

and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Tribal Maternal, Infant, and Early Childhood Home Visiting Program Implementation Plan Guidance and

Form 1: Demographic and Service Utilization Data.

*OMB No.:* 0970-0389 (expired).

*Description:* Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended by the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (Public Law (Pub. L.) 114-10), created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation (authorized in Section 511(j)) for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions (authorized in Section 511(c)), and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The Administration for Children and Families, Office of Child Care and Office of the Deputy Assistant Secretary for Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awarded grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs and readiness assessments, plan for and implement high-quality, culturally-relevant, evidence-based home visiting

programs in at-risk Tribal communities, and engage in rigorous evaluation activities to build the knowledge base on home visiting among American Indian and Alaska Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment and (2) develop a plan to respond to identified needs. Grantees will be required to conduct or update a needs and readiness assessment and develop an implementation plan to respond to those needs, including a plan for demographic and service utilization data, performance measurement, and continuous quality improvement, and participating in or conducting rigorous evaluation activities. Grantees are expected to submit the implementation plan by the end of Year 1 of the grant, with draft submission milestones throughout the first year. As part of the non-competing continuation application for Years 3-5 of the grant, Tribal MIECHV grantees will update their implementation plans as necessary to ensure that the plan accurately reflects activities to be completed throughout the remainder of the grant.

Following each year that Tribal MIECHV grantees implement home visiting services, they must also submit Form 1: Demographic and Service Utilization Data.

*Respondents:* Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees. (The information collection does not include direct interaction with individuals or families that receive the services).

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Maternal, Infant, and Early Childhood Home Visiting Implementation Plan Guidance .....	25	1	1000	25,000
Tribal MIECHV Form 1 Demographic & Service Utilization Data & Service Data .....	25	1	500	12,500
Estimated Annual Burden Hours .....	.....	.....	.....	37,500

*Estimated Total Annual Burden Hours:* 37,500.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title

of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the

proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn:

Desk Officer for the Administration for Children and Families.

**Robert Sargis,**  
*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[CFDA Number: 93.676]

**Announcement of the Award of Two Single-Source Program Expansion Supplement Grants Under the Unaccompanied Children’s (UC) Program**

**AGENCY:** Office of Refugee Resettlement, ACF, HHS.

**ACTION:** Notice of award of two single-source program expansion supplement grants under the Unaccompanied Children’s (UC) Program.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of two single-source program expansion supplement grants for a total of \$16,476,723 under the Unaccompanied Children’s (UC) Program.

Organization	Location	Amount
BCFS Health and Human Services .....	San Antonio, TX .....	\$9,525,387
Southwest Key, Inc .....	Austin, TX .....	6,951,336

ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Children at the U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Children referred to its care by the Department of Homeland Security (DHS).

The expansion supplement grants will support the need to increase shelter capacity to accommodate the increasing numbers of UCs being referred by DHS. Both grantees 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 grantees provide 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](mailto:DCSProgram@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** ORR is continuously monitoring its capacity to shelter the unaccompanied children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

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 those requirements. The expansion of the existing program and its services through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Children referred to its care by DHS and so that the US Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

**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, Office of Administration, Office of Financial Services, Division of Grants Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-D-0350]

**Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process’; Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.’” FDA has developed this guidance document to assist industry in preparing Premarket Applications (PMAs), Humanitarian Device Exceptions (HDEs), Investigational Device Applications (IDEs), Premarket Notifications (510(k)s), and de novo requests for medical devices that come into direct contact or indirect contact with the human body in order to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body.

The purpose of this guidance is to provide further clarification and updated information on the use of International Standard ISO 10993-1, “Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process” to