103091OMB—SUPPORTING STATEMENT

Federal Agency Retail Pharmacy Program – 0720-0032

A. Justification

1. Need for Information

The Department of Defense (DoD) receives Federal Ceiling Prices (FCP) [i] in the military treatment facilities and the TRICARE Mail Order Pharmacy program. Through authority provided in Section 703 of the Fiscal Year 2008 (FY08) National Defense Authorization Act (NDAA) and the final implementing regulation DoD obtains similar federal pricing discounts in the TRICARE retail network pharmacies. The government collects approximately $1.1B a year based on this requirement/information collection. Section 703 of the NDAA FY08 enacted Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, 10 United States Code (U.S.C) 1074g(f) which makes drugs provided to eligible covered beneficiaries through the TRICARE Retail Pharmacy Program (TRRP) subject to the pricing standards of the Veterans Health Care Act. Under the authority of 10 U.S.C 1074g(h), 32 Code of Federal Regulation (CFR) 199.21(q)(3) requires information collection to implement 10 U.S.C 1074g(f). Beginning as of the effective date of implementing regulations, May 26, 2009, the DoD started the process of collecting federal pricing discounts for covered drugs provided to TRICARE beneficiaries through TRICARE retail network pharmacies. FCP discount reductions are achieved through quarterly collection of refunds from pharmaceutical manufacturers based on the utilization of their covered drug in the TRICARE retail network pharmacies. Specifically, under the collection of information, pharmaceutical manufacturers validate refund amounts (that they owe the Government) based on refund calculation reporting requirements on the difference between the average non-Federal price of the drug sold by the pharmaceutical manufacturer to

wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, at the discretion of the pharmaceutical manufacturer, the difference between the FCP and direct commercial contract sales prices, specifically attributable to the reported TRICARE paid pharmaceuticals determined for each applicable National Drug Code (NDC) listing, per Refund Procedures outlined in CFR 199.21. The DoD uses the reporting and audit capabilities of the Pharmacy Data Transaction Service (PDTS) to validate refunds owed to the Government.

Pursuant to the terms of a contract awarded by the DoD, a commercial Pharmacy Benefits Manager (PBM) provides a retail pharmacy network for the Defense Health Agency (DHA). This retail pharmacy network also includes long term care facilities, specialty pharmacies, pharmacies inside physician offices and hospitals, and all other pharmacies identified as part of the TRICARE retail network. The PBM issues payment with government funds for prescriptions dispensed by retail network pharmacies to TRICARE beneficiaries. The DoD provides pharmaceutical manufacturers with itemized utilization data on covered drugs dispensed to TRICARE beneficiaries through TRICARE retail network pharmacies in order to obtain appropriate refunds.

2. Use of Information

The DoD provides pharmaceutical manufacturers with itemized utilization data on covered drugs dispensed to TRICARE beneficiaries through TRICARE retail network pharmacies. The billing periods span the calendar quarters January through March, April through June, July through September, and October through December. The TRICARE Retail Refund Program Manufacturer Policy and Procedures Guide (Guide), which outlines the refund payment process, and billing schedule are posted on the DHA Pharmaceutical Manufacturers Homepage,

http://www.health.mil/About-MHS/Defense-Health-Agency/Healthcare-Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers. In summary:

a) Itemized utilization data files that are encrypted and in the standard National Council for Prescription Drug Programs (NCPDP) format are made available for pharmaceutical manufacturers on the PDTS contractor Secure File Transfer Protocol (SFTP) server. The manufacturers are issued a username and password to access their data. DHA Pharmacy Operations Division (POD) has also made a condensed version of the NCPDP itemized utilization data files (e.g., removing filler columns) available on the web based TRICARE Retail Refunds Website (TRRWS) for pharmaceutical manufacturers that are unable to utilize the standard NCPDP file format, that is available at https://refunds.ha.osd.mil. The manufacturers are provided credentials to access TRRWS with a password, personal identification number (PIN) and user name.

b) The pharmaceutical manufacturers validate the refund owed based on the refund calculation referenced in the Need for Information section (pages 1 and 2).

c) The pharmaceutical manufacturers have at least 70 days from the date the DoD makes the TRICARE itemized utilization data available to validate the refund amount before the refund payment due date.

d) The Pharmaceutical manufacturers are required by the Guide to submit NDC level payment details on the Request for Quarterly Utilization (RQU). It is available on TRRWS for refunds from each quarter invoiced. If a manufacturer cannot access the TRRWS RQU, they are required by the Guide to submit their RQU/NDC payment level detail, and disputes of the

accuracy of TRICARE's itemized utilization data in accordance with 32 CFR 199.21(q)(3)(iv) via email to UFVARR_Request@mail.mil in the format provided in the Guide.

e) The pharmaceutical manufacturer refund is paid directly to DHA Government account.

f) If applicable, resolution of disputes of the accuracy of TRICARE refund utilization data and refund amount due are performed by DHA Contract Resource Management (CRM) and POD TRICARE Retail Refund Team (TRRT).

3. Use of Information Technology

The DoD provides pharmaceutical manufacturers with itemized utilization data files, that are made available quarterly via the PDTS contractor's SFTP server or the POD web-based system, TRRWS. Pharmaceutical manufacturers can retrieve itemized utilization data for their covered drugs dispensed to TRICARE beneficiaries at TRICARE retail network pharmacies. They may also utilize the POD web-based system, TRRWS to submit RQU payment information, and disputes of the accuracy of TRICARE's itemized utilization data in accordance with 32 CFR 199.21(q)(3)(iv). The number of manufacturers using electronic submission of payments increased from previous years. Over 95 percent of pharmaceutical manufacturers are submitting responses electronically. On January 29, 2015, POD hosted an information session webinar with pharmaceutical manufacturers, entitled; "An Overview of the TRICARE Retail Refund Program Policies and Procedures" to brief them streamlining the refund payment submission and reconciliation processes. Topics included, Refund Utilization Calculation, Refund Billing Detail, and Dispute Process.

4. Non- duplication

[i] The FCP is the maximum price that pharmaceutical manufacturers can charge the Big Four for brand-name drugs

There are no existing data that can be used for these purposes. The TRRP calculates the manufacturer refund data based on the pricing cost information received from the VA, which is the authoritative source.

5. Burden on Small Business

There are no identified small business burdens. The POD has made a condensed version of the NCPDP itemized utilization data files (e.g., removing filler columns) available on TRRWS for pharmaceutical manufacturers that are unable to utilize the standard NCPDP file format that is available on the PDTS contractor SFTP server

6. Less Frequent Collections

Under the authority of 10 USC 1074g(h), 32 CFR 199.21(q)(3)(i), the Refund Procedures to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures provide the manufacturer at least 70 days from the date of submission of the TRICARE itemized utilization data needed to calculate the refund before the refund payment is due. If the proposed data collection is not approved at least quarterly, DoD may not be able to maximize refund recoupment on covered drugs dispensed to TRICARE beneficiaries throughout the FY.

7. Paperwork Reduction Act Guidelines

There are no special circumstances that require this information collection to be conducted in a manner that is inconsistent with the guidelines in 5 CFR 1320. 5(d)(2). It is necessary for the proper performance of TRRP functions, informs respondents about use of information, and displays currently valid OMB Control Number on TRRWS.

8. Consultation and Public Comments

a. A 60-day notice published in the *Federal Register* Vol. 80, No 213 on November 4, 2015(80 FR 68301-68302). No comments were received. A 30-day notice published in the *Federal Register* Vol. 81, No 108 on June 6, 2016 (81 FR 36282).

b. On January 29, 2015, POD hosted an information session webinar with pharmaceutical manufacturers, entitled, "An Overview of the TRICARE Retail Refund Program Policies and Procedures". Topics included, Refund Utilization Calculation, Refund Billing Detail, and Dispute Process. The pharmaceutical manufacturers were given the opportunity to provide input for consideration into the final version of the Guide which was distributed to pharmaceutical manufacturers in July 2015.

9. Gifts or Payment

No payments or gifts will be provided to respondents.

10. Confidentiality

The utilization data used by the pharmaceutical manufacturers and the TRRP team will be used solely for the purpose of obtaining appropriate refunds on covered drugs dispensed to TRICARE beneficiaries. Refunds due are based solely on utilization of covered drugs dispensed to TRICARE beneficiaries through TRICARE retail network pharmacies. The TRRP utilizes PDTS to generate standard NCPDP reports. PDTS provides an extensive audit trail and reporting process for transaction-based invoicing. The itemized utilization data provided to pharmaceutical manufacturers does not contain any personally identifiable information such as patient names and social security numbers.

