ADDRESSES: You may submit comments, identified by DFARS Case 2003–D025, using any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Defense Acquisition Regulations Web Site: *http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm*. Follow the instructions for submitting comments.
- E-mail: *dfars@osd.mil*. Include DFARS Case 2003–D025 in the subject line of the message.
- Fax: (703) 602–0350.
- Mail: Defense Acquisition Regulations Council, Attn: Ms. Debbie Tronic, OUSD (AT&L) DPAP (DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.
- Hand Delivery/Courier: Defense Acquisition Regulations Council, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

All comments received will be posted to *http://emissary.acq.osd.mil/dar/dfars.nsf*.

FOR FURTHER INFORMATION CONTACT: Ms. Debbie Tronic, (703) 602–0289.

SUPPLEMENTARY INFORMATION:

A. Background

DFARS Transformation is a major DoD initiative to dramatically change the purpose and content of the DFARS. The objective is to improve the efficiency and effectiveness of the acquisition process, while allowing the acquisition workforce the flexibility to innovate. The transformed DFARS will contain only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal operating procedures of DoD or a significant cost or administrative impact on contractors or offerors. Additional information on the DFARS Transformation initiative is available at *http://www.acq.osd.mil/dpap/dfars/transf.htm*.

This proposed rule is a result of the DFARS Transformation initiative. The proposed changes—

- Revise DFARS 244.301 to clarify Government responsibilities for conducting reviews of contractor purchasing systems.
- Delete text at DFARS 244.304 containing examples of weaknesses in a contractor's purchasing system that may indicate the need for a review. This text will be relocated to the new DFARS companion resource, Procedures, Guidance, and Information (PGI), available at *http://www.acq.osd.mil/dpap/dars/pgi*.
- Update the clause at DFARS 252.244–7000 to reflect the current title of the clause at FAR 52.244–6, Subcontracts for Commercial Items.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule makes no significant change to DoD contracting policy. Therefore, DoD has not performed an initial regulatory flexibility analysis. DoD invites comments from small businesses and other interested parties. DoD also will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 2003-D025.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 244 and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

Therefore, DoD proposes to amend 48 CFR Parts 244 and 252 as follows:

1. The authority citation for 48 CFR Parts 244 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 244—SUBCONTRACTING POLICIES AND PROCEDURES

2. Section 244.301 is revised to read as follows:

244.301 Objective.

The administrative contracting officer (ACO) is solely responsible for initiating reviews of the contractor's purchasing systems, but other organizations may request that the ACO initiate such reviews.

3. Section 244.304 is revised to read as follows:

244.304 Surveillance.

(b) The ACO, or the purchasing system analyst (PSA) with the concurrence of the ACO, may initiate a special review of specific weaknesses in the contractor's purchasing system. See PGI 244.304(b) for examples of weaknesses.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.244–7000 [Amended]

4. Section 252.244–7000 is amended as follows:

a. By revising the clause date to read ''(XXX 2005)''; and

b. In the introductory text of the clause by removing the phrase ''and Commercial Components''.

[FR Doc. 05–7091 Filed 4–11–05; 8:45 am]

BILLING CODE 5001–08–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 538 and 552

[GSAR 2005–G501]

RIN 3090–AI06

General Services Acquisition Regulation; Federal Agency Retail Pharmacy Program

AGENCY: Office of the Chief Acquisition Officer, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Services Administration (GSA) is proposing to amend the General Services Acquisition Regulation (GSAR) to add a new subpart and clause required by the Department of Veterans Affairs (VA), consistent with Congressional intent under Section 603 of the Veterans Health Care Act of 1992 (VHCA) that certain Federal agencies (*i.e.,* VA, Department of Defense (DoD), Public Health Service (including the Indian Health Service), and the Coast Guard) have access to Federal pricing for pharmaceuticals purchased for their beneficiaries.

GSA is responsible for the schedules program and rules related to its operation. Under GSA's delegation of authority, the VA procures medical supplies under the VA Federal Supply Schedule program. VA and DoD seek this amendment. This new subpart adds a clause unique to the virtual depot system established by a Federal Agency Retail Pharmacy Program utilizing contracted retail pharmacies as part of a centralized pharmaceutical commodity management program. At this time, only DoD has a program in place, and the rule would facilitate DoD's access to Federal pricing offered on Federal Supply Schedule (FSS) pharmaceutical

contracts for covered drugs purchased by DoD and dispensed to TRICARE beneficiaries through retail pharmacies in the TRICARE network.

DATES: Interested parties should submit comments in writing on or before June 13, 2005 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments identified by GSAR case 2005–G501 by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web Site: *http://www.acqnet.gov/GSAM/gsamproposed.html.* Click on the GSAR case number to submit comments.
- E-mail: *gsarcase.2005–G501@gsa.gov.* Include GSAR case 2005–G501 in the subject line of the message.
- Fax: 202–501–4067.
- Mail: General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW, Room 4035, ATTN: Laurieann Duarte, Washington, DC 20405.

