# TRICARE RETAIL REFUND PROGRAM

Manufacturer Policy and Procedures Guide

Standard Discount Program (SDP) and Additional Discount Programs (ADP)

VERSION 5.3

LAST UPDATED: September 2022

#### **Updates**

#### Major updates to the guide are listed below

Release Date	Major Updates
July 2015	Policy and Procedures Guide Released
June 2017	<ul> <li>Updated dispute codes</li> <li>Overview of the Dispute Resolution Process added</li> <li>Made all appendix documents available on Manufacturer Homepage</li> </ul>
December 2018	<ul> <li>Updated Dispute Resolution Section</li> <li>Added updated Questionnaire/Appendix A Forms</li> <li>Updated listed Operational Documents section</li> <li>Updated Quarterly Utilization Data Process and TRRWS language.</li> </ul>
September 2022	<ul> <li>UPDATED</li> <li>Updated Dispute Resolutions section for 340B (K Code) process.</li> <li>Updated definition of Dispute Code A.</li> <li>340B Verification Form updated.</li> <li>TRICARE Retail Refund Program NDC Transfer Request Form added (Appendix I).</li> </ul> REMOVED <ul> <li>Questionnaire Form Discontinued.</li> <li>Appendix A Transfer Form Discontinued.</li> </ul>

Please note that the most current version of the
TRICARE Retail Refund Program Manufacturer Policy and Procedure Guide
and documents described within supersedes all previously distributed documents. For the most
current program forms please visit our <u>Information for Pharmaceutical Manufacturers Homepage</u>.

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#### **Acronyms & Definitions**

This list defines terms and abbreviations, including acronyms, used in this policy and procedures guide.

**ACH** – Automated Clearing House

**BPA** – Blanket Purchase Agreement

ADP - Additional Discount Program

CN File - Product Level Data

**COB** – Coordination of Benefits

CP File - Transaction Level Data

**CRM** – Contract Resource Management

**DAW** – Dispense as Written

**DEERS** – Defense Enrollment Eligibility Reporting System

**DHA** – Defense Health Agency

**DoD** – Department of Defense

**EFT** – Electronic Funds Transfer

FCP - Federal Ceiling Price

**FCP-ADP** – Federal Ceiling Price Additional Discount Program

**FDA** – U.S. Food and Drug Administration

FM - Financial Manager

FSS - Federal Supply Schedule

**HIPAA** – Health Insurance Portability and Accountability Act

ICD - Interface Control Document

**ID** – Identification

IHS - Indian Health Service

MTF – Military Treatment Facility

**NCPDP** – National Council for Prescription Drug Programs

**NDC** – National Drug Code, the 11-digit number the Manufacturer or labeler and FDA assigns to a pharmaceutical product. It attaches to the product container at the time of packaging.

**non-FAMP** – Non-Federal Average Manufacturer Price

**NPI** – National Provider Identifier

**OCC (Other Coverage Code)** – A billing code that indicates whether a patient has other insurance coverage.

**OHI (Other Health Insurance)** – Any non-TRICARE health insurance that is not considered a supplement. TRICARE pays second after all other health plans except for Medicaid, or other programs or plans as identified by TRICARE.

**OTC (over-the-counter drugs)** – Drugs that do not require a prescription under federal law before they can be sold or dispensed.

**P&T** – DoD Pharmacy and Therapeutics Committee

**PA** – TRICARE Retail Refund Program Pricing Agreement

**PBM** – Pharmacy Benefit Manager

**PDTS** – Pharmacy Data Transaction Service

**PGP Public Key** – Password Generator Protocol

PHS - Public Health Service

**POC** – Point of Contact

**POS** – Point of Service

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RA - Refund Analyst

**RCA** – Reconciliation Analyst

**RQU** – TRICARE Retail Refund Reconciliation of Quarterly Utilization

SDP - Standard Discount Program

**TED** – TRICARE Encounter Data

Terminated National Drug Code (TNDC) – An NDC that is discontinued by the Manufacturer for any reason. The NDC may be terminated immediately due to health or safety issues or it may be phased out based on the product's shelf life.

**TMOP** – TRICARE Mail Order Pharmacy **TRRP** – TRICARE Retail Refund Program

TRRT - TRICARE Retail Refund Team

**TPRs** – Temporary Price Reductions

TRRWS - TRICARE Retail Refund Website

TRRx - TRICARE Retail Pharmacy

**UF** – Uniform Formulary

**UF-ADP** – Uniform Formulary Additional Discount Program

VA - Department of Veterans Affairs

VHCA - Veterans Health Care Act

**WAC –** Wholesale Acquisition Cost

**WAC- ADP –** Wholesale Acquisition Cost-Additional Discount Program

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#### 1. POLICY GUIDELINES

#### 1.1 INTRODUCTION

As required by 10 U.S.C. § 1074g(f), with respect to any prescription filled after January 28, 2008 (the date of enactment of the National Defense Authorization Act for Fiscal Year 2008 (NDAA-08)), 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. § 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 section 1074g are subject to the pricing standards in section 8126. 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. This statute is implemented by the regulation at 32 C.F.R. § 199.21(q) under the Final Rule republished in the Federal Register on October 15, 2010. The statute requires Manufacturer refunds, the process for which the Final Rule established the TRICARE Retail Refund Program (TRRP). Manufacturers may use the drug-by-drug opt- out provision in the regulation to voluntarily remove, in writing, a drug from coverage in the TRICARE Pharmacy Benefits 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 Treatment Facility (MTF) pharmacies and mail order pharmacy, preserving the Manufacturer's voluntary choice on whether it wants to participate in the TRICARE Pharmacy Benefits Program.

Refunds due to TRICARE are based solely on utilization of pharmaceutical agents dispensed through a TRICARE Retail Pharmacy (TRRx)¹ to DoD beneficiaries. A TRICARE Retail Refund Program Pricing Agreement (PA) is signed and executed between the Manufacturer and Defense Health Agency (DHA) to honor the pricing standards required under the above paragraph. This agreement provides eligibility for inclusion of the Manufacturer's drugs on the preferred Tier 2 of the Uniform Formulary (UF). Without a PA in place covering the specific pharmaceutical agent, DHA may consider the pharmaceutical agent for non-formulary Tier 3 placement. Agents designated Tier 3 will be designated non step-preferred and a prior authorization process will require new patients to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to the patient at any MTF, Retail, or Mail Order point of service. Additionally, DHA may forward to the Department of Veterans Affairs (VA) a list of those drugs that are not included on a PA or for which the Manufacturer refuses to comply with the statutory requirement. A signed and executed PA does not guarantee which tier a drug will be placed on in the UF.

Manufacturers may offer additional discounts through placement of an Additional Discount Program (UF-ADP) Agreement. The UF-ADP is contingent on the successful placement of the agent on Tier 1, Tier 2, or non-Formulary Tier 3. Refund quotes for UF-ADPs 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-ADPs as part of the evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the placement of pharmaceutical agents on the DoD UF.

Manufacturers may offer to pay additional refunds for their drugs through submission of an Unsolicited ADP Agreement. The Unsolicited 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 P&T Committee. DoD reserves the right to reject unsolicited refund offers.

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<sup>&</sup>lt;sup>1</sup> Includes long term care facilities, specialty pharmacies, pharmacies inside physician offices or urgent care centers, hospitals, and all other pharmacies identified as part of the TRICARE Retail Network

#### 1.2 DEMAND LETTERS

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 PA, 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 <u>Information for Pharmaceutical Manufacturer's Webpage</u> for Refund Payment Due and Dispute Cut-Off Dates.

