orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 13, 2006.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Victoria Ferretti-Aceto at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 13, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–11471 Filed 7–18–06; 8:45 am]

BILLING CODE 4160–01–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, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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)—Extension

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 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 Office of Pharmacy Affairs (OPA) 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 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 OPA for review. The office will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA OPA 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 OPA 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 OPA, 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 OPA. 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.

The estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Audits					
Audit Notification of Entity*	2	1	2	4	8
Audit Work Plan	1	1	1	8	8

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Audit Report	1	1	1	1	1
Entity Response	0	0	0	0	0
Dispute Resolution					
Mediation Request	2	4	8	10	80
Rebuttal	2	1	2	16	32
Total Reporting	8		14		129
Recordkeeping Requirement					
Dispute Records	10	1	10	.5	5
Total Recordkeeping	10				5

*Prepared by the manufacturer.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 12, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–11440 Filed 7–18–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Survey of Estimated Glomerular Filtration Rate Reporting Practices of Clinical Laboratories

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 25, 2006, page 4151–4152 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. This 30-day submission is modified in order to reflect an increase in sample size. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: A Survey of Estimated GFR Reporting Practices of Clinical Laboratories.

Type of Information Collection Request: New.

Need and Use of Information Collection: This study will assess the level of U.S. clinical laboratory reporting of estimated GFR as a measure of kidney function through a baseline survey of a representative sample of clinical laboratories in the U.S. Results will later serve as comparison to measure an anticipated increase in use of estimated GFR, following implementation of the National Kidney Disease Education Program's communications and Lab Working Group (LWG) activities promoting use of estimated GFR for patients at risk for kidney disease. The LWG, whose members are experts in their field, strongly believes that routine reporting of estimated GFR will result in a significant increase in early detection of chronic kidney disease, therefore enabling treatment that can slow or prevent patients' progression to kidney failure.

Frequency of Response: Baseline survey only.

Affected Public: Clinical laboratory community.

Type of Respondents: Laboratory directors.

The annual reporting burden is as follows:

Estimated Number of Respondents: Anticipate 5,085 completed surveys;

Estimated Number of Responses per Respondent: Respondents will complete one paper-and-pencil or Web-based survey;

Average Burden Hours Per Response: .083 hours [5 minutes]; and

Estimated Total Annual Burden Hours Requested: 422.06 hours. The annualized total cost to respondents is estimated at $14,408.96.

Note: Completing this survey is similar to other data reporting carried out by lab directors. Since lab directors will be able to respond to the survey within their usual workday, this collection of information will not cost labs/employers additional time and money.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual total burden hours requested
Clinical Laboratory Directors	5,085	1.0	.083	422.06
Total	5,085	1.0	.083	422.06