

words such as “must,” “shall,” and “will” in the original VICH document have been substituted with “should.” Similarly, words such as “require” or “requirement” have been replaced by “recommend” or “recommendation” as appropriate to the context.

The draft VICH guidance (#177) is consistent with the agency’s current thinking on the subject matter. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. 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. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may also be submitted via the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2005D-0200 entitled “Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products” (VICH GL40) and follow the directions.

Copies of the draft guidance document entitled “Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products” (VICH GL40) may be obtained on the Internet from the Center for Veterinary Medicine home page at <http://www.fda.gov/cvm>.

Dated: May 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-10625 Filed 5-24-05; 11:50 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2005

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 2005 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. Public Law 106-554, dated December 21, 2000, authorized IHS facilities to file Medicare Part B claims with the carrier for payment for physician and certain other practitioner services provided on or after July 1, 2001.

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

Calendar Year 2005

Lower 48 States—\$1,542
Alaska—\$2,032

Outpatient Per Visit Rate (Excluding Medicare)

Calendar Year 2005

Lower 48 States—\$223
Alaska—\$391

Outpatient Per Visit Rate (Medicare)

Calendar Year 2005

Lower 48 States—\$181
Alaska—\$371

Medicare Part B Inpatient Ancillary Per Diem Rate

Calendar Year 2005

Lower 48 States—\$312
Alaska—\$635

Outpatient Surgery Rate (Medicare)

Established Medicare rates for freestanding Ambulatory Surgery Centers.

Effective Date for Calendar Year 2005 Rates

Consistent with previous annual rate revisions, the Calendar Year 2005 rates will be effective for services provided on/or after January 1, 2005 to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: May 20, 2005

Charles W. Grimm,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 05-10650 Filed 5-26-05; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2005-21202]

Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Number: 1625-0018

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of one Information Collection Request (ICR). The ICR comprises (1) 1625-0018, Official Logbook. Before submitting the ICR to OMB, the Coast Guard is inviting comments on it as described below.

DATES: Comments must reach the Coast Guard on or before July 26, 2005.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG-2005-21202] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received

from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICR are available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (CG-611), U.S. Coast Guard Headquarters, room 6106 (Attn: Ms. Barbara Davis), 2100 Second Street, SW., Washington, DC 20593-0001. The telephone number is 202-267-2326.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Davis, Office of Information Management, telephone 202-267-2326, or fax 202-267-4814, for questions on these documents; or telephone Ms. Andrea M. Jenkins, Program Manager, Docket Operations, 202-366-0271, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to respond to this request for comment by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>, and they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this request for comment [USCG-2005-21202], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the

underlying requirements in view of them.

Viewing comments and documents: To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

Information Collection Requests

1. **Title:** Official logbook.

OMB Control Number: 1625-0018.

Summary: The Official Logbook contains information about the voyage, the vessel's crew, drills, and operations conducted during the voyage. Official Logbook entries identify all particulars of the voyage, including the name of the ship, official number, port of registry, tonnage, names and merchant mariner document numbers of the master and crew, the nature of the voyage, and class of ship. In addition, it also contains entries for the vessel's drafts, maintenance of watertight integrity of the ship, drills and inspections, crew list and report of character, a summary of laws applicable to Logbooks, and miscellaneous entries.

Need: Title 46, United States Code (USC) 11301 requires most merchant vessels to maintain an Official Logbook. The manner of making entries and penalties are set forth in 46 U.S.C. 11302 and 11303. The Official Logbook contains information about the vessel, voyage, and crew. Lack of these particulars would make it difficult for a seaman to verify vessel employment and wages, and for the Coast Guard to verify compliance with laws and regulations concerning vessel operations and safety procedures. The Official Log serves as an official record of recordable events transpiring at sea such as births, deaths, marriages, and disciplinary actions. Absent the Official Log, there would be no official civil record of these events. The courts accept log entries as proof that the logged event occurred. If this information was not collected, the Coast

Guard's commercial vessel safety program would suffer, as there would be no official record of U.S. merchant vessel voyages. Similarly, those seeking to prove that an event occurred would not have any record available.

Respondents: Shipping Companies.

Frequency: On occasion.

Burden Estimate: The estimated burden remains the same, 1,750 hours a year.

Dated: May 19, 2005.

Dr. Nathaniel Heiner,

Acting, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 05-10589 Filed 5-26-05; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2005-20457]

Collection of Information under Review by Office of Management and Budget (OMB): 1625-0013, 1625-0032, 1625-0037, 1625-0041, and 1625-0042.

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard has forwarded five Information Collection Reports (ICRs)—(1) 1625-0013, Plan Approval and Records for Load Lines; (2) 1625-0032, Vessel Inspection Related Forms and Reporting Requirements Under Title 46 U.S. Code; (3) 1625-0037, Certificates of Compliance, Boiler/Pressure Vessel Repairs, Cargo Gear Records, and Shipping Papers; (4) 1625-0041, Various International Agreement Pollution Prevention Certificates and Documents, and Equivalency Certificates, and (5) 1625-0042, Requirements for Lightering of Oil and Hazardous Material Cargoes—abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) for review and comment. Our ICR describes the information we seek to collect from the public. Review and comment by OIRA ensures that we impose only paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before June 27, 2005.

ADDRESSES: To make sure that your comments and related material do not reach the docket [USCG-2005-20457] or OIRA more than once, please submit