

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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This draft guidance refers to previously approved collections of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.*

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

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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)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Transformation Accountability Reporting System—(OMB No. 0930-0285)—Revision**

This revised instrument will allow SAMHSA to collect information on two new strategic initiatives—*Trauma and Violence and Military Families*. The new items will be added to the Transformation Accountability (TRAC) Reporting System is a real-time, performance management system that captures information on mental health services delivered in the United States. A wide range of client and program information is captured through TRAC for approximately 400 grantees.

With the addition of new questions regarding military families, experiences with trauma, and experiences with violence GFA, there is a proposed new data collection instrument up for comment. Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

CMHS has increased the number of questions in the instrument to satisfy reporting needs. The following paragraphs present a description of the changes made to the information collection. These questions will be contained in new sections in the Services tool.

*Violence and Trauma*—CMHS proposes to add the following 6 items in

a new section entitled “Violence and Trauma”

1. Have you ever experienced violence or trauma in any setting (including community or school violence; domestic violence; physical, psychological, or sexual maltreatment/assault within or outside of the family; natural disaster; terrorism; neglect; or traumatic grief)? No, (skip to next section)

2. Did any of these experiences feel so frightening, horrible, or upsetting that in the past and/or the present that you:

2a. Have had nightmares about it or thought about it when you did not want to?

2b. Tried hard not to think about it or went out of your way to avoid situations that remind you of it?

2c. Were constantly on guard, watchful, or easily startled?

2d. Felt numb and detached from others, activities, or your surroundings?

3. In the past 30 days, how often have you been hit, kicked, slapped, or otherwise physically hurt?

• *Experiences with Violence and Trauma*—One of SAMHSA’s 10 Strategic Initiatives is trauma and violence. In order to capture this information, CMHS is adding six new questions to be asked of respondents. This information will help in SAMHSA’s overall goal of reducing the behavioral health impacts of violence and trauma by encouraging substance abuse treatment programs to focus on trauma-informed services.

*Military Family and Deployment*—CMHS proposes to add the following 6 new items in a new section entitled “Military Family and Deployment”

1. Have you ever served in the Armed Forces, in the Reserves, or the National Guard [select all that apply]? No, (Skip to #2)

1b. Are you currently on active duty in the Armed Forces, in the Reserves, or the National Guard [select all that apply]?

1c. Have you ever been deployed to a combat zone?

2. Is anyone in your family or someone close to you on active duty in the Armed Forces, in the Reserves, or the National Guard, or separated or retired from Armed Forces, Reserves, or the National Guard? No, (Skip to next section)

3. What is the relationship of that person (Service Member) to you?

3b. Has the Service Member experienced any of the following (check all that apply):

- Deployed in support of Combat Operations (e.g. Iraq or Afghanistan)
- Was physically Injured during combat Operations
- Developed combat stress symptoms/difficulties adjusting following deployment, including PTSD, Depression, or suicidal thoughts
- Died or was killed

• *Veteran Family Status and Areas of Deployment*—SAMHSA is also interested in collecting data on active duty and veteran military members. Collection of these data will allow CMHS to identify the number of veterans served, deployment status and location, and family veteran status in conjunction with the types of services they may receive. Identifying a client’s veteran status and deployment area allows CMHS and the grantees to monitor these clients and explore whether special services or programs are needed to treat them for substance abuse and other related issues. Identification of veteran status and other military family issues will also allow coordination between SAMHSA and other Federal agencies in order to provide a full range of services to veterans. CMHS will also be able to monitor their outcomes and activities per the NOMS. The total annual burden estimate is shown below:

