

knowledge of beneficiaries' experiences with the care, as well as information on any potential health consequences due to changes in IG medication or participation in the Demonstration. Lastly, we will gather the physicians and nurses' views of the degree to which beneficiaries believe the program is effective, including the cost effectiveness for beneficiaries who use the services provided under the Demonstration. *Form Number:* CMS-10600 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; State, Local or Tribal Governments; Private Sector (Business or other for-profit); *Number of Respondents:* 2,488; *Total Annual Responses:* 2,488; *Total Annual Hours:* 483. (For policy questions regarding this collection contact Pauline Karikari-Martin at 410-786-1040).

Dated: April 19, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-09415 Filed 4-21-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1490S and CMS-10458]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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.

**DATES:** Comments must be received by June 21, 2016.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### CMS-1490S Patient's Request for Medicare Payment

#### CMS-10458 Consumer Research Supporting Outreach for Health Insurance Marketplace

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient's Request for Medicare Payment; *Use:* The Form CMS-1490S form provides beneficiaries with a relatively easy form to use when filing their claims. Without the collection of this information, claims for reimbursement relating to the provision of Part B medical services/supplies could not be acted upon. This would result in a nationwide paralysis of the operation of the Federal Government's Part B Medicare program, and major problems for the patients/beneficiaries inflicting severe physical and financial hardship on beneficiaries. This form was explicitly developed for easy use by beneficiaries who file their own claims. The CMS-1490S form can be obtained from any Social Security office or Medicare Administrative Contractors or CMS. When the CMS-1490S is used, the beneficiary must attach to it his/her bills from physicians or suppliers. The form is, therefore, designed specifically to aid beneficiaries who cannot get assistance from their physicians or suppliers for completing claim forms. The form is currently approved under 0938-1197; however, we are submitting for approval as a standalone information collection request. Once a new OMB control number is issued, we will remove the burden for the CMS-1490S that is currently approved under OMB control number 0938-1197. *Form Number:* CMS-1490 (OMB control number: 0938-NEW); *Frequency:* Occasionally *Affected Public:* Individuals and Households; *Number of Respondents:* 167,839; *Total Annual Responses:* 167,839; *Total Annual Hours:* 83,920. (For policy questions regarding this collection contact Sumita Sen at 410-786-5755.)

## 2. Type of Information Collection

*Request:* Extension of a currently approved collection; *Title of Information Collection:* Consumer Research Supporting Outreach for Health Insurance Marketplace; *Use:* The Centers for Medicare and Medicaid Services is requesting reapproval for two surveys that aid in understanding levels of awareness and customer service needs associated with the Health Insurance Marketplace established by the Affordable Care Act. Because the Marketplace will provide coverage to the almost 50 million uninsured in the United States through individual and small employer programs, we have developed one survey to be administered to individual consumers most likely to use the Marketplace and another to be administered to small employers most likely to use the Small Business Health Options portion of the Marketplace. These brief surveys, designed to be conducted quarterly, give CMS the ability to obtain a rough indication of the types of outreach and marketing that will be needed to enhance awareness of and knowledge about the Marketplace for individual and business customers. CMS' biggest customer service need is likely to be providing sufficient education so consumers: (a) Can take advantage of the Marketplace and (b) know how to access CMS' customer service channels. The surveys will provide information on media use, concept awareness, and conceptual or content areas where education for customer service delivery can be improved. Awareness and knowledge gaps are likely to change over time based not only on effectiveness of CMS' marketing efforts, but also of those of state, local, private sector, and nongovernmental organizations. *Form Number:* CMS-10458 (OMB control number: 0938-1203); *Frequency:* Quarterly; *Affected Public:* Individuals or households, Private Sector (business or other for-profits); *Number of Respondents:* 40,200; *Total Annual Responses:* 40,200; *Total Annual Hours:* 2,480. (For policy questions regarding this collection contact Frank Funderburk at 410-786-1820.)

Dated: April 19, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-09425 Filed 4-21-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3330-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 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 accreditation meets or exceeds the applicable CLIA requirements. We are announcing the approval and grant ASHI deeming authority for a period of 6 years.

**DATES:** *Effective Date:* This notice is effective from April 22, 2016 to April 21, 2022.

**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, we 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 us as an accreditation organization under CLIA.

## II. Notice of Approval of 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 ASHI meets or exceeds the applicable CLIA requirements. We have also determined that 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 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 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 ASHI Commission Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that ASHI accreditation program meets the necessary requirements to be approved by us and that, as such, we may approve ASHI as an accreditation program with deeming authority under the CLIA program. ASHI formally applied to us 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: