

TRICARE Retail Refund Unsolicited Additional Discount Program (ADP) Agreement

CAVEATS:

The parties acknowledge that 32 C.F.R. §199.21 (q), effective May 26, 2009, provides that as a condition for placement on the Uniform Formulary (UF), manufacturers are required to agree to honor Federal Ceiling Prices (FCP) for prescriptions filled in retail network pharmacies. That regulation implements 10 U.S.C. §1074g(f), which provides:

PROCUREMENT OF PHARMACEUTICALS BY TRICARE RETAIL PHARMACY PROGRAM: With respect to any prescription filled after January 28, 2008, the TRICARE Retail Pharmacy Program shall be treated as an element of the Department of Defense (DoD) for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. Section 8126 to the extent necessary to ensure that pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under section 1074g are subject to the pricing standards Section 8126.

GENERAL CONCEPT: ADP is **NOT** contingent upon pharmaceutical agents being placed on the generic (1st tier) or formulary (2nd tier) of the DoD UF. Unsolicited ADP refund offers may be submitted only for pharmaceutical agents that have **NOT** been scheduled for review by the DoD Pharmacy & Therapeutics (P&T) Committee. **Note:** DoD makes no promises or implied expectations of future action of any kind in response to the submission of an ADP, and DoD reserves the right to reject unsolicited refund offers. Submission of an Unsolicited ADP refund offer, for example, will not result in formulary status change or preference for the product. Submission of an Unsolicited refund offer will not impact utilization management tools already in place (e.g., prior authorization criteria or quantity limit levels).

Unsolicited ADP Refund Offer

1. REFUND: By submitting this Unsolicited ADP refund offer, the pharmaceutical manufacturer listed in Paragraph 13 below, henceforth the Company, agrees to provide the additional refunds to the Government based on the accrued utilization of and the refund stated for the pharmaceutical agent(s) listed herein. As noted in the General Concept paragraph above, the Company will provide the additional refunds to the Government without any conditions, implied expectations or promises of future action of any kind including, but not limited to, changes in formulary status or in utilization management tools (e.g., prior authorization criteria or quantity limit levels).

2. SCOPE: The Company's quoted refund along with quarterly TRICARE retail pharmacy network utilization for the pharmaceutical agent(s) will be used to calculate the quarterly amount due under this Agreement and the amount to be paid to the Government as outlined in this Agreement.

3. EFFECTIVE DATE and PERIOD OF RESULTING PRICING AGREEMENT: The Agreement effective date shall be the date the Defense Health Agency (DHA) signs the Agreement. Refund accrual and invoicing will be calculated in accordance with Paragraph 6, below. In the event that a pharmaceutical agent's

drug class is reviewed in a P&T Committee meeting in the future, the existing Agreement will be terminated upon the implementation specified in the UF decision. The Agreement will continue until terminated in accordance with Paragraph 8, Termination, below.

4. ELIGIBLE TRANSACTIONS: The refund will apply to all prescription transactions where a TRICARE retail network pharmacy dispenses the pharmaceutical agent listed in the ADP Appendix to a DoD beneficiary in accordance with terms of the TRICARE Retail Refund Program (TRRP).

The Company shall not be required to pay a refund under this Agreement with respect to utilization of a pharmaceutical agent if such agent was dispensed at a Military Treatment Facility; TRICARE Home Delivery; or non-network retail pharmacies.

For more information regarding TRRP, exclusions, and eligibility, please refer to the most recent TRICARE Retail Refund Program Manufacturer Policy and Procedures Guide, found on the Pharmacy Division Information for Pharmaceutical Manufacturers site under Operational Documents or by accessing the following link:

<http://health.mil/About-MHS/Defense-Health-Agency/Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers/Operational-Documents>

5. REFUND:

(1) Refunds will be submitted as a percentage (**expressed to four (4) decimal places XX.XXXX%**) of the most recent annual Non-Federal Average Manufacturer Price (Non-FAMP). The additional refund will be added to the refund required by 10 U.S.C. §1074g(f) and 32 C.F.R. §199.21 (q), the Standard Discount Program refund. The most recent annual non-FAMP is the annual non-FAMP (reported to the Department of Veterans Affairs) from which the current annual Federal Ceiling Price (FCP) calculated ceiling is derived. The most recent annual non-FAMP is applicable to all prescriptions filled during a calendar year. The refund percentage will remain static during the life of the agreement but the most recent annual non-FAMP, and thus the calculated refund, may change each calendar year.

Upon agreement between both parties, the Company may use Wholesale Average Cost (WAC) in place of non-FAMP for some medications/devices.

During the time period that the ADP is in effect, the Company may offer larger refunds at any time.

