceutical industry assert that best business practice calls for the voluntary agreement of the parties and that only a procurement-type contract is consistent with this practice. But the all covered prescriptions option also provides for the voluntary agreement of the parties; no pharmaceutical manufacturer is forced to do business with DoD under 10 U.S.C. 1074g or other agencies under 38 U.S.C. 8126. Manufacturers make a voluntary choice to do business with DoD under the applicable terms. The difference between the two options is not in the *nature* of the voluntary participation, it is in the *terms* of the voluntary participation. The procurement-type contract option seeks more limited *terms,* such as that FCPs will only apply if drugs receive *preferred* status under the uniform formulary, rather than *covered* status. The 2009 final rule attaches FCP applicability to a voluntary decision by the manufacturer to keep its drugs covered by TRICARE, rather than take the opt-out opportunity provided in the rule. Voluntariness is preserved under both options. Under the all covered prescriptions option, preferred formulary status is based on cost-effectiveness, which means a price no higher than the FCP, and for drug classes that have competition among covered drugs, generally a price below the FCP. Taking advantage of competition in drug classes to produce prices below FCP (*i.e.,* refunds greater than the FCP-level refund) is more consistent with best business practice. All of this has to do with the *terms* of doing business, not with the nature of the business practice.

(c) *Assessment of options for practicability of administration concerning FCP applicability.*

Both options rely upon the same implementation apparatus, so both options are administratively practicable.

(d) *Conclusion on the issue of to what do FCPs apply.*

DoD has concluded that the option that all covered drug TRICARE retail pharmacy network prescriptions are subject to FCPs is the better option because: It is in harmony with the statute and legislative history, while the alternative, procurement-type contract option is not; it is more consistent with best business practice; and it is comparable in administrative practicability.

C. Additional Issues Raised by Public Comments

What follows is a brief summary of the 2009 final rule and a discussion of the new public comments received pertinent to those provisions. The 2009 final rule added to section 199.21 of the TRICARE regulation, the section governing the Pharmacy Benefits Program, a new paragraph (q) regarding pricing standards for the retail pharmacy program.

1. Section 199.21(q)(1).

As in paragraph (1) of the 2008 proposed rule, paragraph (1)(i) of the 2009 final rule repeated the statutory requirement, virtually verbatim. Like the statute, both the proposed and final rules applied FCPs to "any prescription filled on or after the date of the enactment" of the statute. Paragraph (1)(ii) was added in the 2009 final rule to state in simpler terms (similar to the primary statement in the legislative history of § 1074g(f)) DoD's interpretation of the statute as requiring that all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to FCPs.

Applicability of FCPs to All Covered Drug Prescriptions (Para. (q)(1)(ii))

Comment: Pharmaceutical industry commenters recommended an exemption, which could potentially be added to this paragraph, for prescriptions filled after January 28, 2008, but covered by pre-existing Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs) that provided for less than FCP-based discounts, the exemption lasting as long as necessary to implement the termination clause of the VARR. The rationale was that this would show appropriate deference to the terms of the pre-existing agreements.

Response: For the reasons given above relating to the starting date for applying FCPs under the statute, DoD has concluded that the final rule should not be changed, and that it should, as the proposed rule did, mirror the statute's applicability to "any prescription filled on or after the date of enactment." The statutory effective date, of which everyone had notice, obviated the need for DoD to cancel the pre-existing UF–VARRs, which also could have been canceled at any time by the manufacturer. The applicability of FCPs on or after January 28, 2008, is not dependent on Tier 2 Uniform Formulary status or the existence of a VARR or pricing agreement. If there is some special circumstance regarding any particular drug, it can be addressed under the waiver/compromise authority of paragraph (q)(3)(iii).

2. Section 199.21(q)(2).

Paragraph (q)(2) provided, similar to the proposed rule, that a written agreement by a manufacturer to honor Federal Ceiling Prices in the retail pharmacy network is with respect to a particular covered drug a condition for inclusion of that drug on the uniform formulary (Tier 2, or in the case of covered generic drugs, Tier 1) and for the availability of that drug through retail network pharmacies without preauthorization.

Preauthorization of Tier 3 Drugs (Para. (q)(2)(ii))

Comment: Pharmaceutical industry commenters recommended removal of the requirement that drugs not covered by voluntary pricing agreements and thus disqualified from Tier 2 uniform formulary status also become subject to preauthorization for dispensing at the retail pharmacy. The argument was made that this preauthorization conflicts with other preauthorization requirements in the TRICARE Pharmacy Benefits Program regulation.

