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>
<thead>
<tr>
<th>FDA Form Number</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
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<td>1</td>
<td>5,214</td>
<td>.30</td>
<td>1,564</td>
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</tbody>
</table>

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


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.


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.

1 PMA means premarket approval application, PDP means product development protocol, PMR means postmarketing requirements, and BLA means biologics license applications.