

Voluntary Agreements for TRICARE Retail Pharmacy Refunds (VARR) for Uniform Formulary Placement

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. This regulation implements 10 U.S.C. § 1074g(f), as amended by § 703 of the National Defense Authorization Act for Fiscal Year 2008, which provides:

PROCUREMENT OF PHARMACEUTICALS BY TRICARE RETAIL PHARMACY PROGRAM: *With respect to any prescription filled on or after the date of 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 (DoD) for purposes of the procurement of drugs by Federal agencies under § 8126 to title 38 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 this section are subject to the pricing standards in such § 8126.*

GENERAL CONCEPT: The Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF-VARR) is contingent upon pharmaceutical agents being placed on the generic (1st tier) or formulary (2nd tier) of the DoD Uniform Formulary. Refund quotes for UF-VARRs may be submitted only for pharmaceutical agents that are scheduled for review by the DoD Pharmacy & Therapeutics (P&T) Committee at the next Committee meeting. The DoD P&T Committee will consider refund quotes for UF-VARRs as part of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the placement of pharmaceutical agents on the DoD Uniform Formulary.

Refund Quote for Inclusion on Uniform Formulary (UF)

- 1. REFUND QUOTE FOR INCLUSION ON THE UNIFORM FORMULARY:** By submitting this Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF-VARR) quote, the pharmaceutical manufacturer listed in Paragraph 13, The Company, below (henceforth The company) agrees to provide refunds to the Government based on the accrued utilization of and the refund stated for the pharmaceutical agent(s) listed on the attached UF VARR Appendix. All NDC-11s of each pharmaceutical agent are covered by this agreement and must be listed on the attached UF VARR Appendix.

The accrued utilization will be based on the listed pharmaceutical agents that are dispensed to eligible beneficiaries by TRICARE network pharmacies under the DoD pharmacy benefits management contract associated with the TRICARE Retail

Pharmacy Program. The refund quote(s) for the pharmaceutical agent(s) listed in the UF VARR Appendix is (are) contingent upon such pharmaceutical agent(s) being included on the DoD Uniform Formulary in not worse than the formulary (2nd) cost share tier.

The DoD P&T Committee will consider the refund quote for the pharmaceutical agent(s) listed in the UF VARR Appendix in the cost to the Government portion of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the selection of agents for the UF, and the classification of a pharmaceutical agent in the generic (1st), formulary (2nd), or non-formulary (3rd) cost share tier. If the DoD P&T Committee determines that a pharmaceutical agent should be recommended for inclusion on the UF, the DoD P&T Committee will also make a recommendation whether the pharmaceutical agent should be placed in the generic or formulary cost share tier in accordance with 32 C.F.R. 199.21(j).

If the Director, TRICARE Management Activity (TMA), makes a final decision to accept the recommendations of the P&T Committee relative to the pharmaceutical agent(s) contained in the Company's refund quote and places the pharmaceutical agent(s) on the UF in not worse than the formulary (2nd) cost share tier, the TMA Chief, Pharmaceutical Operations Directorate, on behalf of the Department of Defense, will establish a UF-VARR by completing Paragraph 14, UF-VARR Execution, below.

2. **SCOPE:** The Company's quoted refund along with quarterly TRICARE Retail Pharmacy Network utilization for the quoted NDCs will be used to calculate the 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 Director, TMA, makes the final decision regarding placement of the pharmaceutical agent(s) on the UF. Refund accrual and invoicing will be calculated in accordance with Paragraph 8. The Agreement will continue until the effective date of any change in the classification of the pharmaceutical agent(s) contained in the Agreement as UF agent(s), or is otherwise terminated in accordance with Paragraph 10, Termination, below.
4. **ELIGIBLE TRANSACTIONS:** The refund will apply to all prescription transactions where a TRICARE Retail Network Pharmacy dispenses a pharmaceutical agent listed in the UF VARR Appendix to a DoD beneficiary in accordance with terms of the DoD pharmacy benefits management contract associated with the TRICARE Retail Pharmacy Program.

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 (MTF); TRICARE Mail Order Pharmacy (TMOP); or non-network retail pharmacies. Additionally, the Company shall not be required to pay a refund under this Agreement for retail dispensings submitted for reimbursement by

eligible beneficiaries as a Direct Member Reimbursement (DMR)(paper) claim; retail dispensings submitted for reimbursement by state Medicaid agencies; retail dispensings submitted for reimbursement by commercial payers (e.g., Coordination of Benefits (COB) claims); retail dispensings submitted for reimbursement by aggregators/clearinghouses; compound prescriptions; or repackaged products.

