

good manufacturing practice regulations and other regulatory requirements. Materials providing guidance on ANDA submissions and related topics will also be discussed at the workshop.

Dated: March 10, 1997.

William K. Hubbard,  
Associate Commissioner for Policy  
Coordination.

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## Health Resources and Services Administration

### Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Mechanism

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** Section 602 of Public Law 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 request comments on the proposal of a rebate process for State AIDS Drug Assistance Programs (ADAPs) receiving funds under Title XXVI of the PHS Act.

**DATES:** The public is invited to submit comments on the proposed rebate process by April 14, 1997. After consideration of comments submitted, the Secretary will issue the final guideline.

**ADDRESS:** Comments should be submitted to: Annette Byrne, R. Ph., M.S., Director, Office of Drug Pricing Program, 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.

**FOR FURTHER INFORMATION CONTACT:** Robert Staley, R. Ph., Senior Program Manager, Office of Drug Pricing Program, 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:** Section 340B requires manufacturers, as a condition for the receipt of Medicaid

matching funds with respect to their covered outpatient drugs, to charge participating entities no more than a ceiling price for such drugs. This price is determined by reducing the average manufacturer price of the drug by a rebate percentage. Entities eligible to access section 340B pricing (covered entities) include certain PHS grantees (e.g., federally-qualified health centers, certain family planning projects, AIDS assistance programs, black lung clinics, hemophilia treatment centers, Native Hawaiian health centers, and centers that treat sexually-transmitted disease and/or tuberculosis) and certain disproportionate share hospitals.

Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount system) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate system).

Section 340B(a)(1) of the PHS Act provides that the amount to be paid to the manufacturers for covered drugs takes "into account any rebate or discount, as provided by the Secretary \* \* \*". Further, section 340B does not specify whether entities should receive the section 340B pricing "through a point of purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug assistance programs \* \* \* [T]he Secretary of HHS \* \* \* will use the mechanism that is the most effective and most efficient \* \* \*". H.R. Rep. No 102-384, 102d Cong., 2d Sess., pt. 2, at 16 (1992).

Initially, HRSA guidance for the section 340B program described only a discount process. Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.

Although the discount system is functioning successfully for most covered entities, most ADAPs have drug purchasing systems that have prevented their participation in the section 340B discount program. The use of a rebate mechanism (in addition to the discount mechanism) should allow these groups to access section 340B pricing.

The HRSA recognizes rebates obtained by the State ADAPs as a method of accessing the section 340B discount price. The rebate for covered outpatient drugs should be equal to or greater than the section 340B discount at the time of purchase price. State

ADAPs wishing technical assistance in developing a rebate program should contact HRSA's Office of Drug Pricing at (301) 594-4353 or (800) 628-6297.

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. The HRSA believes that these guidelines and remedies will apply fully to drugs purchased under a rebate procedure and that instituting rebates will not increase the potential for diversion.

Dated: March 10, 1997.

Ciro V. Sumaya,  
Administrator.

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4200-N-34]

### Notice of Proposed Information Collection for Public Comment

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments due: May 13, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451-7th Street, SW, Room 9116, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Daniel Kahn, telephone number (202) 708-2121 (this is not a toll-free number) for copies of the proposed forms and other available documents.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the