FDA requests comments on which ''B-list'' activities should be elevated to the ''A-list'' for completion in 2004. Finally, as noted, FDA requests comments on new program areas or activities that should be added as a high priority for FY 2004.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14106 Filed 6–4–03; 8:45 am]

BILLING CODE 4106–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Revision

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.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Pharmacy Affairs Branch (PAB) has developed a 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 notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA PAB for review. The office will review the documentation to determine if reasonable cause exist. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA PAB 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 disputes involving covered entities and participating drug manufacturers, the HRSA PAB 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 PAB, 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 PAB. 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, but two disputes have reached the level where a committee review may be 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/ response	Total burden hours
AUDITS					
Audit Notification of Entity [1]	2	1	2	4	8
Audit Workplan [1]	1	1	1	8	8
Audit Report [1]	1	1	1	1	1

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
Entity Response	0	0	0	0	0
DISPUTE RESOLUTION					
Mediation Request	2	4	8	10	80
Rebuttal	2	1	2	16	32
Total	8	1.8	14	9.2	129

[1] Prepared by the manufacturer.

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	10	.5	5

The total burden is 134 hours.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 30, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–14217 Filed 6–4–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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:

Proposed Project: Health Care for the Homeless Program User/Visit Surveys—NEW

The Bureau of Primary Health Care (BPHC) of HRSA is planning to conduct User/Visit Surveys of the Health Care for Homeless Program (HCHP). The purpose of this study is to conduct nationally representative surveys, which have the following components: (1) A personal interview survey of HCHP site users; and (2) a record-based study of visits to HCHP sites.

The HCHP is the Federal program with the sole responsibility for addressing the critical primary health care needs of homeless individuals. The HCHP is administered by the BPHC. The BPHC is interested in knowing more about the general and specific characteristics of the HCHP users and their visits to the HCHP sites. As a consequence, a personal interview survey (User Survey) will be administered to a nationally representative sample of HCHP users and a representative sample of medical visits of HCHP sites (Visit Survey) will be examined as well.

These surveys are designed and intended to be primary sources of information on the health and visits of the HCHP users. The information will provide policy makers with a better understanding of the services that HCHP users are receiving at HCHP sites and how well these sites are meeting the needs of HCHP users.

Data from the surveys will provide quantitative information on the homeless population served by the HCHP, specifically: (a) Sociodemographic characteristics, (b) health care access and utilization, (c) health status and morbidity, (d) health care experiences and risk behaviors, (e) content of medical encounters, (f) preventive care, and (g) and living conditions. These surveys will provide data useful to the HCHP and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993.

The estimated burden on respondents and HCHP site staff is as follows:

Form	Number of respondents	Responses per respondent	Total response	Hours per response	Total burden hour
Grantee Recruitment	30 grantees	1	30	1	30
Grantee Sampling Methods	30 grantees	1	30	3	90
User Survey	1,020 users	1	1,020	1	1,020
Visit Survey	1,020 visits	1	1,020	.25	255
Total	2,070		2,070		1,395