

## Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

### CMS-10635 Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

1. *Type of Information Collection Request*: New collection (Request for a new OMB control number); *Title of Information Collection*: Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation; *Use*: CMS approved the Montana Health and Economic Livelihood Partnership (HELP) demonstration in November 2015. The demonstration provides flexibility for the expanded Medicaid

population under the Affordable Care Act for individuals in the state of Montana (hereinafter, “State” or “Montana”).

Montana expects to achieve the following: (1) Premiums and copayment liability that will encourage HELP Program enrollees to be discerning health care purchasers, take personal responsibility for their health care decisions and develop health-conscious behaviors as consumers of health care services; (2) 12 month continuous eligibility to improve continuity of care. The State also seeks to demonstrate the following over the life of the demonstration: (1) Premiums will not pose a barrier to accessing care for HELP Program beneficiaries; (2) HELP Program enrollees will exhibit health-conscious health care behaviors without harming beneficiary health; and (3) 12 month continuous eligibility will promote continuity of coverage and reduce churning rates.

The demonstration includes the authority to charge premiums of 2 percent of household income to individuals in the new adult group with incomes between 50 and 133 percent of the FPL. The state will credit such individuals' premium obligation towards copayments due. Non-payment of premiums may result in disenrollment for individuals with incomes above 100 percent of the FPL after notice and a grace period. Individuals at or below 100 percent who stop paying premiums will not be disenrolled.

To adequately inform CMS decision-making regarding Section 1115 Demonstrations, this federal evaluation of Montana's HELP demonstration includes surveys and associated focus groups, and informational interviews conducted during site visits and via phone.

*Form Number*: CMS-10635 (OMB control number: 0938—New); *Frequency*: Once and on occasion; *Affected Public*: Individuals and Households, Business or other for-profits and Not-for-profits institutions, and State, Local, or Tribal Governments; *Number of Respondents*: 1,458; *Total Annual Responses*: 1,458; *Total Annual Hours*: 497. (For policy questions regarding this collection contact Serge King at 410-786-6052.)

Dated: October 18, 2016.

**William N. Parham, III**,  
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-25547 Filed 10-20-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.576]

#### Announcement of the Award of 38 Single-Source Low-Cost Extension Supplement Grants Under the Refugee School Impact Grant Program

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

**ACTION**: Notice of award of 38 single-source low-cost extension supplement grants under the Refugee School Impact Grant Program.

**SUMMARY**: ACF, ORR announces the award of 38 single-source low-cost extension supplement grants for a total of 2,500,000 under the Refugee School Impact Grant Program.

State	Grantee	Amount
Alaska .....	Catholic Social Services .....	\$25,736
Arizona .....	Arizona Department of Social Security .....	102,972
California .....	California Department of Social Services .....	171,426
Colorado .....	Colorado Department of Human Services .....	67,332
Connecticut .....	Connecticut Department of Social Services .....	25,736
Florida .....	Florida Department of Children and Families .....	171,426
Georgia .....	Georgia Department of Human Services .....	108,709
Idaho .....	Jannus Inc. ....	32,098
Illinois .....	Illinois Department of Human Services .....	77,224
Indiana .....	Indiana Division of Disability & Rehabilitation .....	49,713
Iowa .....	Iowa Department of Human Services .....	25,736
Kentucky .....	Catholic Charities of Louisville .....	67,784
Maine .....	Maine Department of Health and Human Services .....	25,736
Maryland .....	Maryland Department of Human Resources .....	51,296
Massachusetts .....	Massachusetts Office for Refugees and Immigrants .....	69,049
Michigan .....	Michigan Department of Human Services .....	116,658
Minnesota .....	Minnesota Department of Human Services .....	86,304
Missouri .....	Missouri Department of Social Services .....	42,081
Nebraska .....	Nebraska Dept. of Health and Human Services .....	30,969
Nevada .....	Clark County School District .....	25,736

State	Grantee	Amount
New Hampshire .....	NH. Dept. of Health & Human Services .....	25,736
New Jersey .....	New Jersey Department of Human Services .....	25,736
New Mexico .....	New Mexico Human Services Department .....	25,736
New York .....	NY Office of Temporary and Disability Assistance .....	171,426
North Carolina .....	North Carolina Dept. of Health & Human Services .....	84,000
North Dakota .....	North Dakota Department of Public Instruction .....	25,736
Ohio .....	Ohio Department of Job and Family Services .....	73,746
Oregon .....	Lutheran Community Services Northwest .....	39,822
Pennsylvania .....	Commonwealth of Pennsylvania .....	100,488
Rhode Island .....	Rhode Island Department of Human Services .....	25,736
South Dakota .....	Lutheran Social Services of South Dakota .....	25,736
Tennessee .....	Catholic Charities of Tennessee, Inc. ....	56,671
Texas .....	Texas Health and Human Services Commission .....	171,426
Utah .....	Utah Department of Workforce Services .....	43,797
Vermont .....	Vermont Agency of Human Services .....	25,736
Virginia .....	Virginia Department of Social Services .....	66,428
Washington .....	WA State Department of Social & Health Services .....	107,083
Wisconsin .....	Wisconsin Department of Public Instruction .....	31,240
Total .....	.....	2,500,000

ORR provides 28 States and ten Wilson-Fish agencies with Refugee School Impact funding to undertake a comprehensive statewide approach supporting local school systems that are impacted by significant numbers of newly arrived refugee children. As currently awarded, the FY14–16 Refugee School Impact funding period concludes on August 14, 2016. Beginning in FFY17, ORR will award Refugee School Impact funding as a formula set-aside within the Refugee Social Services funding awarded to all States and Wilson-Fish programs coordinating refugee resettlement. This change in timing for Refugee School Impact funding will create a gap in Refugee School Impact program services between August 15, 2016 and October 1, 2016. The low-cost extensions will support refugee access to services critical to refugee student success at the beginning of the school year, when such services are greatest and most urgent.

**DATES:** Low-cost extension supplement grants will support activities from August 15, 2016, through September 30, 2016.

**FOR FURTHER INFORMATION CONTACT:** Carl Rubenstein, Director, Division of Refugee Assistance, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: [carl.rubenstein@acf.hhs.gov](mailto:carl.rubenstein@acf.hhs.gov).

**Statutory Authority:** This program is authorized by Section 412(c)(1)(A)(iii) of the Immigration and Nationality Act (INA), 8 U.S.C. 1522(c)(1)(A)(iii).

**Christopher Beach,**  
Senior Grants Policy Specialist, Office of Administration, Office of Financial Services, Division of Grants Policy.

[FR Doc. 2016–25496 Filed 10–20–16; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0319]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by November 21, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0754. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information—OMB Control Number 0910–0754—Extension

This final Guidance for Industry and FDA staff entitled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information” offers specific guidance to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising.

This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information and have been unable to communicate it to patients because the letters’ content and length have made it difficult to find the relevant information. In addition, letters have