

potential long term effects caused by lead exposure, this single source emergency funding opportunity must solely be available to the Greater Flint Health Coalition (GFHC) which is uniquely positioned to meet the goals of the emergency cooperative agreement based on the organization's location, capacity, partnerships, resources, prior experience, and ability to begin implementing the project immediately. Prior to the water crisis in Flint, the GFHC worked to significantly improve the health status of Flint residents by establishing a common health agenda and instituting a shared measurement system among local hospitals with mutually reinforcing health activities. In addition, this organization currently administers programs that involve a variety of constituents important to reaching and enrolling children in Medicaid and CHIP, such as schools, health homes, safety net providers, and various government organizations. The GFHC's presence in the greater Flint community enabled them to become an early leader in alerting the public about the lead exposure related to the Flint water system.

Utilizing the funding under this single-source award, the GFHC will be able to immediately hire an outreach and enrollment coordinator to educate beneficiaries about Medicaid and CHIP services available to affected children and families in Flint, Michigan and to coordinate community-based activities designed to support Medicaid enrollment for eligible children. More broadly, this funding will enable the GFHC to address the lead exposure related to the Flint water system by promoting critical public health, medical, and community-based services and interventions that address and mitigate the detrimental short and long term impacts of lead. Due to these reasons and the GFHC's cross sector collaboration with Genesee County's

public health leadership, physicians, hospitals, and health insurers, GFHC has the full capacity to begin implementation of the project tasks immediately.

### III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 16, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.583]

### Announcement of the Award of Single-Source Grants Under the Wilson-Fish Alternative Program (W-F)

**AGENCY:** Office of Refugee Resettlement, ACF, HHS.

**ACTION:** Announcement of 13 single-source awards under the Wilson-Fish (W-F) Alternative Program.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of 13 single-source grants for a total of \$35,513,938 under the W-F Alternative Program.

**DATES:** September 30, 2015 through September 29, 2016.

### FOR FURTHER INFORMATION CONTACT:

Colleen Mahar-Piersma, Program Analyst, Office of Refugee Resettlement, Aerospace Building, 8th Floor West, 901 D Street SW., Washington, DC 20447. Telephone: 202-401-6891; Email: [colleen.mahar-piersma@acf.hhs.gov](mailto:colleen.mahar-piersma@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Wilson-Fish Alternative Program is intended to be an alternative to state-administered refugee assistance program that ensures that refugee assistance programs exist in every state where refugees are resettled. The W-F Alternative Program provides integrated assistance (cash and medical) and services (employment, case management, English language instruction, and other social services) to eligible clients in order to increase their prospects for early employment and self-sufficiency, reduce their level of welfare dependence, and promote coordination among voluntary resettlement agencies and service providers. W-F Alternative Program eligible clients include refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, Trafficking Victims, and Iraqi/Afghani Special Immigrant Visa holders.

The W-F Alternative Program, which operates in 13 states, is one of three models outlined in the ORR regulations for the purpose of providing refugee cash assistance (RCA) to new arrivals. The W-F Alternative Program utilizes a "one stop shop" model in which services and assistance are administered by a single agency.

Grant awards were made to 12 statewide W-F Alternative Programs in Alabama, Alaska, Colorado, Idaho, Kentucky, Louisiana, Massachusetts, Nevada, North Dakota, South Dakota, Tennessee, and Vermont. An award was also made to one countywide program in San Diego County, CA.

The W-F grant recipients are:

Grantee name	Location	Award amounts
Catholic Social Services .....	Mobile, AL .....	\$414,037
Catholic Social Services .....	Anchorage, AK .....	718,916
Colorado Department of Human Services .....	Denver, CO .....	2,955,177
Jannus Inc.—Idaho Office for Refugees .....	Boise, ID .....	2,304,414
Catholic Charities—Louisville .....	Louisville, KY .....	4,856,018
Catholic Charities Diocese of Baton Rouge .....	Baton Rouge, LA .....	1,463,000
Massachusetts Office of Refugees & Immigrants .....	Boston, MA .....	3,814,588
Catholic Charities of Southern Nevada .....	Las Vegas, NV .....	4,349,921
Lutheran Social Services of North Dakota .....	Fargo, ND .....	1,378,169
Catholic Charities Diocese of San Diego .....	San Diego, CA .....	3,534,100
Lutheran Social Services of South Dakota .....	Sioux Falls, SD .....	841,890
Catholic Charities of Tennessee, Inc. .....	Nashville, TN .....	8,299,523
US Committee for Refugees & Immigrants .....	Burlington, VT .....	584,185

It is expected that ORR will continue to provide awards to the listed grantees for a 4-year project period. Grantees will be required to submit applications for noncompetitive awards for the subsequent years of the project period. Future noncompetitive awards will be based on the grantee's performance, the availability of funds, and the best interest of the Federal Government.

**Statutory Authority:** The Refugee Act of 1980 as amended, Wilson-Fish Amendment, Public Law 98-473, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

**Mary M. Wayland,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-1021]

**Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled "Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development" that appeared in the **Federal Register** of December 29, 2016 (80 FR 81335). The document announced the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in Fiscal Year (FY) 2016. The document was published with the incorrect number of years in which CDRH committed to finalize, withdraw, re-open the comment period, or issue another draft guidance on the topic for 80 percent of the documents. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Tuesday, December

29, 2015, in FR Doc. 2015-32726, the following correction is made:

1. On page 81336, in the third column, in the 13th sentence of the second paragraph under section II, *CDRH Guidance Development Initiative*, "2 years" is corrected to read "3 years".

Dated: August 16, 2016.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-2473]

**Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests; Public Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests." The purpose of this workshop is to obtain feedback on two FDA draft guidances, "Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases" and "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics" that describes new approaches to regulate NGS-based tests.

**DATES:** The public workshop will be held on September 23, 2016, from 9 a.m. to 3 p.m. Submit either electronic or written comments on the public workshop by October 6, 2016.

**ADDRESSES:** The workshop will be held in Masur Auditorium at the NIH Campus, 9000 Rockville Pike, Bldg. 10, Bethesda, MD 20814. For parking and security information, please refer to the NIH Campus Visitor Information: <http://www.nih.gov/icd/od/ocpl/VIC/index.htm>.

You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-2473 for "Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The