Response: There is no conflict. There are simply two different types of preauthorization. One type of prior authorization relates to *whether* a patient needs a particular drug. The preauthorization required under this paragraph relates to *where* the patient should receive it. If the manufacturer refuses to comply with the requirement to apply FCPs at the retail venue, TRICARE will consider other options to meet the patient's needs, which may include dispensing that same drug at the mail order venue.

Comment: Retail pharmacy industry commenters also recommended elimination of the prior authorization requirement on the grounds that it potentially shifts business from retail pharmacies to the mail order pharmacy and that DoD should force manufacturers to honor FCPs without disadvantaging retail pharmacies.

Response: DoD hopes it will not be necessary to rely on either Tier 3 status or the preauthorization process to reinforce the FCP requirement under paragraph (q), but is unable at this point to forgo the option, when needed. Therefore, this provision is retained in the new final rule.

Inclusion of Authorized Generics as "Covered Drugs" (Para. (q)(2)(iii))

Comment: Pharmaceutical industry commenters recommended exclusion of authorized generics from the definition of covered drugs. Authorized generics are drugs that were approved by the Food and Drug Administration under a new drug application (NDA), rather than an abbreviated new drug application (ANDA) under section 505(j) of the Food, Drug, and Cosmetic Act, and are still marketed under the original NDA approval, but are no longer single source drugs. The rationale was that generic drug competition usually produces a low price and it is unfair to impose an additional FCP-based discount to the authorized generics when their competitor ANDA generics have no such requirement.

Response: With awareness of the statutory reference to "the pricing standards in * * * section 8126," the 2009 final rule maintained the section 8126 definition of covered drugs. Covered drugs, including authorized generics, are subject to FCPs under section 8126 and are sold at the FCP (or FSS price if lower) for prescriptions filled at military facility pharmacies and the mail order pharmacy program. In regard to the economics of authorized generics, manufacturers still have marketing options to protect profits. In any event, the Department of Veterans Affairs, the lead agency for FCP implementation government-wide, has not recommended exemption of authorized generics as covered drugs, and DoD has concluded that following the lead agency's policy on this is advisable. Therefore, the new final rule is unchanged on this point.

Exclusion of 340B Drugs (Para. (q)(2)(iii)(E))

Comment: Pharmaceutical industry commenters recommended the continued exclusion of 340B program drugs.

Response: This provision is unchanged in the new final rule. They are excluded.

Comment: Commenters on behalf of specialty providers under the 340B program agreed that 340B covered drugs should be excluded from covered drugs under this rule, but expressed concern that this might be causing their newly restricted ability to participate in the TRICARE Retail Pharmacy Network.

Response: DoD is aware of and seeking to address issues between some of these providers, such as comprehensive hemophilia treatment centers, and TRICARE's Pharmacy Benefits Manager contractor. These issues, however, are not affected by the exclusion of 340B program drugs from this final rule and thus are outside the scope of this rulemaking.

3. Section 199.21(q)(3).

Paragraph (q)(3) of the 2009 final rule addressed refund procedures. As under the proposed rule, paragraph (q)(3)(iii) of the 2009 final rule stated that a refund due under the final rule is subject to section 199.11 of the TRICARE regulation, the section that governs "overpayments recovery." The 2009 final rule was 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. Also, in response to pharmaceutical industry complaints that the rule would make the imposition of FCPs involuntary on manufacturers since they could not control the flow of their products through the supply chain that end up as prescriptions filled under the TRICARE Retail Pharmacy Program, the 2009 final rule was 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. Based on such a voluntary opt-out, DoD could block the prescription at the retail network pharmacy and in other transactions pertinent to the military facility pharmacies and mail order pharmacy, thus preserving the manufacturer's voluntary choice on whether it wants to participate in the TRICARE Pharmacy Benefits Program.

FCP Calculation (Para. (q)(3)(ii))

Comment: Pharmaceutical industry commenters suggested that DoD apply an alternative Federal Ceiling Price under this rule, one that would not include the computation under § 8126(d)(1) that is referred to as the "FSS Max Cap."

