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, 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.

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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,