Instructions: Please submit comments only and cite GSAR case 2005–G501 in all correspondence related to this case. All comments received will be posted without change to *http://www.acqnet.gov/far/ProposedRules/proposed.htm*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT The Regulatory Secretariat (VIR), Room 4035, GS Building, Washington, DC 20405, (202) 208–7312, for information pertaining to status or publication schedules. For clarification of content, contact Ms. Kimberly Marshall at (202) 219–0986, or by e-mail at *kimberly.marshall@gsa.gov.* Please cite GSAR case 2005–G501.

SUPPLEMENTARY INFORMATION:

A. Introduction

Under the General Services Administration (GSA) Schedules (also referred to as Multiple Award Schedules and Federal Supply Schedules) Program, 41 U.S.C. 259(b) and 40 U.S.C. 501, GSA establishes long-term Governmentwide contracts with commercial firms to provide access to over four million commercial services and products that can be ordered directly from GSA Schedule contractors or through the GSA *Advantage!* ™ online shopping and ordering system.

GSA Schedules offer customers direct delivery of millions of state-of-the-art, high-quality commercial services and products at volume discount pricing. All customers, even those in remote locations, can order the latest technology and quality services and products, conveniently, and at most-favored customer prices. GSA Schedules also offer the potential benefits of shorter lead-times, lower administrative costs, and reduced inventories. When using GSA Schedules, ordering activities have the opportunity to meet small business goals, while promoting compliance with various environmental and socioeconomic laws and regulations.

The General Services Administration has delegated the responsibility for certain Federal Supply Schedules to the Department of Veterans Affairs (VA). This includes Federal Supply Classification (FSC) Group 65, which includes pharmaceuticals and drugs. Federal agencies and certain other organizations are eligible to purchase pharmaceuticals and drugs from VA supply schedules.

B. Background

1. *The Federal Agency Retail Pharmacy Program Supply Schedule clause.* These changes will allow VA to revise its schedule contracts to accommodate the ordering needs of Federal agencies, *i.e.* DOD, VA, the Public Health Service (including the Indian Health Service), and the Coast Guard, pursuant to 38 U.S.C. 8126, through virtual depot systems. These depot systems will use contracted retail pharmacies as part of the centralized pharmaceutical commodity management program. DoD's TRICARE Retail Pharmacy Program is the first such virtual depot system and will be the prototype for future systems. This rule will allow Federal agencies to take advantage of FSS pricing and receive a refund, where appropriate, from drug manufacturers for sales to those agencies through the retail pharmacy network virtual depot system, for their beneficiaries.

In general, Federal pricing of pharmaceuticals refers to discounts (Federal Ceiling Prices (FCPs)) available from manufacturers under Section 603 of the Veterans Health Care Act (VHCA) of 1992 (38 U.S.C. 8126), and Federal Supply Schedule (FSS) prices under the VA Federal Supply Schedule program. The VHCA requires drug manufacturers to enter into a Master Agreement with VA under which a Pharmaceutical Pricing Agreement is executed establishing a discount for covered drugs obtained by VA, DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard purchased by these Federal agencies under depot contracting systems or listed on the FSS. Specifically, this rule adds a new subpart to the GSAR on Federal Agency Retail Pharmacy Program (subpart 538.XX) and a new clause, Federal Agency Retail Pharmacy Program Supply Schedule (GSAR 552.238–XX) for those Federal Agency Retail Pharmacy Programs determined by the VA Secretary to qualify as a ''depot'' contracting system as set forth in 38 U.S.C. 8126.

This rulemaking assists the ongoing reengineering of the TRICARE Pharmacy Benefits Program (TPBP), consistent with the Congressional actions and DoD's prior rulemaking described below. This rulemaking is consistent with the authority provided by 38 U.S.C. 8126 to acquire drugs at the statutorily provided discount through use of a depot contracting system.

Pursuant to the Federal Agency Retail Pharmacy Program clause, the drugs for beneficiaries will be deemed to be ordered by the Federal agencies through the FSS contract solely for the purposes of pricing, delivery, and scope of coverage, but does not confer rights for any other purpose. The Federal agencies will obtain refunds on covered drugs purchased through the retail pharmacy network by those agencies and dispensed to beneficiaries. The drug manufacturer will base the refund 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 Supply Schedule price (the Federal Ceiling Price or FSS negotiated price, whichever is lower).

