Drug Pricing Program Reporting Requirements
SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collected

This is a request for an extension of OMB approval for burden associated with the Drug Pricing Program reporting and recordkeeping requirements. The requirements are currently approved under OMB number 0915-0176 which expires 11/30/06. To date, there have been *no* requests for audits or for formal dispute resolution. In order to comply with P.L. 102-585, burden has been approved for the process for audits and other disputes in the event that such a request is made.

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992" (the "Act"), enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities". Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed that amount determined under a statutory formula.

The Act was designed to establish price controls to limit the cost of drugs to Federal purchasers and to certain grantees of Federal agencies. In l990, Congress identified a problem with increasing drug prices and enacted the Omnibus Budget Reconciliation Act of 1990. This attempt at drug price control focused only on the Medicaid program and established a best-price policy. Under the Medicaid drug rebate program, pharmaceutical manufacturers initially gave State Medicaid agencies the greater of a minimum 12.5 percent flat rebate of the average manufacturer price (AMP) or the difference between the AMP and the best price paid by the customer for single source or innovator multiple source drugs. To provide a phase-in period, the rebate amount was capped at a specific percentage of the AMP which increased from 1991 through 1993. Generic manufacturers gave States a ten percent of AMP flat rebate which increased to 11 percent in 1994.

The Veterans Health Care Act is an attempt to provide Federal purchasers with a process whereby they will receive drug discounts or rebates. Section 601 of Pub. L. 102-585 amends the Medicaid rebate program, section 602 provides drug discounts

primarily to certain grantees of the Public Health Service, and section 603 enacts a drug discounting process administered by the Department of Veterans Affairs for the benefit of several Federal agencies.

Entities eligible to receive the discount pricing are as follows (except as otherwise indicated, references are to sections of the Public Health Service Act):

1. Federally-qualified health centers (migrant, community and homeless health centers) as defined in section 1905(l)(2)(B) of the Social Security Act, 42 U.S.C. 1396d.

2. Health centers for residents of public housing funded under section 340A, 42 U.S.C. 256a.

3. Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 300.

4. An entity receiving a grant for outpatient early intervention services for HIV disease under subpart II of part C of title XXVI, 42 U.S.C. 300ff-51 et seq.

5. A State-operated AIDS drug purchasing assistance program receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff-26.

6. A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. 937(a).

7. A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. 701(a)(2).

8. A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. 11701 et seq.

9. An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, 25 U.S.C. 1651 et seq.

10. Any entity, certified by the Secretary, receiving assistance under title XXVI of the Act, 42 U.S.C. 300ff et seq., (other than a State or unit of local government or an entity described in #4).

11. Any entity, certified by the Secretary, receiving funds relating to the treatment of sexually transmitted diseases under section 318, 42 U.S.C. 247c, or relating to the treatment of tuberculosis under section 317(j)(2), 42 U.S.C. 247b, through a State or unit of the local government.

12. A "disproportionate share" hospital as defined in section 1886(d)(1)(B) of the Social Security Act, which (for the most recent cost reporting period that ended before the calendar quarter involved) had a disproportionate share adjustment greater than 11.75 percent, and which is (1) owned or operated by a State or local government, (2) a public or private nonprofit corporation formally granted governmental powers by a State or local government, or (3) a private nonprofit hospital with a State or local government contract to provide health services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under the State plan. The discount need not be provided for drugs which the hospital obtains through a group purchasing arrangement.

The Office of Pharmacy Affairs (OPA) has provided a list of eligible entities to each participating manufacturer (approximately 600 manufacturers) and has notified each covered entity (approximately 10,000 eligible entities) of its eligibility to purchase drugs at the discounted prices. The current list of both eligible entities and manufacturers has been placed on electronic data retrieval system for public access and an Internet site. This list is continually updated on a quarterly basis.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

The participating entity must permit the manufacturer of a covered outpatient drug who has signed the Agreement with the Secretary, HHS, to audit its records that directly pertain to the entity's compliance with section 340B(a)(5)(A) and (B) requirements with respect to drugs of the manufacturer. Manufacturer audits must be conducted in accordance with

guidelines developed by the Secretary, HHS, section 340B(a)(5)(C).

The Office of Pharmacy Affairs developed manufacturer guidelines pursuant to section 340B(a)(5)(C). All audits will be conducted in accordance with Government Auditing Standards, Current revision, developed by the Comptroller General of the United States. A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already completed or that may be planned. Only one audit will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's failure to comply with section 340B(a)(5)(A) and (B), the Office of Pharmacy Affairs shall determine whether an audit should be performed by the (1) Government or (2) a manufacturer, and, if so, which manufacturer.

The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of Section 340B. The manufacturer must then submit an audit work plan describing the audit to the Office of Pharmacy Affairs for review. The work plan will be reviewed for reasonable purpose, scope, and a determination that only those records of the covered entity that directly pertain to the potential violation will be accessed.

