

recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon.

**Location:** Hilton, 620 Perry Pkwy., Gaithersburg, MD.

**Contact:** Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On March 15, 2001, the committee will hear presentations, discuss and make recommendations on the comparative sensitivity of Hepatitis B Virus nucleic acid testing versus Hepatitis B Surface Antigen testing. In the afternoon, the committee will hear presentations, discuss and make recommendations on the implementation of nucleic acid testing for Hepatitis C Virus and human immunodeficiency virus, testing donor and product management, and blood bags for diversion of the initial collection. On March 16, 2001, the committee will hear updates on the following topics: (1) Summaries of the Transmissible Spongiform Encephalopathies Advisory Committee Meeting and the Public Health Service Advisory Committee Meeting on blood safety and availability, and (2) The Office of Inspector General's report on tissue and organ regulation. The committee will additionally hear presentations, discuss and make recommendations on the topic of guidance on malaria, applicability to plasma.

**Procedure:** On March 15, 2001, from 8:30 a.m. to 6 p.m. and on March 16, 2001, from 8:30 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 9, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m., 1:30 p.m. and 2:30 p.m., and 4:30 p.m. and 5:30 p.m. on March 15, 2001, and 10:15 a.m. and 10:30 a.m. on March 16, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 9, 2001, and submit a brief statement of the general nature of the evidence or

arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the March 15 to 16, 2001, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 28, 2001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 01-5375 Filed 3-1-01; 11:53 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-1728]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Type of Information Collection Request:** Revision of a currently approved collection; **Title of**

**Information Collection:** Home Health Agency Cost Report and Supporting Regulations in 42 CFR 413.20, 413.24 and 413.106; **Form No.:** HCFA-1728 (OMB No. 0938-0022); **Use:** Participating providers are required to submit annual information to HCFA in order to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The HCFA-1728 is the form used by Home Health Agencies to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries; **Frequency:** Annually; **Affected Public:** Business or other for profit, Not for profit institutions, and State, Local or Tribal Gov.; **Number of Respondents:** 7,310; **Total Annual Responses:** 7,310; **Total Annual Hours Requested:** 1,293,870.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 15, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01-5181 Filed 3-2-01; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-108]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the

following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Criteria for Medicare Coverage of Liver Transplants; *Form No.:* HCFA-R-108 (OMB# 0938-0580); *Use:* Medicare participating hospitals must file an application to be approved for coverage and payment of liver transplants performed on Medicare beneficiaries; *Frequency:* Monthly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 12; *Total Annual Responses:* 12; *Total Annual Hours:* 2,110.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 14, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01-5182 Filed 3-2-01; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-170]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Criteria for Medicare Coverage of Lung Transplants; *Form No.:* HCFA-R-170 (OMB# 0938-0670); *Use:* Medicare participating hospitals must file an application to be approved for coverage and payment of lung transplants performed on Medicare beneficiaries; *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 6; *Total Annual Responses:* 6; *Total Annual Hours:* 900.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New

Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 14, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01-5183 Filed 3-2-01; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-2068-N]

#### Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of the American Society for Histocompatibility and Immunogenetics as a CLIA Accreditation Organization

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the continued approval of the American Society for Histocompatibility and Immunogenetics (ASHI) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by ASHI meet the conditions required by CLIA and its implementing regulations. Consequently, laboratories that voluntarily become accredited by ASHI would meet the CLIA condition level requirements for laboratories and, therefore, are not subject to routine inspection by State survey agencies to determine their compliance with CLIA requirements. These laboratories are, however, subject to Federal validation and complaint investigation surveys.

**EFFECTIVE DATE:** This notice is effective for the period March 5, 2001 through October 31, 2006.

**FOR FURTHER INFORMATION CONTACT:** Minnie Christian, (410) 786-3339.

#### SUPPLEMENTARY INFORMATION:

#### I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100-578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by