

Estimated Total Annual Burden

Hours: 1,296 hours

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail address:

grjohnson@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, Attn: Desk Officer for ACF, E-mail address:

Katherine_T._Astrich@omb.eop.gov.

Dated: September 16, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05-19011 Filed 9-22-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: DHHS/ACF/ASPE/DOL Enhanced Services for the Hard-to-Employ Demonstration and Evaluation: Rhode Island 15-Month Survey Amendment.

OMB No.: 0970-0276.

Description: The Enhanced Services for the Hard-to-Employ Demonstration and Evaluation Project (HtE) is the most ambitious, comprehensive effort to learn

what works in this area to date and is explicitly designed to build on previous and on going research by rigorously testing a wide variety of approaches to promote employment and improve family functioning and child well-being. The HtE project will “conduct a multi-site evaluation that studies the implementation issues, program design, net impact and benefit-costs of selected programs”¹ designed to help Temporary Assistance for Needy Families (TANF) recipients, former TANF recipients, or low-income parents who are hard-to-employ. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS), and the U.S. Department of labor (DOL).

The evaluation involves an experimental, random assignment design in four sites, testing a diverse set of strategies to promote employment for low-income parents who face serious obstacles to employment. The four include: (1) Intensive care management to facilitate the use of evidence-base treatment for major depression among parents receiving Medicaid in Rhode Island; (2) job-readiness training, worksite placements, job coaching, job development and other training opportunities for recent parolees in New York City; (3) pre-employment services and transitional employment for long-term TANF participants in Philadelphia; and (4) home- and center-based care, enhanced with self-sufficiency services, for low-income families who have young children or are expecting in Kansas and Missouri.

Materials for follow-up surveys for each of these sites were previously submitted to OMB and were approved on April 29, 2005. The purpose of this submission is to introduce an addition to the OMB-approved follow-up survey effort in the Rhode Island site that will be used to collect follow-up data on children’s development.

The additional content we propose for the follow-up survey effort will be used

to address two questions: (1) What are the effects of a telephonic care management intervention for parents’ depression on parents’ parenting and on children’s health, behavior, and development; and (2) To what extent can intervention effects on children’s development be attributed to changes in maternal depressive symptomatology that result from the intervention?

Two follow-up surveys are included in this submission:

1. A 15-month follow-up parent survey that will supplement other information already collected from parents by addressing questions about parenting and children’s well-being.
2. A 15-month follow-up direct child assessment for up to two selected children of these parents. For younger children, this assessment will consist of cognitive and behavioral assessments conducted directly with the children; older children will be administered a survey, in addition to direct assessments.

Respondents: The respondents to these follow-up surveys will be low-income parents and their children from the Rhode Island site currently participating in the HtE Project. As described in the prior OMB submission, these parents are Medicaid recipients between the ages of 18 and 45 receiving Medicaid through the managed care provider United Behavioral Health (UBH) in Rhode Island who meet study criteria with regard to their risk for depression. Children are the biological, adopted, and step-children of these parents, between the ages of 1 and 18 years of age.

Prior to this follow-up survey, all parents will have completed a more detailed baseline survey, which is required to establish baseline measures of depression and related conditions, in addition to providing critical demographic data. The baseline survey was previously approved by OMB.

The annual burden estimates are detailed below, and the substantive content of each survey will be detailed in the supporting statement attached to the forthcoming 30-day notice.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
RI 15-month, parent survey	560	1	45 minutes or .75 hrs	420
RI 15-month, direct child assessment	980	1	45 minutes or .75 hrs	735

¹ From the Department of Health and Human Services RFP No.: 233-01-0012.

Estimated Total Annual Burden Hours: 1,155

In compliance with the requirements of Section 3506(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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: grjohnson@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.

Dated: September 16, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05-19012 Filed 9-22-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Improper Payments Information Survey for the CCDF Program.

OMB No.: New Collection.

Description: This survey for the Child Care and Development Fund (CCDF) program will request that States Voluntarily provide information including how they define improper payments in their State, the process used to identify such payments and what actions are taken in the State to reduce or eliminate improper payments. HHS/ACF intends to establish a repository for the State submissions, which will be available to all States for viewing on an HHS/ACF Web site. This Web site will provide information that will help States improve their program integrity systems so that improper payments in the program can be reduced.

Respondents: The 50 States of the United States, the District of Columbia, and the Territories of Guam, Puerto Rico and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Improper Payments Information Survey for the CCDF Program	54	1	24	1,296

Estimated Total Annual Burden Hours: 1,296 hours.

Additional Information:

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OMB Comment:

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Dated: September 16, 2005.

Robert Sargin,

Reports Clearance Officer.

[FR Doc. 05-19013 Filed 9-22-05; 8:45am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0363]

Preparation for International Conference on Harmonization Meetings in Chicago, Illinois; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH meetings in Chicago, Illinois" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Chicago, IL. The topics to be discussed

are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Chicago, IL, November 7 through 10, 2005, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on October 20, 2005, from 1:30 p.m. to 4 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd Fl., Maryland Conference Room, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 1:25 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Maryland Conference Room.

Contact: Sema Hashemi, Office of the Commissioner (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3050, FAX: 301-480-0716, e-mail: Sema.Hashemi@fda.hhs.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax