information to be submitted. The environmental information to be submitted with petitions for certain food labeling regulations is listed in 21 CFR 101.12(h)(12), 101.69(h), and 101.70(f)F.

Thus, FDA collects information on the potential for environmental impacts of its actions in the form of environmental assessments and claims for categorical exclusions from interested parties who request agency action by submitting to the agency any of the above listed petitions, requests for exemption, or food contact substance notifications. After this information has been collected, the agency will use it to determine whether its action may significantly affect the quality of the human environment.

FDA has collected information from interested parties requesting agency action for many years. Over the years, this collected information has taken several different forms. The agency amended its environmental regulations in the 1997 rule to reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant affect on the quality of the human environment. In the 1997 rule, FDA also removed the formats for EAs from its regulations and, instead, now directs interested parties to the agency's Centers for information on what is needed in EAs. This draft guidance is FDA's current thinking on what information is needed for the environmental documentation of the actions that are most often requested. The draft guidance contains requests for certain information that has not been requested routinely in the past. FDA is now requesting that submitters provide certain information to support their claims that the categorical exclusions listed in § 25.32(i), (o), and (q) will be applicable to their requested actions. Since these informational requests are new, FDA is requesting approval from OMB for this collection of information. The remainder of the environmental information requests are covered by the information collection approvals for the underlying actions, i.e., the OMB control number for food additive petitions is 0910–0016; for color additive petitions, 0910–0185; for requests for exemption from regulation as a food additive under § 170.39, 0910–0298; for notifications for food contact substances, 0910–0480; for GRAS affirmation petitions, 0910–0132; and for petitions for food labeling regulations, 0910–0183.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

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

Table 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
25.32(i)	137	0.5	68	4	272
25.32(o)	1	1	1	1	1
25.32(q)	10	0.5	5	1	5
Total	148		74		278

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

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received since its environmental regulations were amended to include additional categorical exclusions. Please note that, since the agency revised its environmental regulations, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The hours per response were estimated as follows: First, FDA assumed that the new information it suggest be submitted in this guidance for each of these three categorical exclusions is readily available to the submitter. For the new information suggested for the exclusion in § 25.32(i), FDA expects that the submitter would gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. FDA believes that this effort should take about 4 hours per submission. For the new information suggested for the exclusions in § 25.32(o) and (q), the submitters almost always would only copy existing documentation and attach it to the claim for categorical exclusion. FDA believes that this should take no longer than about 1 hour per submission.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: September 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23623 Filed 9–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2003

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 section 601 of 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 2003 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. Physician services being paid by Medicare was generated through legislation, effective July 1, 2001, that allows IHS facilities to file claims with the carrier for physician payment.

	Calendar Year 2003
Inpatient Hospital Per Diem Rate (Excludes Physician Services)	
Lower 48 States	$1,526
Alaska	2,049
Outpatient Per Visit Rate (Excluding Medicare)	
Lower 48 States	206
Alaska	360
Outpatient Per Visit Rate (Medicare)	
Lower 48 States	175
Alaska	332
Medicare Part B Inpatient Ancillary Per Diem Rate	
Lower 48 States	298
Alaska	589
Outpatient Surgery Rate (Medicare)	
Established Medicare rates for freestanding Ambulatory Surgery Centers.	

Effective Date for Calendar Year 2003 Rates

Consistent with previous annual rate revisions, the Calendar Year 2003 rates will be effective for services provided on/or after January 1, 2003, to the extent consistent with payment authorities including the applicable Medicaid State plan.

Regulatory Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all cost and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($110 million or more annually). This notice is not a major rule because we have determined that the economic impact will be negligible.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will not have a significant economic effect on these governments or the private sector.

The Department has determined that this notice does not have a substantial effect on States or local governments under Executive Order 13132 and will not interfere with the roles, rights and responsibilities of States or local governments.

We are not preparing an analysis for the RFA because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities.

In accordance with the provisions of Executive Order l2866, this notice was reviewed by the Office of Management and Budget.

Dated: September 10, 2003.

Michel E. Lincoln,

Deputy Director.

[FR Doc. 03–23731 Filed 9–16–03; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: July 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of July 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Office of Investigation Office of Inspector General—DHHS Case Investigation Management System For Press Release From 07/01/2003–07/31/2003

Subject name	Address	Effective date
Program-Related Convictions:		
Loccisano, Gina Maria	Cranston, RI	8/20/2003
McGovern, Dana E.	Port Charlotte, FL	8/20/2003
McGovern's Ambulance Service, Inc.	Port Charlotte, FL	8/20/2003
Okoye, Patrick C.	Montgomery, AL	8/20/2003
Okoye, Godwin S.	Montgomery, AL	8/20/2003
Capobianco, Leo J.	Las Vegas, NV	8/20/2003
Khalatov, Leonid	Woodmere, NY	8/20/2003
Dooley, Michael F.	Carthage, NY	8/20/2003
Grim Thirty-Three, Inc.	Smithtown, NY	8/20/2003
Grimaldi, John	Lake George, NY	8/20/2003
JDS Ambulance Corp.	Woodmere, NY	8/20/2003
Murphy Jr., James E.	Niverville, NY	8/20/2003
Abrams, Barry	Flushing, NY	8/20/2003
Sabot, Theodore J.	Pittsfield, MA	8/20/2003
Houchins, Ednalee	S. Charleston, WV	8/20/2003