#### 1.3 WAIVERS

Pursuant to the provisions of 32 C.F.R. § 199.21(q) and 32 C.F.R. § 199.11, a Manufacturer may request a waiver and/or compromise of a refund amount due under 10 U.S.C. § 1074g (f). This includes the ability to request compromise of refund debt, and/or waiver of associated interest, penalties, and administrative charges, which should be supported by justification(s) of why the relief is appropriate under section 199.11 and other applicable authorities. Requests for waiver/compromise may be sent directly to your assigned Financial Manager (FM) or to the address below:

DHA Office of General Counsel Claims Collection Branch 16401 East Centretech Parkway Aurora, CO 80011

DHA, TRICARE will respond to requests as quickly as practicable, but Manufacturers must note that interest, penalties, and administrative charges continue to accrue during the pendency of any waiver/compromise request.

#### 1.4 GENERAL CONCEPT

The TRICARE Retail Refund Team (TRRT) provides program management and oversight for the TRRP.

Pharmacy Data Transaction Service (PDTS) provides the TRRT with an extensive audit trail and reporting process for transaction-based invoicing.

The TRRP operates independently from other Federal Pricing Programs, such that, agreements with or participation under other programs has no bearing on a pharmaceutical agent's covered status or refund eligibility. Some examples of other Federal Pricing Programs not currently applicable to TRRx purchases, unless specific language to that effect is included in the Standard Discount Program (SDP) or ADP, are:

- Federal Supply Schedule (FSS) Pricing
- Incentive Agreements
- Blanket Purchase Agreements (BPAs)
- Temporary Price Reductions (TPRs)
- VA/DoD Contracts

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#### 2. CUSTOMER SERVICE SUPPORT

For the most current contact information and FAQs please visit our Contact Us and FAQs page

#### 2.1 PROGRAM SUPPORT

General questions about the TRRP, Disputed Claims, File Format, and Manufacturer forms:

Phone Number	Hours	Questions
703-681-8494	8:00am to 5:00pm (EST) Monday - Friday	Submit email inquiries to: <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a>

Please include the following information in the subject line of any email sent to help facilitate your request:

- Labeler Code
- Manufacture Name
- Question/Issue (i.e. TRRWS Access)

Example Subject: "X00000 - MFG Company Name - Trouble Accessing TRRWS

#### 2.2 TRICARE RETAIL REFUND WEBSITE (TRRWS) SUPPORT

Communication, Connectivity, File Downloading and Decrypting, Password Resets, and System Availability:

Phone Number	Hours	Questions
703-681-8494	8:00am to 5:00pm (EST) Monday - Friday	Submit email inquiries to: <a href="mailto:dha.ncr.j-3.mbx.trrws-it-support@health.mil">dha.ncr.j-3.mbx.trrws-it-support@health.mil</a>

#### 2.3 FINANCIAL MANAGEMENT SUPPORT

Demand Letters, Payments, Adjustments, Credits, Statements of Account, Waiver/Compromise Requests, Disputes Resolution Summary Reports:

Phone Number	Hours	Questions
303-676-3637	8:00am to 5:00pm (MST) Monday - Friday	Submit email inquiries to: Your Assigned FM and dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil

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#### 3. PROCESS OVERVIEW

#### 3.1 DATA FLOW

- 1. The prescription is presented at a network pharmacy
- 2. The Pharmacy Benefit Manager (PBM) verifies beneficiary eligibility via interface to the Defense Eligibility Enrollment Reporting System (DEERS);
- 3. PBM conducts coverage determination and formulary edits;
- 4. The transaction is captured by PBM and PDTS;
- 5. PBM notifies the retail network pharmacy of dispensing authorization based on eligibility verification and edits;
- 6. The pharmacy collects the cost shares.

#### 3.2 REFUND CYCLE

The TRRT uses PDTS to generate standard National Council for Prescription Drug Programs (NCPDP) (Version 3.02 and Version 5.01 or current version) reports, based on paid TRICARE Encounter Data (TED) claims:

- 1. The TRRT makes utilization data reports available to Manufacturers;
- 2. The FM provides demand letters to the Manufacturers;
- 3. Manufacturers review utilization data and demand letters;
- 4. Refund paid directly to DHA Government Account;
- 5. Resolution of disputes through the TRRT, as defined in the dispute process (see section 7.2), if applicable;

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#### 4. OPERATIONAL DETAILS

#### **4.1 CLAIMS COVERAGE**

The refund process applies only to prescriptions that have been identified as being dispensed through a TRICARE network pharmacy. The data file provided to the Manufacturers will consist only of claim types included in the refund process.

Claims excluded from the TRICARE Retail Refund reports are:

- Compound prescriptions;
- Repackaged products;
- o TRRx claims with an Other Coverage Code (OCC) of 2 where TRICARE was not the primary payer;
- Dispensing that occurred at:
  - MTF
  - TRICARE Mail Order Pharmacy (TMOP)
  - Non-network pharmacies
  - Indian Health Service (IHS) Pharmacies
  - VA Pharmacies

#### **4.2 FILE DELIVERY**

The billing periods span the calendar quarters: January through March, April through June, July through September, and October through December. The billing schedule is updated annually and posted to the Defense Health Agency Pharmaceutical Manufacturers Homepage.

The initial demand letters are mailed to Manufacturers forty (40) days after the utilization data is released.

Condensed and expanded data files (XUD) will be available via the TRICARE Retail Refund Website (TRRWS) located at <a href="https://trrws.health.mil/">https://trrws.health.mil/</a> and will be emailed directly to you by your assigned FM.

As of April 12, 2021 all Questionnaire updates must be made through the TRRWS. Data on TRRWS will only be available to those assigned as a Point of Contact (POC).

Questionnaires completed by the Manufacturer will include the Manufacturer's primary and secondary points of contact (i.e., third party) and any changes or updates that have occurred to the contact information. Third-party consultants cannot be the Primary POC.

Updated Manufacturer Information on TRRWS is used to track POC contact information, send out Manufacturer notices, and send out quarterly billing invoices. DHA, TRICARE advises all Manufacturers to maintain up to date contact information.

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#### 4.3 FORMAT

Individual .CN and .CP files are available for download on <u>TRRWS</u>. In addition to this, Manufacturers have the option to download all files (.CN and .CP) in various formats in a single encrypted zip file. Instructions for downloading and decrypting all data are provided in the TRICARE Retail Refund Program Download and Decryption Guide located on the Defense Health Agency <u>Pharmaceutical Manufacturers Homepage</u> under <u>Operational Documents</u>. The instructions can also be found on <u>TRRWS</u> under the 'Download Files' option of the Utilization Menu. The formats available are listed below:

- X99999-21Q2-F01 DoD by DHA.zip.wzd\*
- X99999-21Q2-F01 NCPDP by DHA.zip.wzd\*
- X99999-21Q2-F01 XUD by DHA.zip\*

The two (2) utilization data file types (CP and CN – defined below) are generated per program per quarter in which utilization data is being reported. The programs are identified within each respective quarter as:

- 006 = Standard Discount Program Utilization Files (SDP)
- 009 = Additional Discount Program Utilization Files based on Wholesale Acquisition Cost (WAC-ADP)
- 010 = Additional Discount Program Utilization Files based on Federal Ceiling Price (FCP-ADP)

The CN and CP files that will be delivered each quarter are defined as:

 Summary Utilization Flat File: Product Level Data (CN) – Utilization detail records will be provided at a National Drug Code (NDC) level to report product level data. This report contains metric quantity of all prescriptions dispensed for the specified 11-digit NDC Number.