Reports must be prepared at the completion of the audit. Copies of the audit report will be prepared in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision. The manufacturer will submit copies of the audit report to the Office of Pharmacy Affairs for review and resolution of the findings, as appropriate. The manufacturer will also submit informational copies of the audit report to the HHS Office of Inspector General and the Health Resources Services Administration (HRSA) Administrator. The cost of the audit shall be borne by the manufacturer, as provided by section 340B(a)(5)(C) of the PHS Act.

Because of the potential for audit and other disputes involving covered entities and participating drug manufacturers the Office of Pharmacy Affairs has developed a formal dispute resolution process. Section 340B (a)(5)(D) of the PHS Act and section IV(a) of the Agreement provide the covered entity with

"notice and hearing," if the entity is believed to be in violation of section 340B(a)(5)(A) or (B). Further, section IV(b) of the Agreement provides the manufacturer with "notice and hearing," if the manufacturer is believed to be in violation of the Agreement.

The types of disputes resolved by these procedures include:

(a) A manufacturer believes a covered entity is in violation of the prohibition against resale or transfer of a covered outpatient drug provided in section 340B(a)(5)(B) of the PHS Act, or the prohibition against duplicate discounts or rebates provided in section 340B(a)(5)(A) of the PHS Act;

(b) A covered entity believes that a manufacturer is charging a price for a covered outpatient drug that exceeds the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(c) A manufacturer is conditioning the sale of covered outpatient drugs to a covered entity on the entity's provision of assurances or other compliance with the manufacturer's requirements that are based upon section 340B provisions;

(d) A manufacturer has refused to sell a covered outpatient drug to a covered entity at or below the ceiling price as determined by section 340B(a)(1) of the PHS Act;

(e) A manufacturer believes a covered entity is dispensing a covered outpatient drug in an unauthorized service (e.g., inpatient services or ineligible clinics within the same health system);

(f) The Department or a manufacturer believe that a covered entity has not complied with the audit requirements of section 340B(a)(5)(C) of the PHS Act; and

(g) The entity disputes the results of an audit performed by a manufacturer pursuant to section 340B(a)(5)(C) or the Office of Pharmacy Affairs' determination of the audit.

The Director of the Bureau of Primary Health Care (BPHC) shall appoint a committee to review the documentation submitted by the disputing parties and make a determination. A minimum of three individuals shall be appointed (one of whom shall be designated as a chairperson) either on an ad hoc, case-by-case

basis, or as regular members of the review committee. The chairperson shall be from the Office of Pharmacy Affairs and the committee members shall be from other sections of the Public Health Service (e.g., chief pharmacist, auditor) or a HRSA contractor.

If dispute resolution is desired, a party must submit a written request for a review of the dispute to the Director of the Office of Pharmacy Affairs. Upon receipt of a request for a review, the chairperson of the review committee will send a letter to the party alleged to have committed a violation. The letter will include (1) the name of the party making the allegation(s), (2) the allegation(s), (3) documentation supporting the party's position, and (4) a request for a response to or rebuttal of the allegations within 30 days.

Upon receipt of the response or rebuttal, the review committee chairperson shall review all documentation. The request and rebuttal information shall be reviewed for (1) evidence that a good faith effort was made to resolve the dispute, (2) completeness, (3) adequate documentation supporting the issues, and (4) the reasonableness of the allegations.

The reviewing committee may, at its discretion, invite parties to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

The reviewing committee shall propose to dismiss the dispute, if it conclusively appears from the data, information, and factual analyses contained in the request for a review and rebuttal documents that there is no genuine and substantial issue of fact in dispute. This proposed finding of the committee will be submitted to the Director of the Office of Pharmacy Affairs for consideration and approval. A written decision of dismissal shall be sent to each party and shall contain the review committee's findings and conclusions in detail and reasons why the request for a review did not raise a genuine and substantial issue of fact.

With all other proposed findings, the review committee shall prepare a written document containing the findings and detailed reasons supporting the proposed decision. The document is to be signed by the chairperson and each of the other committee members. The chairperson shall submit the proposed findings to the Director of the Office of Pharmacy Affairs for consideration

and approval. Once approved the written decision will be sent with a transmittal letter to both parties.

If the covered entity or the manufacturer does not agree with the Office of Pharmacy Affairs' determination, the covered entity or the manufacturer may appeal such a determination to an appeals officer appointed by the Administrator of the Health Resources and Services Administration (HRSA).

2. Purpose and Use of Information

There are two situations in which HRSA foresees information that will be needed from participating manufacturers and/or covered entities. First, the proposed manufacturer audit guidelines contain the following reporting/notification requirements:

(1) manufacturers must notify the entity in writing when it believes a violation has occurred;

(2) manufacturers must submit an audit work plan;

(3) manufacturers must submit the audit report to the Office of Pharmacy Affairs and informational copies to the Office of Inspector General and the PHS Office of Audit Services; and

(4) the covered entity must provide a written response to the audit report.

These activities are necessary to provide the eligible entities with protection from potential abusive audit tactics.

