

**Department of Defense (DoD) Retail Refund Pricing Agreement
Between
TRICARE Management Activity (TMA)
(Hereinafter Referred to "TMA")
And
The Manufacturer Identified in Section IX of this Agreement
(Hereinafter Referred to as "The Manufacturer")**

Note: *This agreement satisfies the requirement of TRICARE regulation (32 CFR 199.21(q)(2)(i)) for a manufacturer's written agreement and for establishing refund procedures (32 CFR 199.21(q)(3)(i)). However, use of this agreement template is not required by the regulation or by TRICARE Management Activity (TMA).*

Note: *This agreement does not cover drugs which are currently part of an executed Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF-VARR) and the Manufacturer.*

Note: *This agreement only covers brand medications. For the purposes of this Agreement, this Agreement does not include: (a) a drug that is not included in the term "covered drug" under 38 U.S.C. 8126; (b) a drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f); (c) a drug that is not provided through a retail network pharmacy under this section; (d) any pharmaceutical for which the TRICARE Pharmacy Benefits Program is the second payer; (e) any drug provided under a prescription and dispensed by a pharmacy under Section 340B of the Public Health Service Act; (f) over-the-counter (OTC) drugs, which are drugs that may be sold without a prescription and which is prescribed by a physician or other persons authorized to prescribe such drugs under Federal or State law; (g) generic medications approved by the Food and Drug Administration under 505J; (h) any exception, consistent with law, established by TMA.*

The TRICARE Management Activity (TMA), on behalf of the United States Department of Defense, and _____, on its own behalf, for purposes of Title 10, United States Code, Section 1074(g)(f) and Title 32, Code of Federal Regulations, Paragraph 199.21(q), hereby agree to the following:

I. DEFINITIONS

(a) “Covered Branded Drug” — will have the meaning set forth in 32 CFR 199.21(q)(2)(iii).

(b) “Director” — means the Director of TRICARE Management Activity, as defined in 32 CFR 199.2.

(c) “Federal Ceiling Price (FCP)” — is the maximum price manufacturers can charge for Federal Supply Schedule (FSS)-listed brand name drugs to the Department of Defense (DoD), under section 8126 of title 38, United States Code, even if the FSS price is higher.

(d) “Federal Supply Schedule (FSS)” — means the Federal Supply Schedule for drugs, biologicals, and pharmaceuticals negotiated, awarded, and administered by the Department of Veterans Affairs (VA) on behalf of the General Services Administration (GSA).

(e) “Manufacturer” — will have the meaning set forth in section 8126(h)(3) of title 38, United States Code, except, for the purposes of this agreement, shall mean the entity holding legal title to or possession of the NDC number for the covered branded drug.

(f) “NDC – National Drug Code” — the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the agreement the complete eleven (11) digit NDC number will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.

(g) “Non-Federal Average Manufacturer Price (non-FAMP)” — shall have the meaning set forth in section 8126(h)(5) of title 38, United States Code. “Nominal prices” excluded from the non-FAMP calculation means any price less than 10% of the non-FAMP in the previous quarter.

(h) “POD” — Pharmaceutical Operations Directorate, TMA.

(i) “Quarter” — means calendar quarter unless otherwise specified.

(j) “Refund Payment” — the Manufacturer’s payment of a refund due under 32 CFR 199.21(q).

(k) “TRICARE Retail Utilization Pharmaceutical Data” — means the information on the total number of units of each dosage form and strength of the Manufacturer’s covered branded drug. This information is based upon the number of pharmaceuticals paid by TRICARE that are provided by TRICARE retail network pharmacies during a calendar quarter. The TRICARE Retail Utilization Pharmaceutical Data to be supplied includes: (1) NDC number; (2) Product name; (3) Units paid during the quarter by NDC number; and (4) Total number of prescriptions paid for during the quarter by NDC number.

(l) “Unit” — means drug unit in the lowest identifiable amount (i.e., tablet or capsule for dosage forms, milliliter for liquid forms, gram for ointments or creams).

(m) “Wholesaler” — means merchant middleman, including a prime vendor or similar distribution system, who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users, mainly for resale or business use. For drugs only sold directly to the retailer, other merchants, or industrial, institutional, or commercial users, the buyer will be considered to be the wholesaler.

II. MANUFACTURER’S RESPONSIBILITY

Pursuant to requirements under 32 CFR 199.21(q), the Manufacturer agrees to the following:

(a) To honor the pricing standards required by 10 U.S.C. § 1074g(f) and referred to in 32 CFR 199(q)(1), for covered branded drugs listed on Appendix A and provided through a TRICARE retail network pharmacy.

(b) Provide refund payment within seventy (70) days from the date of submission of the TRICARE retail utilization pharmaceutical data except for any refund amount disputed by the Manufacturer under the Dispute Resolution Process (Appendix B) or for which the Manufacturer has submitted a written request for waiver or compromise under 32 CFR 199.21(q)(3)(iii).

(c) To select one of the following methods of calculation and follow said method for all drugs listed on Appendix A for the duration of this Agreement:

Note: *The current annual FCP and non-FAMP on which it was based will be those applicable during the calendar year in which the prescription was filled.*

- Calculation of the refund for each applicable NDC listing will be the difference between the average non-federal price of the drug sold to wholesalers, as represented by the annual non-FAMP and the corresponding FCP.
- Calculation of the refund for each applicable NDC listing will be the difference between FCP and direct commercial contract sales prices specifically attributed to the reported TRICARE paid pharmaceuticals.

(d) To select one of the following methods of calculation and follow said method for all drugs listed on Appendix A for the duration of this Agreement:

- Calculate the refund based upon the units reported on the utilization reports.
- Calculate the total number of package sizes units by dividing the total metric quantity by the package size (contents metric quantity) of the 11-digit NDC number, rounding the resulting number of package size units down to the next whole number package size for purpose of refund calculations.

(e) To retain all records that may be necessary to provide information for not less than three (3) years from the date of their creation.

(f) To notify TMA when a new NDC is released.

(g) To notify TMA when a NDC is sold or discontinued.

III. TMA'S RESPONSIBILITY

Pursuant to the requirements under 32 CFR 199.21(q), TMA agrees to the following:

(a) To include drugs listed in Appendix A of this Agreement onto the Three Tiered DoD Uniform Formulary and to consider each such drug for 2nd tier status no later than the next scheduled review of the applicable drug class by the P&T Committee.

(b) To ensure availability of drugs listed in Appendix A of this Agreement and placed on the 2nd tier of the Formulary through TRICARE retail network pharmacies without preauthorization under 32 CFR 199.21(k).

IV. DISPUTE RESOLUTION

(a) In the event that in any quarter a discrepancy in TRICARE Retail Utilization is discovered by the Manufacturer, the Manufacturer will provide written notice of the discrepancy, by NDC number to the POD within ten (10) business days of receipt of the utilization data under the Disputes Resolution Process at Appendix B.

(b) If the Manufacturer believes the utilization data are erroneous the Manufacturer shall pay DoD the portion of the refund amount claimed which is not disputed. Upon resolution, the balance due, if any, plus interest from the date payment of the amount was initially due, consistent with 32 CFR 199.11, will be paid by the Manufacturer or credited by TMA, by the due date of the next quarterly payment after resolution of the dispute.

(c) TMA and the Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of such notification.

(d) In the event that TMA and the Manufacturer are unable to resolve the discrepancy within sixty (60) days, the Director, POD will review all pertaining evidence and render an administrative decision.

(e) In the event the administrative decision is issued, the Manufacturer may request reconsideration or appeal the decision under the provisions of 32 CFR 199.10. Upon resolution, the balance due, if any, plus interest from the date payment of the amount was initially due, consistent with 32 CFR 199.11 will be paid by the Manufacturer or credited by TMA, by the due date of the next quarterly payment after resolution of the dispute.

V. CONFIDENTIALITY PROVISIONS

(a) Any proprietary information contained in a report submitted to the POD shall remain privileged and confidential pursuant to authority under the Freedom of Information Act, 5 U.S.C. 552(b)(4), except as TMA determines necessary to carry out provisions of 10 U.S.C. 1074g(f), and to permit the Comptroller General and the Director of the Congressional Budget Office to review the provided information.

(b) The Manufacturer will hold audit information confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to TMA to enable TMA to carry out the provisions of section III.

(c) Notwithstanding the non-renewal or termination of this Agreement for any reason, the above confidentiality provisions will remain in full force and effect.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of one (1) year, beginning on the date specified in section VIII of the Agreement. It shall be automatically renewed for additional successive terms of one (1) year unless the Manufacturer gives written notice of intent not to renew the Agreement at least ninety (90) days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective ninety (90) days after the Manufacturer provides written notice requesting termination.

(c) Upon the failure of the Manufacturer to honor this Agreement with respect to a particular covered drug listed in Appendix A, TMA shall terminate the Agreement sixty (60) days after giving written notice to the Manufacturer of said violation. In addition, TMA reserves the right to take all other actions authorized under 32 CFR 199.21(q) or as authorized by law.

(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section II until a period of one (1) complete calendar quarter has elapsed from the effective date of the termination, unless TMA finds good cause for earlier reinstatement.

VII. GENERAL PROVISIONS

(a) The Manufacturer is required to have an existing FSS Contract for all pharmaceuticals listed in Appendix A.

(b) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing to:

Pharmaceutical Operational Directorate
TRICARE Retail Refund Program '
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042

(c) Notice to the Manufacturer will be sent to the address provided with the Agreement and updated upon Manufacturer notification to TMA at the address in the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing and signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of TMA, and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, the report or other item required by this Agreement will be due on the first business day following the weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date of 10 U.S.C. 1074g(f) of 28 January 2008.

IX. SIGNATURES

TRICARE MANAGEMENT ACTIVITY

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

MANUFACTURING COMPANY:

Physical Address of Manufacturer:	
Mailing Address of Manufacturer:	

The Manufacturer point of contact for administration and management of this Agreement is:

Name:	
Title:	
Address:	
Telephone:	
Email:	
Fax:	
Tax Payer Identification Number:	

ACCEPTED FOR THE MANUFACTURER: I certify that I have made no alterations, amendments or other changes to this Pricing Agreement.

Signature:	
Name:	
Title:	
Date:	

X. APPENDIX A

Drugs listed here are covered by this Agreement.

COVERED DRUGS

The following drugs are covered under the Agreement between the Manufacturer and the Department of Defense (DoD) via the "Department of Defense (DoD) Retail Formulary Pricing Agreement."

Note: Providing the FCP and Non-FAMP constitutes placement of NDC-11 onto this Pricing Agreement.

NDC-11	PRODUCT	STRENGTH	PACKAGE SIZE	FCP NON-	FAMP

XI. APPENDIX B – DISPUTE RESOLUTION PROCESS

Overview

If a Manufacturer disputes the accuracy of TMA’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 following procedures established by TMA. When the dispute is resolved, any refund owed relating to the amount in dispute will be due with interest from the date payment of the amount was initially due, consistent with 32 CFR 199.11, and will be paid by the Manufacturer or credited by TMA by the due date of the next quarterly payment after resolution of the dispute.

Dispute Resolution Process

1. The Pharmaceutical Operations Directorate (POD) Program Office will submit a Reconciliation of Quarterly Invoices (RQI) with each invoice submitted to the Manufacturer.
2. In the event that a discrepancy in TRICARE Retail Utilization Pharmaceutical Data is discovered by the Manufacturer, the Manufacturer will submit the completed RQI to the POD.

The following fields will have been populated with the current quarter’s data:

- NDC
- Product Name
- Rebate per Package/Rebate per Unit
- Units Invoiced
- Rebate Amount Invoiced

The Manufacturer will complete the following fields:

- Units Paid – Total units not in dispute.
- Units Disputed – Total units disputed.
- Dispute Code – The dispute codes for the corresponding claims.

- Withheld Invoice Amount – The amount of the disputed claims which are not being paid at this time.
 - Rebate Amount Paid – The amount being paid for the NDC.
3. The Manufacturer must also submit a disputed claims report for each disputed claim. This report can be generated from the manufacturers' database; however, the following information must be included for each disputed claim:
- Rx Number
 - NDC
 - Product Name
 - Units/Quantity
 - Date of Service/Fill Date
 - Pharmacy Identification Number
 - Claim/Authorization Number
 - Dispute Code
 - Any required supporting documentation
4. The Manufacturer may submit disputes utilizing one of the following methods:
- As an electronic version to: ufvarr@tma.osd.mil.
 - Via fax to 703-681-1940

Upon receipt, a POD staff member will acknowledge receipt of the RQI and provide the point of contact (POC) for the dispute.

5. If the Manufacturer believes the utilization data is erroneous, the Manufacturer shall pay the portion of the refund amount claimed which is not disputed.

Upon resolution, the balance due, if any, plus interest from the date payment of the amount was initially due, consistent with 32 CFR 199.11, shall be paid by the Manufacturer or credited by the POD by the due date of the next quarterly payment after resolution of the dispute.

6. The POD and the Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of the RQI and the disputed claim report.

7. In the event the POD and the Manufacturer are unable to resolve the discrepancy within sixty (60) days, the Director, POD, will review all pertaining evidence and render an administrative decision.
8. In the event an administrative decision is issued, the Manufacturer may request reconsideration or appeal the decision under the provisions of 32 CFR 199.10. Upon resolution, the balance due, if any, plus interest from the date payment of the amount was initially due, consistent with 32 CFR 199.11, shall be paid by the Manufacturer or credited by the POD by the due date of the next quarterly payment after resolution of the dispute.

Dispute Codes

A	Duplicate Claim
B	Invalid/Miscoded NDC
C*	NDC transferred to another labeler code or company.
D	Discontinued/terminated NDC for which the shelf life expired more than one (1) year from the dispense date.
E	Invalid Pharmacy Identification Number/NCPDP Provider ID
F	Missing/Invalid Prescription (Rx) Number
G	Decimal Discrepancy or Rounding Problem
H*	Package Size Discrepancy
I*	Units invoiced exceed unit sales.
J*	Product not eligible for a refund.
K	PHS/340B entity not extracted from utilization data.
L	Utilization/quantity inconsistent with number of prescriptions.
M*	Utilization/quantity inconsistent with historical trends or current program information.
N	Utilization/quantity inconsistent with lowest dispensable package size.
O	Utilization/quantity exceeds normal/usual and customary.
P*	Other
Q	Closed out; all disputes resolved.
R	Duplicate Claim - Coordination of Benefit (COB)/Other Health Insurance (OHI)
*	Supported Documentation Required