CN files retrieved from the TRRWS include the following (by column number):

- 1. Record Type
- 2. Line Number
- 3. Data Level
- 4. Product Code Qualifier
- 5. Product Code
- 6. Product Description
- 7. Total Metric Decimal Quantity

- 8. Unit of Measure
- 9. Total Number of Prescriptions
- 10. Reimbursement
- 11. Record Purpose Indicator
- 12. Rebate Per Unit Amount
- 13. Requested Rebate Amount

 Claim Level Utilization Flat File: Transaction Level Data (CP) – Utilization detail records will be provided at the individual claim level to report prescription level data. This report is provided so Manufacturers may validate the summary report.

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<sup>\*</sup> Example quarter of 21Q2.

In accordance with Health Insurance Portability and Accountability Act (HIPAA), no patient names or identification (ID) numbers are provided in the detail files. The data provided is consistent with HIPAA-recognized use for treatment, payment, and operations.

CP files retrieved from the TRRWS include the following (by column number):

- Record Type
- 2. Line Number
- 3. Data Level
- 4. Pharmacy ID Qualifier
- 5. Pharmacy ID Code
- 6. Pharmacy Zip Code
- 7. Product Code Qualifier
- 8. Product Code
- 9. Product Description
- Dispense as Written (DAW)/ Product Selection Code
- 11. Total Metric Decimal Quantity
- 12. Unit of Measure

- 13. Rebate Days' Supply
- 14. Prescription Type
- 15. Prescription Number/ Service Reference Number
- 16. Date Filled/ Date of Service
- 17. New/ Refill Code
- 18. Record Purpose Indicator
- 19. Rebate per Unit Amount
- 20. Requested Rebate Amount
- 21. Claim Number<sup>2</sup>
- 22. Original Claim Number
- 23. Other Coverage Code (OCC)

#### 4.4 PRIOR PERIOD ADJUSTMENTS

The pharmacy industry standard is to process reversals if the prescription has not been dispensed or picked up by the beneficiary. Reversals may also occur when a claim needs to be adjusted due to an audit or change in the claim initiated by the pharmacy. However, if a reversal is not processed within the billing quarter, the reversal will be captured in data from a subsequent quarter. These out-of-cycle reversals will be annotated in the detail transaction file by negative transaction types and embedded in the totals of the summary report.

#### 4.5 QUALITY ASSURANCE

The presumption is that the U.S. Government's utilization data is correct. PDTS provides an extensive audit trail for an entire transaction (i.e., eligibility, cost, and point of service). The pharmacies are responsible for the accurate input of the quantity dispensed, day supply, and the NDC number correlating to dispensed products. To ensure the accuracy, completeness, and timeliness of the TRRP, the TRRT confirms that refunds are validated and calculations are verified.

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<sup>&</sup>lt;sup>2</sup> As of 2015-05-01 the claim number consists of 18 bytes of numbers (i.e., 1-9) and must be handled as a text or character field when processed, not as a numeric field

#### 4.6 OPERATIONAL DOCUMENTS

The forms provided in the appendixes in this Guide are intended as informational examples. The most current versions of the listed Operational Documents are available for download on the DHA, TRICARE <u>Information for Pharmaceutical Manufacturers Homepage</u>.

- TRICARE Retail Refund Program Pricing Agreement
  - A TRICARE Retail Refund Program Pricing Agreement (PA) is signed and executed between the Manufacturer and DHA, TRICARE to honor the pricing standards required under the above paragraph.
     This agreement provides eligibility for inclusion of the Manufacturer's drugs on the preferred Tier 2 of the UF.
- Manufacturer Policy and Procedure Guide
  - The current copy of the TRICARE Retail Refund Manufacturer Policy and Procedure Guide. All previous copies prior to v5.3 are now obsolete.
- National Defense Authorization Act for Fiscal Year 2008, Section 703
  - o Inclusion of TRICARE Retail Pharmacy Program in federal procurement of pharmaceuticals.
- TRICARE Dispute Resubmission form
  - Disputes that have been rejected can be resubmitted by completing this form and providing it along with additional supporting evidence within 30 days of communication of the Dispute Report provided by FM.
- TRICARE Retail Refund Program NDC Transfer Request Form
  - Any product that has been transferred requires the submission of a new form. Products that have been transferred between Manufacturers must have a signature from each Manufacturer prior to updating billing.
- TRICARE Retail Refund Website Manufacturer User Guide
  - Assists users in creating a new Manufacturer, updating Manufacturer information, maintaining POC access, and downloading data via TRRWS
  - Updated Manufacturer Information on TRRWS is used to track POC contact information, send out Manufacturer notices, and send out quarterly billing invoices. Newly submitted Manufacturer information replaces old Manufacturer information and new POCs replace previously designated POCs.
  - Effective July 2020, Any Manufacturers'/Third Party Shared or Group Emails will NOT be allowed as a POC on TRRWS.
  - Only Primary POCs may complete and submit updates on the Manufacturer Information Page.
     Updates may not be completed by a Third Party Consultant. Third Party Consultants cannot be the Primary POC.
- Encryption Wizard Info
  - TRRWS specific instructions for the download and decryption of utilization files.
- 340B Verification Form
  - Supporting documentation required by the Manufacturer when disputing with a K code.
     Manufacturers must have the dispensing pharmacy complete the form.

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#### 5. REFUND UTILIZATION CALCULATION

#### **5.1 BACKGROUND**

The Veterans Health Care Act of 1992 (VHCA) established a price cap, known as the Federal Ceiling Price (FCP), for sales of covered drugs to the DoD, VA, Public Health Service (PHS) and Coast Guard or "Big Four". The FCP is based on a Manufacturer's Non-Federal Average Manufacturer Price (non-FAMP). The non-FAMP is the weighted average price of each single form and dosage unit of a drug that is paid to a Manufacturer by wholesalers for non-federal purchasers, taking into account any cash discounts or similar price reductions. The non-FAMP does not reflect refunds paid by the Manufacturer to third-party payers.

The FCP is 76% of the annual non-FAMP, minus any additional discounts designed to offset annual increases in the non-FAMP exceeding the inflation rate.

Manufacturers may not charge a "Big Four" agency a price exceeding the FCP for covered drugs procured by the agency.

#### **5.2 CURRENT PROCESS**

All covered Drugs are eligible for the TRICARE Retail Refund Program.\*

- When calculating refunds, DoD uses the non-FAMP and FCP amounts provided by the VA. DHA, TRICARE will request, from the VA, the current annual FCP and the annual non-FAMP from which it was derived prior to compiling each quarterly invoice. The pricing data obtained will be applicable to all prescriptions filled during each respective quarter. In the case of reversals and prior quarter claims, DHA, TRICARE will use the appropriate value provided by the VA at the time of billing. Drugs that have a negative minimum refund value with the VA are not invoiced.
- These quarterly updates to the annual non-FAMP and the annual FCP should not be mistaken for the quarterly reporting of non-FAMP by Manufacturers.

\*For Rebilled Periods 2008-2011, DoD requested, from the VA, one file that captured previously reported updates to the current annual FCP and the annual non-FAMP from which it was derived prior to compiling all quarterly invoices for each rebilled year.