Second, the proposed formal dispute resolution process requires the participating manufacturer or covered entity requesting dispute resolution to provide the Office of Pharmacy Affairs with a written request. The party alleged to have committed a section 340 violation, will be required to provide a response or rebuttal. This information is necessary in order to provide a fair hearing - that the dispute will be resolved in a fair and equitable manner.

The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of Section 340B.

3. Use of Improved Information Technology

The burden for these reporting requirements is for a non-routine process and there are no forms of any kind; therefore, there are no data collection instruments.

4. Efforts to Identify Duplication

The information is collected for the purposes of this program and is not available elsewhere.

5. Involvement of Small Entities

Smaller covered entities may be involved in both the audit and dispute process but can submit minimum information to document their case.

6. Consequences If Information Collected Less Frequently

It is in the interest of both the participating manufacturers and the covered entities to submit required information in a timely manner. Only in this way can the Office of Pharmacy Affairs monitor activities and evaluate compliance with the statute.

7. Consistency With Guidelines in 5 CFR 1320.6

This information collection fully complies with 5 CFR 1320.6.

8. Consultation Outside Agency

The notice requesting public comment required in 5 CFR 1320.8(d) was published in the Federal Register on July 19, 2006 (71 FR 41028-41029). No comments were received. The final guidelines were published in the December 12, 1996 Federal Register (61 FR 65406).

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

Any proprietary or confidential information will be used only for internal purposes. The information will be kept in locked file cabinets, and only authorized personnel will have

access to the files. Copies of the audit reports will be sent to the Office of the Inspector General and the HHS Cost and Audit Management Branch which generally handles these types of reports. These departments already have security procedures in place and the usual security procedures will apply.

11. Questions of a Sensitive Nature

There are no sensitive questions.

12. Estimates of Annualized Hour Burden

Reporting/Notification Burden:

Reporting/ Notification Requirement	No. of Respon-dents	Responses per Respondent	Total Responses	Hours/ Response	Total Burden Hours	Wage Rate	Total Hour Cost
AUDITS							
Audit Notification of Entity[1]	2	1	2	4	8	$20	$160
Audit Workplan[1]	1	1	1	8	8	$20	$160
Audit Report[1]	1	1	1	1	1	$20	$20
Entity Response	0	0	0	0	0	$20	$0
DISPUTE RESOLUTION							
Mediation Request	2	4	8	10	80	$20	$1600
Rebuttal	2	1	2	16	32	$20	$640
TOTAL	8		14		129	$20	$2580

[1] Prepared by the manufacturer

Recordkeeping Burden:

Recordkeeping requirement	**Number of recordkeepers**	**Hours of recordkeeping**	**Total Burden**
Dispute Records	10	0.5	5

Basis for Burden Estimates:

There have been no requests for audits or for formal dispute resolution since the inception of the program. This is attributed to the success of the informal dispute resolution process established by the OPA in which entities call in to the 800-number (or regular number) to discuss any questions or concerns with OPA staff. The staff have been successful in answering all questions and resolving all issues that might otherwise have escalated to the level of a formal request for audit or dispute resolution. Most problems are found to be the result of miscommunication or misunderstandings that are quickly resolved.

Audits:

Although the program estimates 2 manufacturers will notify covered entities every year of a possible violation, only 1 work plan will be submitted; the other will be resolved informally. Also, it is possible that the entity alleged to have violated the statute will alter the suspect behavior rendering audit activity unnecessary. Of the 1 audit performed, the program estimates that no violation requiring an entity response will be found.

Dispute Resolution:

Again, the program estimates that most disputes will be resolved by interaction with the program. There have been no disputes which reached the point of formal mediation, but with the changes to the program, this may occur more often. The program estimates that five disputes will reach the point of formal mediation each year, and that two of them will require a rebuttal by the party alleged to have committed a violation.

Recordkeeping Burden

In our experience, the informal process for resolving disputes/answering questions occurs so quickly that no recordkeeping is required. Therefore, only the five disputes which reach the point of formal mediation will require recordkeeping by both parties involved in the dispute, for a total of ten recordkeepers.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or startup costs or operation or maintenance costs; the only costs are the staff time required to prepare and submit the reports.

14. Estimates of Annualized Cost to the Government

There have been no additional costs to the Government to date because the audit and dispute resolution mechanisms have not been used. If requests for audit or dispute resolution are received at the level estimated in 12, some minimal level of Federal effort will be required; probably totaling less than .1 FTE at a GS-14 level ($80,000 x .1 = $8,000).

15. Changes in Burden

There are currently 134 hours in the OMB inventory. There are no changes for the extension request.

16. Time Schedule, Publication and Analysis Plans

The program does not plan to tabulate or use the information for publication purposes.

17. Exemption for Display of Expiration Date

There are no standard instruments, forms, or screens for this activity.

18. Certifications

This project fully complies with the requirements in 5 CFR 1320.9. The certifications are included in the package.