

comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 7, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04-13872 Filed 6-18-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Reimbursement Rates for Calendar Year 2004**

**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(a) and 249(b)) and the Indian Health Care Improvement Act (25 U.S.C. 1601), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2004 for Medicare and Medicaid Beneficiaries and Beneficiaries of other Federal Agencies. 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. Legislation, effective July 1, 2001, allows IHS facilities to file Medicare claims with the carrier for payment for physician services.

**Inpatient Hospital per Diem Rate (Excludes Physician Services) Calendar Year 2004**

Lower 48 States .....	\$1,512
Alaska .....	\$1,837

**Outpatient per Visit Rate (Excluding Medicare) Calendar Year 2004**

Lower 48 States.....	\$402
Alaska .....	

**Outpatient per Visit Rate (Medicare) Calendar Year 2004**

Lower 48 States.....	\$367
Alaska .....	

**Medicare Part B Inpatient Ancillary per Diem Rate Calendar Year 2004**

Lower 48 States .....	\$307
Alaska .....	\$638

**Outpatient Surgery Rate (Medicare)**

Established Medicare rates for freestanding Ambulatory Surgery Centers.

**Effective Date for Calendar Year 2004 Rates**

Consistent with previous annual rate revisions, the Calendar Year 2004 rates will be effective for services provided on/or after January 1, 2004, to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: February 3, 2004.

**Charles W. Grim,**

*Assistant Surgeon General, Director, Indian Health Service.*

**Editorial Note:** This document was received by the Office of the Federal Register on June 15, 2004.

[FR Doc. 04-13892 Filed 6-18-04; 8:45 am]

BILLING CODE 4160-16-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Multi-Ethnic Study of Atherosclerosis (Mesa) Event Surveillance**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection:* Title: Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. Type of Information Request: Renewal (OMB No. 0925-0493). Need and Use of Information Collection: The study, MESA, will identify and quantify factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings will provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE-99-11-08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. Frequency of response: Once per CVD event. Affected public: Individuals. Types of Respondents: Physicians and selected proxies of individuals recruited for MESA. The annual reporting burden is as follows: Estimated Number of Respondents: 555; Estimated Number of Responses per respondent: 1.0; and Estimated Total Annual Burden Hours Requested: 42.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physicians .....	279	1.0	0.20	19
Participant proxies .....	276	1.0	0.25	23
Total .....	555	1.0	0.225	42

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*For Further Information Contact:* To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Diane Bild, Division of Clinical Applications, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, MSC #7938, Bethesda, MD, 20892-7938, or call non-toll-free number (301) 435-0457, or e-mail your request, including your address to: [bildd@nhlbi.nih.gov](mailto:bildd@nhlbi.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: June 9, 2004.

**Peter Savage,**

Director, DECA, NHLBI, National Institutes of Health.

[FR Doc. 04-13888 Filed 6-18-04; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Monoclonal Antibodies (MAbs) Define Human Cytochrome P450 Drug Metabolism**

Harry V. Gelboin *et al.* (NCI)  
*Licensing Contact:* Fatima Sayyid;  
301/435-4521; [sayyidf@mail.nih.gov](mailto:sayyidf@mail.nih.gov).

The application of the invention reported herein will be useful for reducing the incidence of adverse drug reactions (ADR) causing serious toxicity and mortality from certain drugs and toxicity from drug-drug interactions (DDI). The MAb system will be useful in the search for new drugs in Drug Discovery. The system engages the use

of specific inhibitory monoclonal antibodies (MAbs) to identify, measure and quantitate the role of each human Cytochrome P450 in the metabolism of drugs, NCEs (new chemical entities) or xenobiotics that can be toxic to the human population. Hybridoma clones have been isolated that produce MAbs uniquely specific to human P450s 1A1, 1A2, 2A6, 2C8, 2C9, 2C9\*2, 2C19, 2C family (8,9,18,19), 2D6, 2E1, and 3A4/5. The MAbs are highly inhibitory (80-90%) to the enzyme activity of the target P450 and thus the amount of inhibition of the metabolism of the substrate drug incubated with human liver microsomes defines the maximum contribution of the target P450 to the metabolism of the drug or other substrate. The MAbs also immunoblot the target P450 permitting the identification of the target P450 in cells and tissues. In stark contrast to other complex commonly used analytic systems that are selective, the MAb system is specific to the target P450 and is the basis for an extraordinary simple in vitro methodology. The microsome-MAb system (in vitro) defines the contribution of the target P450 to the metabolism of the substrate and identifies substrates metabolized by a single or multiple P450s and P450s catalyzing alternate metabolic pathways. Substrates metabolized by a single P450 or through a specific metabolic route can be used as a marker probe (in vivo) for examining the role of different P450 isoforms in the metabolism of drugs. They are also used for individual phenotyping for studying the genetic potential for individual drug metabolism. Additional applications include the study of polymorphic P450s to identify the metabolic consequences of the absence of a polymorphic P450 in an individual. The MAbs, listed below, are present in ascites fluid and are generally useful for all of the procedures described above. Some are also available in purified form.

**INHIBITORY MONOCLONAL ANTIBODIES (MABS) TO HUMAN LIVER CYTOCHROME P450S**

Human P450	Monoclonal anti-body (MAb clone #)	DHHS reference No.
1A1 .....	1-7-1	B-043-1994/0
1A2 .....	*26-7-5	E-122-1998/0
2A6 .....	*151-45-4	E-150-1998/0
2B6 .....	*49-10-20	B-043-1994/1
2C8, 9, 18, 19 .....	1-68-11	B-043-1994/0
2C8 .....	*281-1-1	E-077-1999/0
2C9*1,*2,*3 .....	1763-15-5	E-077-1999/0
2C9*2 .....	1292-2-3	E-077-1999/0
2C19 .....	1-7-4-8	E-200-2001/0
2D6 .....	*512-1-8 50-1-3	E-046-1997/0
2E1 .....	1-73-18	E-185-1995/0
3A4/5 .....	3-29-9	E-185-1995/0

\*Also Immunoblots.