The Federal Agency Retail Pharmacy Program Supply Schedule clause in this rule refers to a VA clause, ''Industrial Funding Fee and Sales Reporting (JUL 2003)(Variation)''. This clause is available at the following website: *http://www.va.gov/oamm/nac/fsss/.*

2. *The TRICARE Pharmacy Benefits Program (TPBP) of the Department of Defense.* This rule is required by DoD in order to reengineer its TRICARE Pharmacy Benefits Program. DoD is directed by statute (title 10, United States Code, chapter 55) to provide an improved and uniform health care benefits program in order to create and maintain high morale in the uniformed services. TRICARE is DoD's comprehensive health care program for over 9.3 million beneficiaries—active duty Service members and their families, as well as retirees and their families and survivors—and includes a robust pharmacy benefit that gives beneficiaries the option of obtaining drugs from military treatment facilities, by mail order, or through retail

pharmacies. The TRICARE pharmacy website is at *http://www.tricare.osd.mil/pharmacy/.* The TRICARE Pharmacy Benefits Program uses the VA supply schedules, among other vehicles.

Section 703 of the National Defense Authorization Act for FY 1999 (Public Law 105–261) required the Secretary of Defense to plan a ''system-wide redesign of the military and contractor retail and mail-order pharmacy system of the Department of Defense by incorporating 'best business practices' of the private sector.'' In addition, section 701 of the FY 2000 National Defense Authorization Act (Public Law 106–65) enacted 10 U.S.C. 1074g, which directed the Secretary to ''establish an effective, efficient, integrated pharmacy benefits program.''

DoD has reengineered the TPBP to meet these Congressional requirements. The redesign of the TPBP was the subject of public rulemaking (see 69 FR 17035, April 1, 2004) and is codified at 32 CFR Section 199.21.

One key goal of the reengineering effort is to extend Federal pricing of pharmaceuticals to prescriptions filled for TRICARE beneficiaries by retail pharmacies in the TRICARE network. DOD has taken advantage of the statutory pricing authority with respect to drugs purchased and dispensed through the TRICARE mail order pharmacy program and military hospitals. DoD is now in a position to extend Federal pricing to the TRICARE retail pharmacy network. As a result of reengineering, DoD is able to link DoD's drug purchases from network pharmacies to the manufacturer of the purchased drug, including those manufacturers with FSS contracts.

In particular, the redesigned TPBP leverages new technology to create a centralized commodity management system as required under the VHCA for a depot contracting system. As previously stated, the VHCA requires drug manufacturers to enter into a Master Agreement with VA under which a Pharmaceutical Pricing Agreement is executed establishing a discount for covered drugs purchased by VA, DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard under depot contracting systems or listed on the FSS. All drug manufacturers that signed a Master Agreement and Pharmaceutical Pricing Agreement with VA were advised by letter signed by the Acting Executive Director, VA National Acquisition Center, dated October 14, 2004 (which letter is hereby incorporated by reference), that the VA Secretary had determined that DoD's TRICARE Retail Pharmacy Program was a centralized pharmaceutical commodity management system that met the definition of ''depot'' contracting system as set forth in 38 U.S.C. 8126. While that letter authorized DoD to obtain Federal Ceiling Prices for drugs purchased through the TRICARE retail pharmacy network after September 30, 2004, this rule will extend FSS pricing to such drugs.

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.

DoD will use the reporting and audit capabilities of the Pharmacy Data Transaction Service (PDTS) to verify beneficiary eligibility, authorize prescription payments, and validate the refund owed to the Government.

The PBM contractor has no role in DoD's process for obtaining refunds based on FSS prices (whether Federal Ceiling Prices or negotiated lower FSS prices) already established by VA. Nor is DoD's payment to the PBM contractor related, either directly or indirectly, to Federal pricing of pharmaceuticals dispensed to TRICARE beneficiaries by network pharmacies.

Congress has anticipated the extension of Federal pricing to the redesigned TPBP. In the Defense Appropriations Act for FY 2005 (Public Law 108–287), Congress decreased the funding in the Defense Health Program account to reflect savings generated from the application of Federal pricing to the TRICARE pharmacy program. In addition, Senate Report No. 108–260, accompanying the proposed National Defense Authorization Act for Fiscal Year 2005, S. 2400, reiterates an expectation for savings and recommends further decreases to TRICARE program funding. The report (page 313) states:

> The budget request reflected $172.0 million in savings related to the use of federal pricing for retail pharmaceuticals in fiscal year 2005. The committee understands that the funding in the defense health program request did not reflect anticipated savings for retail pharmaceuticals beginning in June 2004, when federal pricing authorized by the Secretary of Veterans Affairs under title 38, United States Code, is applied in a new retail pharmacy program. Accordingly, the committee recommends a decrease of $44 million in the defense health program account.

It should be noted that the effective date in the aforementioned committee report has been extended to October 1, 2004.

3. *The Department of Veterans Affairs.* The General Services Administration is promulgating this rule also to assist efforts by the Department of Veterans Affairs to provide medical care and associated services to veterans of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF), as well as to provide more efficient access to newly written prescriptions for veterans currently receiving medical care at locations where VA pharmacy services are not immediately available. Such venues primarily include Community Based Outpatient Clinics (CBOCs). As is the current practice, refills would be handled at VA's consolidated mail outpatient pharmacies (CMOPs).

