

tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal years 2009 through 2011. FDA received

cover sheets for the following medical device submissions (average annual): 38 premarket approval applications (PMA, PDP, PMR, BLA),¹ 3,561 premarket notifications, 12 panel track supplements, 180 real-time supplements, 127 180-day supplements, 749 30-day notices, 84 513(g) requests, and 463 annual fees for periodic reporting. The number of received annual responses included the cover sheets for applications that were

qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form Number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	5,214	1	5,214	.30	1,564

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 31, 2012.
Leslie Kux,
Assistant Commissioner for Policy.
 [FR Doc. 2012-13666 Filed 6-5-12; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2012

AGENCY: Indian Health Service, HHS.
ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2012 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements.

Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)
Calendar Year 2012

Lower 48 States: \$2,169
 Alaska: \$2,350

Outpatient per Visit Rate (Excluding Medicare)
Calendar Year 2012

Lower 48 States: \$317
 Alaska: \$515

Outpatient per Visit Rate (Medicare)
Calendar Year 2012

Lower 48 States: \$273
 Alaska: \$468

Medicare Part B Inpatient Ancillary Per Diem Rate
Calendar Year 2012

Lower 48 States: \$477
 Alaska: \$811

Outpatient Surgery Rate (Medicare)

Established Medicare rates for freestanding Ambulatory Surgery Centers.

Effective Date for Calendar Year 2012 Rates

Consistent with previous annual rate revisions, the Calendar Year 2012 rates will be effective for services provided on/or after January 1, 2012 to the extent consistent with payment authorities including the applicable Medicaid State plan.

¹ PMA means premarket approval application, PDP means product development protocol, PMR

means postmarketing requirements, and BLA means biologics license applications.

Dated: February 9, 2012.
Yvette Roubideaux,
Director, Indian Health Service.
 [FR Doc. 2012-13627 Filed 6-5-12; 8:45 am]
BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 materials, 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 Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders K.

Date: June 25-26, 2012.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-435-6033, rajarams@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Exploratory Clinical Trials SEP.

Date: June 26, 2012.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-435-6033, rajarams@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 31, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-13719 Filed 6-5-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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

The meeting 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 Institute of General Medical Sciences Special Emphasis Panel MBRs SCORE Grant Applications.

Date: June 27, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Robert Horowitz, Ph.D., Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18, Bethesda, MD 20892-6200, 301-594-6904, horowitr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 31, 2012.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-13754 Filed 6-5-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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

The meeting 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 Institute of General Medical Sciences Special Emphasis Panel, Review of SCORE Grant Applications.

Date: June 26, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.18, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Horowitz, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18, Bethesda, MD 20892-6200, 301-594-6904, horowitr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry

Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 31, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-13753 Filed 6-5-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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

The meeting 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 Institute of General Medical Sciences Special Emphasis Panel, Review of Microbial Communities Grant Applications.

Date: June 26, 2012.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington, DC Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Arthur L. Zachary, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12, Bethesda, MD 20892-6200, 301-594-2886, zacharya@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)