**ESTIMATES OF ANNUALIZED HOUR BURDEN—CMHS CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS**

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage cost	Total hour cost
Client-level baseline interview .....	15,681	1	15,681	0.48	7,527	\$15 <sup>1</sup>	\$112,905
Client-level 6-month reassessment interview	10,646	1	10,646	0.367	3,907	15	58,605
Client-level discharge interview <sup>2</sup> .....	4,508	1	4,508	0.367	1,655	15	24,825
Client-level baseline chart abstraction .....	2,352	1	2,352	0.1	235	15	3,525
Client-level reassessment chart abstraction <sup>3</sup> .....	9,017	1	9,017	0.1	902	15	13,530
Client-level Sub-total <sup>4</sup> .....	15,681	.....	15,681	.....	14,226	15	213,390

ESTIMATES OF ANNUALIZED HOUR BURDEN—CMHS CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS—  
Continued

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Hourly wage cost	Total hour cost
Infrastructure development, prevention, and mental health promotion quarterly record abstraction .....	942	4	3,768	4	15,072	35 <sup>5</sup>	527,520
Total .....	16,623	.....	.....	.....	29,298	.....	740,910

<sup>1</sup> Based on minimum wage.

<sup>2</sup> Based on an estimate that it will be possible to conduct discharge interviews on 40 percent of those who leave the program.

<sup>3</sup> Chart abstraction will be conducted on 100 percent of those discharged.

<sup>4</sup> This is the maximum additional burden if all consumers complete the baseline and periodic reassessment interviews.

<sup>5</sup> To be completed by grantee Project Directors, hence the higher hourly wage.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, 1 Choke Cherry Road, Rockville, MD 20857 or e-mail her a copy at [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received within 60 days of this notice.

Dated: June 8, 2011.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2011-14797 Filed 6-14-11; 8:45 am]

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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)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: National Outcome Measures (NOMs) for Substance Abuse Prevention—(OMB No. 0930-0230)—Revision**

This revised instrument will allow SAMHSA to collect information on a new strategic initiative—*Military Families*. The new items will be added to the Center for Substance Abuse Prevention's (CSAP) National Outcome Measures for Substance Abuse Prevention (NOMs). Data are collected from SAMHSA/CSAP grants and contracts where community and participant outcomes are assessed. The analysis of these data helps determine whether progress is being made in achieving SAMHSA/CSAP's mission. The primary purpose of this system is to promote the use among SAMHSA/CSAP grantees and contractors of common National Outcome Measures recommended by SAMHSA/CSAP with significant input from panels of experts and state representatives.

With the addition of new questions regarding military families, there is a proposed new data collection instrument up for comment. Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance, and address goals and objectives outlined in the Office of National Drug Control Policy's Performance Measures of Effectiveness.

CSAP has increased the number of questions in the instrument to satisfy

reporting needs. The following paragraphs present a description of the changes made to the information collection. These questions will be contained in new sections in the Services tool.

*Military Family and Deployment*—CSAP proposes to add the following 6 new items in the adult tool and 3 new items in the youth tool in a new section entitled "Military Family and Deployment."

**Adult**

1. Have you ever served in the Armed Forces, in the Reserves, or the National Guard [select all that apply]? No, (Skip to #2)
  - 1b. Are you currently on active duty in the Armed Forces, in the Reserves, or the National Guard [select all that apply]?
    - 1c. Have you ever been deployed to a combat zone?
2. Is anyone in your family or someone close to you on active duty in the Armed Forces, in the Reserves, or the National Guard, or separated or retired from the Armed Forces, Reserves, or the National Guard? No, (Skip to next section)
3. What is the relationship of that person (Service Member) to you?
  - 3b. Has the Service Member experienced any of the following (check all that apply):
    - Deployed in support of Combat Operations (e.g. Iraq or Afghanistan)
    - Was physically Injured during Combat Operations
    - Developed combat stress symptoms/difficulties adjusting following deployment, including PTSD, Depression, or suicidal thoughts
    - Died or was killed

**Youth**

1. Is anyone in your family or someone close to you on active duty in the Armed Forces, in the Reserves, or the National Guard, or separated or retired from Armed Forces, Reserves, or the National Guard? No, (Skip to next section)
2. What is the relationship of that person (Service Member) to you?