In accordance with Health Insurance Portability and Accountability Act (HIPAA), no patient names are provided in the itemized utilization data files. The data provided is consistent

with HIPAA-recognized use for treatment, payment, and operations. The quarterly itemized utilization data files are made available via the PDTS contractor's SFTP secure server or TRRWS.

A Privacy Act System of Records Notice (SORN) ID and Privacy Impact Assessment and Privacy Act Statement is not required for this collection. TRRWS does not create records containing Personally Identifiable Information or Protected Health Information that is routinely retrieved by an individual's name or other unique personal identifier.

11. Sensitive Questions

There are no questions of a sensitive nature included in the collection.

12. Respondent Burden, and its Labor Costs

a. Estimation of Respondent Burden

Estimation of Respondent Burden Hours					
	Number of Respondents	Number of Responses per Respondent	Number of Total Annual Responses	Response Time (Amount of time needed to complete the collection instrument)	Respondent Burden Hours (Total Annual Responses multiplied by Response Time) Please compute these into hours)
Collection Instrument #1(Name of collection instrument, i.e. form number)	300	4	1200	8 hours	9,600
Total	300	4	1200	8 hours	9,600

b. Labor Cost of Respondent Burden

Labor Cost of Respondent Burden					
	Number of Responses	Response Time per Response	Respondent Hourly Wage	Labor Burden per Response (Response Time multiplied by Respondent Hourly Wage)	Total Labor Burden (Number of Respondents multiplied by Response Time multiplied by Respondent Hourly Wage)
Collection Instrument #1(Name of collection instrument, i.e. form number)	1200	8	$42.08	$336.64	$403,968
Total	1200	8	$42.08	$336.64	$403,968

Respondent Wage Reference Source: U.S. OFFICE OF PERSONNEL MANAGEMENT, Salary Table 2016 https://archive.opm.gov/flsa/oca/09tables/indexgs.asp

13. Capital, Start-up, and Maintenance Costs

Respondents will be asked to maintain records. No additional equipment purchases will be made to support data collection processes or record keeping, thus no incremental cost above the cost of the collection of the information will be incurred.

14. Cost to Federal Government

Total cost to the government for collecting this information approximately $4.36 million. As of December 31, 2015, the government received approximately $1.1 billion from pharmaceutical manufacturers as a result of the program/refund reporting requirement for FY15.

	Collection Instrument #1	Total
Number of Responses	1200	1200

Processing Time Per Response (in hours)	24 hours	24 hours
Hourly Wage of Worker(s) Processing Responses	$40.00 GS 7 Step 1 https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf	$40.00
Cost to Process Each Response (Processing Time Per Response multiplied by Hourly Wage of Worker(s) Processing Responses)	$960	$960.00
Total Cost to Process Responses (Cost to Process Each Response multiplied by Number of Responses	$1,152,000	1,152,000

Operational and Maintenance Costs						
Equipment (Maintenance)	Printing	Postage	Software Purchases	Licensing Costs	Other (Server Costs)	Total
$900	N/A	N/A	N/A	N/A	$12,620	$13,520

Total Cost to the Federal Government		
Operational and Maintenance Costs	Labor Cost to the Federal Government	Total Cost (O&M Costs + Labor Cost)
$13, 520	$4,347,600	$4,361,120

15. Reasons for Change in Burden

This collection is in existence with OMB approval. There has been an increase in the number of pharmaceutical manufacturers who have covered drugs eligible for the TRRP. Based upon analysis of the utilization data used in prior billings, DHA determined it needed to re-bill the 3rd Quarter Calendar Year (QCY) 2009 to 4th QCY 2011 utilization data during the last OMB renewal period. DHA does not anticipate that re-billing additional quarters will be necessary. As a result, this reduces the number of responses per respondent from 8 to 4 annually.

16. Publication of Results

The data collected will be used for internal DoD use only and there are no plans for outside publication of results.

17. Non-Display of OMB Expiration Date

Approval is not sought for avoiding display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Submissions

The proposed data collection does not involve any exceptions to the certification statement identified in line 19 of OMB Form 83-I. As required, an agency disclosure statement is prominently displayed on the information collection (TRRWS).