#### **Example:**

The November 2020 reported annual non-FAMP and the 2021 FCP will be used in refund calculations based on TRRx transactions that are billed during the calendar quarters of 2021. If a reversal for 1Q21 is reported in 3Q21 utilization, DHA, TRICARE will use the non-FAMP and FCP prices from 1Q21 for the reversed utilization only.

#### **5.3 NEW DRUGS**

For a new drug without sales history that the VA reports, the first (provisional) benchmark is the initial listed wholesale price minus any discounts; it will be the price used to begin the TRRx refund calculation. Thereafter, the normal reporting of temporary and first, annual (permanent) non-FAMPs will be used to determine the TRRx benchmark prices. Provisional, temporary, and permanent FCPs, as appropriate, will be applied to these new drug benchmarks. If there are multiple entries for the same, most current, status, the discontinuation date for each entry will be taken into account and TRICARE will use the pricing associated with the date that has not passed (if available). If a Manufacturer believes that the data provided by the VA to TRICARE is erroneous, it is

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the Manufacturer's responsibility to contact the VA to address any restatements or corrections. If a Manufacturer wishes to inquire as to which status/pricing was used for a given quarter, they may contact the TRRT. The TRRP will use the value provided by the VA at the time that the claim is billed, which may not be the most up-to-date value at the time of invoice.

A covered drug is eligible for a refund regardless of the presence of a PA, FSS, or any other federal contract. DHA, TRICARE will use the date that covered drug utilization first appears as reported in PDTS.

Provided that a Manufacturer has signed a PA V5.1 or later, all covered drugs belonging to the Manufacturer will be covered by the Agreement. For a Manufacturer with a PA version in place prior to these, they must add drugs not originally covered under their PA via completion of the TRICARE Retail Refund Program NDC Transfer Request Form or by signing the PA Amendment.

Please note, to transfer a drug between Manufacturers, both parties (the previous Manufacturer and new Manufacturer) are required to complete a TRICARE Retail Refund Program NDC Transfer Request Form (<u>Appendix I</u>) in its entirety and submit it to <u>dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</u>. The completed form must contain the signatures of both parties.

If a pharmaceutical agent being transferred has an active ADP Agreement in place, contact <u>DHA Contracting</u> or the <u>DHA Industry Technical Liaison</u> via Email. Please note that unless terminated prior per Manufacturer or DHA Contracting Officer, all UF-ADP Agreements executed will remain in effect until the drug class is next reviewed by the DoD P&T Committee.

Once the TRRT receives, reviews, and approves the forms, billing can be updated. If the changes are submitted with transfer dates in a previous quarter, the transfer will be reflected in the upcoming billing quarter.

#### 5.4 REFUND CALCULATIONS FOR STANDARD DISCOUNT PROGRAM

Calculation of the refund for each applicable NDC is the difference between the average non-FAMP of the drug sold to wholesalers, as represented by the annual non-FAMP, and the corresponding FCP. This is the Minimum Refund per full FCP Package for the respective NDC.

Manufacturers may elect one of the following methods of calculation in their PA to be applied to all covered drugs invoiced under the SDP:

- SDP per-unit calculation: Based on the total quantity of individual units dispensed for each NDC in a dispensing quarter and reported in the particular billing quarter. The difference between the non-FAMP and FCP is divided by the package size for each NDC to yield the appropriate refund due per unit. The per-unit rate is rounded to five (5) decimal places and multiplied by the total quantity dispensed to calculate the refund amount due for that NDC.
- SDP per-package calculation: Based on the total number of full packages dispensed for each NDC and dispensing quarter and reported in the particular billing quarter. Total utilization is divided by the package size. The resulting package count will be rounded down to the nearest whole number for the purpose of refund calculations. The remainder (fractional or decimal units) from this calculation will not carry over to the next billing cycle. Manufacturers will be billed using the per-package calculations until a billing method is selected by the Manufacturer on an approved PA. The Manufacturer will calculate the refund for that NDC using the total package quantity multiplied by either the Minimum

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Refund per full FCP Package (non-FAMP minus FCP) or the difference between FCP and direct commercial sales, as described in the refund calculation methods outlined below.

**Unit Example:** Divide refund per FCP package size and then multiply by units dispensed.

137 tablets were dispensed in 1Q20 for a product.

The package size was 30. SDP Minimum Refund: \$100.00 (\$100/30) × 137 = \$456.67

<u>Package Example:</u> <u>Divide quantity by package size, round down to the next full package number, then multiply the result by the standard minimum refund.</u>

137 tablets dispensed in 1Q20.

The package size was 30

Standard Minimum refund: \$100.00

137/30 = 4.56 packages. Round **down** to 4 packages, then  $4 \times $100.00 = $400.00$ 

Note: If the Manufacturer identifies pricing that appears incorrect, they should submit billing quarter and year information, NDC, refund price calculated, and values used to arrive at the refund to <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a>. For more information please see Section 7.

#### 5.5 ADDITIONAL DISCOUNT PROGRAM

Each quarter, the DoD P&T Committee reviews certain drug classes for formulary placement. If their drug is to be reviewed in an upcoming meeting, Manufacturers may offer additional discounts to improve the chance that their pharmaceutical agents will be included on the generics Tier 1, the formulary Tier 2 or moved from Not Covered Tier 4 to Non-Formulary Tier 3 of the DoD UF through placement of an UF-ADP Agreement. The UF-ADP is contingent on the successful placement of the agent on Tier 1, Tier 2, or Tier 3. Unless terminated prior per Manufacturer or DoD, all UF-ADP Agreements executed will remain in effect until the drug class is next reviewed by the DoD P&T Committee.

The refund quotes will be based on FCP, as outlined in the ADP Agreement Appendix, unless otherwise stated. WAC is used for products that do not have a FCP, such as diabetic supplies (i.e., test strips), and may also be applied to covered drugs per terms of ADP.

If a pharmaceutical agent being transferred has an active ADP Agreement in place, contact <u>DHA Contracting</u> or the <u>DHA Industry Technical Liaison</u> via Email.

If an NDC is not included on an ADP Agreement and the pharmaceutical agent is the same for the NDC(s) for which an ADP Agreement is in place, it will be referred to the Contracting Office for review and decision.

For additional information regarding UF-ADP Agreements and DoD P&T Committee Meetings, please visit: https://health.mil/PandT

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#### 5.5.1 FCP-ADP AGREEMENT - BASED ON FCP (Per Package Calculation)

When a Manufacturer offers an additional discount based on the FCP, the formulas and rounding for the SDP, as provided in Section 5.4, are utilized. The refund is the difference between the reported annual non-FAMP and corresponding FCP plus any additional discount provided.

If the percentage offered by the Manufacturer yields an ADP refund that does not meet or exceed the Minimum Refund, TRICARE will adjust the calculations so that the offered refund meets the Minimum Refund as required by legislation.

**Example**: An additional discount quote is offered on an 11-digit NDC that has a non-FAMP of \$200 and a FCP of \$100. The resulting minimum refund is \$100 per whole FCP package. The Manufacturer then offers an additional discount of 25% of non-FAMP, which yields a total ADP refund quote of \$150 per full FCP package for that NDC. The ADP refund formula is illustrated as ((non-FAMP – FCP) + (non-FAMP × Additional % of non-FAMP)) unless otherwise stated on prior Agreements.