As some portion of OIF and OEF veterans will be returning from combat areas to their homes in locations where VA pharmacy services are not immediately available, VA is currently contemplating how to meet the needs of these returning soldiers for timely, high-quality and cost-effective prescription services. Based upon the July 29, 2004, VHA report, ''Analysis of VA Health Care Utilization Among Veterans of Operation Iraqi Freedom and Operation Enduring Freedom'', approximately 27,571 (16 percent) of the 168,528 separated OIF veterans and 5,113 (11 percent) of the 45,880 separated OEF veterans identified by VA based on data provided by DoD, have sought VA health care since they were deployed. VA believes that contractual arrangements whereby VA pays for new prescriptions at Federal prices in community settings will allow VA to meet its obligations to its existing patients, as well as newly enrolled OIF and OEF beneficiaries, in a cost-effective and timely manner.

In the future, it is likely that VA will make use of this rule to provide prescription services to beneficiaries authorized to receive services under one or more of the following programs: VA's CHAMPVA, VA Fee Program, Spina Bifada Health Care Program, Children of Women Vietnam Veterans Program, or other contracted medical care programs. While VA does not currently have contractual arrangements in place to immediately take advantage of this rule, it is actively engaged in the preparatory work to solicit for such contracts.

CHAMPVA

CHAMPVA is a health care benefits program for—

- Dependents of veterans who have been rated by the VA as having a total and permanent disability;
- Survivors of veterans who died from VA-rated service-connected conditions, or, who at the time of death, were rated permanently and totally disabled from a VA-rated service-connected condition; and
- Survivors of persons who died in the line of duty and not due to misconduct and not otherwise entitled to benefits under DoD's TRICARE program.

Under CHAPVA, VA shares the cost of covered health care services and supplies with eligible beneficiaries. As is the current practice, patients would continue to have a choice to refill their medications through the VA CMOP under the Made-by-Mail program. For fiscal year 2004 (FY 04), there were 234,000 beneficiaries enrolled and 149,400 unique users for the CHAMPVA program.

VA Fee Program

The VA Fee program provides authorization for certain veterans to receive community-based medical care, hospital care, home care, nursing home care, and services when VA facilities are not available. Fee care is governed by 38 U.S.C. 1703, 38 U.S.C. 1725, and 38 U.S.C. 1728. Approved services are generally paid on a fee-for-service or contract schedule. Authorization may be for brief or long-term episodes of care.

Spina Bifida Health Care Program

Spina Bifida Health Care Program provides benefits to Vietnam veterans' birth children diagnosed with spina bifida and who are in receipt of a VA regional office award for spina bifida benefits. Under this program, VA assumes financial responsibility for medical service and supplies related to the treatment of spina bifida, including complications and associated conditions, excluding spina bifida occulta. Spina bifida beneficiaries are not responsible for a cost share. In FY 04, there were 1,164 beneficiaries enrolled and 689 unique users for the Spina Bifida Health Care program.

Children of Women Vietnam Veterans Program

Children of Women Vietnam Veterans (CWVV) program provides benefits for women Vietnam veterans' birth children diagnosed with one or more covered birth defects as determined by the Denver VA regional office. Under this program, VA assumes financial responsibility for medical services and supplies related to the treatment of the covered birth defects, including complications and associated conditions. CWVV beneficiaries are not responsible for a cost share. In FY 04, there were eight beneficiaries enrolled and no unique users for the CWVV program.

4. *The U.S. Public Health Service (including the Indian Health Service).* Although the U.S. Public Health Service/Indian Health Service do not have current plans to establish a Federal Agency Retail Pharmacy program, if and when the VA Secretary determines that such a program initiated by these agencies qualifies as a ''depot'' contracting system as set forth in 38 U.S.C. 8126, this rule would apply to that program.

C. Executive Order 12866

We have examined the impacts of the proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. This proposed rule is considered a significant regulatory action under the Executive order.

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the implicit GDP deflator for 2003, the most recent year for which final data exist. This proposed rule does not contain such a mandate.

E. Congressional Review Act

The Congressional Review Act (5 U.S.C. 804) requires that regulations that have been identified as being major must be submitted to Congress before taking effect. If implemented as proposed, this rule is not a major rule under the Congressional Review Act.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612), requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rulemaking assists VA's efforts to revise its schedule to accommodate the ordering needs of Federal agencies, i.e., DoD, VA, the Public Health Service (including the Indian Health Service), and the Coast Guard, pursuant to 38 U.S.C. 8126, through virtual depot systems. At this time, only DoD has a program in place, TRICARE Retail Pharmacy Program, that is designed to work through a virtual depot system. The Coast Guard utilizes the TRICARE Retail Pharmacy Program and, thus, is included in the DoD TRICARE Retail Pharmacy Initial Regulatory Flexibility Analysis discussion below.