(2) In the event that the Company transfers the right to manufacture the pharmaceutical agent(s) covered by this agreement, whether by change in the Company's corporate ownership or otherwise, this ADP is automatically assigned to the transferee and all terms and conditions of this ADP remain in effect. The Company remains liable for all refunds on pharmaceutical agents dispensed within thirty (30) days after its notification to the Pharmacy Operations Division of the pending or completed transfer.

6. UTILIZATION ACCRUAL AND INVOICING: (1) For purpose of calculating the refund in excess of the current FCP, the accrual of TRICARE retail network utilization will begin on the date that this Agreement is signed by DHA. The Government shall provide utilization data to the Company on a quarterly basis.

The billing cycle will be calendar quarters, with billing periods of January – March, April – June, July – September, and October – December. The payment due date is seventy (70) days from the date the utilization data is made available to the manufacturers.

Failure to pay in full without following the outlined dispute resolution process by the designated payment due dates, or without an approved extension may result in the termination of this ADP.

The DoD will provide billing information for the payment of pharmaceutical agents on the ADP and reconciliation materials due by the Company, and obtain invoicing information for the Company's agent listed in Paragraph 13, The Company, below. Invoices will note the billing period, and provide a summary of accrued utilization by product listing (NDC-11) for that billing period by unit (tablet, capsule, inhaler, etc.) and the percent refund in this ADP.

(2) The Company may also obtain reporting of the billing period's accrued utilization by transaction from DoD.

7. RESOLUTION OF DISAGREEMENTS CONCERNING DATA USED TO DETERMINE REFUNDS:

In the case of a manufacturer disputing the accuracy of DHA's utilization data, the refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with the procedures laid out below. Disputes must be submitted no later than seventy (70) days following the date of the release of the utilization data; the same date that refund payment is due. Please refer to the Information for Pharmaceutical Manufacturer's webpage for Refund Payment Due and Dispute Cut-Off Dates. When the dispute is resolved, any refund owed relating to the amount in dispute will be due with interest from the date of the demand letter, consistent with 32 C.F.R. § 199.11, and will be paid by the manufacturer or credited by DHA by the due date of the next quarterly payment after resolution.

Please refer to the most recent TRICARE Retail Refund Program Manufacturer Policy and Procedures Guide, found on the Pharmacy Operations Division Information for Pharmaceutical Manufacturers site under Operational Documents or by accessing the following link:

<http://health.mil/About-MHS/Defense-Health-Agency/Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers/Operational-Documents>

8. TERMINATION: Either party may terminate this ADP by providing written notice to the other party. Such notice shall be effective one hundred-twenty (120) days following receipt of written notice of termination by the other party.

9. ADP SUBMISSIONS: Send all submissions to (either):

Pharmacy Contracting Officer
Contracting Office, Defense Health Agency
16401 East Centretech Parkway

Aurora CO 80011-9043

Or

UFVARR_Requests@mail.mil

See next page for ADP submission signature page.

THE COMPANY: The Company point of contact for the administration and management of this agreement is:

Name:	
Title:	
Address:	
Telephone Number:	
Email Address:	
Fax Number:	

FOR THE COMPANY

By: (Signature)	
Date:	
Name:	
Title:	
Name of Company:	

ADP Execution: An Unsolicited ADP is hereby established between the Company and the DoD for the pharmaceutical agents and applicable refunds on the attached ADP Appendix.

By: (Signature)	
Signed Date:	
Effective Date:	
Name:	

Unsolicited ADP Appendix

Pharmaceutical companies must submit a separate pricing appendix for each NDC-11.

NDC	Drug Name	Strength	Dosage Form	Package Size

<i>Most recent Annual Non-Federal Average Manufacturer's Price (non-FAMP) per FCP Package Size**</i>	Current Annual Federal Ceiling Price (FCP) per FCP Package Size**	Standard Refund per FCP Package Size** (non-FAMP – FCP)	Additional Offered Refund (Y%) per FCP Package Size. Percentage is Static and is a percentage of non-FAMP (non-FAMP*Y%)	Total Calculated Retail Refund per FCP Package Size** ((non-FAMP – FCP) + (non-FAMP *Y%)) = Total Calculated Refund
\$	\$	\$	%	\$

* Only one price per category may be submitted.

** Based on the most recent annual non-FAMP (reported to the Department of Veterans Affairs) from which the current annual Federal Ceiling Price (FCP) calculated ceiling is derived. The current annual FCP and the annual non-FAMP from which it is derived will be applicable to all prescriptions filled during a calendar year. The additional refund percentage will remain static during the life of the agreement but the most recent annual non-FAMP, and thus the calculated refund, may change each calendar year.