ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196	54	4	8	1,728

Estimated Total Annual Burden Hours: 1,728.

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: *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, Attn: Desk Officer for ACF. E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: February 6, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–1293 Filed 2–10–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

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 ongoing 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-based 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. 15-month follow-up youth survey will be administered to up to two of the older focal children of these parents.

3. Additionally, a 15-month follow-up direct child assessment for up to two younger children will be conducted. This assessment will consist of cognitive and behavioral assessments conducted directly with the children. These procedures are described in the OMB Supporting Statement.

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 17 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.

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

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burde hours
RI 15-month, parent child add-on survey	400	1	45 minutes or .75 hrs.	300
RI 15-month, youth survey	298	1	45 minutes or .75 hrs.	223.5
RI 15-month, direct child assessment	164	1	45 minutes or .75 hrs.	123

Estimated Total Annual Burden Hours: 646.5.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail: *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, Attn: Desk Officer for ACF. E-mail: *Katherine_T._Astrich@omb.eop.gov.*

Dated: February 7, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–1294 Filed 2–10–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0353]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pharmaceutical Development Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 15, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pharmaceutical Development Study

FDA's Office of Pharmaceutical Science of the Center for Drug Evaluation and Research is proposing collaboration under a Cooperative Research and Development Agreement (CRADA) with Conformia Software, Inc., of Redwood City, CA (hereafter referred to as ''CRADA Partner''), to collect information using focus group discussions with firms to determine what factors may influence pharmaceutical development. These factors include development information bottlenecks, pilot plant information management, manufacturing science, information retrieval, quality systems and preclinical development challenges.

FDA has introduced three new initiatives to help manufacturers develop higher quality drugs faster and cheaper. These initiatives include, but are not limited to, the following:

- Challenge and Opportunity on the Critical Path to New Medical Products (commonly referred to as the ''Critical Path Initiative'')
- Pharmaceutical cGMPs for the 21st Century—A Risk Based Approach
- International Conference on Harmonisation (ICH) Steering Committee Guidelines—Pharmaceutical Development, ICH Q8 (Defining the Design Space)

The proposed study is designed to augment and support these initiatives by providing practical industry experience and feedback to help FDA refine these initiatives. The scope of the proposed collaboration is aligned with FDA's ''Critical Path'' of development; specifically, the area between selection of drug candidates and commercial manufacturing.

Gathering information through this collaboration represents an opportunity for FDA to gain insights into current industry practices and provide the opportunity to better understand the specific factors that contribute to drug development difficulties. There is a perceived reluctance by industry to share information with regulatory bodies (outside of the formal review processes). Therefore, obtaining necessary and timely information through this collaboration will help the Critical Path Initiative progress.

The information collected will be used to create a clearer picture of current developmental bottlenecks, identify current State practices, highlight potential improvements in production, and provide feedback to FDA on the impact of current regulatory guidance.

Use of information: The three groups who will be involved with the study may benefit by the collection of this information as follows:

- Industry—Participants will compare current drug development practices and processes identified in the study with current FDA guidance. Companies will be able to gain a better understanding of the steps needed to achieve the operational goals introduced through the Critical Path, ICH-Q8, and Pharmaceutical cGMPs for the 21st Century.