

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.

[FR Doc. 97-6410 Filed 3-13-97; 8:45 am]

BILLING CODE 4160-01-F

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.

[FR Doc. 97-6414 Filed 3-13-97; 8:45 am]

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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

proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Request for Insurance Endorsement Under the Direct Endorsement Program.

OMB Control Number: 2502-0365.

Description of the need for the information and proposed use: The Direct Endorsement Program permits mortgage lenders to underwrite applications for mortgage insurance and close mortgage loans without prior HUD review. Lenders then submit the closing package to HUD with request for insurance endorsement. The request is keyed into HUD's computer system to speed the process of issuing a computer-generated mortgage insurance certificate.

Agency forms, if applicable: HUD-54111.

Members of affected public: lenders performing underwriting functions.

Status of the proposed information collection: extension without change.

Authority: Section 236 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 4, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 97-6460 Filed 3-13-97; 8:45 am]

BILLING CODE 4210-27-M

[Docket No. FR-4200-N-40]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, 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: John Coonts, Director, Office of Insured Single Family Housing, Telephone number (202) 708-3046 (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 proposed collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Insurance of Adjustable Rate Mortgages.

OMB Control Number: 2502-0322

Description of the need for the information and proposed use: P.L. 98-181 requires lenders to furnish to the borrower a disclosure statement indicating that the interest rate may change. This disclosure also must identify the index used, indicate the frequency of the adjustments and provide any potential payment schedule showing increases over the first five years. An annual disclosure of interest rate adjustment is also required.

Agency form number: N/A.

Members of affected public: Business or other for-profit and individuals or households.

An estimation of the total numbers of hours needed to prepare the information collection is 1400, the number of respondents is 20,000, frequency of response is annually or on occasion, and the hours of response is 0.07 per response.

Status of the proposed information collection: Extension of a currently approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 7, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 97-6461 Filed 3-13-97; 8:45 am]

BILLING CODE 4210-27-M

[Docket No. FR-4124-N-29]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventy Street SW, Washington, DC 20410; telephone (202) 708-1226; TDD number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v.*