

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Innovative Strategies for Increasing Self-Sufficiency: Baseline Data Collection.

OMB No.: 0970-0343.

Billing Accounting Code (BAC): 418409 (CAN G996121).

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Innovative Strategies for Increasing Self-Sufficiency (ISIS) demonstration and evaluation. The ISIS project will test a range of promising strategies to promote employment, self-sufficiency, and reduce dependence on cash welfare.

The ISIS project will evaluate multiple employment-focused strategies that build on previous approaches and are adapted to the current Federal, State, and local policy environment. The major goals of the project include increasing the empirical knowledge about the effectiveness of a variety of programs for low-income families to sustain employment and advance to positions that enable self-sufficiency, as well as producing useful findings for both policymakers and program administrators.

This proposed information collection activity focuses on collecting baseline data elements. Two data collection instruments will be completed by all participants prior to random assignment, and a third will be an interview guide to collect information from program staff. The first is a short baseline information form (BIF) that will collect basic identification, demographic, and contact information.

The form will include relatively standard items from prior evaluations and national surveys. The second instrument will be a self-administered questionnaire (SAQ), covering information related to the project goals. The third instrument, baseline implementation data collection interviews, will be used to collect information from knowledgeable informants about the service context for each evaluation site using a baseline implementation guide. The purpose of such interviews is to document and assess the service environment in which the evaluation is implemented and the opportunities for control group members to access the same or similar services as the treatment group members.

Respondents: Individuals enrolled in ISIS demonstration interventions, control group members, ISIS program operators (BIF and SAQ) and State and local informants (interviews).

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Baseline Information Form	4,800	1	0.75	3,600
Self-Administered Questionnaire	4800	1	0.75	3,600
Baseline Implementation Data Collection Interviews	30	1	1	30

Estimated Total Annual Burden Hours: 7,230

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@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 21, 2010.

Steven M. Hanmer,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0428]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." This draft guidance document describes a means by which the herpes simplex virus (HSV) serological assay device type may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to designate this guidance as the class II special control. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 27, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" to the Division of