

Dated: October 27, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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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 (OMB), 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

Section 602 of Pub. L. 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
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.

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

Dated: October 26, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6-18508 Filed 11-2-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(6), as amended. The discussions could disclose personal information concerning NCI Staff and/or its contractors, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Open: November 30, 2006, 8:30 a.m. to 4:45 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Closed: November 30, 2006, 4:45 p.m. to 5:30 p.m.

Agenda: Review intramural program site visit outcomes; Discussion of confidential personnel issues.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Open: December 1, 2006, 8:30 a.m. to 12 p.m.

Agenda: Program reports and presentations; Business of the Board.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/ncab.htm where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 26, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the Public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Minority Tobacco Cessation.

Date: November 27, 2006.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: William J. Johnson, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, NIH/NHLBI, 6701 Rockledge Drive, Bethesda, MD 20892-7924, 301-435-0317, johnsonw@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Routine Clinical Practice.

Date: November 30, 2006.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Mark Roltsch, PhD, Scientific Review Administrator, Review Branch, NHLBI, National Institutes of Health, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301-435-0287, roltschm@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Research Network on Environmental Interaction.

Date: December 7, 2006.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Keith A. Mintzer, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892, 301-435-0280, mintzerk@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Continuing Education Training Grants.

Date: December 12, 2006.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Keith A. Mintzer, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892, 301-435-0280, mintzerk@nhlbi.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for