The changes may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. However, this appears to be very unlikely. The Initial Regulatory Flexibility Analysis is as follows:

Initial Regulatory Flexibility Analysis, GSAR Case 2005–G501, Federal Agency Retail Pharmacy Program

This Initial Regulatory Flexibility Analysis has been prepared in accordance with Section 603, Title 5, of the United States Code.

1. *Description of the reasons why action by the agency is being considered.* This rule amends the General Services Acquisition Regulation (GSAR) to add a new subpart and clause to complement ongoing efforts by the Department of Defense (DoD) to reengineer its TRICARE Retail Pharmacy Benefits Program, and the Department of Veterans Affairs' (VA) plans to create a similar program. This is consistent with Congressional intent under Section 603 of the Veterans Health Care Act of 1992 (VHCA) that certain Federal agencies (*i.e.,* VA, DoD, Public Health Service (including the Indian Health Service), and the Coast Guard) have access to Federal pricing for pharmaceuticals purchased for their beneficiaries.

2. *Succinct statement of the objectives of, and legal basis for, the rule.* Section 603 of the VHCA requires that certain Federal agencies (*i.e.,* VA, DoD, Public Health Service (including the Indian Health Service), and the Coast Guard) have access to Federal pricing for pharmaceuticals purchased for their beneficiaries. This rule would facilitate DoD's access to Federal pricing offered on Federal Supply Schedule (FSS) pharmaceutical contracts for covered drugs purchased by DoD and dispensed to TRICARE beneficiaries through retail pharmacies in the TRICARE network. It would also facilitate access to the same Federal pricing for retail network pharmacy programs instituted by the other agencies named in section 603. GSA has overall responsibility for the schedules program and

rules related to its operation and have empowered VA, under a GSA delegation of authority, to procure medical supplies under the VA Federal Supply Schedule program. VA and DoD both seek this amendment to the GSAR.

3. *Description of and, where feasible, estimate of the number of small entities to which the rule will apply.* The changes may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, but this appears to be very unlikely because of the research conducted (queries of the Central Contractor Registration system database, as well as information provided directly by DoD and VA officials).

It is estimated that the rule will apply to approximately two dozen small businesses as a result of these changes. It should be noted that more than half of these businesses have annual gross sales exceeding $20 million, thus comparing very favorably with their large business counterparts. Further, the high gross sales figures of the small businesses in the pharmaceutical industry indicates the reporting of sales and the payment of refunds to the Federal agencies named in section 603 will have little significant impact on them.

Since subcontractors are not required to be registered in CCR, the total number of small businesses positively impacted may be greater than this; but not significantly so, since subcontracting is not common in the production of pharmaceuticals.

4. *Description of projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.* The rule will impose a new three-step reporting/recordkeeping requirement on *all* entities that hold VA Federal Supply Schedule contracts (for FSC Group 65, which includes covered pharmaceuticals and drugs), including small entities. The first step is the reporting of VA schedule sales of covered drugs (under section 603) under the TRICARE and other Federal agency retail pharmacy programs. The second step is the calculation and the payment of the refunds owed to DoD and other named Federal agencies with similar programs. The third step is the calculation and payment of the industrial funding fee owed to VA. This paperwork justification covers the calculation of the refunds owed to DoD. The types of professional skills necessary for the reporting/recordkeeping and processing of payment is very minimal—predominately spreadsheet and database operational skills which are both essentially clerical. The recordkeeping and processing of payment transactions can both be accomplished electronically, so the effort to be expended on this is minimal.

5. *Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the rule.* This rule is to assist DoD in the final phase of implementing the following: Section 703 of the National Defense Authorization Act for FY 1999 (Public Law 105–261) which required the Secretary of Defense to plan a system-wide redesign of the military and contractor retail and mail-order pharmacy system of the Department; and Section 701 of the FY 2000 National Defense Authorization Act (Public Law 106–65) enacted 10 U.S.C. 1074g, which directed the Secretary to establish an effective, efficient, integrated pharmacy benefits program. This rule also facilitates access to the same Federal pricing for retail network pharmacy programs instituted by other agencies under section 603. There are no other known Federal rules which may duplicate, overlap, or conflict with this rule.

6. *Description of any significant alternatives to the rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities.* There are no known alternatives to accomplish the stated objectives to assist DoD's reengineered TRICARE Retail Pharmacy Benefits Program and VA's planned retail pharmacy program, which would further lessen any significant economic impact of the rule on small entities. As stated previously, the economic impact is deemed to be minimal.

The Regulatory Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. Interested parties may obtain a copy from the Regulatory Secretariat. The Councils will consider comments from small entities concerning the affected GSAR Parts 538 and 552 in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 601, *et seq.* (GSAR case 2005–G501), in correspondence.