Response: Under paragraph (q)(3)(ii), DoD applies the FCP as it is calculated and provided by the Department of Veterans Affairs (DVA). The DVA's calculations in second and subsequent years of multi-year contracts take into account prices reflected in those contacts, referred to as the FSS Max Cap. In those years the resulting FCP is applicable to all covered drug contracts and applicable to the TRICARE Retail Pharmacy Program. Based on this comment, DoD considered asking DVA to produce an alternative set of FCPs for the TRICARE Retail Pharmacy Program that would exclude any impact of the FSS Max Cap. Assuming the technical feasibility of this option, it was considered under the same criteria used for the major issues assessed in this rulemaking reconsideration process. With respect to consistency with the statute and legislative history, there is clear legislative history that Congress intended "that drugs purchased by the Department of Defense through the TRICARE retail pharmacy network are subject to the same federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program." S. Rept. 109–254, pp. 342–343. The use of two sets of FCPs—one for military facilities and the mail order program and a different set for the retail program—would conflict with this Congressional intent. In addition, with respect to administrative practicability, there is currently only one set of FCPs calculated by DVA, and while it is not impossible to calculate an alternative set of FCPs, doing so for one segment of

covered drugs for one of the "big four" agencies covered by section 8126 could create confusion and administrative difficulties. Further, in connection with implementation of the 2009 final rule to date and the voluntary agreements made under it, DoD is unaware of any request from a manufacturer for use of anything other than the normal FCPs, nor of any request from a manufacturer for a waiver or compromise of the refund amount based on the possible effect on the FCPs of the FSS Max Cap. Were there special circumstances relating to application of the FCP in a particular case, the compromise process would be the appropriate one to find a remedy. Based on these considerations, it is DoD's judgment that the single set of FCPs calculated by DVA under section 8126 apply to the TRICARE Retail Pharmacy Program as they do to the TRICARE Pharmacy Benefits Program generally.

Overpayments Recovery Procedures (Para. (q)(3)(iii)(A))

Comment: Pharmaceutical industry commenters recommended deletion of the provision stating that the normal TRICARE overpayments recovery procedures of 32 CFR 199.11 would apply to retail refunds due under § 199.21(q), or revision to limit overpayments recovery to refunds owed under contracts. Comments argued that properly constructed voluntary refunds do not fit the purposes and scope of § 199.11.

Response: DoD believes § 199.11, which has been incorporated by reference since the proposed rule, is properly used for all refunds under § 199.21(q), all of which are based on the voluntary decision of the manufacturer to participate in TRICARE. Section 199.11 applies to "erroneous payments," which are "expenditures of government funds which are not authorized by law or this part" (*i.e.,* Part 199, the TRICARE Regulation). Because this final rule is intended, in the terms used in the statute, to ensure that covered prescriptions are subject to the FCP pricing standards, it fits § 199.11 very well to view the amount paid that exceeds FCPs as an expenditure of government funds in excess of the amount authorized by the TRICARE regulation, specifically § 199.21(q), which in turn is authorized by the statute.

Opt-Out Provision (Para. (q)(3)(iii)(C))

Comment: Pharmaceutical industry commenters recommended that remedial actions continue to be on a drug-by-drug basis, rather than a company-by-company basis, to give manufacturers flexibility on deciding whether they wish to do business with TRICARE.

Response: The opt-out provision continues to be on a drug-by-drug basis. A manufacturer is not required by this regulation to remove all of its drugs from TRICARE coverage in order to remove any. However, DoD makes no representation that selective opt-outs would be consistent with the manufacturer's obligations under its § 8126 master agreement, a matter which is outside DoD's authority.

Comment: Pharmaceutical industry commenters commented that manufacturers should be given notice and an opportunity to opt-out in order to avoid liability for prescriptions filled prior to the effective date of the regulation.

Response: The opt-out opportunity has been available since the effective date of the 2009 final rule, May 26, 2009. The 2009 final rule provided for "the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program." To date, no manufacturer has opted out. DoD takes this as a voluntary agreement to participate in the TRICARE Pharmacy Benefits Program under the terms of the TRICARE Regulation. The opt-out opportunity remains available under this new final rule, and it may be coupled with a request for waiver or compromise.

Comment: Pharmaceutical industry commenters asserted that in the absence of a voluntary agreement between a manufacturer and DoD, a refund requirement conflicts with the Unfunded Mandates Reform Act.

Response: This program is neither unfunded nor a mandate. The opt-out provision ensures that the application of FCPs is a function of the voluntary decision of manufacturers to participate in the TRICARE Pharmacy Benefits Program under the terms required or authorized by statute, including 10 U.S.C. 1074g(f). The economic impact of this regulation is not in the nature of a mandatory expenditure by the private sector, but in the nature of reduced Federal expenditures for pharmaceuticals paid for by DoD under TRICARE, which is precisely what Congress intended.

