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: Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey: National Baseline Medicare Beneficiary Knowledge Supplement; *Form No.:* HCFA–P–0015S; *Use:* This survey will establish baseline measures of Medicare beneficiary knowledge / understanding of the Medicare program, their new choices legislated under the Balanced Budget Act (BBA) which will allow HCFA to quantify current knowledge and attribute future changes in their understanding and knowledge to HCFA information and education initiatives. *Frequency:* Biennially; *Affected Public:* Business or other for-profit; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 2,667.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, 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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 28, 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. 98–28290 Filed 10–21–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0153]

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:* Drug Utilization Review and Supporting Regulations in 42 CFR 456.700, 456.705, 456.709, 456.711, and 456.712; *Form No.:* HCFA–R–153, HCFA–R–153a (OMB# 0938–0659); *Use:* These information collection requirements are necessary to establish patient profiles in pharmacies, identify problems in prescribing and/or dispensing, determine each program's ability to meet minimum standards required for Federal financial participation, and ensure quality pharmaceutical care for Medicaid patients. State Medicaid agencies that have prescription drug programs are required to perform prospective and retrospective drug use review in order to identify aberrations in prescribing, dispensing and/or patient behavior; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government, Business or other for-profit, and Not for profit institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 655,067.

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, D.C. 20503

Dated: October 15, 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. 98–28344 Filed 10–21–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice Regarding HRSA Grant Requirement—Participation in the 340B Drug Pricing Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (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 a proposed grant award requirement in which all entities, except those entities which fall within excepted categories, that receive HRSA grants listed in section 340B(a)(4) and that purchase or reimburse for covered outpatient drugs must participate in the 340B Drug Pricing Program, or demonstrate good cause for nonparticipation.

When the Prime Vendor program is operational, HRSA intends to publish a second **Federal Register** notice proposing an expansion of the grant award requirement to include participation in the Prime Vendor Program.

DATES: The public is invited to submit comments on the proposed grant requirement by December 21, 1998. After consideration of comments submitted, HRSA will determine whether to issue a final notice imposing the grant requirement.

ADDRESSES: Comments should be submitted to: Director, Division of Grants and Procurement Management,

Health Resources and Services Administration, Room 13A03, 5600 Fishers Lane, Rockville, Md 20857; Phone (301) 443–1433; FAX (301) 443–6830. All comments will be available for public inspection at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT: See above section, **ADDRESSES** for contact information.

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 eligible entities (i.e., ''covered entities'' as defined in section 340B(a)(4)) no more for such drugs than a specified ceiling price. The ceiling price is determined by a formula provided in section 340B(a)(1) & (2), and ''covered outpatient drug'' is defined in section 340B(b). HRSA has established the Drug Pricing Program to implement this statutory mandate.

Section 340B covered entities include certain HHS grantees, as specified in section 340B(a)(4). This proposed grant requirement will apply only to the following covered entities (HRSA grantees): health centers receiving grants under section 330 of the PHS Act, 42 U.S.C. § 254b; black lung clinics receiving assistance under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. § 937(a); comprehensive hemophilia diagnostic treatment centers receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. § 701(a)(2); Native Hawaiian Health Centers receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. § 11701 *et seq.*; an entity receiving a categorical grant for early intervention services for HIV disease under section 2651 of the PHS Act, 42 U.S.C. § 300ff–51, a State-operated AIDS drugs assistance program (ADAP) receiving financial assistance under title XXVI of the PHS Act, 42 U.S.C. § 300ff *et seq.*; and all other entities (other than States and units of local government) receiving assistance under title XXVI of the PHS Act, 42 U.S.C. § 300ff *et seq.* It also should be noted that entities seeking to qualify as ''Federally-Qualified Health Centers'' (FQHCs) as ''lookalikes''—i.e., entities which meet all the requirements for receiving a grant under section 330 of the PHS Act but which do not receive such a grant—will also have to satisfy the grant requirement specified below in order to qualify as a FQHC. Further, please note that eligibility to access 340B discount pricing is not contingent upon purchasing drugs with Federal grant funds. A covered entity ''may use any revenues or funds available to it to procure drugs.'' *See* H.R. Rep. No. 102–384, 102d Cong., 2d Sess. pt. 2, at 16 (1992).

It is the policy of the Department that funds which are utilized by grantees for the acquisition of drugs must be expended in the most economical manner feasible. *See* 42 C.F.R. Part 50, Subpart E. In addition, allowable costs under a grant award, among other criteria, must be reasonable for the performance of the grant. ''Reasonable cost'' is defined as one that is ordinary and ''does not exceed that which would be incurred by a prudent person'' using sound business practices and arms length bargaining. *See* OMB Circular A–122, ''Cost Principles for Nonprofit Organizations.'' *See also* OMB Circular A–87, ''Cost Principles for State, Local and Indian Tribal Governments.'' Consequently, HRSA covered entity grantees must utilize an economical and reasonable method of purchasing their outpatient drugs, and section 340B was enacted to provide an effective means of lowering drug prices for covered entities.