#### 5.5.2 WAC-ADP AGREEMENT - BASED ON WAC (Per Unit Calculation)

The WAC is obtained from First Databank via daily price updates; it is maintained at the dispensing unit level to five (5) decimal places. If the WAC changes during a calendar quarter, an average WAC will be calculated on a daily weighted basis (per unit only).

WAC is used for products that do not have a FCP, such as diabetic supplies (i.e. test strips), and can also be applied to covered drugs.

#### **Example:**

NDC:	11111-11-1111
Total Quantity Dispensed:	1,575 tablets
WAC Discount:	25%
	Day 1 to 20 (20 days) @ \$1.00 = (20/90) 22% x 1.00 = .22
Unit WAC:	Day 21 to 90 (70 days) @ \$1.50 = (70/90) 78% x 1.50 = 1.17
	Daily Weighted Average WAC: .22 + 1.17 = \$1.39 per tablet
Calculated Unit Refund:	\$1.39 x 25% = \$0.3475 per tablet
Total Refund:	1,575 tablets x \$0.3475 = \$547.31

#### 5.6 PROPRIETARY INFORMATION & SECURITY

The Covered Drug List received from the VA and maintained by TRRP can only be accessed by the Manufacturer POCs responsible for the labeler and the TRRP members authorized to access them. This includes any discussion regarding non-FAMP and FCP values.

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#### 6. PAYMENT INFORMATION

#### **6.1 PAYMENT TIMELINE**

Refunds along with a completed TRICARE Retail Refund Reconciliation of Quarterly Utilization (RQU) or payment detail are due to DHA, TRICARE no later than seventy (70) days following the date of the release of utilization data.

#### **6.2 PAYMENTS**

To submit payments for TRICARE Retail Pharmacy Refunds, one of the following payment methods may be used. Submitted payments require supporting payment detail and relevant disputes as required by DHA, TRICARE to efficiently process your payment.

Payments may be sent as an Automated Clearing House (ACH) or Electronic Funds Transfer (EFT) using CREDIT GATEWAY or Pay.gov.

CREDIT GATEWAY INFORMATION		
FED Wires	ACH	
TREAS NYC	CREDIT GATEWAY ACH RECEIVER	
ABA/Routing#:021030004	ABA/Routing#: 051036706	
Account#: 897000012002	Account#: 897000012002	

Pay.gov (https://www.Pay.gov)		
	TRICARE Retail Pharmacy Program	
Labeler Code:		
Calendar Year:		
Quarter:		
Program:		
Amount Due:		

If paying by check or money order, please reference the demand letters for which payment is being submitted and make payable to U.S.TREASURY/DHA. Send payments to:

Defense Health Agency Attn: Accounting Officer 16401 East Centretech Parkway Aurora, CO 80011

#### **6.3 LATE PAYMENTS**

The Federal Claims Collection Act, beginning at 31 U.S.C. § 3701, requires federal agencies, including DHA, to collect funds owed to the United States arising out of that agency's activities. Further, pursuant to 31 U.S.C. § 3717, government agencies are required to collect interest on all delinquent debts at the interest rate set forth in the demand letter, currently one percent (1%) per year. Interest charges will be waived if this debt is paid in full within seventy (70) days from the date the utilization data were made available. If payment is not made within seventy (70) days from the date the utilization data were made available, interest will accrue from the date of the demand letter. Additionally, federal agencies are required to assess a penalty charge, not to exceed six percent (6%) per year, on any portion of amounts owed that are delinquent for more than ninety (90) days and assess administrative costs resulting from the delinquency.

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#### 6.3.1 Interest

Interest is calculated from the **demand letter date**. The interest rate on future debts may change and is listed in the demand letter.

#### 6.3.2 Administrative Fees

Administrative fees are assessed from the **scheduled payment due date** based on an aging schedule.

#### 6.3.3 Penalty

Penalties begin accruing once the outstanding balance has aged over ninety (90) days from the **scheduled payment due date**. When ninety-one (91) days have been reached, penalties are calculated from the scheduled payment due date. The penalty rate is six percent (6%) and is listed in the demand letter.

Days Late	Fee Cost
1 to 30	\$5.00
31 to 60	\$10.00
61 to 90	\$22.00
91 to 120	\$37.00
121 to 150	\$50.00
151 to 180	\$67.00
181 to 210	\$82.00
211 to 240	\$97.00
241 to 270	\$112.00
271 to 300	\$127.00
301 to 330	\$142.00
331 to 360	\$157.00
361 to 390	\$172.00
391 to 420	\$187.00
421 and Over	\$195.64

#### 6.3.4 Examples

#### Example 1:

Utilization data is released on January 1, 2021. DHA, TRICARE mails demand letters dated February 10, 2021. The refunds are due March 12, 2021. ABC Pharmaceuticals receives a demand letter for \$10,000 and sends a late payment for \$10,000.00 via CREDIT GATEWAY ACH RECEIVER on April 1, 2021. The payment is 50 days late from the date of the demand letter and 20 days late from the scheduled payment due date; the open balance will therefore accrue \$13.70 in interest and \$5.00 in administrative fees. The administrative fees and interest are paid first, leaving an \$18.70 principal balance, which will continue to accrue additional administrative fees, interest, and penalties until paid in full.

#### Example 2:

Utilization data is released on January 1, 2021. DHA, TRICARE mails demand letters dated February 10, 2021. The refunds are due March 12, 2021. XYZ Pharmaceuticals receives a demand letter for \$10,000 and sends a late payment for \$10,000.00 via CREDIT GATEWAY ACH RECEIVER on July 1, 2021. The payment is 141 days late from the date of the demand letter and 111 days late from the scheduled payment due date. The open balance will therefore accrue \$38.63 in interest, \$37.00 in administrative fees, and \$182.47 in penalties. The penalty, administrative fees, and interest are paid first, leaving a \$258.10 principal balance, which will continue to accrue additional administrative fees, interest, and penalties until paid in full.

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#### 7. RESOLUTION PROCESS

#### **7.1 OVERVIEW**

In the case of a Manufacturer disputing the accuracy of DHA, TRICARE'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 (for information regarding late Dispute Code K submissions, see section 7.4.2). Please refer to the <u>Information for Pharmaceutical Manufacturer's Webpage</u> 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, TRICARE by the due date of the next quarterly payment after resolution.

#### 7.2 SUBMITTING PAYMENT DETAIL/RQUS AND DISPUTES

#### A. Overview of the Dispute Resolution Process:

- DHA, TRICARE releases the Utilization Detail (UD) data files on the File Delivery Date. If applicable, DHA,
   TRICARE will notify Manufacturers by email of additional processing instructions for the UD data files.
- DHA, TRICARE emails the Manufacturer POCs an Excel workbook containing the Recon form(s) (one for Standard Discount Program or SDP, and/or one for Additional Discount Program or ADP; as appropriate) and a Dispute form template, no later than five business days after the file delivery date. DHA, TRICARE will provide the password for the Excel workbook in a separate email. The Recon form(s) show the pricing data and the summary utilization data, as well as the computational formulas, used by DHA, TRICARE for the refund calculations.
- DHA, TRICARE emails the Manufacturer POCs two Excel workbooks five business days after the file delivery date. The first workbook uses a sample set of the DHA, TRICARE Expanded Utilization Detail (XUD) data to illustrate how all invoice data on a Recon form can be traced back to the XUD data, and the second workbook contains the actual XUD data.
- DHA, TRICARE mails the initial demand letter(s) (one for ADP and/or one for SDP) to the Manufacturer (Invoice Date = File Delivery Date + 40). If applicable, DHA, TRICARE may email an updated Recon form(s) to the Manufacturer POCs. The Total Amount Due on a demand letter should match the Total Refund Amount Invoiced on the corresponding Recon Form.
- The Manufacturer processes the utilization data files and reviews the pricing data and summary utilization data shown on the Recon form(s). If the Manufacturer believes there are errors in the DHA, TRICARE data, it must report pricing data errors ("pricing disputes") on the Recon form(s) and it must report utilization data errors ("utilization disputes" against individual claims) using the Dispute form. Manufacturers must provide supporting documentation for all disputes. DHA, TRICARE cannot process or accept disputes not properly submitted by Manufacturers.
- Manufacturers must report on the Recon form(s) the amounts submitted for payment ("Refund Amount Paid") and the amounts it is not paying ("Refund Amount Withheld") for all line items. The Total Refund

