SUPPORTING STATEMENT - PART A

Federal Agency Retail Pharmacy Program – 0720-0032

1. Need for the Information Collection

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 the 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

100% of responses are collected electronically. 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).

4. Non-duplication

The information obtained through this collection is unique and is not already available for use or adaptation from another cleared source.

5. Burden on Small Businesses

This information collection does not impose a significant economic impact on a substantial number of small businesses or entities.

6. Less Frequent Collection

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

This collection of information does not require collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2).

8. Consultation and Public Comments

Part A: PUBLIC NOTICE

A 60-Day Federal Register Notice for the collection published on Monday, June 10, 2019. The 60-Day FRN citation is volume number 84 FRN 26822.

No comments were received during the 60-Day Comment Period.

A 30-Day Federal Register Notice for the collection published on Thursday, August 29, 2019. The 30-Day FRN citation is volume number 84 FRN 45474.

Part B: CONSULTATION

No additional consultation apart from soliciting public comments through the 60-Day Federal Register Noticed was conducted for this submission.

9. Gifts or Payment

No payments or gifts are being offered to respondents as an incentive to participate in the collection.

10. Confidentiality

A Privacy Act Statement is not required for this collection because we are not requesting individuals to furnish personal information for a system of records.

A System of Record Notice (SORN) is not required for this collection because records are not retrievable by PII.

A Privacy Impact Assessment (PIA) is not required for this collection because PII is not being collected electronically.

Records Retention and Disposition Schedule:

"Records will be maintained in accordance with the following approved disposition schedule:
Subject: Agency Studies, Reviews and Analyses (Health Industry Trends, Pricing Structure Cost Analyses, and DHA Budget Analysis)
Cutoff: Annually
Disposition: Temporary. Destroy 5 years after cutoff.
OSD RDS Series File Number: 906-03
NARA Authority: NC1-330-77-5

11. Sensitive Questions

No questions considered sensitive are being asked in this collection.

12. Respondent Burden and its Labor Costs

a. Estimation of Respondent Burden

1. TRICARE Retail Refunds Website
a. Number of Respondents: 300
b. Number of Responses Per Respondent: 4
c. Number of Total Annual Responses: 1200
d. Response Time: 8 hours
e. Respondent Burden Hours: 9600 hours

2. **Total Submission Burden**
a. Total Number of Respondents: 300
b. Total Number of Annual Responses: 1200
c. Total Respondent Burden Hours: 9600 hours

b. Labor Cost of Respondent Burden

1. TRICARE Retail Refunds submission

a. Number of Total Annual Responses: 1200
b. Response Time: 8 hours
c. Respondent Hourly Wage: $40.05
d. Labor Burden per Response: $320.40
e. Total Labor Burden: $384,480

2. **Overall Labor Burden**
a. Total Number of Annual Responses: 1200
b. Total Labor Burden: $384,480

Respondent Wage Reference Source: Bureau of Labor Statistics, average hourly wage for Pharmaceutical and Medicine Manufacturing in 2018
https://www.bls.gov/oes/current/oes414011.htm

13. Respondent Costs Other Than Burden Hour Costs

There are no annualized costs to respondents other than the labor burden costs addressed in Section 12 of this document to complete this collection.

14. Cost to the Federal Government

a. Labor Cost to the Federal Government

1. TRICARE Retail Refunds submission
a. Number of Total Annual Responses: 1200
b. Processing Time per Response: 24 hours
c. Hourly Wage of Worker(s) Processing Responses: $10.82
d. Cost to Process Each Response: $259.68
e. Total Cost to Process Responses: $311,616

2. Overall Labor Burden to Federal Government
a. Total Number of Annual Responses: 1200
b. Total Labor Burden: $311,616

Hourly wage is for a GS 7 Step 1 worker in 2019
(https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/GS_h.pdf)

b. Operational and Maintenance Costs

a. Equipment: $0
b. Printing: $0
c. Postage: $0
d. Software Purchases: $0
e. Licensing Costs: $0
f. Other (server costs): $756,000
g. Total: $756,000

1. Total Operational and Maintenance Costs: $756,000
2. Total Labor Cost to the Federal Government: $311,616
3. Total Cost to the Federal Government: $1,067,616

15. Reasons for Change in Burden

There has been no change in burden since the last approval.

16. Publication of Results

The results of this information collection will not be published.

17. Non-Display of OMB Expiration Date

We are not seeking approval to omit the display of the expiration date of the OMB approval on the collection instrument.

18. Exceptions to "Certification for Paperwork Reduction Submissions"

We are not requesting any exemptions to the provisions stated in 5 CFR 1320.9.

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