

Proposed Project

Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)—Extension, No Change—Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, 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 with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

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.

Because of the potential for disputes and/or audits involving covered entities and participating drug manufacturers; the HRSA Office of Drug Pricing Program has developed an informal dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit guidelines: 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. The manufacturer must submit a request for an audit of a covered entity to the HRSA Office of Drug Pricing Program. The manufacturer must then submit an audit work plan describing the audit to the HRSA Office of Drug Pricing Program for review. The manufacturer will submit copies of the audit report to the HRSA Office of Drug Pricing Program for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute resolution guidelines: Because of the potential for audit and other disputes involving covered entities and participating drug

manufacturers, the HRSA Office of Drug Pricing Program has developed an informal dispute resolution process, which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA Office of Drug Pricing Program, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA Office of Drug Pricing Program. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/re-sponse	Total burden hours
Audits:					
Audit request ¹	2	1	2	4	8
Audit workplan ¹	1	1	1	8	8
Audit report ¹	1	1	1	1	1
Entity response	1	1	1	16	16
Dispute resolution:					
Mediation request	5	1	5	8	40
Rebuttal	2	1	2	16	32
Total	10	1.2	12	8.75	105

¹ Prepared by the manufacturer.

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	8	.5	4

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 26, 1997.

J. Henry Montes,
Director, Office of Policy and Information Coordination.

[FR Doc. 97-5560 Filed 3-6-97; 8:45 am]

BILLING CODE 4160-15-P

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Customer Survey of Entities Eligible To Participate in the Drug Pricing Program—New

Section 602 of the Veterans Health Care Act of 1992 enacted Section 340B of the Public Health Service (PHS) Act, "Limitation of Prices of Drugs Purchased by Covered Entities." This section provides that a manufacturer that sells outpatient drugs to covered

entities must agree to charge a price that will not exceed the amount determined under a statutory formula. The covered entities—certain PHS grantees, disproportionate share hospitals (DSHs), and other selected entities, total approximately 11,000 sites. Most of these entities serve the economically disadvantaged or medically uninsured. The legislative intent of Section 340B is “to enable * * * certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients.”

Because of the significant savings that covered entities can realize if they are able to access Section 602 pricing, it is imperative to know the degree of satisfaction with various aspects of the program service and where improvements can be made; and to identify the barriers to access and what changes can be made to reduce them. The HRSA Office of Drug Pricing Program (ODPP) administers the program and has designed a survey with questions that relate to the two areas that they can modify readily: The

availability of information about the program, and the design of the program. The survey also includes questions on the amount of savings realized by participating entities, how the savings are used, and factors affecting satisfaction with savings. Participating and non-participating entities will be surveyed, and the results will be used to guide program changes that will increase customer satisfaction and ultimately increase program participation.

The estimated burden is as follows:

Respondents	Number of Respondents	Responses per respondent	Burden per response (hours)	Total burden hours
Covered entities	1,508	1	.25	377

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Laura Oliven, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 3, 1997.
 J. Henry Montes,
Director, Office of Policy and Information Coordination.
 [FR Doc. 97-5559 Filed 3-6-97; 8:45 am]
 BILLING CODE 4160-15-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4124-N-28]

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 unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.
EFFECTIVE DATE: March 7, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh 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 the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: February 27, 1997.
 Jacquie M. Lawing,
Deputy Assistant Secretary for Economic Development.
 [FR Doc. 97-5296 Filed 3-6-97; 8:45 am]
 BILLING CODE 4210-29-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Extension Approval Under the Paperwork Reduction Act

SUMMARY: The proposal for the collection of information listed below has been submitted to OMB for extension approval under the provisions of the Paperwork Reduction Act. Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Service Information Collection Clearance Officer at the address listed below.
DATES: Comments must be submitted on or before April 7, 1997.
ADDRESSES: Comments and suggestions on the requirement should be sent

directly to the Office of Information and Regulatory Affairs; Office of Management and Budget; Attention: Interior Desk Officer; Washington, DC 20503; and a copy of the comments should be sent to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 224-ARLSQ; 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Phyllis H. Cook, Service Information Collection Clearance Officer, 703/358-1943; 703/358-2269 (fax).

SUPPLEMENTARY INFORMATION: Comments are invited on (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on respondents.

Title: Federal Subsistence Hunt Application and Permit and Designated Hunter Permit Application and Permit.

OMB Approval Number: 1018-0075.
Service Form Number(s): 7-FS 1

(Federal Subsistence Hunt Application and 7-FS 2 (Federal Subsistence Application for the Designated Hunter).

Description and Use: The Alaska National Interest Lands Conservation Act (ANILCA) and Fish and Wildlife Service regulations found in 50 CFR (Code of Federal Regulations) 100, require that persons engaged in taking fish and wildlife must comply with reporting provisions of the Federal Subsistence Board. The harvest activity must be reported. In many cases, a special permit is required for the rural