

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Care Financing Administration**

[Document Identifier: HCFA-R-227]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request****AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Research and Analytic Support for Implementing Performance Measurement in Medicare Fee for Service; *Form No.:* HCFA-R-227 (OMB# 0938-0718); *Use:* As required by the Balanced Budget Act (BBA), Section 1851(d), the Health Care Financing Administration (HCFA) needs to develop comparable performance measures for Fee For Service (FFS) Medicare. This project will enable HCFA to evaluate the effectiveness and outcomes of FFS services purchased. HCFA may potentially disseminate this information to Medicare beneficiaries so that they may make informed health care choices; *Frequency:* Biennially; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, Farms, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 6,670; *Total Annual Responses:* 6,670; *Total Annual Hours:* 2,223.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/>

regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 22, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 98-17154 Filed 6-26-98; 8:45 am]

BILLING CODE 4120-03-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option****AGENCY:** Health Resources and Services Administration, HHS.**ACTION:** Final notice.

**SUMMARY:** Section 602 of Pub. L. 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service (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 with the Secretary of 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 purpose of this notice is to inform interested parties of the final guidelines recognizing a rebate option for State AIDS Drug Assistance Programs (ADAPs) receiving funds under Title XXVI of the PHS Act as an optional alternate means of accessing section 340B discount pricing.

**EFFECTIVE DATE:** July 29, 1998.**FOR FURTHER INFORMATION CONTACT:**

Robert Staley, R. Ph., Senior Program Manager, Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, MD

20814, Phone (301) 594-4353; Fax (301) 594-4982.

**SUPPLEMENTARY INFORMATION:****(A) Background**

The proposed guidelines, recognizing a rebate option for State AIDS Drug Assistance Programs (ADAPs), were announced in the **Federal Register** at 62 FR 45823 on August 29, 1997. A period of 30 days was established to allow interested parties to submit comments. The Department received comments from eleven sources including State AIDS Drug Assistance Programs, pharmaceutical manufacturers, and organizations representing pharmaceutical manufacturers or covered entities. Ten commenters supported the proposed guideline. There were no comments strongly in opposition to the recognition of an ADAP rebate option. The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing these final guidelines. The rebate option is adopted with several modifications based upon these comments.

**(B) Comments and Responses***Standardization of Systems*

*Comment:* It is hoped that the guideline will ensure a rebate process similar to the Medicaid model and voluntary systems currently utilized by most drug companies in that such standardization will ensure a more efficient rebate system.

*Response:* The **Federal Register** notice requested comments only on the recognition of a rebate option and did not propose a specific mechanism for accessing such rebates. State ADAPs and manufacturers are encouraged to follow standard business practices in designing the contracts and agreements for such a rebate mechanism. The voluntary rebate agreements and the Medicaid rebate program may be used as models for development of the ADAP rebate agreements. The process for claim submission and payment is expected to be similar. The stipulations found in 59 FR 25113, May 13, 1994, section XI, entitled "Manufacturer's Contracts Requiring Entity Compliance" are also deemed to be applicable in that a manufacturer may not condition a rebate contract or agreement upon an entities' compliance with the provisions of section 340B. Manufacturer stipulated requirements for participation in the manufacturer designed voluntary rebate agreements, if predicated on section 340B compliance,

should be renegotiated for the section 340B rebate agreements.

*Comment:* Guidelines should allow State ADAPs with negotiated voluntary rebate agreements to continue to provide utilization data according to the terms of existing agreements.

*Response:* Voluntary rebate agreements with covered entities that provide at least the minimum statutory discount and do not contain requirements inconsistent with section 340B and published program guidelines will be considered consistent with the section 340B rebate program. State ADAPs may not need to negotiate new agreements if these conditions are met, and the ADAP or the manufacturer does not desire a new agreement. ADAPs may continue to provide utilization data according to terms of existing agreements if so desired.

*Comment:* Unlike the Medicaid rebate program, the proposed rebate program lacks specificity regarding program provisions and safeguards. It is critical that standardized contracts that provide for efficient and accountable procedures, systems, and data reporting formats be defined and implemented in conjunction with the program. The purpose of these provisions would be to protect the integrity of the program by safeguarding against errors, misunderstanding, and the potential for duplicate discounts and rebates.

*Response:* This notice only recognizes an ADAP rebate option and does not provide in-depth implementation strategies. Standard business practices should be utilized by State ADAPs and manufacturers. The mechanisms developed and used in the Medicaid rebate program and the current voluntary rebate programs (consistent with the requirements of section 340B and program guidelines) are models to be emulated. Of course, a 340B discount and a Medicaid rebate on the same covered drug are prohibited by section 340B.