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- Amount Paid *must* match the sum of actual payment amount and, if applicable, the amount of credit carried over from another billing period.
- The Manufacturer, at its sole discretion, may elect to have zero amounts withheld and pay the full Total Refund Amount Invoiced, so as to avoid any possible interest, penalty, and administrative charges.
- Manufacturers must return the Recon form(s), the Dispute form, supporting documentation for all disputes, and payment to DHA, TRICARE (Payment Due Date = Dispute Cut-off Date = Invoice Date + 30).
   DHA, TRICARE cannot process or accept disputes that are submitted by Manufacturers past the deadline or that are submitted without sufficient supporting documentation.
- K Code Disputes (340B duplicate discounts) are granted an additional quarter for submittal. For example, 20Q2 claims that are deemed Dispute Code K, may be submitted by the Dispute Cut-off Date for 20Q3 (see Section 7.4.2 for additional details).
- If applicable, DHA, TRICARE emails Manufacturer POCs a Dispute Receipt Report (in Excel) in five to ten business days after receiving a correctly submitted Dispute form.
- As required by law, DHA, TRICARE mails the second demand letter(s) to Manufacturers (Payment Due Date + 30) if the Manufacturer has not paid the refund amounts in full as of that date.
- It is DHA, TRICARE's intent to resolve all disputes correctly submitted by Manufacturers and received by DHA, TRICARE (Dispute Cut-off Date + 60). Accepted utilization disputes result in changes to the quantities used in the refund calculations, and accepted pricing disputes result in changes to the pricing data. The refund amounts will be re-calculated to account for the accepted disputes, if any. Payments made by Manufacturers in excess of the re-calculated amounts will be a credit that can be applied to another billing period.
- If applicable, DHA, TRICARE emails Manufacturer POCs a Dispute Status Report (in Excel) (Dispute Cut-off Date + 60 + 10 business days). That report contains information about how claim-level disputes submitted by the Manufacturer have been resolved by DHA, TRICARE (Dispute Cut-off Date + 60 + 5 business days) and what refund amount adjustments, if any, are being applied.
- The Manufacturer pays, and if applicable, submits any requests for resubmission by the Resubmission Cut-off Date (Returned Dispute Status Report Date + 30 days) with additional information for reconsideration of rejected disputes, and/or requests waiver/compromise (See Section 7.5).

#### **B.** Information about the Recon Form:

- Worksheets "Recon Form SDP" and/or "Recon Form ADP" are populated with the actual utilization data.
- Please refer to worksheet "Recon Form ReadMe" for information and instructions.
- The pricing data and the summary utilization data (Total Quantity Dispensed) used by DHA, TRICARE in the refund calculations are in columns E thru L and in column O, respectively. (Total # Claims, in column N, is not used in the calculations and is shown for informational purposes only.) The computational formulas actually used by DHA, TRICARE in the refund calculations are in columns M, P, and Q.

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- If the Manufacturer believes there are errors in the DHA, TRICARE pricing data ("pricing disputes"), it must report the errors in the appropriate Recon form(s). For most errors, the Manufacturer can simply enter what it believes are the correct values in columns R thru Y (e.g., if a product is not eligible for refund, the Manufacturer should change Package Refund, if Formulary 006 or 010, or WAC Discount, if Formulary 009, to zero). For the more complicated errors (e.g., if an NDC billed under Formulary 010 for an entire quarter should have been billed under Formulary 010 for the first 25 days of that quarter and under Formulary 006 for the remainder of that quarter), the Manufacturer will need to provide detailed explanation in the comment area. Manufacturers must provide sufficient supporting documentation for all disputes.
- If the Manufacturer believes there are errors in the DHA, TRICARE utilization data ("utilization disputes") resulting in an incorrect Total Quantity Dispensed in column O, it must report the errors using the Dispute form and enter Total Quantity Disputed in column AD. Manufacturers must provide supporting documentation for all disputes.

#### C. Information about the Dispute Form:

- Worksheet "Dispute Sub Form" is a template for Manufacturers to use to submit utilization disputes.
- Please refer to worksheet "Dispute Sub Form ReadMe" for instructions. The Dispute form is to be used only for submitting utilization disputes against individual claims. That is, Manufacturers should use the Dispute form when and only when it believes that DHA, TRICARE has billed refunds on individual claims that should have been excluded (duplicates, TRICARE-as-secondary-payer, 340B dispensing, VA dispensing, IHS dispensing, etc.) and/or that have incorrect quantities and/or incorrect units of measure. Such errors cause an incorrect Total Quantity in column O on the Recon form.
- Manufacturers will NOT need to submit a Dispute form unless the Manufacturer believes that there are specific errors with certain individual claims.

**Example**: Manufacturer A believes that DHA, TRICARE used an incorrect Package Size for an invoice line item with 547 claims.

- Scenario 1: Manufacturer A finds no issues with those 547 claims. Required Action 1: Manufacturer
   A must enter the correct Package Size in column V on the Recon form; and Manufacturer A should
   NOT report any of the 547 claims on the Dispute form.
- Scenario 2: Manufacturer A believes that, among those 547 claims, 2 were 340B dispensing and 5
  had incorrect quantities. Required Action 2: Manufacturer A must enter the correct Package Size in
  column V on the Recon form; Manufacturer A must enter Total Quantity Disputed in column AD on
  the Recon form; and Manufacturer A must submit those 7 utilization disputes on the Dispute form.
- If a Manufacturer believes there are multiple errors with the same claim, it should submit separate
  utilization disputes. For example, if a Manufacturer believes a certain claim was dispensed as a 340B
  dispensing and it had an incorrect quantity, then two separate disputes against that claim should be
  submitted.

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#### **7.3 DISPUTE CODES**

If a Manufacturer believes there are errors in the DHA, TRICARE data, it must report pricing data errors ("pricing disputes") on the Recon form(s) and it must report utilization data errors ("utilization disputes" against individual claims) using the Dispute form. The Manufacturer must provide supporting documentation for all disputes\*. DHA, TRICARE cannot process or accept disputes not properly submitted by the Manufacturer.

Pricing Disputes Utilization Disputes
---------------------------------------

CODE	NAME	CODE	NAME
С	NDC Transferred to Another Labeler Code OR Manufacturer	Α	Duplicate Claim
D	Discontinued/Terminated NDC (Shelf life expired more than one (1) year from dispense date.)	E	Invalid Pharmacy Identification Number/NCPDP PROVIDER ID
G	Decimal Discrepancy or Rounding Problem	J	Product Not Eligible for a Refund
Н	Package Size Discrepancy	K	PHS/340B Entity not Extracted from Utilization Data
		N	Utilization/Quantity Inconsistent with Lowest Dispensable Package Size
		0	Utilization/Quantity Exceeds Normal/Usual and Customary
		Р	Other
		R	СОВ/ОНІ

<sup>\*</sup>DHA, TRICARE requires that Manufacturers provide all supporting documentation at the time of dispute unless otherwise specified.

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#### 7.3.1 Dispute Code Descriptions

A Code: The Manufacturer contends that the claims had been adjudicated more than once with the same date of service, NDC, and prescription number, and fill number (refill number).

The Manufacturer needs to dispute all claim numbers that have been duplicated and/or provide documentation that a refund for the same claim had previously been paid to TRICARE.

C Code: The Manufacturer contends that the NDC has been transferred to another labeler code or Manufacturer.

The Manufacturer that is billed needs to dispute all claims that should be billed to another labeler code or Manufacturer. Both Manufacturers will be required by DHA, TRICARE to complete a TRICARE Retail Refund NDC Transfer Form agreeing to the date of transfer.

D Code: The Manufacturer contends that the NDC(s) has/have been discontinued/terminated.

The Manufacturer needs to dispute all claims that should not have been billed after the discontinued/terminated date plus three hundred and sixty-five (365) days and provide documentation of termination date.

Example: Notice to pharmacies or patients with discontinued/termination date.

E Code: The Manufacturer contends that the pharmacy's NCPDP or NPI is invalid, unknown, or terminated.

**G Code:** The Manufacturer contends that the units submitted for payment are incorrect due to rounding or incorrect placement of decimal. This is a reconciliation issue; please contact your FM regarding this dispute code before submitting a dispute. This dispute code is intended to be used for pricing disputes.

**H Code:** The Manufacturer contends that the incorrect package size was used to calculate the refund amount due. The Manufacturer needs to provide documentation of the correct package size to be used per industry standard.

**J Code:** The Manufacturer contends that the product is not eligible for a refund.

The Manufacturer needs to dispute the claims in question and provide documentation by email to <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a> regarding why the product is not eligible for a refund.

K Code: The Manufacturer contends that the claim was filled using a 340B discounted product.

The Manufacturer will need to provide a completed copy of 340B Verification Form (Appendix II) as supporting documentation that 340b product was dispensed. Claims submitted by the pharmacy with a submission clarification code of "20" for a 340B product dispensed will be excluded from the utilization data as they are not eligible for a refund.

**N Code:** The Manufacturer contends that the utilization/quantity is inconsistent with the lowest dispensable package size available as submitted by the pharmacy.

The Manufacturer needs to dispute the claims in question and provide documentation and/or justification by email to dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil.

**O Code:** Manufacturer contends that the utilization/quantity is inconsistent or exceeds amount dispensed, based on the information submitted by the pharmacy.

The Manufacturer needs to dispute the claims in question and provide documentation and/or justification by email to <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a>.

**P Code:** The Manufacturer contends that the claim is not eligible for a refund for reasons not identified in the dispute codes available. The Manufacturer needs to dispute the claims in question and provide documentation and/or justification by email to dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil.

**R Code:** The Manufacturer contends that the claim is a coordination of benefits or the TRICARE member has Other Health Insurance (OHI). DHA, TRICARE requires supporting documentation that a secondary insurance paid and that the claim was reversed by the pharmacy and resubmitted with an OCC of 2. Otherwise TRICARE is the primary payer on all claims that were not submitted to a secondary insurance at the point of service. TRICARE is the primary payer on all Medicaid claims.

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#### 7.4 DISPUTE RESOLUTION

The dispute resolution process starts 70 days after the quarterly invoice period; also referred to as the refund payment due date. This date is set to allow enough time for the Manufacturers to send their quarterly payment and DHA, TRICARE to allocate all payments received.

All disputes must be reviewed and verified before a final decision to accept or reject the dispute is made.

- 1. A report will be generated to identify active disputes submitted by the Manufacturer.
- 2. The Refund Analyst (RA) will research the invalid, terminated, or refund ineligible disputes.

During the dispute resolution process, the RA will utilize multiple resources to solve the dispute including, but not limited to information provided by **FDB**, **VA**, and **FDA**. Manufacturers are encouraged to maintain updated information with these organizations to avoid potential disputes of the utilization data.

#### 7.4.1 Refund Payment Schedule Examples

#### Example 1:

Utilization data is released on January 1, 2021. DHA, TRICARE mails demand letters dated February 10, 2021. The refunds are due March 12, 2021. ABC Pharmaceuticals receives a demand letter for \$10,000. ABC Pharmaceuticals sends a payment for \$10,000.00 via CREDIT GATEWAY ACH RECEIVER and provides documentation disputing \$1,500.00 in claims to the TRRT on March 12, 2021. Disputes are resolved on July 10, 2021. ABC Pharmaceuticals receives its dispute resolution summary report from its FM, indicating \$500 of disputes was accepted and \$1,000 was rejected. Since ABC Pharmaceuticals paid in full, the Manufacturer can arrange with the FM to apply the \$500 credit for accepted disputes to a future quarter.

#### Example 2:

Utilization data is released on January 1, 2021. DHA, TRICARE mails demand letters dated February 10, 2021. The refunds are due March 12, 2021. XYZ Pharmaceuticals receives a demand letter for \$10,000. XYZ Pharmaceuticals sends a payment for \$8,500.00 via CREDIT GATEWAY ACH RECEIVER and provides documentation disputing \$1,500.00 in claims to the TRRT on March 12, 2021. Disputes are resolved on July 10, 2021. XYZ Pharmaceuticals receives its dispute resolution summary report from its FM, indicating \$500 of disputes was accepted and \$1,000 was rejected. XYZ Pharmaceuticals requests a payoff statement from its FM with a payoff date of August 1, 2021. The payoff statement will include \$4.71 in interest, \$52.00 in administrative fees, and \$23.34 in penalties for a total payoff of \$1180.05.

#### 7.4.2 Dispute Code K (340B Duplicate Discounts) Dispute Resolution

- 1. To accommodate the time required to obtain completed 340B Verification Forms (Appendix II); one (1) quarter will be added onto the timeline for submission of K code (340B) disputes.
  - **Example:** All other disputes codes for 20Q2 utilization will be due on the Dispute Cut-off Date of 11/20/2020, K Code disputes from 20Q2 utilization will have until the 20Q3 Utilization Dispute Cut-off Date of 02/19/2021 to be submitted. Manufacturers may choose to submit their "K" code disputes any time within that 2 quarter window.
- 2. Only claims that have completed 340B Verification Forms (<u>Appendix II</u>) marked "Yes" are to be submitted as K Code Disputes by the Manufacturer.

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3. Manufacturers should submit their K code dispute submissions AND their 340B Dispute Verification forms simultaneously to their assigned FM and also to <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a>.