5. **FINAL APPROVAL BY THE GOVERNMENT:** In submitting this UF-VARR refund quote for the pharmaceutical agent(s) listed in the UF VARR Appendix hereto, the Company understands that the DoD P&T Committee will consider the quoted refund(s) in determining the cost of such pharmaceutical agent(s) to the Government as part of its relative cost effectiveness evaluation of such pharmaceutical agent(s). The incorporation of a refund quote into DoD executed UF-VARR is contingent upon final decision of the Director, TMA, approving the recommendations of the DoD P&T Committee.
6. **EXTENT OF GOVERNMENT OBLIGATION:** The placement of the listed pharmaceutical agent(s) in the UF is not worse than the formulary (2nd) cost share tier in accordance with the final decision of the Director, TMA, is a condition of receiving funds under this Agreement. This Agreement imposes no obligation on the DoD to purchase any product.
7. **REFUND and NATIONAL DRUG CODE (NDC) CHANGES:** (1) The Company agrees to hold open its UF-VARR refund quote for one hundred- eighty (180) days.

(2) Refund quotes will be submitted as a percentage (expressed to two (2) decimal places XX.XX%) of the Non-Federal Average Manufacturer Price (Non-FAMP) for each NDC-11. Under 38 U.S.C. 8126, Federal Ceiling Price (FCP) is the maximum price manufacturers can charge for FSS-listed brand name drugs to the Big 4, even if the FSS price is higher. The FCP must be at least 24% below Non-FAMP. Non-FAMP and FCP prices are not publicly available.

During the time period that the UF-VARR is in effect, the Company may offer larger refunds at any time. After UF decisions for pharmaceutical agents included in this Agreement are made and while this Agreement is in effect, the Company may submit supplementary performance-based agreements for increased refunds for consideration by the DoD but shall be under no obligation to do so.

(3) In the event that the Company ceases manufacturing and/or selling any NDC of any pharmaceutical agent(s) listed in this UF-VARR agreement, such NDC shall be deemed deleted from this UF-VARR effective one hundred-twenty (120) days after notice is given by the Company to the Government.

If any NDC-11 is deleted or for any reason no longer available for purchase, the Company shall work with the Government to identify new or reasonably equivalent product listings (NDCs), in order that the Government will continue to receive refunds commensurate with UF placement for these pharmaceutical agents. Generally, the Company may calculate an equivalent refund at the product strength level.

- 8. 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 the UF status becomes effective in the TRICARE Retail Pharmacy Network. The Government shall provide utilization data to the Company in accordance with the "Process and Procedures Guide – Retail Utilization Refunds and Voluntary Agreements for Uniform Formulary Placement" found at http://www.tricare.mil/pharm_mfg/default.cfm. Specifically, refund calculation information can be found in the aforementioned guide in the "Refunds Calculations for Voluntary Agreements for Retail Refunds" section beginning on page 11.

The billing cycle will be calendar quarters, with billing periods of January – March, April – June, July – September, and October – December. Invoices for pharmaceutical agents on the UF-VARR will be distributed by the DoD on or about the 15th day of the month following the preceding billing period with payment due seventy (70) days from the invoice date. A request for an extension of the invoice due date must be submitted to the Pharmaceutical Operations Directorate (POD) no later than fourteen (14) calendar days prior to the invoice due date.

Failure to pay in full without following the outlined dispute resolution process by the designated invoice due date, or without an approved extension may result in the termination of this UF-VARR and reconsideration by the DoD P&T Committee of the listed pharmaceutical agents' placement on the UF, in addition to any other remedies available to DoD.

(2) The DoD will provide billing information for the payment of pharmaceutical agents on the UF-VARR 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 UF-VARR. The Company will submit the TRICARE Retail Refunds Reconciliation of Quarterly Utilization with the payment to include the current FCP (as of the invoice date) for each invoiced product listed and the dollar total of the refund by product listing (NDC-11).

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

- 9. RESOLUTION OF DISAGREEMENTS CONCERNING DATA USED TO DETERMINE REFUNDS:** If the Company disputes the accuracy of the 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 outlined in the "Process and Procedures Guide – Retail Utilization Refunds and Voluntary Agreements for Uniform Formulary Placement" beginning on page 12 under the "Dispute Resolution Process."
- 10. TERMINATION:** Except as provided in Paragraph 7(1) of this Agreement, either party may terminate this UF-VARR by providing written notice to the other party as identified in Paragraphs 12 and 13 respectively. Such notice shall be effective one

hundred-twenty (120) days following receipt of written notice of termination by the other party.

- 11. **GENERAL PROVISIONS:** The Company is required to have an existing FSS Contract for any pharmaceutical agent(s) quoted in this UF-VARR.

- 12. **UF-VARR SUBMISSIONS:** Send all submissions to:
Chief, Pharmaceutical Operations Directorate
ATTN: UF-VARR
Skyline Five, Suite 810
5111 Leesburg Pike
Falls Church, VA 22041-3206

- 13. **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:	

- 14. UF-VARR EXECUTION:** A Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF-VARR) is hereby established between the Company and the Department of Defense for the pharmaceutical agents and applicable refunds quoted on the attached UF VARR Appendix based on the final decision of the Director, TMA, to include the pharmaceutical agents on the Uniform Formulary.

BY: (Signature)	
Date:	
Name:	Thomas J. McGinnis Rear Admiral, RPh, USPHS Chief, Pharmaceutical Operations Directorate