

characteristics of in vitro diagnostic devices for the detection of MRSA, including those for the detection or detection and differentiation of MRSA versus SA in either human specimens or bacterial growth detected by continuous monitoring blood culture systems. These devices are used to aid in the prevention and control of MRSA/SA infections in health care settings. This document is limited to studies intended to establish the performance characteristics of devices that detect MRSA by growth in culture media or those devices that test for the protein, penicillin-binding protein 2a (PBP2a or PBP2'), expressed by the *mecA* gene. This includes culture-based devices that use selective or chromogenic media. It does not address the detection of serological response from the host to the MRSA antigens or establish the performance of non-MRSA components of multianalyte or multiplex nucleic acid based devices.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection of MRSA for culture-based devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Methicillin-Resistant *Staphylococcus Aureus* (MRSA) for Culture-Based Devices," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1729 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of

information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485; and the collections of information in 42 CFR 493.15 have been approved under OMB control number 0910-0598.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 9, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Refugee Resettlement

#### Award of an Urgent Single-Source Grant to Heartland Alliance, Chicago, IL

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

**ACTION:** Notice.

*CFDA Number:* 93.676.

**Statutory Authority:** Awards announced in this notice are authorized by Section 412 (c)(1)(A) of the Immigration and Nationality Act (INA) (8 U.S.C. 1522(c)(1)(A), as amended, and the Refugee Assistance Extension Act of 1986, Public Law 99-605, Nov 6, 1986, 100 Stat. 3449.

**Project Period:** June 1, 2011-May 31, 2012.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of a single-source grant for

training and technical assistance on incoming Lesbian, Gay, Bi-Sexual and Transgender (LGBT) refugee cases to Heartland Alliance, Chicago, IL, for a total of \$250,000. The additional funding provided by the award will support services to refugees through May 31, 2012.

The current resettlement network has limited understanding of the issues and subgroups. Heartland Alliance will develop training and technical assistance resources, including capacity building and service delivery, specifically targeted at assisting newly arriving LGBT refugees.

Heartland Alliance will have the opportunity to receive a continuation award at the same amount in FY 2012, which will provide the grantee with a two-year project period.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Tota, Deputy Director, Office of Refugee Resettlement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone (202) 401-4858.

Dated: June 10, 2011.

**Eskinder Negash,**

*Director, Office of Refugee Resettlement.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)