

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.

**Elizabeth Leo,**

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

[FR Doc. 2021-25973 Filed 11-29-21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Mother and Infant Home Visiting Program Evaluation (MIHOPE): Long-Term Follow-Up, Kindergarten data collection (MIHOPE-K) [OMB #0970-0402]**

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF), in partnership with the Health Resources and Services Administration (HRSA), both of the U.S. Department of Health

and Human Services (HHS), is proposing to extend data collection activity as part of the kindergarten phase of the Mother and Infant Home Visiting Program Evaluation Long-Term Follow-Up project (MIHOPE-K). The purpose of MIHOPE-K is to conduct a follow-up study that assesses the long-term impact of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program when the participating children are in kindergarten. This **Federal Register** notice is seeking to extend data collection for the kindergarten follow-up. The original **Federal Register** notices for the MIHOPE-K data collection were titled under MIHOPE-Long-Term Follow-Up (MIHOPE-LT).

**DATES:** Comments due December 30, 2021. OMB must make a decision about 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.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**SUPPLEMENTARY INFORMATION:** *Description:* This request for an extension is to complete the following data collection activities for MIHOPE-K:

(1) A survey with the child’s primary caregiver (who will be the mother if she is available), (2) direct assessments of child development, (3) surveys with the child’s teacher, (4) a direct assessment of the caregiver, (5) videotaped interactions between the caregiver and child, (6) a caregiver website to provide current contact information, (7) state child welfare records, and (8) school records. In addition to collecting these data, the MIHOPE-K project will continue to maintain up-to-date consent forms for the collection of administrative data. Future information collection requests and related **Federal Register** notices will describe future data collection efforts for this project.

Data collected during the kindergarten follow-up study is being used to estimate the effects of MIECHV-funded programs on the following seven domains: (1) Maternal health, (2) child health, (3) child development and school performance, (4) child maltreatment, (5) parenting, (6) crime or domestic violence, and (7) family economic self-sufficiency.

*Respondents:* The respondents in this extension will include 1,391 families who have not yet participated in the kindergarten follow-up study activities. We have assumed that only 25 percent of respondents will complete the caregiver website. We will also obtain child welfare data from the 11 MIHOPE states and school records data from state and local agencies. We have assumed that we will obtain data from 11 states and 5 local education agencies.

**ANNUAL BURDEN ESTIMATES**

Instrument	No. of respondents (total over request period)	No. of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
<b>Burden for previously approved, ongoing data collection</b>					
Survey of caregivers .....	1,391	1	0.99	1,377	689
Direct assessments of children .....	1,391	1	1.33	1,850	925
Survey of the focal children’s teachers .....	1,391	1	0.5	696	348
Direct assessments of caregivers .....	1,391	1	0.17	236	118
Videotaped caregiver-child interactions .....	2,782	1	0.25	696	348
Caregiver website .....	348	1	0.17	59	30
State child welfare records: data file submission .....	11	2	15	330	165
School records: data file submission .....	16	2	22.5	720	360

*Estimated Total Annual Burden Hours: 2,983*

*Authority:* Social Security Act Title V 511 [42 U.S.C. 711]. As extended by the

Bipartisan Budget Act of 2018 (Pub. L. 115-123) through FY22.

Linda Hitt,

ACF Certifying Officer.

[FR Doc. 2021-26102 Filed 11-26-21; 4:15 pm]

BILLING CODE 4184-74-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.676]

#### Announcement of Intent To Issue Replacement Award To Provide Residential Services (Shelter)

**AGENCY:** Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

**ACTION:** Notice of issuance of Replacement Award to Lutheran Social Services of the South Upbring (LSS Upbring).

**SUMMARY:** ACF, ORR announces the intent to award a Replacement Award to LSS Upbring in the amount of up to \$20,929,074 in Brownsville, Texas. On September 17, 2021, Comprehensive Health Services, LLC (CHS) relinquished a federally funded discretionary grant. Per HHS policy, ORR has identified current recipient LSS Upbring to transfer the current permanent capacity to provide shelter for apprehensions of Unaccompanied Children (UC) at the Southwest Border. The continuation of permanent capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter and appropriate services for UC referred to its care by the Department of Homeland Security. The purpose of this award is to ensure the continuation of residential services for the capacity of 76 shelter beds for UC.

**DATES:** The proposed period of performance is December 1, 2021–September 30, 2022.

**FOR FURTHER INFORMATION CONTACT:** Stephen Antkowiak, Office of Refugee Resettlement, Division of Unaccompanied Children Operations, 330 Street SW, Washington, DC 20447. Phone: 202-260-6165. Email: [stephen.antkowiak@acf.hhs.gov](mailto:stephen.antkowiak@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** ORR announces the intent to award a Replacement Award to LSS Upbring in the amount of up to \$20,929,074. This award will prevent the disruption in residential services currently available at the CHS Loma Alta location and prevent children unnecessarily pending placement from Border Patrol.

ORR has specific requirements for the provision of services. Award recipients

must have the infrastructure, licensing if applicable, experience, and appropriate level of trained staff to meet those requirements.

**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 UC from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR within HHS.

(B) The Flores Settlement Agreement, Case No. CV85-4544-RJK (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.

Elizabeth Leo,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-D-1146]

#### Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry; 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 a draft guidance for industry entitled “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision-making. This guidance provides sponsors and other stakeholders with considerations when either proposing to design a registry or using an existing registry to support regulatory decision-making about a drug’s effectiveness or safety.

**DATES:** Submit either electronic or written comments on the draft guidance by February 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2021-D-1146 for “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.