

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Work Participation and TANF/WIA Coordination Project.

OMB No.: New collection.

Description: The Administration for Children and Families (ACF) is

proposing an information collection activity as part of the Work Participation and TANF/WIA Coordination Project. The proposed information collection consists of semi-structured interviews with key state/and or local Temporary Assistance for Needy Families (TANF) and Work Investment Act (WIA) respondents on questions of engagement in additional work activities and expenditures of other benefits and services as well as questions concerning TANF/WIA Coordination. Through this

information collection, ACF seeks to elucidate the data presented in reports submitted by states to the ACF Office of Family Assistance (OFA) as required by the Claims Resolution Act of 2010. This collection is separate from the state reports to OFA required by the Act. In addition, it will provide documentation of positive TANF/WIA coordination activities.

Respondents: State and/or local administrators responsible for the TANF and WIA Programs.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide for Use with State TANF officials	40	2	8	640

Estimated Total Annual Burden Hours: 640.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: OPREinfocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget Paperwork Reduction Project Fax: 202-395-6974 *Attn:* Desk Officer for the Administration for Children and Families.

Dated: June 7, 2011.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2011-14627 Filed 6-14-11; 8:45 am]

BILLING CODE 4184-09-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0378]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Methicillin-Resistant *Staphylococcus Aureus* for Culture-Based Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Methicillin-Resistant *Staphylococcus Aureus* for Culture-Based Devices." This draft guidance document provides industry and Agency staff with recommendations for studies for establishing the performance characteristics of in vitro diagnostic devices for the detection of methicillin-resistant *S. aureus* (MRSA), including those for the detection or detection and differentiation of MRSA versus *S. aureus* (SA) in either human specimens or bacterial growth detected by continuous monitoring blood culture systems. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

either electronic or written comments on the draft guidance by September 13, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Methicillin-Resistant *Staphylococcus Aureus* (MRSA) for Culture-Based Devices" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alexandra Wong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5502, Silver Spring, MD 20993-0002, 301-796-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to provide industry and Agency staff with recommendations for studies for establishing the performance

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 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.

[FR Doc. 2011-14789 Filed 6-14-11; 8:45 am]

BILLING CODE 4160-01-P

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.

[FR Doc. 2011-14841 Filed 6-14-11; 8:45 am]

BILLING CODE 4120-27-P

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)