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, 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, 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

the Clinical Laboratories Improvement Act of 1967. HCFA issued a final rule (57 FR 33992) implementing the accreditation provisions of CLIA on July 31, 1992. HCFA may approve a private, nonprofit organization as an approved accreditation organization to accredit clinical laboratories under the CLIA program if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to be an approved accreditation organization. HCFA approves an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must among other conditions and requirements:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HCFA.
- Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HCFA when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories.
- Provide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify HCFA at least 30 days before implementing any proposed changes in its standards.
- If HCFA withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization and authorizes the accreditation organization to submit to HCFA records and other information HCFA may require.

Along with requiring the promulgation of criteria for approving an accreditation organization and for withdrawing this approval, CLIA regulations require HCFA to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that HCFA determines appropriate.

II. Notice of Continued Approval of ASHI as an Accreditation Organization

In this notice, we approve ASHI as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements. HCFA and the Centers for Disease Control and Prevention (CDC) have examined the ASHI application and all subsequent submissions to determine equivalency with HCFA requirements under subpart E of part 493 that an accreditation organization must meet to be granted approved status under CLIA. We have determined that ASHI complied with the applicable CLIA requirements as of March 5, 2001 and grant ASHI approval as an accreditation organization under subpart E, through October 31, 2006, for the following specialty and subspecialty areas:

- Histocompatibility.
- ABO/Rh typing.

As a result of this determination, any laboratory that is accredited by ASHI during this time period for an approved specialty or subspecialty (listed above) is deemed to meet the applicable CLIA condition level requirements for the laboratories found in part 493 of HCFA regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other validly authorized agent.

III. Evaluation of ASHI

The following describes the process used to determine that ASHI, as a private, nonprofit organization, provides reasonable assurance that laboratories it accredits will meet the applicable requirements of CLIA and applicable regulations.

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether we should grant approved status to ASHI as a private, nonprofit organization for accrediting laboratories under CLIA for the specific specialty or subspecialty areas of human specimen testing it requested, we conducted a detailed and in-depth comparison of ASHI's requirements for its laboratories to those of CLIA. In summary, we evaluated whether ASHI meets the following requirements:

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to or more stringent than the CLIA condition level requirements (for the requested specialty and subspecialty) and would, therefore, meet the condition level requirements of CLIA if those laboratories had been inspected against condition level requirements.
- Meets the applicable requirements of part 493, subpart E.

As specified in the regulations of subpart E, the review of a private, nonprofit accreditation organization seeking approved status under CLIA includes, but is not limited to, an evaluation of the following:

- Whether the organization's requirements for its accredited laboratories are equal to or more stringent than the condition level requirements of the CLIA regulations.
- The organization's inspection process to determine the following:

—The composition of the inspection teams, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to all of its inspectors.

—The comparability of the organization's full inspection and complaint inspection requirements to the Federal requirements including, but not limited to, inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories.

—The organization's procedures for monitoring laboratories that it has found to be out of compliance with its requirements.

—The ability of the organization to provide HCFA with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process.

—The ability of the organization to provide HCFA with electronic data related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in HCFA approved PT programs, as well as data related to the PT failures, within 30 days of the initiation of the action.

—The ability of the organization to provide HCFA with electronic data for all its accredited laboratories and the area of specialty and subspecialty testing.

—The adequacy of the numbers of staff and other resources.

—The organization's ability to provide adequate funding for performing the required inspections.

• Whether the organization has an agreement with HCFA that requires it, among other things, to meet the following:

—Notify HCFA of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or that has had any other adverse action taken against it by the accreditation organization, within 30 days of the date the action is taken.

—Notify HCFA within 10 days of a deficiency identified in an accredited laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

—Notify HCFA of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days.

—Notify each laboratory accredited by the organization within 10 days of HCFA's withdrawal of approval of the organization.

—Provide HCFA with inspection schedules, on request, for the purpose of conducting onsite validation inspections.

—Provide HCFA or our agent, or the State survey agency, with any facility-specific data that HCFA requires, including, but not limited to, PT results that constitute unsuccessful participation in an approved PT program and notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

—Provide HCFA with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements.

—Provide upon the request by any person, on a reasonable basis (under State confidentiality and disclosure requirements, if applicable), any laboratory's PT results with the explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by an approved accreditation organization must, among other things, meet the following requirements:

• Authorize the organization to release to HCFA all records and information required.

• Permit inspections as required by the CLIA regulations in part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation under§ 493.61 (Requirements for a certificate of accreditation).

B. Evaluation of the ASHI Request for Continued Approval as an Accreditation Organization Under CLIA

HCFA made the following determinations concerning ASHI's standards for accreditation of laboratories in relation to the CLIA requirements contained in part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

ASHI has submitted and requested re-approval for the specialty of Histocompatibility that it would continue to accredit and new approval for the subspecialty of ABO/Rh typing that it would also accredit. ASHI has submitted a description of its PT monitoring process; inspection process and guidelines; a listing of the size, composition, education, and experience of its inspection teams; its investigative and complaint response procedures; its data management and analysis system; its notification agreements with HCFA; its removal or withdrawal of laboratory accreditation procedures; its current list of accredited laboratories; and its announced or unannounced inspection process. We have determined that ASHI has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

ASHI's requirements for PT are equivalent to those of CLIA for ABO/Rh typing.