Under the proposed policy, HRSA would require all entities that receive HRSA grants listed in section 340B(a)(4) and that purchase or reimburse for covered outpatient drugs to participate in the 340B Drug Pricing Program, unless such requirement is waived by HRSA for good cause. A good cause waiver would be granted if the covered entity submits adequate drug purchasing or reimbursement records that demonstrate that it is accessing drug prices as good as, or better than, the current 340B ceiling price, or for other good causes, as determined by HRSA.

HRSA recognizes that some covered entities will be excepted from the grant requirement or parts of it. Those covered entities which purchase covered outpatient drugs at or below a total cost of $30,000 a year will not be required to participate in the 340B program. However, such entities are not precluded from participation and are welcome to access the benefits of such a program. The $30,000 amount does not include covered drugs purchased at nominal prices—10% of the average manufacturer price, as defined in section I(s) of the Health Care Financing Administration's Manufacturer Rebate Agreement and in section 1927(k)(1) of the Social Security Act. Please note that the $30,000 amount is subject to adjustment by HRSA, as appropriate. HRSA established this amount after consultation with a number of national professional organizations, including the National Association of Community Health Centers, the Pharmaceutical Manufacturers and Research Association, the American Pharmaceutical Association and the National Association of Retail Druggists.

Covered entities, which do not fall within an excepted category or have not been granted a good cause waiver, must purchase all outpatient drugs through participation in the Drug Pricing Program. However, to the extent that a covered outpatient drug is not available at the 340B ceiling price and the quality of patient care will be impacted, the covered entity may purchase the drug at market prices. In such situations, the covered entity will be required to provide HRSA with documentation of the unavailability of the drug. When appropriate, HRSA will refer such information to the appropriate authorities for a complete investigation.

Currently, HRSA grantees must incur only reasonable costs and use only sound business practices and arms length bargaining when purchasing or reimbursing for covered outpatient drugs. Consistent with these principles, HRSA proposes to make this new grant requirement (which will use the 340B ceiling price as a reasonable standard) effective for each of the HRSA programs listed in section 340B(a)(4) at the beginning of the first grant cycle for that program which begins at least 30 days after the date of publication in the **Federal Register** of the final notice formally adopting this policy. At that time, all such HRSA grantees must certify in their grant requests that they participate in the section 340B program, are exempted or have received a good cause waiver. Existing contracts or agreements with manufacturers, prime vendors and other members of the drug distribution network concerning covered drug purchasing and distribution will not be considered a basis for a good cause waiver, unless they provide for pricing at or below the 340B ceiling prices. Section 340B waivers will be effective for the approved project period or other specified time periods, as deemed appropriate by HRSA.

To assist covered entities not only in accessing the section 340B manufacturer drug price reductions, but also in obtaining competitive pricing for wholesaler drug distribution, section 340B(a)(8) mandates the Secretary to establish a prime vendor program for covered entities. To increase the overall benefit of such a prime vendor program, the service of the prime vendor will include price negotiation as well as drug distribution services. HRSA is in the process of developing this program and will notify covered entities when the

prime vendor is selected and service is available. At a later date, after the HRSA Prime Vendor begins operations, HRSA will issue a new **Federal Register** notice soliciting comments on a proposal to require covered entities subject to the grant requirement proposed in this notice to purchase their covered outpatient drugs from the HRSA Prime Vendor. Those AIDS Drug Assistance Projects (ADAPs), which participate in 340B through rebates, would not be subject to this additional grant requirement or eligible to participate in the Prime Vendor Program.

Dated: October 16, 1998.

Claude Earl Fox,

Administrator.

[FR Doc. 98–28275 Filed 10–21–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communication Messages—NEW—As the Federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addition treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, the Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for development and dissemination of a wide range of education and information materials for both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

Activity	Number of respondents	Responses per respondent	Hours per response	Total Hours
Individual in-depth interviews:				
General public	400	1	.75	300
Service Providers	200	1	.75	150
Focus group interviews:				
General public	3,000	1	1.50	4,500
Service Providers	1,500	1	1.50	2,250
Telephone interviews:				
General public	335	1	.08	27
Service Providers	165	1	.08	13
Self-administered questionnaires:				
General public	2,680	1	.25	670
Service Providers	1,320	1	.25	330
Gatekeeper reviews:				
General public	1,200	1	.50	600
Service Providers	600	1	.50	300
Total	11,400			9,140

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

Dated: October 15, 1998.

Richard Kopanda,

Executive Officer SAMHSA.

[FR Doc. 98–28303 Filed 10–21–98; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–003868.

Applicant: International Center for Gibbon Studies, Santa Clara, CA.

The applicant requests a permit to export/re-export 1.1 agile gibbons (*Hylobates agilis*) to the Moscow Zoo for the purpose of enhancement of the survival and propagation of the species through captive breeding.

PRT–003846.

Applicant: Government of the Northwest Territories, Wildlife and Fisheries Division, Yellowknife, NWT, Canada.

The applicant requests a permit to import biological samples from captive wood bison (*Bison bison athabascae*) to Biotracking, Moscow, ID, for pregnancy testing for the purpose of enhancement of propagation. This notification covers