

Prevention and the Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcing the Intent To Award a Single-Source Program Expansion Supplements to Cooperative Agreements Within the Office of Refugee Resettlement's Unaccompanied Children's (UC) Program

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: This notice announces the intent to award a single-source expansion supplement grant to existing grantees', BCFS Health and Human Services (90ZU0075) and the U.S. Committee for Refugees and Immigrants (90ZU0081), Cooperative Agreement within the Office of Refugee Resettlement's Unaccompanied Children's (UC) Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces its intent to award a cooperative agreement of up to \$3,311,087 as a single-source expansion supplements to the Post Release Services Programs within the Unaccompanied Children's (UC) Program.

The expansion supplement grants will support the immediate need for additional post-release services to accommodate the increasing number of UCs being referred by DHS, and as a result, the increase of UCs referred for post-release services. The increase in the UC population necessitates the need for expansion of services to expedite the release of UC. The *Flores v. Reno* settlement agreement requires that requires the timely release of children and youth to qualified parents, guardians, relatives or other adults, referred to as "sponsors."

DATES: Supplemental award funds will support activities from September 30, 2015 through September 29, 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 provide post-release services to the unaccompanied children in HHS custody.

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 post-release services program through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility of safe and timely release of 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-2016-D-1495]

Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions; 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 "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions." This guidance is intended to provide clarity for FDA staff and industry regarding the benefit and risk factors FDA may consider in prioritizing resources for compliance and enforcement efforts to maximize medical device quality and patient safety. Although product availability and other medical device compliance and enforcement decisions are generally fact-specific, FDA believes that explaining how we consider the factors listed in the guidance will improve the consistency and transparency of these kinds of decisions. A common understanding of how FDA considers benefit and risk may better align industry's and FDA's focus on actions that maximize benefit to patients, improve medical device quality, and reduce risk to patients. This guidance is in effect at this time.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").