For the specialty of Histocompatibility, ASHI's requirements exceed those of HCFA. ASHI requires participation in at least one external PT program, if available, in each category of histocompatibility testing with an 80 percent score required for successful participation and enhanced PT for laboratories that fail an event.

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

ASHI exceeds CLIA retention requirements for Test Requisitions, requiring 5 years, whereas CLIA requires § 493.1105 only 2 years. In addition, ASHI requires laboratories to obtain written authorization for all testing performed by the laboratory, which exceeds the CLIA requirements. All other requirements in Patient Test Management are equivalent to those of CLIA on an overall basis.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

The quality control (QC) requirements of ASHI have been evaluated against the applicable requirements of CLIA and its implementing regulations. We have determined that ASHI's requirements, when taken as a whole, are more stringent than the CLIA requirements. For instance, ASHI's Nucleic Acid Analysis addresses DNA extraction and digestion, amplification, contamination, physical containment, and multiple quality controls for the test systems. HCFA regulations do not include this requirement.

Subpart M—Personnel for Moderate and High Complexity Testing

We have found that ASHI personnel requirements, when taken as a whole, are equal to or more stringent than the CLIA requirements for Histocompatibility. Experience requirements for Director, Technical Supervisor, and General Supervisor exceed CLIA's personnel experience requirements in the specialty of Histocompatibility.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that ASHI's requirements are equal to the CLIA requirements of this subpart. ASHI has adopted the CLIA quality assurance requirements in their entirety and included them in ASHI's checklist.

Subpart Q—Inspections

We have determined that ASHI's inspections are more frequent than CLIA requires. ASHI performs an onsite inspection every 2 years and requires submission of a self-evaluation inspection in the intervening years. If the self-evaluation inspection indicates that an onsite inspection is warranted, ASHI conducts an additional onsite review. In addition, ASHI inspectors provide onsite proficiency testing samples to be processed during the inspection.

Subpart R—Enforcement Procedures for Laboratories

ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. ASHI policy stipulates the action it takes when laboratories it accredits do not comply with its requirements. ASHI shall

withdraw, revoke, or limit accreditation of a laboratory as appropriate and report the action to HCFA within 30 days. ASHI also provides an appeal process for laboratories that have had accreditation denied, revoked, suspended, or limited.

We have determined that ASHI's laboratory enforcement and appeal policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of ASHI accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by HCFA or our agent, or the State survey agency, will be HCFA's principal means for verifying that the laboratories accredited by ASHI remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide, in part, that we may remove the approval of an accreditation organization, such as that of ASHI, for cause, before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs), HCFA will conduct a review of an approved accreditation organization's program. We also conduct a review when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2 (Definitions)), indicate widespread or systemic problems in the organization's accreditation processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole. If validation inspection results over a 1-year period indicate a rate of disparity of 20 percent or more between the findings of the organization and those of HCFA, HCFA will conduct a review under § 493.575(a)(4).

If HCFA determines that ASHI has failed to adopt or maintain requirements that are equal to or more stringent than the CLIA requirements, or systematic problems exist in its inspection process, a probationary period as determined by HCFA, not to exceed 1 year, may be given to ASHI to adopt equal or more stringent requirements. HCFA will make a final determination as to whether or not ASHI retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as ASHI may resubmit its application if it revises its program to address the rationale for the withdrawal, demonstrates that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. If, however, an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until HCFA issues a final reconsideration determination.

Should circumstances result in ASHI having its approval withdrawn, HCFA will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management of Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 2, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01–4928 Filed 3–2–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Clinical Pharmacy Demonstration Project Evaluation: NEW

The Clinical Pharmacy Demonstration Projects, a supplemental grant opportunity for health center networks, were established to evaluate the impact of comprehensive pharmacy services on the patients served by Health Resources and Services Administration (HRSA) supported programs. The overarching mission is to demonstrate the effect of implementing comprehensive pharmacy services in underserved populations. By collecting data regarding health outcomes and the level of pharmacy services provided, the Office of Pharmacy Affairs hopes to establish the provision of comprehensive pharmacy services as a key to improving access and eliminating health disparities.

The grantee networks will provide valuable pharmacy services to patients, and in the process generate data that will demonstrate the effect of the projects on health outcomes. Patient encounter data will be collected (baseline and semi-annual) for diabetic patients who receive clinical pharmacy services. In addition, each participating pharmacy will complete survey instruments (baseline, annual) for utilization, financial, and process data which describe the program. These data will result in the following: the creation of a database to document the nationwide impact of implementing comprehensive pharmacy services through the Clinical Pharmacy Demonstration Projects in underserved areas; and, information sources for the sharing of best practices, with the ultimate goal of aiding other health