*Comment:* The HRSA draft guidance does not address the mechanics of communication between an ADAP and a manufacturer about drugs reimbursed by the ADAP for which it claims a rebate from a manufacturer. It is recommended that HRSA consider requiring the ADAPs to use the claim form that State Medicaid programs use in submitting rebate requests to manufacturers.

*Response:* The **Federal Register** notice did not address the mechanics of the rebate process. However, ADAPs are encouraged to use Medicaid claim form HCFA-R-144 as a model for two reasons. First, this form can be considered a standard business practice

model. Second, manufacturers should find it advantageous to receive rebate claims from State ADAPs in a similar form and format to that received from the State Medicaid programs.

#### *Diversion and Duplicate Discounts*

*Comment:* The State ADAP and the manufacturer are able to avoid the problems of diversion and double discounting if both the ADAP and the manufacturer have reached an understanding concerning the arrangements the ADAP has made to meet its statutory obligations (to avoid diversion and claims resulting in a duplicate discount).

*Response:* Guidelines have been issued to minimize the potential for duplicate discounting and covered drug diversion (59 FR 25110, May 13, 1994), and manufacturers have available to them auditing and dispute resolution remedies if they believe that duplicate discounting or covered drug diversion has occurred (61 FR 65406, December 12, 1996). In addition, manufacturers and covered entities are referred to 59 FR 25113 for a reminder that "a manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions."

*Comment:* It would be difficult to administer a rebate program in which a given State ADAP used both the discount option and the rebate option. HRSA should clarify the policy that the rebate option is an "alternate to" the direct discount mechanism and the choice of a single mechanism should be made by each State ADAP. We urge that HRSA clarify that the ADAP rebate is available only for those drugs not purchased at the PHS (section 340B) discount. Additionally it is recommended that HRSA maintain a list of which option has been selected by each ADAP.

*Response:* The State ADAP 340B rebate option is an alternate method of accessing 340B pricing developed by HRSA in response to a clear need by certain State ADAPs which are unable to access such pricing through the direct discount option. We anticipate that these State ADAPs will promptly begin accessing 340B pricing using this rebate option. However, in States which have decentralized drug purchasing, there is the possibility that some decentralized ADAP components may elect to access pricing through a rebate mechanism while other ADAP components may develop systems to access a direct discount. States with decentralized drug purchasing are encouraged to centralize drug reimbursement mechanisms, so that from this central location, they can

effectively maintain the necessary records to document appropriate drug reimbursement activity for the entire State. Using this drug reimbursement documentation, the central ADAP can then monitor reimbursement activity and prevent any duplicate rebate/discount on the same drug. In addition, the centralized ADAP can request appropriate rebates from the manufacturers in a more efficient and reliable manner. A State ADAP participating in the State ADAP section 340B rebate program will be listed as a covered entity, Entity Type "RWIIR."

*Comment:* Under a decentralized system, it may be difficult to assure that duplicate discounts will not occur on drugs provided to Medicaid patients. At any rate, coordination between the ADAPs and State Medicaid agencies will be required.

*Response:* Section 340B(a)(5)(A) prohibits a covered entity's request for a discount on a drug subject to an agreement under section 340B if the drug is subject to the payment of a rebate under Medicaid. This requirement applies whether the State ADAP uses a decentralized system or a centralized system. The mechanism to prevent a duplicate discount was published in the **Federal Register** on May 7, 1993 (58 FR 27293). This mechanism was developed in consultation with HCFA. In order to avoid a duplicate discount, the State ADAP must refrain from billing the State Medicaid agency unless the manufacturer's 340B rebate (either estimated or actually paid) is deducted from the price paid by the ADAP. This will help ensure that the State ADAP will only bill the State Medicaid agency at the actual acquisition cost plus a reasonable dispensing fee established by the State Medicaid agency. If the manufacturer's rebate is different from the estimated amount, the amounts billed to the State Medicaid agency will need to be reconciled.

#### *Manufacturer Participation*

*Comment:* All pharmaceutical manufacturers whose products are on any State ADAP formulary should be mandated to participate in the 340B rebate program.

*Response:* Only those manufacturers that have signed the section 340B Pharmaceutical Pricing Agreement (PPA) with HHS must honor appropriate section 340B rebate requests from covered entities. The rebate option is a component of the section 340B program specific to State ADAPs; therefore, manufacturers, receiving an appropriate rebate claim from a covered entity listed on the Electronic Data Retrieval System

(EDRS) as a State ADAP participating in the section 340B rebate program, are required to provide a rebate that meets or exceeds the 340B discount. Manufacturers who do not provide a rebate will be considered out of compliance with the PPA.

#### *Technical Comments and Contractual Agreements*

*Comment:* The notice does not detail the way in which State ADAPs would or should invoice manufacturers for rebates. For example, there are no statements on determination of actual units utilized during a specific period of time or a statement as to the time frame in which an ADAP must submit invoices.

