

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
Annual Staff Key Informant Interview	MSI staff .....	14	1	4	56
Monthly Progress Reports .....	MSI HIV staff .....	14	12	1	168
Semi-Annual Reporting of Site Evaluation Findings.	MSI HIV staff .....	14	2	5	140
Annual Site Visit Partner Key Informant Interview.	MSI community partners .....	14	1	2	28
Pre- and Post- Tests .....	Students .....	420	2	15/60	210
Pre- and Post surveys .....	Students .....	1,000	2	1	2,000
Focus Groups .....	Students .....	50	1	1	50
Total .....	.....	1,526	.....	.....	2,652

**Mary Forbes,**  
Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* National Survey of Early Care and Education.

*OMB No.:* New Collection.

*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 National Survey of Early Care and Education (NSECE) which will be conducted December, 2011 through

June, 2010. The objective of the NSECE is to document the nation's current need for and availability of early care and education and including school-age care (ECE/SA), and to deepen our understanding of the extent to which families' needs and preferences coordinate well with providers' offerings and constraints. The proposed collection will consist of four survey components: (1) A survey of households with children under the age of 13 for participation in a questionnaire on the need for and use of early care and education (Household Interview), (2) a survey of households with individuals providing care for children under the age of 13 in a residential setting (Home-based Provider Interview), (3) a survey of providers of care to children under 13 in a non-residential setting (Center-based Provider Interview), and (4) a survey conducted with individuals employed in center-based child care programs (Workforce Provider Interview).

These data collection efforts will provide urgently needed information about the provision of ECE/SA across the country and spanning many sectors of care providers such as community-based child care, Head Start, school-based Pre-K, family child care, family, friend and neighbor care, and after-school programs. The study will also dramatically extend the available resources for understanding how families use, seek, and cope with the ECE/SA choices that are available to them. Perhaps most significantly, the NSECE will allow the policy and research communities to merge data from families and providers at the local level—where the two actually meet.

*Respondents:* General population households, home-based and center-based child care providers (including public schools) serving children under 13, and selected staff members from center-based child care providers (including public schools) serving children under 13.

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Household screener .....	83,767	1	.1	8,377
Household Interview .....	17,512	1	.75	13,134
Home-based Provider Interview .....	11,260	1	.3	3,378
Center-Based Provider Interview .....	12,520	1	.67	8,389
Workforce Provider Interview .....	9,390	1	.33	3,099

Estimated Total Annual Burden Hours: 36,377.

**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:* OPRE Reports Clearance Officer. All requests should be

identified by the title of the information collection. *E-mail address:* [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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:* 202-395-6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: June 13, 2011.

**Steven M. Hammer,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Information Comparison with Insurance Data.

*OMB No.:* 0970-0342.

**Description**

The Deficit Reduction Act of 2005 amended Section 452 of the Social Security Act (the Act) to authorize the Secretary, through the Federal Parent Locator Service (FPLS), to conduct

comparisons of information concerning individuals owing past-due child support with information maintained by insurers (or their agents) concerning insurance claims, settlements, awards, and payments. Public Law 109-171, § 7306. The Federal Office of Child Support Enforcement (OCSE) operates the FPLS in accordance with section 453(a)(1) of the Act. The Federal Case Registry of Child Support Orders (FCR) is maintained in the FPLS in accordance with section 453(h)(1) of the Act.

At the option of an insurer, the comparison may be accomplished by either of the following methods. Under the first method, an insurer or the insurer's agent will submit to OCSE information concerning claims, settlements, awards, and payments. OCSE will compare that information with information pertaining to individuals owing past-due support.

Under the second method, OCSE will furnish to the insurer or the insurer's

agent a file containing information pertaining to individuals owing past-due support. The insurer or the insurer's agent will compare that information with information pertaining to claims, settlements, awards, and payments. The insurer will furnish the information resulting from the comparison to OCSE.

On a daily basis OCSE will furnish the results of the comparison by transmitting the Insurance Match Response Record to the state agencies responsible for collecting past-due child support from the individuals. The results of the comparison will be used by the state agencies to collect past-due child support from the insurance proceeds.

**Respondents**

Insurers or their agents, including the U.S. Department of Labor and State agencies administering Workers Compensation program, and the Insurance Services Office (ISO).

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Insurance Match Agreement .....	22	1	0.50	11
Insurance Match File .....	22	0.50	0.50	132

Estimated Total Annual Burden Hours: 143.

**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](mailto: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, *E-mail:* [OIRA\\_SUBMISSION@OMB.eop.gov](mailto: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**

**Food and Drug Administration**

[Docket No. FDA-2011-D-0429]

**Draft Guidances for Industry and Food and Drug Administration Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues; and Interpretation of the Term "Chemical Action" in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of two related draft

guidances for industry and FDA staff entitled "Draft Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues" and "Draft Guidance for Industry and FDA Staff: Interpretation of the Term 'Chemical Action' in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act." These draft guidances provide the Agency's current thinking on approaches for classifying products as drugs and devices, certain additional product classification issues, and the interpretation of the term "chemical action" under the FD&C Act.

**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 comments on these draft guidances before it begins work on the final versions of these guidances, submit either electronic or written comments on the draft guidances by September 19, 2011.

**ADDRESSES:** Submit written requests for single copies of these draft guidances to the Office of Combination Products, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive