Department of Defense (DoD) Retail Refund Pricing Agreement Between

Defense Health Agency (DHA)
(Hereinafter Referred to "DHA")
And

The Manufacturer Identified in Section IX of this Agreement
(Hereinafter Referred to as "The Manufacturer")

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)).

Drugs covered by this Agreement are those covered drugs belonging to the Manufacturer under 38 U.S.C. 8126, as defined in 31 CFR 199.21(q)(2)(iii). New covered drugs and new NDCs for existing covered drugs are covered under this agreement.

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[1] 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 DHA.

[1] All Pharmacies identified as part of the TRICARE Retail Network including long term care facilities, specialty pharmacies, and pharmacies inside physician officers/hospitals.

The Defense Health Agency (DHA), 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 Drug"* – A covered drug is a drug that is a covered drug under 38 U.S.C. § 8126. If TRICARE provides utilization data of covered drugs, a refund is owed.

(b) *"Federal Ceiling Price (FCP)"* – is the maximum price manufacturer may charge for a covered drug sold to the "Big Four".

(c) *"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 drug.

(d) *"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.

(e) *"Non-Federal Average Manufacturer Price (non-FAMP)"* – shall have the meaning set forth in section 8126(h)(5) of title 38, United States Code.

(f) *"POD"* – Pharmacy Operations Division, DHA.

(g) *"Quarter"* – means calendar quarter unless otherwise specified.

(h) *"Refund Payment"* – the Manufacturer's payment of a refund due under 32 CFR 199.21(q).

(i) *"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 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.

(j) *"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).

(k) *"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 199.21(q)(1), for covered drugs of the manufacturer under 38 U.S.C. 8126, as defined in 32 CFR 199.21 (q)(2)(III) and provided through a TRICARE retail network pharmacy.

(b) The due date for payment is set forth in a demand letter. Refunds will be due at least seventy (70) days after the utilization data are released to Manufacturers. All Manufacturers, even those without a Pricing Agreement, will receive a demand letter thirty (30) days before the due date unless the refunds are paid in full before the demand letters are released. Please refer to the Information for Pharmaceutical Manufacturer's webpage for Refund Payment Due and Dispute Cut-Off Dates.

(c) To follow said method for all covered drugs for which a refund is owed:

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.

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.*

(d) To select one of the following methods of calculation and follow said method for all covered drugs 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 DHA via a TRICARE Retail Refund Appendix A Change Request form when a new NDC is released, sold, or discontinued.

https://health.mil/trrp

III. DHA'S RESPONSIBILITY

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

(a) To include covered drugs as defined above 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 covered drugs placed on the 2nd tier of the Formulary through TRICARE retail network pharmacies without preauthorization under 32 CFR 199.21(k).

IV. DISPUTE RESOLUTION

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 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.

Refer to the latest Policy and Procedures Guide which can be found on the TRICARE Retail Refunds Website under Operational Documents or by using the following link:

https://health.mil/trrp

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

DHA 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 DHA to enable DHA 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, DHA shall terminate the Agreement sixty (60) days after giving written notice to the Manufacturer of said violation. In addition, DHA 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 DHA finds good cause for earlier reinstatement.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement may be sent electronically to UFVARR_Requests@mail.mil or in writing to:

Pharmacy Operations Division
TRICARE Retail Refund Program
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042

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

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

(d) 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 constructed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

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

(f) 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.

(g) 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 DHA, and the Manufacturer.

(h) 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

DEFENSE HEALTH AGENCY:

Signature:	
Name:	Col Paul Hoerner, USAF, BSC Deputy Chief, Pharmacy Operations Division Healthcare Operations Directorate Defense Health Agency
Date:	

MANUFACTURING COMPANY:

Physical Address of Manufacturer:	
Mailing Address of Manufacturer:	

ACCEPTED FOR THE MANUFACTURER:

Signature:	
Name:	
Title:	
Date:	

☐ **I certify that I have made no alterations, amendments or other changes to this Pricing Agreement.**

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