Government, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 1.

It should be noted for the HCFA–R–142, OMB 0938–0667, that based on industry input and HCFA analysis, the applicability and burden associated with the information collection requirements (ICR) captured in this submission have been adjusted to properly reflect the degree of burden associated with this collection. In particular, the ICRs captured in this submission have been determined to be either exempt or the burden has been deemed usual and customary in accordance with the 1995 PRA. In order to comply and properly reflect the Act, HCFA assigned a token one-hour of burden for this submission.

To obtain copies of the supporting statement and any related forms 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: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 18, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–22451 Filed 8–22–97; 8:45 am]

BILLING CODE 4120–03–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: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Extension and 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.

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Drug Pricing Program 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 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. As a result of public comment on the draft audit guidelines, one of the requirements has changed. The manufacturer is no longer required to submit a request for an audit of a covered entity to the HRSA Office of Drug Pricing Program. Instead, the manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B.

Dispute resolution guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Drug Pricing Program has developed a 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/response	Total burden hours
Audits:					
Audit Notification of Entity [1]	2	1.0	2	4.0	8
Audit Workplan [1]	1	1.0	1	8.0	8
Audit Report [1]	1	1.0	1	1.0	1
Entity Response	0	0.0	0	16.0	0

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/response	Total burden hours
Dispute resolution:					
Mediation Request	5	1.0	5	8	40
Rebuttal	2	1.0	2	16	32
Total	9	1.2	11	8.1	89

[1] Prepared by the manufacturers.

Recordkeeping requirement	No. of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	10	.5	5

The total burden is 94 hours.

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: August 19, 1997.

Jane Harrison,

Acting Director, Divison of Policy Review and Coordination.

[FR Doc. 97–22423 Filed 8–22–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1997:

Name: National Advisory Committee on Rural Health

Dates and Time: September 15—September 17, 1997

Place: Radisson Barcelo Hotel Washington, 2121 P Street, NW., Washington, DC 20037, Phone: (202) 293–3100, FAX: (202) 857–0134.

The meeting is open to the public.

Agenda: The plenary session on Monday morning September 15, will include a presentation and discussion of the Child Health Initiative and a presentation of the Balanced Budget Amendment, followed by a panel discussion on its implications for rural health. Also to be on the agenda is an update on rural AIDS issues. The latter part of the afternoon will be spent with the Work Groups discussing, in concurrent sessions, what the Balanced Budget Amendment means for rural health services, education, and health care financing. Strategies for addressing the issues will be explored on Tuesday in concurrent Work Group sessions. The final plenary session will be convened on Wednesday, September 17, at 8:30 a.m. During this session the Work Groups will report on their activities and information regarding the next agenda and future meeting dates and places will be discussed. The meeting will be adjourned at 12 Noon.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson or Lilly Smetana, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Agenda Items are subject to change as priorities dictate.

Dated: August 20, 1997.

Jane M. Harrison,

Committee Management Office, Health Resources and Services Administration.

[FR Doc. 97–22552 Filed 8–22–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Meeting of the National Advisory Council for Human Genome Research

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Human Genome Research Institute, September 11–12, 1997, Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD.

This meeting will be open to the public on Thursday, September 11, 8:30 a.m. to approximately 3 p.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on September 11, from 3 p.m. to recess and on September 12, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Human Genome Research Institute, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20892, (301) 496–0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jane Ades, (301) 594–0654, two weeks in advance of the meeting.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycles.

(Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: August 19, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–22545 Filed 8–22–97; 8:45 am]

BILLING CODE 4140–01–M