of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (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.

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations (EFIOs); *Use:* Health care providers can currently obtain a National Provider Identifier (NPI) via a paper application or over the Internet through the National Plan and Provider Enumeration System (NPPES). These applications must be submitted individually, on a per-provider basis. The Electronic File Interchange (EFI) process allows provider-designated electronic file interchange organizations (EFIOs) to capture multiple providers' NPI application information on a single electronic file for submission to NPPES. This process is also referred to as ''bulk enumeration.'' To ensure that the EFIO has the authority to act on behalf of each provider and complies with other Federal requirements, an authorized official of the EFIO must sign a certification statement and mail it to the Centers for Medicare and Medicaid Services (CMS). *Form Number:* CMS–10175 (OMB# 0938–0984); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 300.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Disclosure of Financial Relationships Report (''DFRR''); *Use:* Section 1877(f) of the Social Security Act requires that each entity providing covered items or services for which payment may be made shall provide the Secretary with information concerning the entity's ownership and investment interests, and compensation arrangements, in such form, manner, and at such times as the Secretary shall specify. The DFRR collection instrument will be used by CMS to (1) identify arrangements that potentially may not be in compliance with the physician self-referral statute and implementing regulations; and (2) to identify examples and areas of non-compliance that may assist us in any future rulemaking concerning the reporting requirements and other physician self-referral provisions. *Form Number:* CMS–10236 (OMB# 0938–New); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 40,000.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material and Medicaid State Plan—Base Plan, Attachments and Supplemental Pages and Supporting Regulations in 42 CFR 430.10–430.20 and 440.167; *Use:* The Medicaid State base plan pages and attachments are documents utilized by State and territorial agencies which have the responsibility for administering the Medicaid program. The Medicaid State plan is comprised of ''pages'' and organized by subject matter which includes Medicaid eligibility services, payment for services, and general, financial and personnel administration. When States seek to change selected pages of their State plans, the page(s) are transmitted to CMS for review and approval by the CMS Central and Regional Offices prior to amending its State plan. *Form Number:* CMS–179 (OMB# 0938–0193); *Frequency:* Once and as needed; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 4,681; *Total Annual Hours:* 9,271.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *January 20, 2009.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: December 12, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–30327 Filed 12–18–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2295–N]

RIN 0938–AP20

Deeming Notice for American Society for Histocompatibility and Immunogenetics (ASHI) as an Accrediting Organization Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: The American Society for Histocompatibility and Immunogenetics (ASHI) was granted deeming authority as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program on March 25, 2005. The deeming authority was granted for the CLIA specialty of Histocompatibility and the subspecialty ABO/Rh. In this notice, we approve and grant ASHI deeming authority for the additional CLIA subspecialty of General Immunology.

DATES: *Effective Date:* This notice is effective from December 19, 2008 until March 25, 2011.

FOR FURTHER INFORMATION CONTACT: Penelope Meyers, (410) 786–3366.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, CMS may grant deeming authority to an accreditation organization that accredits clinical laboratories if the organization meets certain requirements. Among other requirements, an organization's requirements for laboratories accredited under its program must be equal to or more stringent than the applicable CLIA program requirements in 42 CFR part

493 (Laboratory Requirements). This requirement and others in subpart E of that part (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an approved State Laboratory Program) specify the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of Deeming Authority for ASHI in the Subspecialty of General Immunology

In this notice, we approve ASHI as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements in the subspecialty of General Immunology. We have examined the initial ASHI application and all subsequent submissions to determine their accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that ASHI meets or exceeds the applicable CLIA requirements. We have also determined that the ASHI program will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, K and M. Therefore, by this notice we grant ASHI approval as an accreditation organization under subpart E of part 493, for the period stated in the ''*Effective Date*'' section of this notice for the subspecialty area of General Immunology. As a result of this determination, any laboratory that is accredited by ASHI during the time period stated in the ''*Effective Date*'' section of this notice for the approved subspecialty of General Immunology is deemed to meet the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is generally not subject to routine inspections 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 CMS, or its agent(s).

