

Description: The Office of Refugee Resettlement (ORR) reimburses, to the extent of available appropriations, certain non-federal costs for the provision of cash and medical assistance to refugees, along with allowable expenses for the administration the refugee resettlement program at the State level. States (Replacement Designees and Wilson/Fish projects; *i.e.*, alternative projects for the administration of the refugee resettlement program) currently submit the ORR-2 Quarterly Report on Expenditures and Obligations, which provides aggregate expenditure and obligation data. This proposed data collection collects expenditures and obligations data separately for each of the four CMA program components:

Refugee cash assistance, refugee medical assistance, cash and medical assistance administration, and services for unaccompanied minors. This breakdown of financial status data allows ORR to track program expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at CFR 400.211 to collect these data for use in estimating future costs of the refugee resettlement program. ORR must implement the methodology at CFR 400.211 each year after receipt of its annual appropriation to ensure that appropriated funds will be adequate for reimbursement to States of the costs for assistance provided to entering refugees. The estimating methodology prescribed in the

regulations requires the use of actual past costs by program component. In the event that the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance. This proposed single-page financial report allows ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations.

Respondents: State governments, Replacement Designees, and Wilson/Fish Alternative Projects.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR Financial Status Report Cash and Medical Assistance Program, Quarterly Report on Expenditures and Obligations	57	4	1.50	342

Estimated Total Annual Burden Hours: 342.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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, 330 C Street SW, Washington, DC 20201. 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

Administration for Children and Families

[OMB No.: 0970-0422]

Submission for OMB Review; Comment Request

Title: Adoption and Foster Care Analysis Reporting System for title IV-B and title IV-E (AFCARS).

Description: The Adoption and Foster Care Analysis and Reporting System (AFCARS) is mandated by 42 U.S.C. 679. The regulation at 45 CFR 1355 sets forth the requirements of the statute for the collection of uniform, reliable information on children who are under the responsibility of the State or Tribal

title IV-B/IV-E agency for placement, care, and adoption. Effective October 1, 2009, section 479B(b) of the Act authorizes direct Federal funding of Indian Tribes, Tribal organizations, and Tribal consortia that choose to operate a foster care, adoption assistance and, at Tribal option, a kinship guardianship assistance program under title IV-E of the Act. The Federal regulations at 45 CFR 1355.40 were amended as part of an Interim Final Rule published January 6, 2012 to apply the same regulatory requirements for data collection and reporting to a Tribal title IV-E agency as are applied to a State title IV-E agency.

The data collected will inform State/Tribal/Federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data are used for short/long-term budget projections, trend analysis, child and family service reviews, and to target areas for improved technical assistance. The data will provide information about foster care placements, adoptive parents, length of time in care, delays in termination of parental rights and placement for adoption.

Respondents: Title IV-E State and Tribal Child Welfare Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS	72	2	1,786	257,184

Estimated Total Annual Burden Hours: 257,184.

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

[OMB No. 0970-0177]

Proposed Information Collection Activity; Comment Request

Title: OCSE-157 Child Support Enforcement Program Annual Data Report.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-157	54	1	7	378

Estimated Total Annual Burden Hours: 378.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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, 330 C Street SW, Washington, DC 20201. 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-2017-D-6554]

Refuse To File: New Drug Application and Biologics License Application Submissions to the Center for Drug Evaluation and Research; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Refuse to File: NDA and BLA Submissions to CDER." The purpose of this guidance is to clarify certain circumstances under which FDA's Center for Drug Evaluation and Research (CDER) may refuse to file a new drug application (NDA) or