*Response:* Standard business practices should be utilized. A manufacturer and a State ADAP are encouraged to specify in a contract or agreement the units and required time frame for claim data reporting. Unit definitions for reporting and report periods similar to those used in the Medicaid agreements and voluntary rebate agreements and contracts are considered standard business practices and thus acceptable. A standard State ADAP section 340B rebate claim submission and processing guideline was not specified so as to allow maximum flexibility between a State ADAP and manufacturers in the development of contracts and agreements.

*Comment:* There is no explicit audit provision in place to assure that the amount of units claimed for rebates coincides with the actual units of product dispensed. In addition, there is no specific procedure referenced for dispute resolution when a manufacturer disagrees with the amount invoiced from a State ADAP.

*Response:* Sections 340B(a)(5)(A) and (B) prohibit a 340B discount and a Medicaid rebate on the same drug and the resale or transfer of a 340B discounted drug to an individual who is not a patient of the covered entity. The manufacturer audit guidelines and the informal dispute resolution process guidelines (61 FR 65406-65412, December 12, 1996) allow manufacturers to audit covered entities pursuant to guidelines and dispute, among other issues, certain covered entity claims (e.g., rebates for covered drugs given to individuals who are not patients of the covered entity).

*Comment:* Manufacturers must have the freedom to enter into contractual agreements with individual State ADAP programs to address potential problems.

*Response:* Manufacturers and State ADAPs are able to enter into contractual agreements that address potential

problems and mutually acceptable solutions.

*Comment:* A comprehensive and enforceable contract between the State ADAP program and the manufacturer should be developed through a public comment process and implemented prior to the establishment of the proposed new rebate mechanism. Specific elements that should be incorporated in any such agreement include: drug National Drug Code (NDC); prescription number; date reimbursed; quantity; unit type; amount reimbursed to the pharmacy; and dispensing pharmacy name, city, and state. Absent these provisions, the guidelines and principles proposed in the notice are not sufficient to ensure that the rebate option can operate equitably and efficiently.

*Response:* Requiring a "comprehensive and enforceable contract" would delay State ADAP participation in the 340B rebate program. HRSA wishes to allow maximum flexibility between each manufacturer and State ADAP in reaching such agreements.

Pharmacy specific data (prescription number, date of reimbursement, and similar data elements) are not reported on the initial Medicaid utilization submission and are not considered the standard for initial claim submission. HRSA encourages manufacturers to accept aggregate data (similar to Medicaid form HCFA-R-144) in the initial claim form. HRSA encourages State ADAPs to consider that the more detailed and accurate the initial claim data, the less likelihood a claim will be questioned or disputed.

*Comment:* We recommend that HRSA establish a specific date, such as 60 days after HRSA issues its guidance in final form, after which drugs reimbursed by an ADAP would be eligible for a rebate from a manufacturer with which the ADAP has entered into a rebate agreement.

*Response:* The effective date for the inception of the State ADAP 340B rebate program will be 30 days after the date of publication of this final notice. A State ADAP will not be considered a covered entity participating in the 340B rebate program until it is listed on the ODP Electronic Data Retrieval System (EDRS). At maximum, a period of one hundred and twenty days may elapse between publication of this final guideline and the next quarterly update of the EDRS. State ADAPs listed on the first quarterly EDRS update after the publication of this final notice may submit claims for covered drugs that were purchased 30 days after the date of final notice publication and thereafter.

State ADAPs listed on a later EDRS update may claim rebates only on purchases made after their effective date of listing on the EDRS. ADAPs may need time to work closely with their State Medicaid programs to develop procedures to prevent duplicate discounting. Some ADAPs may find it necessary to improve record keeping and data tracking systems.

*Comment:* We recommend that HRSA establish a time period within which claims may be submitted for a manufacturer rebate. A fixed filing deadline will help avoid disputes and the Medicaid model may provide an analogy wherein Medicaid providers have one year in which to submit claims for reimbursement to state Medicaid programs. The benefit of a uniform expectation about the finality of payments and disputes for a given period may outweigh any concerns about HRSA imposing requirements on ADAPs.

*Response:* HRSA agrees that a maximum time period for submission of claims of one year appears to be within the range of standard business practices. However, a specific guideline for data claim submission and processing for rebates is not included in this guideline.

*Comment:* We urge HRSA to adopt requirements that manufacturer rebates paid to a State ADAP expand the care provided by the ADAP.

*Response:* Although section 340B does not discuss an appropriate use for 340B drug purchasing savings, the legislative history provides that section 340B was enacted to permit scarce Federal dollars to reach more eligible patients and provide more comprehensive services. See H.R. Rep. No. 102-348, 102d Cong., 2d Sess., pt 2, at 16 (1992).

