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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.*

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.

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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