and Evaluation, 330 C Street SW.,
Washington, DC 20201, Attn: ACF
Reports Clearance Officer. Email
address: 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.
[FR Doc. 2016–14229 Filed 6–15–16; 8:45 am]
BILLING CODE 4184–01–P

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

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tribal Maternal, Infant, and Early Childhood Home Visiting Implementation Plan Guidance</td>
<td>25</td>
<td>1</td>
<td>1000</td>
<td>25,000</td>
</tr>
<tr>
<td>Tribal MIECHV Form 1 Demographic &amp; Service Utilization Data &amp; Service Data</td>
<td>25</td>
<td>1</td>
<td>500</td>
<td>12,500</td>
</tr>
<tr>
<td>Estimated Annual Burden Hours</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>37,500</td>
</tr>
</tbody>
</table>

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.

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. Attn:
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, HHHS.

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.

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.

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.

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 (HHHS).
(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.

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, HHHS.
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