G. Paperwork Reduction Act

This rulemaking assists VA's efforts to revise its schedule to accommodate the ordering needs of Federal agencies, *i.e.,* DoD, VA, the Public Health Service (including the Indian Health Service), and the Coast Guard, pursuant to 38 U.S.C. 8126, through virtual depot systems. At this time only DoD has a program in place, TRICARE Retail Pharmacy Program that is designed to work through a virtual depot system. The Coast Guard utilizes the TRICARE Retail Pharmacy Program; and, thus, is included in the DoD TRICARE Retail Pharmacy Paperwork Burden discussion below.

The discussion of information collection activities below applies to the DoD TRICARE program. It is expected that other eligible agencies will request additional collections of information specific to their respective programs. At such time eligible agencies will request OMB numbers for prospective collections and seek public comment.

Summary of Collection of Information: DoD is revising the information collection requirements under current OMB control number 0720–0032. Specifically, under the revised 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. Prior to this rulemaking, drug manufacturers' reporting requirements addressed only the Federal Ceiling Price.

Proposed Use of Information: DoD will use the reporting and audit capabilities of the Pharmacy Data Transaction Service (PDTS) to validate refunds owed to the Government.

Annual Reporting Burden: Public reporting burden for this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: There are approximately 300 drug manufacturers responding to this collection.

Responses per respondent: 4

Total annual responses: 1,200

Preparation hours per response: 8

Total response burden hours: 9,600

H. Request for Comments Regarding Paperwork Burden

Submit comments, including suggestions for reducing this burden, not later than June 13, 2005 to: DoD Health Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405, and a copy to Colonel James Young, or Major Travis Watson, TRICARE Management Activity, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041–3206 (703 681–0039).

Public comments are particularly invited on: whether this collection of information is necessary for the proper performance of functions of the DoD, and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Requester may obtain a copy of the justification from the Colonel James Young or Major Travis Watson, TRICARE Management Activity, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041–3206 (703 681–0039). Please cite OMB Control Number 0720–0032, GSAR case 2005–G501, Federal Agency Retail Pharmacy Program, in all correspondence.

List of Subjects in 48 CFR Parts 538 and 552

Government procurement.

Dated: April 6, 2005.

David A. Drabkin,

Senior Procurement Executive, Office of the Chief Acquisition Officer, General Services Administration.

Therefore, GSA proposes amending 48 CFR parts 538 and 552 as set forth below:

1. The authority citation for 48 CFR parts 538 and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 538—FEDERAL SUPPLY SCHEDULE CONTRACTING

2. Add Subpart 538.XX, consisting of sections 538.XX01 and 538.XX02, to read as follows:

Sec.

Subpart 538–XX—Federal Agency Retail Pharmacy Program

538.XX01 Scope.

This subpart prescribes a clause that applies to a retail pharmacy program of any of the Federal agencies covered by Section 603 of the Veterans Health Care Act (VHCA) of 1992, Public Law 102–585 (38 U.S.C. 8126). As described in 38 U.S.C. 8126(b), the Federal agencies include the Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (including the Indian Health Service), and the Coast Guard.

538.XX02 Contract clause.

The contracting officer shall insert the clause at 552.238–XX, Federal Agency Retail Pharmacy Program Supply Schedule, in solicitation and schedule contracts for Schedule 65, Part I, Section B, to apply only to orders for a Retail Pharmacy Program of the Department of Veterans Affairs, Department of Defense, Public Health Service (including the Indian Health Service), and the Coast Guard.

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. Add section 552.238–XX to read as follows:

552.238–XX Federal Agency Retail Pharmacy Program Supply Schedule.

As prescribed in 538.XX02, insert the following clause:

FEDERAL AGENCY RETAIL PHARMACY PROGRAM SUPPLY SCHEDULE (DATE)

(a) This clause applies only to a Federal Agency Retail Pharmacy Program administered by one of the Federal agencies described in Section 603 of the Veterans Health Care Act (VHCA) of 1992 (38 U.S.C. 8126). When this clause applies, the FAR clauses 52.216–18, 52.216–19, GSAR clause 552.232–74, and FSS clauses I-FSS–103, and F-FSS–202–G do not apply.

(b) The Federal Agency Retail Pharmacy Program procedures, including pricing procedures, and those in this clause, are consistent with 38 U.S.C. 8126. The Federal agency enters into contracts with a commercial pharmacy benefits manager to provide a retail pharmacy network. The pharmacy benefits manager will issue payment with Government funds to the retail pharmacy for prescriptions dispensed to the Federal agency beneficiaries. The Federal agency will provide to FSS contractors itemized data on covered drugs procured through the agency's retail network pharmacies, in order to obtain appropriate refunds on covered drugs delivered to the Federal agency's beneficiaries and subject to Federal pricing. The drugs will be deemed to have been ordered by the Federal agency through the FSS contract, for the purposes of establishing price, delivery, and scope of coverage, but does not confer rights for any other purpose. The Federal agency will obtain refunds on covered drugs from FSS contractors 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 Supply Schedule price (the Federal Ceiling Price or FSS negotiated price, whichever is lower).