Comment: Pharmaceutical industry commenters argued that the opt-out authority should allow manufacturers to opt out of the Retail Pharmacy Program only, rather than opt out of the entire TRICARE Pharmacy Benefits Program. They argued that if they opt out of the TRICARE Pharmacy Benefits Program completely, this will put them in violation of their master agreement with the Department of Veterans Affairs, which includes a requirement to make their products available under the Federal Supply Schedule to DoD.

Response: Again, this is a discussion over *terms* of voluntary participation in the TRICARE Pharmacy Benefits Program, not over the nature of voluntary participation. If the pharmaceutical industry is correct that 39 U.S.C. 8126(g)(2) (which is discussed above) freezes their § 8126 obligations as of the original enactment of that law and that this TRICARE rule creates new obligations beyond the scope of § 8126, they will be able to remain in compliance with § 8126 by demonstrating a willingness to adhere to the original scope of obligations, including a willingness to make their drugs available under the Federal Supply Schedule. If the industry is not correct about that (which DoD believes to be the case), manufacturers remain free voluntarily to decide whether they want to do business with all agencies covered by § 8126 under the terms Congress has established or authorized. For doing business with DoD, DoD believes the terms of voluntary participation are properly set as honoring FCPs in all three venues of the TRICARE Pharmacy Benefits Program—military facility pharmacies, mail order pharmacy, and retail pharmacy network. DoD understands that manufacturers would prefer more favorable terms, but these terms are in harmony with the statute and legislative history, consistent with best business practice, and administratively practicable.

4. Section 199.21(q)(4), Remedies.

Paragraph (q)(4) of the 2009 final rule provided that in the case of the failure of a manufacturer of a covered drug to make or honor an agreement under paragraph (q), DoD may take any action authorized by law. This paragraph was unchanged from the 2008 proposed rule.

Comment: Pharmaceutical industry commenters recommended deletion of the provision stating that in the case of the failure of a manufacturer "to make" an agreement under paragraph (q), DoD may take any other action authorized by law on the grounds that the only appropriate remedy would be under breach of contract rules concerning an agreement that had been voluntarily made.

Response: DoD believes the authority to take any action authorized by law, which has been included since the proposed rule, is properly used for all obligations under the regulation, all of which are based on the voluntary

decision of the manufacturer to participate in the TRICARE Retail Pharmacy Program. However, the point is well taken that under the rule, a failure "to make" an agreement is not an action that should be treated as noncompliance nor be the subject of a remedy. This is because the applicability of FCPs is not dependent upon the making of an agreement. Rather, it is a function of the voluntary decision of a manufacturer to continue to participate in the TRICARE Pharmacy Benefits Program, rather than to take advantage of the opt-out opportunity. Therefore, this paragraph has been revised. The revised paragraph no longer premises a remedy on *a failure* "*to make or honor an agreement under*" *paragraph (q), but on a failure* "to honor a requirement of" paragraph (q) or "to honor an agreement under" paragraph (q). An accompanying revision is also made to paragraph (q)(3)(iii)(B) to state that during the pendency of a request for waiver or compromise of a refund amount, the matter that is the subject of the request will not be treated as a failure to honor a requirement of paragraph (q).

5. Section 199.21(q)(5).

Finally, paragraph (q)(5) of the 2009 final rule authorized beneficiary transition provisions to protect beneficiary access to particular pharmaceuticals even when manufacturers act to avoid the application of FCPs. No comments were received during this new comment period regarding this provision.

D. Provisions of New Final Rule

DoD is readopting the 2009 final rule, with one substantive change and another accompanying revision. The substantive change is to paragraph (q)(4) concerning remedies. An accompanying change is to paragraph (q)(3)(iii)(B) concerning the effect of a pending request for waiver or compromise of a refund amount. Following is a summary of the new final rule.

Section 199.21(q) establishes pricing standards for the retail pharmacy program. Paragraph (1) restates the statutory requirement. With respect to any prescription filled on or after the statutory effective date (January 28, 2008), all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices. Paragraph (1) is unchanged from the 2009 final rule. Paragraph (1) answers the question, "When do FCPs apply?" They apply to all prescriptions filled on or after the date of statutory enactment.

