the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: April 15, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011–9879 Filed 4–21–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier CMS–R–21]**

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

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 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:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Form No.:* CMS–R–21 (OMB#: 0938–0287); *Use:* Section 2104 of the Omnibus Reconciliation Act of 1981 provides CMS with the authority to withhold Medicare payments to recover Medicaid overpayments that the Medicaid State Agency has been unable to recover. When the CMS Regional Office (RO) receives an overpayment case from a State Agency, the case file is examined to determine whether the conditions for withholding Medicare payments have been met. If the RO determines that the case is appropriate for withholding Medicare payments, the RO will contact the institution's intermediary or individual's carrier to determine the amount of Medicare payments to which the entity would otherwise be entitled. The RO will then give notice to the intermediary/carrier to withhold the entity's Medicare payment; *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 27; *Total Annual Hours:* 81. (For policy questions regarding this collection contact Rory Howe at 410–786–4878. For all other issues call 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 *May 23, 2011.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: April 19, 2011.

**Martique Jones,**

*Director, Regulations Development Group—Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2011–9846 Filed 4–21–11; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–2332–FN]**

### Medicare and Medicaid Programs; Approval of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. for Deeming Authority for Organizations That Provide Outpatient Physical Therapy and Speech-Language Pathology Services

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

**ACTION:** Final notice.

**SUMMARY:** This notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for recognition as a national accreditation program for organizations that provide outpatient physical therapy and speech-language pathology services seeking to participate in the Medicare or Medicaid programs.

**DATES:** *Effective Date:* This final notice is effective April 22, 2011 through April 22, 2015.

**FOR FURTHER INFORMATION CONTACT:** Alexis Prete, (410) 786–0375. Patricia Chmielewski, (410) 786–6899.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient physical therapy and speech language pathology covered services from a provider of services, a clinic, a rehabilitation agency, a public health agency, or by others under an arrangement with and under the supervision of such provider, clinic, rehabilitation agency, or public health agency (collectively, "organizations"), provided certain requirements are met. Section 1861(p)(4) of the Social Security Act (the Act) establishes distinct criteria for organizations seeking approval to provide outpatient physical therapy and speech language pathology services. The regulations at 42 CFR part 485, subpart H specify, among other things, the conditions that an organization providing outpatient physical therapy and speech-language pathology services must meet to participate in the Medicare program. Regulations concerning provider agreements are located at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to survey and certification of facilities at 42 CFR part 488.

Generally, in order to enter into a provider agreement, an organization offering outpatient physical therapy and speech language pathology services must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1861(p)(4) of the Act, and 42 CFR part 485, subpart H. Thereafter, the organization is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is an alternative, however, to State compliance surveys. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization (AO) that all applicable Medicare conditions are met or exceeded, we may "deem" that provider entity as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare

participation. A national AO applying for deeming authority under part 488 subpart A, must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

## II. Deeming Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for deeming authority is conducted in a timely manner. The Act provides us 210 calendar days after the date of receipt of a complete application, with any documentation necessary to make a determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

## III. Provisions of the Proposed Notice and Response to Comments

On November 29, 2010, we published a proposed notice in the **Federal Register** (75 FR 73088) announcing AAAASF's request for approval as a deeming organization for organizations that provide outpatient physical therapy and speech-language pathology services. In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of AAAASF's application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An onsite administrative review of AAAASF's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of AAAASF's outpatient physical therapy and speech-language pathology services accreditation standards to our current Medicare outpatient physical therapy and speech-language pathology services conditions of participation (CoPs).
- A documentation review of AAAASF's survey processes to:
  + Determine the composition of the survey team, surveyor qualifications, and AAAASF's ability to provide continuing surveyor training.
  + Compare AAAASF's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  + Evaluate AAAASF's procedures for monitoring organizations providing outpatient physical therapy and speech-language pathology services found to be out of compliance with AAAASF's program requirements. The monitoring procedures are used only when the AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).
  + Assess AAAASF's ability to report deficiencies to the surveyed organizations and respond to the facility's plan of correction in a timely manner.
  + Establish AAAASF's ability to provide us with electronic data and reports necessary for effective validation and assessment of AAAASF's survey process.
  + Determine the adequacy of staff and other resources.
  + Review AAAASF's ability to provide adequate funding for performing required surveys.
  + Confirm AAAASF's policies with respect to whether surveys are announced or unannounced.
  + Obtain AAAASF's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the November 26, 2010 proposed notice also solicited public comments regarding whether AAAASF's requirements meet or exceed the Medicare CoPs for outpatient physical therapy and speech-pathology services. We received 2 comments in response to our proposed notice.