III. Evaluation of ASHI Request for Approval as an Accreditation Organization Under CLIA in the Subspecialty of General Immunology

The following describes the process used to determine that the ASHI accreditation program for the subspecialty of General Immunology met the necessary requirements to be approved by CMS, and that, as such, CMS may approve ASHI as an accreditation program with deeming authority under the CLIA program.

- ASHI formally applied to CMS for approval as an accreditation organization under CLIA for the subspecialty of General Immunology. In reviewing these materials, CMS found as follows for each applicable subpart of the CLIA regulations:

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

ASHI submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the subspecialty area of General Immunology; a list of all its current laboratories and the expiration date of their accreditation; and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. ASHI's proposed policies and procedures for oversight of laboratories performing General Immunology testing would be the same as those previously approved by CMS for laboratory oversight in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. ASHI's proposed requirements for monitoring and inspecting General Immunology laboratories would be the same as those previously approved by CMS for laboratories in the areas of accreditation organization data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of ASHI are equal to the requirements of the CLIA regulations.

ASHI's application and supplemental materials demonstrate that ASHI's accreditation program for General Immunology met the subpart E requirements.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

ASHI's application materials demonstrate that the requirements in ASHI's accreditation program for the subspecialty of General Immunology are equal to the CLIA requirements at § 493.837. Both CLIA regulations and ASHI standards require accredited laboratories to participate in a CMS-approved PT program for any of the tests listed in subpart I. Additionally, ASHI's requirements exceed the CLIA requirements in that it requires laboratories to participate in non-regulated PT programs when available.

ASHI's application and supplemental materials demonstrate that ASHI's accreditation program for General Immunology met or exceeds the subpart H requirements.

Subpart K—Quality System for Nonwaived Testing

The quality control requirements of ASHI have been evaluated against the requirements of the CLIA regulations. ASHI standards contain additional, specific quality control requirements for General Immunology testing. Therefore, the ASHI requirements are more stringent than the CLIA requirements at § 493.1208.

ASHI's application and supplemental materials demonstrate that ASHI's accreditation program for General Immunology exceeds the subpart K requirements.

Subpart M—Personnel for Nonwaived Testing

We have determined that the ASHI requirements are equal to the CLIA requirements at § 493.1441 through § 493.1495 (applicable to laboratories performing testing in the subspecialty of General Immunology).

ASHI's application and supplemental materials demonstrate that ASHI's accreditation program for General Immunology met the subpart M requirements.

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 (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, the State survey agencies, will be our 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 that we may rescind the approval of an accreditation organization, such as that of ASHI, for cause, before the end of the effective date of approval. If we determine that ASHI has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which ASHI would be allowed

to address any identified issues. Should ASHI be unable to address the identified issues within that time frame, CMS may, in accordance with the applicable regulations, revoke ASHI's deeming authority under CLIA.

Should circumstances result in our withdrawal of ASHI's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938–0686.

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

Dated: December 4, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–29659 Filed 12–18–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2274–N]

RIN 0938–AP09

Medicaid Program; Fiscal Year Disproportionate Share Hospital Allotments and Disproportionate Share Hospital Institutions for Mental Disease Limits

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS

ACTION: Notice.

SUMMARY: This notice announces the final Federal share disproportionate share hospital (DSH) allotments for Federal fiscal year (FFY) 2007 and the preliminary Federal share DSH allotments for FFY 2009. This notice also announces the final FFY 2007 and the preliminary FFY 2009 limitations on aggregate DSH payments that States may make to institutions for mental disease and other mental health facilities. In addition, this notice includes background information describing the methodology for determining the amounts of States' FFY DSH allotments.

DATES: *Effective Date:* This notice is effective on 60 days after the date of publication in the **Federal Register**. The final allotments and limitations set forth in this notice are effective for the fiscal years specified.

FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019.

SUPPLEMENTARY INFORMATION:

I. Background

A. Disproportionate Share Hospital Allotments for Federal Fiscal Year 2003

Under section 1923(f)(3) of the Social Security Act (the Act), States' Federal fiscal year (FFY) 2003 disproportionate share hospital (DSH) allotments were calculated by increasing the amounts of the FFY 2002 allotments for each State (as specified in the chart, entitled ''DSH Allotment (in millions of dollars),'' contained in section 1923(f)(2) of the Act) by the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the prior fiscal year. The allotment, determined in this way, is subject to the limitation that an increase to a State's DSH allotment for a fiscal year cannot result in the DSH allotment exceeding the greater of the State's DSH allotment for the previous fiscal year or 12 percent of the State's total medical assistance expenditures for the allotment year (this is referred to as the 12 percent limit).

Most States' *actual* FY 2002 allotments were determined in accordance with the provisions of section 1923(f)(4) of the Act. However, as indicated previously, the calculation of States' FFY 2003 allotments was *not* based on the actual FFY 2002 DSH allotments; rather, section 1923(f)(3) of the Act requires that the States' FY 2003 allotments be determined using the amount of the States' FY 2002 allotments specified in the chart in section 1923(f)(2) of the Act. The exception to this is the calculation of the FFY 2003 DSH allotments for certain ''Low-DSH States'' (defined in section 1923(f)(5) of the Act). Under the Low-DSH State provision, there is a special calculation methodology for the Low-DSH States only. Under this methodology, the FFY 2003 allotments were determined by using (that is, increasing) States' actual FFY 2002 DSH allotments (not their FFY 2002 allotments specified in the chart in section 1923(f)(2) of the Act) by the percentage change in the CPI–U for the previous fiscal year.

B. DSH Allotments for FFY 2004

Section 1001(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) amended section 1923(f)(3) of the Act to provide for a ''Special, Temporary Increase in Allotments on a One-Time, Non-Cumulative Basis.'' Under this provision, States' FFY 2004 DSH allotments were determined by increasing their FFY 2003 allotments by 16 percent, and the fiscal year DSH allotment amounts so determined were not subject to the 12 percent limit.

C. DSH Allotments for Non-Low DSH States for FFY 2005, and Fiscal Years Thereafter

Under the methodology contained in section 1923(f)(3)(C) of the Act, as amended by section 1001(a)(2) of the MMA, the non-Low-DSH States' DSH allotments for FFY 2005 and subsequent fiscal years continue at the same level as the States' DSH allotments for FFY 2004 until a ''fiscal year specified'' occurs. The ''fiscal year specified'' is the first fiscal year for which the Secretary estimates that a State's DSH allotment equals (or no longer exceeds) the DSH allotment as would have been determined under the statute in effect before the enactment of the MMA. We determine whether the fiscal year specified has occurred under a special parallel process. Specifically, under this parallel process, a ''parallel'' DSH allotment is determined for FFYs after 2003 by increasing the State's DSH allotment for the previous fiscal year by the percentage change in the CPI–U for the prior fiscal year, subject to the 12 percent limit. This is the methodology as would otherwise have been applied under section 1923(f)(3)(A) of the Act notwithstanding the application of the provisions of MMA. The ''fiscal year specified,'' is the fiscal year in which the parallel DSH allotment calculated under this special parallel process finally equals or exceeds the FY 2004 DSH allotment, as determined under the MMA provisions. Once the fiscal year specified occurs for a State, that State's fiscal year DSH allotment will be calculated by increasing the State's previous actual fiscal year DSH allotment (which would be equal to the FY 2004 DSH allotment) by the percentage change in the CPI–U for the previous fiscal year, subject to the 12 percent limit. The following example illustrates how the fiscal year DSH allotment would be calculated for fiscal years after FFY 2004.

Example—In this example, we are determining the parallel FFY 2009 DSH