#### **Example:**

Date	Event
9/11/2020	20Q2 Utilization Data Release
11/20/2020	20Q2 Dispute Cutoff Date (Non-K Codes)
12/11/2020	20Q3 Utilization Data Release
2/19/2021	20Q3 Dispute Cutoff (Non-K Codes) + 20Q2 Dispute Cut Off (K Codes Only)

#### 7.5 RESOLVED DISPUTES

DHA, TRICARE makes every effort to resolve all disputes within sixty (60) days. DHA, TRICARE will consider requests from Manufacturers to waive a portion of interest, penalties, and administrative charges in cases where disputes were not resolved within sixty (60) days. Your FM will provide a dispute status summary and detail reports via email. Adjustments to principal for accepted disputes will have been made by your FM prior to receiving the dispute status email. Based on prior payment(s) received, if an overpayment exists, DHA, TRICARE at this time will not issue a refund of any overage balances. DHA, TRICARE will be applying additional monies received over and above the original calculations to NDCs that still have outstanding balances. The additional amount of the overpayment will be held until further communication is received from the Manufacturer. Please contact your FM to coordinate the application of these funds to any outstanding balances in subsequent quarters. Your FM will also be able to provide a statement of account with accrued interest, administrative fees, and penalties upon request.

After a Manufacturer has been notified that their dispute has been rejected, DHA, TRICARE will allow these disputes to be resubmitted with updated supporting documentation and a completed Dispute Resubmission form (Appendix III), and located under Operational Documents on the Information for Pharmaceutical Manufacturers Page, no more than thirty (30) days after the communication of the final decision.

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## 8. APPENDIX I \_ TRICARE RETAIL REFUND PROGRAM NDC TRANSFER REQUEST FORM

## TRICARE RETAIL REFUND PROGRAM NDC TRANSFER REQUEST FORM

Complete ALL of the following information to transfer the billing liability for the requested products. Selecting "All NDCs" will transfer all NDC-11s of each product under the current Manufacturer and covered by your DoD Retail Refunds Pricing Agreement unless a specific NDC-11 is listed or it is otherwise stated in the comment box.

Current Manufacturer:  Labeler Code:  Date of Transfer: (Last day billed to Current Manufacturer)  Drug Name  Generic Name  All NDCs  Specific N  I I I I I I I I I I I I I I I I I I						
Date of Transfer: (Last day billed to Current Manufacturer)  Date of Liability: (First day billed to New Manufacturer)	Current Manufacturer	r.		New Manufactu	urer:	
(Last day billed to Current Manufacturer)  (First day billed to New Manufacturer)	Labeler Code:			Labeler Code:		
Drug Name Generic Name All NDCs Specific N	(Last day billed to Current			(First day billed to New	r:	
	Drug Na	ame	Generi	c Name	All NDCs	Specific NDC
Comments:	Comments:					
Note: Drugs listed here are covered drugs under 32 CFR 199.21(q)(2)(iii) which states, "For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126."	"For pu	_		-		
If a pharmaceutical agent being transferred has an active ADP Agreement in place, contact the Contracting Office RFQ POC 1-210-536-6048, 1-210-536-6020, or via email dha.san-antonio-tx.healthcare-ops.mbx.pharmacy-opsmbxpod-industr@health.		-	•	-	•	
Current Manufacturer Signatory: New Manufacturer Signatory:		Current Manufact	urer Signatory:	New Ma	nufacturer Signa	atory:
Name:	Name:					
Signature:	Signature:					

Completed form must include signatures from both parties.

Email completed form to: dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil

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#### 9. APPENDIX II \_ 340B DISPUTE VERIFICATION FORM

# TRICARE Retail Refund Program Manufacturer 340b Verification Form

Please fill in all information requested. Any missing or invalid information in (\*) fields may delay the processing of your dispute or result in its rejection.

1. To be completed by the Manufactur	turer:	Manuf	the	b	oleted	com	be	To	1.
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cy):	
1505	NDI NCDDD*-
Address:	NPI or NCPDP*:
3	acy): Address:

#### 3. To be completed by the Manufacturer and Each Covered Entity (Pharmacy):

	Prescription Number*	NDC	Date of Service*	Was the dispensed	
				Yes	No
Ex:	000123456789	01234567891	dd/mm/yyyy	X	
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Date
Authorized Representative Title

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### Instructions for Completing the TRICARE Retail Refund Program 340b Verification Form

#### Please complete this form as instructed below.

#### **Instructions for the Manufacturer:**

Please provide all requested information on the form provided below. Missing or invalid information will delay the processing of your dispute. Completed forms are to be emailed to the Defense Health Agency (DHA) at dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil.

#### **Notes for Completing the Form:**

This form is to be completed by an authorized representative (Pharmacist, Technician, or other Pharmacy Representative) at the Covered Entity (Pharmacy) that can verify that the prescription was dispensed/billed as a 340b product.

This form is intended to be filled out by **ONLY 1 Covered Entity (Pharmacy)** as designated by their National Provider Identifier (NPI)

Please fill in all information requested. Any Missing or invalid information in (\*) fields may delay the processing of your dispute or result in its rejection.

#### Section 1: To be completed by the Manufacturer

Use of the Manufacturer Name and Labeler ID under which the product was billed in the TRICARE Retail Refund Program (TRRP) is preferred.

#### Section 2: To be completed by Each Covered Entity (Pharmacy)

#### The Covered Entity (Pharmacy) should provide:

- A. Name of the Pharmacy
- B. Address
- C. Nation Provider Identifier (NPI) or NCPDP
  - NPI is preferred over the National Council for Prescription Drug Programs (NCPDP) number

#### Section 3: To be completed by the Manufacturer and Each Covered Entity (Pharmacy)

#### The Manufacturer should provide:

- A. Prescription number (RX #)
- B. NDC (optional)
- C. Date of service based on the utilization data provided to the manufacturer

#### The Covered Entity (Pharmacy) should provide:

A. Verification that the prescription was or was not billed/dispensed as a 340b productby selecting yes or no.

#### The Authorized Representative will provide:

- A. Signature and printed name
- B. Date of Signature
- C. Title
  - i. i.e., Pharmacist, Technician, 340b Specialist, etc.

#### 10. APPENDIX III\_DISPUTE RESUBMISSION FORM

#### TRICARE DISPUTE RESUBMISSION FORM

If a Manufacturer disagrees with the Defense Health Agency's (DHA) decision regarding resolved disputes, the Manufacturer may request to resubmit their disputes. The request for resubmission must be submitted within **30 days** from the date the Manufacturer was notified of the dispute outcome. All requests must include new documentation pertaining to the disputes in question.

#### **INSTRUCTIONS**

Requests for resubmission must include this completed form and be submitted by email with all supporting documentation to <a href="mailto:dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil">dha.ncr.healthcare-ops.mbx.ufvarr-requests@health.mil</a>.

Disputes should only be resubmitted after considering the following:

- If the manufacturer believes the DHA has made an incorrect decision based on supporting documentation not available at the time the dispute was originally submitted.
- If the manufacturer believes the information/data used by the DHA is incorrect.

nufacturer Name:	Labeler:	Billing Quarter:
scription of Reason for Resubmission ubmission.	on: Please provide thorough description	n of why the Manufacturer is requesting a
inoissinii.		
Provide Excel spreadsheet of dis	putes to be resubmitted with the follo	wing headings:
	putes to be resubmitted with the follo	
Provide Excel spreadsheet of disp	putes to be resubmitted with the follo	wing headings:  Dispute Reason
Claim Number	Dispute Code	Dispute Reason
Claim Number	Dispute Code	Dispute Reason
Claim Number  Name (Manufacturer POC)	Dispute Code	Dispute Reason
Claim Number	Dispute Code	Dispute Reason
Claim Number  Name (Manufacturer POC)	POC Email Address	Dispute Reason

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