

and the Child Abuse, Domestic Violence, Adoption and Family Services Act of 1992 (Pub. L.) 102-295, conducted between 1993 and 1995, and reported in 1996. NIS-4, mandated by the Keeping Children and Families Safe Act of 2003 (Pub. L.) 108-36), will be reported in 2006.

NIS is unique in that it goes beyond the abused and neglected children who come to the attention of the Child Protective Services (CPS) system. In contrast to the National Child Abuse and Neglect Data Systems (NCANDS), which rely solely on reported cases. The NIS design assumes that reported children represent only a portion of the children who actually are maltreated. Following the implications of its assumptions, NIS estimates the scope of the maltreated child population by combining information about reported cases with data on maltreated children identified by professionals (called "sentinels") who encounter them during the normal course of their work in a wide range of agencies in representative

communities. Sentinels are asked to remain on the lookout for children whom they believe are maltreated during the study reference period and to provide information about these children. Children identified by sentinels and those children whose alleged maltreatment is investigated by CPS during the same period are evaluated against standardized definitions, and only children who meet the study standards are used to develop the study estimates. The study estimates are couched in terms of numbers of maltreated children, with data unduplicated so that a given child is counted only once. Confidentiality of all participants is carefully protected.

A nationally representative sample of 120 counties will be selected and all local CPS agencies serving the selected counties will be identified. Plans will be developed to obtain data on cases investigated during the study reference period, September 4, 2005 to December 3, 2005. Sentinels in the selected counties will be identified through

samples of agencies in 11 categories: county juvenile probation departments, sheriff (and/or state police) departments, public health departments, public housing departments, municipal police departments, hospitals, schools, day care centers, social service agencies, mental health agencies, and shelters for battered women or runaway/homeless youth. A total of approximately 1,600 sentinel agencies will be sampled. Plans will be developed to identify staff in these agencies who have direct contact with children to serve as sentinels during the study by submitting data on maltreated children they encounter during the study reference period. In preparation for the study, letters will be sent to the directors of the selected agencies asking them to permit their agencies to participate in NIS-4, and describing the general nature of the data collection effort. HHS will issue a subsequent notice of proposed data collection for this study after data collection plans are developed.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter to CPS Agencies	120	1	.20	24
Letter to Sentinel Agencies	1,600	1	.20	320
	12,000	1	.20	2,400
<i>Estimated Total Annual Burden Hours</i>			.20	2,744

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: October 26, 2004.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed information Collection Activity; Comment Request

Proposed Projects

Title: Social Services Block Grant Postexpenditure Report.

OMB No. 0970-0234.

Description:

Purpose: To improve the quality of Social Services Block Grant (SSBG) expenditure data, the postexpenditure reporting form and instructions need minor formatting revisions to reduce confusion and reporting inconsistencies that have resulted from the current form. As a block grant, SSBG provides the States with a flexible source of funds for social service needs. Accurate accounting of how these funds are used and whom they serve is critical to ensure that necessary and sufficient funding continues to be allocated. For

this reason, the following changes are being proposed to the current form:

1. The expenditures columns will be reordered so that when reading left to right, the three types of funding that sum to total expenditures—SSBG allocation, funds transferred into SSBG, and expenditures of all other Federal, State, and local funds—are listed prior to total expenditures.
2. A space will be added, and referenced in item 29, where States can report more detail about other services. This added information will help to define the specific services funded under this service category.
3. The column for total adults will be removed. A new column, “Adults of Unknown Age” will be added. The three age groups of adults—“Adults Age 59 and younger,” “Adults Age 60 and older,” and “Adults of Unknown Age”—should equal the total number of adults.
4. The recipients columns will be reordered so that when reading left to right, the four ages of recipients—children, adults age 59 and younger, adults age 60 and older, and adults of unknown age—are listed prior to total recipients.

The SSBG program provides funds to assist States in delivering social services directed toward the needs of children

and adults in each State. Funds are allocated to the States in proportion to their populations. States, including the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Northern Mariana Islands, and American Samoa, have substantial discretion in their use of funds and may determine what services will be provided, who will be eligible, and how funds will be distributed among the various services. State or local SSBG agencies (*i.e.*, county, city, or regional offices) may provide the services or may purchase them from qualified agencies, organizations, or individuals. States report as recipients of SSBG-funded services any individuals who receive a service funded at least partially by SSBG.

States are required to report their annual SSBG expenditures on a standard postexpenditure report, which includes a yearly total of adults and children served and annual expenditures in each of 29 service categories. Reporting requirements for SSBG were originally described in the Federal Register, Volume 58, Number 218, on Monday, November 15, 1993. The report is due either 6 months after the end of the reporting period or at the time the State submits the preexpenditure report for the reporting

period beginning after that 6 month period. The report must address: (1) The number of individuals (as well as number of children and number of adults) who receive services paid for in whole or in part with Federal funds under the Social Services Block Grant; (2) The amount of Social Services Block Grant funds spent in providing each service; (3) The total amount of Federal, State, and local funds spent in providing each service, including Social Services Block Grant funds; and (4) The method(s) by which each service is provided, showing separately the services provided by public agencies and private agencies.

Information collected on the postexpenditure report is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services. The information contained in this report is used to establish how SSBG funding is used for the provision of services in each State to each of many specific populations of needy individuals.

Respondents: This report is completed once annually by a representative of the agency that administers the Social Services Block Grant at the State level in each State, the District of Columbia, and the Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Postexpenditure Report	56	1	110	6,160

Estimated Total Annual Burden Hours: 6,160.

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 Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20477, 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: October 26, 2004.
Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0459]

Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling.” This guidance discusses agency recommendations on issues to consider when designing and