

settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS-1728-94 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. *Form Number:* CMS-1728-94 (OMB control number: 0938-0022); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 11,352; *Total Annual Responses:* 11,352; *Total Annual Hours:* 2,576,904. (For policy questions regarding this collection contact Angela DiGorgio at 410-786-4516.)

Dated: February 5, 2016.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.
OMB No.: 0970-0223.
Description: Section 454(15)(A) of the Social Security Act, as amended by the

Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@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: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for

the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Microenterprise and Refugee Home-Based Child Care Microenterprise Development Programs
OMB No.: New
Description: The Office of Refugee Resettlement (ORR) within the Administration for Children and Families (ACF) is responsible for resettling thousands of refugees every year from all over the world. The main goal of the ORR (US) refugee domestic resettlement program is to assist the refugees in becoming self-reliant at the shortest time possible. ORR has many different discretionary grants that it employs to accomplish this goal. Two of the discretionary grants are the Refugee Microenterprise Development (MED) and the Refugee Home-Based Child Care

Microenterprise Development (HBCC MED) Programs. The goals of the MED program are to assist refugees in becoming economically self-sufficient, assist refugee serving organizations galvanize resources to strengthen their capacities to expand and continue their microenterprise services at an expanded and sustainable level, and enhance the integration to the mainstream and realize the American Dream. The focus of the HBCC Program is on women that have limited opportunity to get employment at livable wages because of limited transferable skills and lack of knowledge of the English language. Through the program women refugees are provided basic training in child care and development, state and local legal requirements to get a license and to establish a home-based child care service. The ultimate goal of the program is to enable the women refugees establish a home-based child care service in their neighborhood.

ORR works with nonprofit organizations in implementing these projects. Currently, there are 22 projects in the Refugee Microenterprise Development Program and 23 projects in the Refugee Home-Based Child Care Microenterprise Development Program. It is critical to collect data through a semi-annual report in order to determine whether or not the programs are achieving their intended goals, to address concerns, issues, and challenges

the grantees may be experiencing in implementing their projects on a timely

manner, and, for writing Annual Report to Congress.

Refugee Home-Based Child Care Microenterprise Development Program 23

Respondents: Refugee Microenterprise Development Program 22.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondents	Average burden hours per respondents	Total burden hours
Refugee Microenterprise Development Program	22	8	4	88
Refugee Home-Based Child Care Microenterprise Development Program ...	23	7	4	92
Total Burden				180

Estimated Total Annual Burden Hours: 180

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0343]

Advancing the Development of Biomarkers in Traumatic Brain Injury; 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, "Advancing the Development of Biomarkers in Traumatic Brain Injury." This workshop aims to examine potential biomarkers, discuss the challenges and solutions related to biomarker development methodologies, and establish strategies for data standardization, sharing and analysis of big data sets for traumatic brain injury (TBI). By convening the relevant stakeholders, the goal is to obtain input on the scientific, clinical, patient, and regulatory considerations associated with TBI biomarker development to improve diagnosis and clinical utility for TBI.

DATES: The public workshop will be held on March 3, 2016, from 8 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by May 3, 2016.

ADDRESSES: 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-0343 for "Advancing the Development of Biomarkers in Traumatic Brain Injury." 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.