Billing Code: 5001-06

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD-2015-HA-0119]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by [INSERT 60 DAYS FROM PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301-9010.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at http://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at http://www.regulations.gov for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency, Pharmacy Operations Division, ATTN: CAPT Nita Sood, 7700 Arlington Boulevard, Falls Church, VA 22042-5101.

SUPPLEMENTARY INFORMATION:

TITLE; ASSOCIATED FORM; AND OMB NUMBER: Federal Agency Retail Pharmacy Program; OMB Control Number 0720-0032.

NEEDS AND USES: The Department of Defense (DoD) is extending the information collection requirements under current OMB Control Number 0720–0032. Specifically, under the collection of information, pharmaceutical manufacturers will base 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 Federal Ceiling Price (FCP) or, in 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. DoD will use the reporting and audit capabilities of the Pharmacy Data Transaction Service (PDTS) to validate refunds owed to the Government. In Fiscal Year (FY) 15, the government received approximately $1.1 billion from pharmaceutical manufacturers as a result of this program/refund calculation reporting requirements.

AFFECTED PUBLIC: Business or other for profit; Not-for-profit institutions

ANNUAL BURDEN HOURS: 9,600.

NUMBER OF RESPONDENTS: 300.

RESPONSES PER RESPONDENT: 4.

ANNUAL RESPONSES: 1200.

AVERAGE BURDEN PER RESPONSE: 8 hours.

FREQUENCY: Quarterly.

10 United States Code (U.S.C.) 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 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). The DoD is extending the information collection control number 0720–0032. Specifically, under the collection of information, pharmaceutical manufacturers will base 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-FAMP (reported to the VA) and the corresponding FCP or, in 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 NDC listing, per Refund Procedures outlined in CFR 199.21. The DoD will use the reporting and audit capabilities of the PDTS to validate refunds owed to the Government.

Dated: October 30, 2015.

Aaron Siegel,

Alternate OSD Federal Register

Liaison Officer, Department of Defense.

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