(c) *Ordering.* (1) All Federal agency network retail pharmacy prescription orders for covered drugs are subject to the terms and conditions of this contract. In the event of conflict between a prescription order and this contract, the contract shall control.

(2) A Federal agency's instruction to its contracted or subcontracted retail pharmacy to fill a prescription for a health care beneficiary of the agency, under its virtual depot system for centralized pharmaceutical management, shall be deemed to be an order placed against this contract.

(d) *Invoice payments.* The time and method of payments to the Contractor for FSS items deemed (for the purposes of establishing price, delivery, and scope of coverage) to have been ordered by a Federal agency through its contracted or subcontracted retail pharmacies will be determined according to commercial agreements between the FSS Contractor and such pharmacies or their authorized Pharmaceutical Prime Vendors.

(e) *Scope of contract worldwide.* (1) This solicitation is issued to establish contracts which may be used as sources of supplies or services described herein for domestic and/or overseas delivery.

(2) *Definition. Domestic delivery* is delivery within the 48 contiguous states, Alaska, Hawaii, Puerto Rico, Washington, DC, and U.S. territories. Domestic delivery also includes a port or consolidation point, within the aforementioned areas, for orders received from overseas activities.

(3) Contractor will provide domestic delivery only for Federal agency retail pharmacy orders.

(4) The Contractor is obligated to accept orders received from activities within the Executive branch of the Federal Government. Federal beneficiary prescriptions for FSS-listed covered drugs that are filled through a Federal agency's directly contracted or indirectly subcontracted retail pharmacy, under the agency's virtual depot system for centralized pharmaceutical commodity management, will be deemed to constitute Executive branch orders, solely for the purposes of establishing pricing, delivery, and scope of coverage, but does not confer rights for any other purpose.

(f) *Delivery prices.* Prices offered must cover delivery of FSS covered drugs to all Federal agency contracted or subcontracted retail pharmacies (or to their authorized PPVs) for use in filling prescriptions for such agencies' beneficiaries, as part of the agencies' virtual depot system for centralized pharmaceutical commodity management.

(g)*Electronic Commerce.* A Federal Agency Retail Pharmacy Program will require a Contractor to receive and process refund requests submitted according to the following procedures:

(1) On the 15th of the month following the end of each calendar year quarter, the Federal Agency Pharmacy Benefits Office (PBO) will generate and submit to each pharmaceutical manufacturer a Utilization Flat File Layout Report for their products procured during the prior quarter, based on National Council for Prescription Drug Programs (NCPDP) Standards Version 03 Release 02 (or most current version).

(i) The 15th was selected to enable reversals to clear within the 10-day hold period.

(ii) NCPDP represents industry standards.

(iii) The Federal agency, VA, and industry (as a whole) will establish an interface control document for the transmission and file layout, to include the population of optional and conditional data elements for standardization for all of industry.

(iv) Separate reports will be generated for purchases paid from the Department of Defense's (DoD's) Accrual Fund and DHP account.

(2) Within the Utilization Flat File Detail Record (UD), the product code identifier will be used by the Contractor to sum (grand metric quantity) the total metric decimal quantity of individual records of each product purchased by the Government

through individual Federal agency retail network pharmacies. The grand metric quantity for each product will then be rounded down to the nearest package size based on the product code identifier to yield the total number of units procured by the Federal agency.

(i) The National Drug Code (NDC) number will be used to populate the product code identifier. The NDC should correlate to the actual product dispensed by the pharmacy, based on commercial best practice and data integrity requirements demanded by health plans and other insurers.

(ii) The Federal agency's Office of Program Integrity will be notified of any pharmacies identified (by Government, industry, or other means) as submitting fraudulent NDCs.

(iii) NDCs assigned by product repackagers will only be included in the reports when the repackager NDC can be correlated to the NDC of the originating product.

(3) *Contractor Refund and Reporting Schedule.* (i) The Contractor shall complete refund calculations not later than 60 days following the date of the quarterly UD Report.

(ii) The Contractor shall make refund payments so that such payments are received by DoD not later than 70 days following the date of the quarterly UD Report. At the time of refund payment, the Contractor shall also send to the Federal Agency's Pharmacy Benefits Office (PBO) a Reconciliation Report corresponding to the quarterly UD Report and resulting refund payment.

(h) *Resolution of Refund Data Disagreements.* (1) If the Contractor disagrees with the Federal agency data in the quarterly refund request under paragraph (g) of this clause, the Contractor shall provide prompt written notice to the PBO. Such notice shall be received by the PBO no later than 10 business days after the Contractor's discovery of the alleged error, but in no event no later than one year after the date of the quarterly report containing the alleged erroneous data. The notice shall include specific identification of the alleged error(s) and the specific reason(s) the Contractor believes the data to be in error, along with all available documentation that supports the Contractor's allegation(s).

(2) The Federal agency's PBO will initiate a prompt review of the data following receipt of the notice and documentation provided by the Contractor. The parties agree to use their best good faith efforts to resolve any disagreement within 60 days of the PBO's receipt of the Contractor's written notice. During this period, the Contractor shall proceed diligently with performance of this contract and will exhaust administrative remedies under this clause prior to filing a dispute under the Disputes clause incorporated into this contract. Performance includes remittance of any refund due the Federal agency based upon the data provided by the PBO with which the Contractor disagrees. If the written notice of disagreement is resolved in favor of the Contractor, the Federal agency shall reimburse the Contractor the amount of remitted refund attributed to the error and simple interest on the reimbursed amount at the rate determined in accordance with the Contract Disputes Act of 1978, as amended (41 U.S.C. 601–603), from the date of receipt of the Contractor's remittance of the refund in disagreement.

(3) If the Federal agency and the Contractor cannot resolve the disagreement within 60 days following receipt of the Contractor's written notice (and any time extensions mutually agreed to by the parties), the Contractor shall have exhausted administrative remedies under this clause and may proceed with disputes remedies available under the Disputes clause and the Contract Disputes Act of 1978, as amended.

(i) *Industrial Funding Fee and Sales Reporting.* The Contractor shall report all contract sales covered by this clause and pay the Industrial Funding Fee (IFF) included therein, as required by VA's variation of clause 552.238–74 of the contract, ''Industrial Funding Fee and Sales Reporting (JUL 2003) (Variation''). All sales of covered drugs made through retail pharmacies under this clause are deemed to be reportable when the Contractor receives the quarterly Utilization Flat File Layout Report(s) (or its functional substitute), applies the appropriate FSS contract price (including IFF) to the rounded total number of units of each covered product purchased by the submitting agency (as shown on the Flat File Report), and computes the total dollar sales of each product. These sales are counted as FSS sales on the date the computations are finished (for example, the results of computations finished on March 10 are reported 60 days after the end of the first calendar quarter, on May 30). The grand total of all retail pharmacy sales (at the appropriate FSS contract prices) under this clause computed during a calendar quarter shall be included in the Contractor's quarterly sales report to VA. That information and the resultant IFF shall be provided to VA according to the timelines and procedures established in 552.238–74.

(End of clause)

[FR Doc. 05–7270 Filed 4–11–04; 8:45 am]

BILLING CODE 6820–61–S

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 546 and 552

[GSAR ANPR 2005–N01]

General Services Administration Acquisition Regulation; Waiver of Consequential Damages and ''Post Award'' Audit Provisions (Correction)

AGENCY: Office of the Chief Acquisition Officer, General Services Administration (GSA)

ACTION: Correction to advance notice of proposed rulemaking and notice of public meeting.

SUMMARY: The General Services Administration (GSA) is requesting comments from both Government and industry on whether the General Services Administration Acquisition Regulation (GSAR) should be revised to include a waiver of consequential damages for contracts awarded for commercial items under the FAR. GSA is also requesting comments on whether ''post award'' audit provisions should be included in its Multiple Award Schedules (MAS) contracts and Governmentwide acquisition contracts (GWACs). GSA is further amending the correction notice published in the **Federal Register** at 70 FR 13005, March 17, 2005, to add the following: In addition, GSA is interested in receiving comments on whether the Examination of Records clause at GSAR 552.215–71 should be modified to reinstate post-award access to and the right to examine records to verify that preaward/modification pricing, sales, or other data related to the supplies or services offered under a contract which formed the basis for an award/modification was accurate, current, and complete. The notice published in the **Federal Register** at 70 FR 12167, March 11, 2005, is amended to extend the public comment date to May 10, 2005, and to allow interested parties to submit presentations by April 7, 2005.

DATES: *Comment Date:* Interested parties should submit comments on or before May 10, 2005, to be considered in the formulation of a proposed rulemaking.

Public Meeting Presentation Date: Interested parties may register and submit presentations by April 7, 2005.

ADDRESSES: Submit written comments to:

General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, ATTN: Laurieann Duarte, Washington, DC 20405.

Submit electronic comments via the Internet to: *gsaranpr.2005–N01@gsa.gov*

Submit electronic presentations via the Internet to: *meeting.2005–NO1@gsa.gov.*

Please submit comments or presentations only and cite GSAR ANPR 2005–N01 in all correspondence related to this case. All comments received will be posted without change to *http://www.acqnet.gov/far/ProposedRules/proposed.htm,* including any personal information provided.

Public Meeting: The public meeting will be conducted at the General Services Administration, National Capital Region, 301 7th and D Street, SW, Washington, DC 20407, Auditorium, starting at 9 a.m. to 4:00 p.m. EST., on April 14, 2005, to ensure open dialogue between the Government and interested parties on this important topic.

Special Instructions. The submitted presentations will be the only record of the public meeting. If you intend to