*Comment:* One commenter expressed concern that AAAASF does not have adequate experience and familiarity with organizations that provide outpatient physical therapy and speech-pathology services, nor does AAAASF have accreditation standards that exceed the current Medicare requirements.

*Response:* Regulations at § 488.4 and § 488.8 specify the process to be followed for application, review, approval and renewal of deeming authority for AOs. A national AO applying for approval of deeming authority under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires accredited provider entities to meet the requirements that are at least as stringent as the Medicare conditions. AO standards may, but are not required to, exceed our requirements. AAAASF's application was thoroughly reviewed in accordance with these requirements and found to meet the Medicare requirements.

*Comment:* One commenter expressed concern that AAAASF's application did not include occupational therapy services.

*Response:* The regulations at 42 CFR part 485, subpart H specify, among other things, the conditions that an organization providing outpatient physical therapy and speech-language pathology services must meet to participate in the Medicare program. These regulations do not include a requirement for occupational therapy services. Therefore, it was not necessary for occupational therapy services to be addressed in AAAASF's application.

## IV. Provisions of the Final Notice

### *A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements*

We compared AAAASF's outpatient physical therapy and speech-pathology services accreditation requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AAAASF's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- AAAASF revised its standards to ensure social workers meet the requirements outlined in 42 CFR part 484 for States that do not require licensure.
- AAAASF revised its crosswalk to include the requirements that all vocational specialists must meet to comply with the requirements at § 485.705(c)(7)(i) through (iii).
- AAAASF revised its policies to ensure its survey files were complete, accurate and consistent with the Medicare requirements at § 488.6(a).
- AAAASF revised its accreditation decision letters to ensure they are accurate and contain all of the elements necessary for the CMS Regional Office to render a decision regarding deemed status of an organization that provides outpatient physical therapy and speech-language pathology services.
- AAAASF modified its policies regarding timeframes for sending and

receiving a required plan of correction in accordance with the requirements at section 2728 of the SOM.

*B. Term of Approval*

Based on the review and observations described in section III of this final notice, we have determined that AAAASF's requirements for organizations providing outpatient physical therapy and speech-language pathology services meet or exceed our requirements. Therefore, we approve AAAASF as a national accreditation organization for organizations that provide outpatient physical therapy and speech-language pathology services that request participation in the Medicare program, effective April 22, 2011 through April 22, 2015.

**V. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 30, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011–9176 Filed 4–21–11; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–2372–N]**

### Announcement of the Re-Approval of the American Society of Histocompatibility and Immunogenetics (ASHI) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the application of the American Society for Histocompatibility and Immunogenetics (ASHI) for re-approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the following specialty and subspecialty areas: General Immunology; Histocompatibility; and ABO/Rh typing. We have determined that the ASHI meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and grant ASHI deeming authority for a period of 5 years.

**DATES:** *Effective Date:* This notice is effective from April 22, 2011 to April 22, 2016.

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

**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 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 those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

**II. Notice of Approval of the ASHI as an Accreditation Organization**

In this notice, we approve ASHI as an organization that may accredit laboratories for purposes of establishing its compliance with CLIA requirements for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. We have examined the initial ASHI application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the ASHI meets or exceeds the applicable CLIA requirements. We have also determined that the ASHI will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the ASHI approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the subspecialty of General Immunology, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. As a result of this determination, any laboratory that is accredited by the ASHI during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be 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 the ASHI Commission Request for Approval as an Accreditation Organization Under CLIA**

The following describes the process used to determine that the ASHI accreditation program meets 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, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

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

The ASHI submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, 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. The ASHI policies and procedures for oversight of laboratories performing laboratory testing for the subspecialty of General Immunology,