Paragraph (2) states that a manufacturer's written agreement to honor the requirement of paragraph (1) is a condition for including a drug on the preferred tier (Tier 2, or in the case of covered drugs that are generics, Tier 1) of the uniform formulary and the availability of that drug through retail network pharmacies without preauthorization. As under the 2008 proposed rule and the 2009 final rule, an agreement to honor FCPs does not guarantee preferred tier placement because FCPs are a ceiling price and the cost-effectiveness standard for Tier 2 (and in some cases Tier 1) placement may result in the FCP being insufficiently cost-effective in particular drug classes. Also as under the 2008 proposed rule and the 2009 final rule, the application of FCPs is not conditional on preferred formulary status. Paragraph (2) also defines covered drugs for purposes of the applicability of FCPs. Paragraph (2) is unchanged from the 2009 final rule. This paragraph (2), along with paragraph (3), answer the questions, "Who bears the burden of FCPs?" and "How do FCPs apply?" Manufacturers bear the burden of FCPs, and they apply through manufacturer refunds.

Paragraph (3) establishes refund procedures. Such procedures may be included in an agreement under paragraph (2) or a separate agreement or default to the standard overpayments recovery procedures of the TRICARE regulation, § 199.11. Also under § 199.11, a manufacturer may request a waiver or compromise of a refund amount due. While a waiver or compromise request is pending, the matter that is the subject of the request will not, under revised wording of this paragraph, be treated as a failure to honor a requirement of paragraph (q) for purposes of DoD pursuing any remedies under paragraph (4). Also under paragraph (3), in addition to other grounds for waiver or compromise, a waiver request may be based on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefits Program. This paragraph (3) answers the question, "To what do FCPs apply?" They apply to all covered drugs the manufacturer has voluntarily chosen to keep in the TRICARE Pharmacy Benefits Program.

Paragraph (4) provides that remedies may be based on any action authorized by law. Paragraph (4) is changed from the 2009 final rule. The revised paragraph no longer promises a remedy on a failure "to make or honor an agreement under" paragraph (q), but on a failure "to honor a requirement of" the regulation "or to honor an agreement under" the regulation. This change reinforces that a manufacturer's failure "to make an agreement" is not subject to a remedial action because the applicability of FCPs is not dependent upon the "making" of an agreement. Rather, a remedy could be based on a failure to honor a requirement under the final rule for a manufacturer who has made the voluntary decision to participate in the TRICARE Pharmacy Benefits Program by not exercising the opt-out opportunity.

Paragraph (5) authorizes special beneficiary transition provisions for the continued availability of pharmaceuticals to beneficiaries. Paragraph (5) is unchanged from the 2009 final rule.

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 spending in the retail pharmacy component of the program.

At various times since the enactment of NDAA–08, DoD estimated the reduced spending associated with applying 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. At the time of the 2008 proposed rule, for example, DoD estimated FY–10 reduced spending of $388 Million for the DHP and $404 for the MERHCF. At the time of the 2009 final rule, DoD used a different estimating model and estimated much larger savings, including for FY–10 for example, reduced spending of $761 Million for the DHP and $910 for the MERHCF. Based on experience since issuance of the final rule and a refined estimating model, DoD now estimates that the reduced spending will be closer to the original, lower estimates. DoD's current estimated cost reductions from applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network in Fiscal Years 2010 through 2015 appear in the following table. FCP savings estimates will continue to be updated as actual refunds are received and estimating methodologies are refined.

Millions of Dollars	
FY–2010 DHP Reduced Spending	375
FY–2010 MERHCF Reduced Spending	474
FY–2011 DHP Reduced Spending	434
FY–2011 MERHCF Reduced Spending	549
FY–2012 DHP Reduced Spending	458
FY–2012 MERHCF Reduced Spending	579
FY–2013 DHP Reduced Spending	490
FY–2013 MERHCF Reduced Spending	619
FY–2014 DHP Reduced Spending	523
FY–2014 MERHCF Reduced Spending	661
FY–2015 DHP Reduced Spending	560
FY–2015 MERHCF Reduced Spending	707

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

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.

Sec. 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 tribal 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(q) is revised 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 paragraph (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 § 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 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 paragraph (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 a requirement or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in § 199.11, 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 section 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 section 199.11 of this part.

(4) *Remedies.* In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to 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: October 7, 2010.

Morgan F. Park,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0926]

Drawbridge Operation Regulations; Hackensack River, Jersey City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 1 & 9 Lincoln Highway Bridge across the Hackensack River, mile 1.8, at Jersey City, New Jersey. The deviation allows the bridge owner to require a two-hour advance notice for openings for two and a half months and several short term bridge closures to facilitate bridge painting operations.

DATES: This deviation is effective with constructive notice from October 15, 2010 through December 15, 2010, and for enforcement with actual notice from October 4, 2010 through October 15, 2010.