#### *Expansion of the Rebate Option to Additional Covered Entities*

*Comment:* The characteristics of State ADAPs and their components make them more like State-run pharmaceutical benefit programs. The commitment of the States to assume responsibility for rebate contracting and administration has been essential to making the voluntary rebate program manageable. Our (favorable) response to the recognition of a rebate program for the ADAPs would be different if HRSA proposed a rebate program for all covered entities. Accordingly, we urge that the rebate mechanism be an option only for meeting the unique needs of the State ADAP programs and that HRSA not consider any further expansion to other categories of entities.

*Response:* At this time, we agree. This notice only recognizes a rebate option

for the State AIDS Drug Assistance Programs that receive assistance under Title XXVI of the PHS Act.

### **(C) The State ADAP Section 340B Rebate Option**

In light of the comments and responses set forth above, the guideline for the state ADAP 340B rebate option is as follows: HRSA recognizes rebates obtained by the State ADAPs or their components that equal or exceed the 340B discount provided by the statutory ceiling price as a method of participating in the 340B program, subject to compliance with other requirements for participation. Standard business practices, such as those reflected in the Medicaid Rebate Program and current voluntary manufacturer rebate programs (consistent with the requirements of section 340B and all program guidance published in the **Federal Register**) are appropriate for the development of rebate contracts and agreements between State ADAPs and manufacturers. State ADAPs or their components and manufacturers wishing technical assistance in developing a rebate program and rebate agreements should contact HRSA's Office of Drug Pricing at (301) 594-4353 or (800) 628-6297.

State ADAPs or their components determined to be eligible for participation in the State ADAP 340B rebate program will be listed on the Office of Drug Pricing (ODP) Electronic Data Retrieval System (EDRS) on the first quarterly update of the EDRS which occurs 30 days following the effective date of this **Federal Register** notice. State ADAPs or their components listed on this update may submit rebate claims to participating manufacturers for covered drugs that are purchased starting 30 days after the date of this final notice publication. State ADAPs or their components listed on a later EDRS update may claim rebates only on purchases made after their effective date of listing on the EDRS.

Section 340B(a)(5)(A) reflects Congressional recognition that there is a potential for a covered drug purchased by a covered entity at the 340B discount price to be subject to a Medicaid rebate, if the drug is reimbursed by the Medicaid program. All program guidance regarding the prevention of such duplicate discounting must be followed by ADAPs participating in the rebate program as well as those participating in the discount program. Guidance regarding billing State Medicaid Agencies at actual acquisition

cost plus a dispensing fee (established by the State Medicaid agency) and the prevention of duplicate discounting was published in the **Federal Register** on May 7, 1993 (58 FR 27293) entitled "Duplicate Discounts and Rebates on Drug Purchases." Further guidance was published in the **Federal Register** on May 13, 1994 (59 FR 25112). State ADAPs may find it necessary to work with State Medicaid Agencies to adapt these guidelines to meet the unique circumstances of each individual State, such as provisions permitting retroactive reimbursement of drug purchases while Medicaid eligibility was pending.

The HRSA is sensitive to concerns about diversion of covered drugs to individuals who are not patients of the covered entities. Guidelines have been issued to minimize this potential, and manufacturers have available to them specified remedies if they believe diversion has occurred. These guidelines and remedies will apply fully to drugs purchased under a rebate option, and we believe that instituting rebates will not increase the potential for diversion.

Dated: May 22, 1998.

**Claude Earl Fox,**  
*Administrator.*

[FR Doc. 98-17142 Filed 6-26-98; 8:45 am]  
BILLING CODE 4160-15-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Notice of Establishment of the Secretary's Advisory Committee on Genetic Testing**

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Secretary's Advisory Committee on Genetic Testing (Committee).

This Committee will advise the Secretary of Health and Human Services on all aspects of the development and use of genetic tests, including making recommendations on policies and procedures for the safe and effective incorporation of genetic technologies into health care; assessing the effectiveness of existing and future measures for oversight of genetic tests; and identifying research needs related to the Committee's purview.

Unless renewed by appropriate action prior to its expiration, the charter for the

Secretary's Advisory Committee on Genetic Testing will expire two years from the date of establishment.

Dated: June 22, 1998.

**Harold Varmus,**

*Director, National Institutes of Health.*

[FR Doc. 98-17168 Filed 6-26-98; 8:45 am]

BILLING CODE 4140-01-M

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Initial Review Group Subcommittee D—Clinical Studies.

*Date:* August 2-5, 1998.

*Time:* 7:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Martin H. Goldrosen, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6130 Executive Boulevard, Rm. 635F, Rockville, MD 20852-7405, (301) 496-7930.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 23, 1998.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 98-17172 Filed 6-26-98; 8:45 am]

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