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:

A. 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, 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, the specialty of Histocompatibility, and the subspecialty of ABO/Rh typing are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. ASHI's requirements for monitoring and inspecting laboratories are the same as those previously approved by us 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 the accreditation programs submitted for approval are equal to the requirements of the CLIA regulations.

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

ASHI's requirements are equal to or more stringent than the CLIA requirements at § 493.801 through § 493.865.

For the specialty of Histocompatibility, ASHI requires participation in at least one external PT program, if available, in histocompatibility testing with an 80 percent score required for successful participation and enhanced PT for laboratories that fail an event. The CLIA regulations do not contain a requirement for external PT for the specialty of Histocompatibility. For the subspecialty of General Immunology, and the subspecialty of ABO/Rh typing, ASHI's requirements are equal to the CLIA requirements.

C. Subpart J—Facility Administration for Nonwaived Testing

ASHI's requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at § 493.1100 through § 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

The ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. For instance, ASHI's control procedure requirements for the test procedures Nucleic Acid Testing and Flow Cytometry are more specific and detailed than the CLIA language for requirements for control procedures. Section 493.1256 paragraphs (c)(1) and (c)(2) require control materials that will detect immediate errors and monitor accuracy and precision of test performance that may be caused by test system failures, environmental conditions and variance in operator performance. ASHI standards provide detailed, specific requirements for the control materials to be used to meet these CLIA requirements.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. Experience requirements for Director, Technical Supervisor, and General Supervisor exceed CLIA's personnel experience requirements in the specialty of Histocompatibility.

F. Subpart Q—Inspections

We have determined that the ASHI requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. ASHI 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.

G. Subpart R—Enforcement Procedures

ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. ASHI policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, ASHI will deny, suspend, or revoke accreditation in a laboratory accredited by ASHI and report that action to us within 30 days. ASHI also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that ASHI's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by ASHI 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, or 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. Withdrawal of Approval as an Accrediting Organization

Our regulations at 42 CFR 493.575 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 timeframe, we 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 document does not impose information collection requirements, that is, reporting, record keeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently

approved under OMB control number 0938–0686.

VII. Executive Order 12866 Statement

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

Dated: April 12, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–09301 Filed 4–21–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award a Single-Source Program Expansion Supplement Grant to BCFS Health and Human Services in San Antonio, TX

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice of award of a single-source program expansion supplement grant to BCFS Health and Human Services (BCFS) in San Antonio, TX.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of a single-source program expansion supplement grant for $5,820,000 to BCFS Health and Human Services (BCFS) in San Antonio, TX, under the Unaccompanied Children's (UC) Program to support a program expansion supplement.

The expansion supplement grant will support the need to increase shelter capacity to accommodate the increasing numbers of UCs being referred by DHS.

BCFS has a network of trained, qualified emergency staff able to bring on board and operate emergency beds in short timeframe. BCFS provides residential services to UC in the care and custody of ORR, as well as services to include counseling, case management, and additional support services to the family or to the UC and their sponsor when a UC is released from ORR's care and custody.

DATES: Supplemental award funds will support activities from October 1, 2015 through September 30, 2016.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: *DCSProgram@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: While the number of referrals, to the Unaccompanied Children Program in FY 2015, was below the total referrals from FY 2014, ORR has seen a change to recent referral trends. The UC program has seen an increase in the numbers of UC referred for placement since January 2015. FY15 was the first fiscal year, in the history of the UC program, in which there were eight (11) consecutive months of steadily increasing referrals. During FY 15, the largest total referrals occurred during August, with over 4,300 referrals, and these high referral numbers continued into the month of September with 4,172 referrals. In October and November, 2015, the DCS program has received referrals for initial placements for 10,158 unaccompanied children. ORR has experienced a steadily increasing census of UC in care, with longer average length of stay. This increase, in UC referred for placement, has increased the need for additional shelter beds.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet the service requirements and the urgent need for expansion of services. The program's ability to avoid a buildup of children waiting, in Border Patrol stations, for placement in shelters, can only be accommodated through the expansion of the existing program and its services through the supplemental award.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub.L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Christopher Beach,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–09383 Filed 4–21–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing a public workshop entitled ''Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Subject to Premarket Approval. The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

DATES: The public workshop will be held on September 8, 2016, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION: The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the rescheduling of a part 15 public hearing to September 12 and 13, 2016, to obtain input on four issued draft guidance