OMB—SUPPORTING STATEMENT

Federal Ceiling Price Retail Pharmacy Program

A. Justification

1. Need for Information

10 United States Code (USC) 1074g(f) makes drugs provided to eligible covered beneficiaries through the TRICARE Retail Pharmacy Program subject to the pricing standards of the Veterans Health Care Act. Under the authority of 10 USC 1074g(h), 32 Code of Federal Regulation (CFR) 199.21(q)(3) requires information collection to implement 10 USC 1074g(f). The Department of Defense is revising the information collection under control number 0720–0032. Specifically, under the collection of information, respondents (drug manufacturers) will base refund calculation reporting requirements on both the Federal Ceiling Price and the Federal Supply Schedule Price, whichever is lower. Previously, drug manufacturers' reporting requirements addressed only the Federal Ceiling Price. The DoD will use the reporting and audit capabilities of the Pharmacy Data Transaction Service (PDTS) to validate refunds owed to the Government.

In addition, pursuant to the terms of a contract awarded by DoD, a commercial pharmacy benefits manager (PBM) will provide a retail pharmacy network for the DoD TRICARE Management Activity. The PBM will issue payment with Government funds for prescriptions dispensed by retail network pharmacies to TRICARE beneficiaries. DoD will provide manufacturers with itemized data on covered drugs purchased through TRICARE retail network pharmacies in order to obtain appropriate refunds on covered drugs delivered to TRICARE beneficiaries.

2. How, by Whom, and for What Purpose Information Will be Used

DoD will provide manufacturers with itemized data on covered drugs purchased through TRICARE retail network pharmacies. The drug manufacturers will validate the refund based on the difference between a benchmark price, consisting of either the manufacturer's actual sales price to the wholesaler or retail pharmacy chain when known and auditable or non-FAMP (non-Federal average manufacturer price) and the Federal Ceiling Price (FCP).

3. Does information collection involve the use of Information Technology

As indicated above DoD will provide manufacturers with itemized data on covered drugs purchased through TRICARE retail network pharmacies. The drug manufacturers will validate the refund based on the difference between a benchmark price, consisting of either the manufacturer's actual sales price to the wholesaler or retail pharmacy chain when known and auditable or non-FAMP (non-Federal average manufacturer price) and the Federal Ceiling Price (FCP).

The manufacturers will IT to download and decrypt their itemized data on covered drugs purchased through TRICARE retail network pharmacies. and utilize the web-based system to obtain their data, submit Reconciliation of Quarterly Utilization (RQU) payment information and enter their disputes of the accuracy of TMA's utilization data in accordance with 32 C.F.R. § 199.21(q)(3)(iv).

4. Efforts to Avoid Duplication

There are no existing data which can be used for these purposes.

5. Small Business Impact

None.

6. Consequences of Not Collecting Information

If the proposed data collection is not approved, DoD not be able to obtain appropriate refunds on covered drugs delivered to TRICARE beneficiaries.

7. Special Circumstances

There are no special circumstances involved in this data collection effort.

8. Applicability to 5 CFR 1320.8(d)

The draft notice was published in the *Federal Register* on October 16, 2012 (77 FR 6329763298). No comments were received.

The average estimated time for addressing the collection requirement is 8 hours per response or 16,000 hours for the total burden.

9. Remuneration to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

Data will be used solely for the purpose of obtaining appropriate refunds on covered drugs delivered to TRICARE beneficiaries and for no other purpose.

11. Questions of a Sensitive Nature

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

12. Hour Burden Estimate

There are an approximate total of 250 drug manufacturers responding to this collection. There will be four responses per year per respondent with an estimated 8 hours of preparation time per response for a total of 16,000 hours.

AFFECTED PUBLIC: Approximately 250 Drug Manufacturers who have entered into a master agreement with the VA.

ANNUAL BURDEN HOURS: 16,000

NUMBER OF RESPONDENTS: 250

RESPONSES PER RESPONDENT: 8

AVERAGE BURDEN PER RESPONSE: 8 hours

FREQUENCY: Quarterly

16,000 hours x $62.17 (representative hourly professional salary including benefits) = $994,720.00

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. Annualized Cost to Federal Government

The total cost to the government for collecting this information $4.3 million. The Government received approximately $1.5 billion from pharmaceutical companies as a result of this program/refund calculation reporting requirement.

15. Changes from OMB Form 83-I

This is a revision of a previously approved collection; therefore, the change in burden is 8,000.

16. Outside Publication

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

17. Expiration Date

The expiration date of the OMB approval will be displayed on the information collection.

18. Certification Statement

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 will be prominently displayed on the information collection.