

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UCEDD Annual Report Template .....	67	1	1,412	94,604

Estimated Total Annual Burden Hours: 94,604.

**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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email 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, Email: [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****Administration for Children and Families****Administration on Children, Youth and Families; Statement of Organization, Functions, and Delegations of Authority**

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** Statement of Organizations, Functions, and Delegations of Authority The Administration for Children and Families (ACF) has reorganized the Administration on Children, Youth and Families (ACYF). This reorganization realigns the Children's Bureau Data and

Technology Team and the Family and Youth Services Bureau Research, Data, and Evaluation Team to create the Office of Data Analysis, Research, and Evaluation. It also renames the Division of Research and Innovation to the Division of Program Innovation. It renames the Division of Youth Services to the Division of Adolescent Development and Support. It deletes the Division of Abstinence Programs. Additionally, it deletes the Mentoring Children of Prisoners program.

**FOR FURTHER INFORMATION CONTACT:**

Bryan Samuels, Commissioner, Administration on Children, Youth and Families, 1250 Maryland Avenue SW., Washington, DC 20024, (202) 205-8347.

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KB, Administration on Children, Youth and Families (ACYF), as last amended 72 FR 24314-24316, May 2, 2007.

I. Under Chapter, KB, Administration on Children, Youth and Families, delete KB in its entirety and replace with the following:

**KB.00 Mission.** The Administration on Children, Youth and Families (ACYF) advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to the sound development of children, youth, and families by planning, developing, and implementing a broad range of activities that prevent or remedy the effects of trauma, abuse, and/or neglect of children and youth and promote child, adolescent, and family well-being.

ACYF administers State grant programs under titles IV-B and IV-E of the Social Security Act; manages the Adoption Opportunities program and other discretionary programs for the development and provision of child welfare services; and implements the Child Abuse Prevention and Treatment Act. It administers programs under the Runaway and Homeless Youth Act; carries out the provisions of the Family Violence Prevention and Services Act; and manages adolescent pregnancy

prevention programs under the Affordable Care Act.

In concert with other components of ACF, ACYF develops and implements research, demonstration, and evaluation strategies for the discretionary funding of activities designed to improve and enrich the lives of children and youth and to strengthen families. It administers Child Welfare Services training and research and demonstration programs authorized by title IV-B of the Social Security Act and oversees promising youth development programs.

**KB.10 Organization.** The Administration on Children, Youth and Families is headed by a Commissioner, who reports directly to the Assistant Secretary for Children and Families, and consists of:

Office of the Commissioner (KBA).

Office of Management Services (KBA1).

Office of Data Analysis, Research and Evaluation (KBA3).

Children's Bureau (KBD).

Children's Bureau Regional Program Units (KBDDI-X).

Office of Child Abuse and Neglect (KBD1).

Division of Policy (KBD2).

Division of Program Implementation (KBD3).

Division of Program Innovation (KBD4).

Division of Child Welfare Capacity Building (KBD5).

Division of State Systems (KBD6).

Family and Youth Services Bureau (KBE).

Division of Adolescent Development and Support (KBE1).

Division of Family Violence Prevention (KBE2).

**KB.20 Functions.** A. The Office of the Commissioner serves as principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other officials of the Department on the sound development of children, youth, and families. It provides executive direction and management strategy to ACYF components. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office.

In addition to the Immediate Office, the Office of the Commissioner contains

the Office of Management Services and the Office of Data Analysis, Research and Evaluation.

1. Office of Management Services manages the formulation and execution of the budgets for ACYF programs and for Federal administration; serves as the central control point for operational and long range planning; functions as Executive Secretariat for ACYF, including managing correspondence, correspondence systems, and electronic mail requests; reviews and manages clearance for funding opportunity announcements for ACYF; coordinates the provision of staff development and training; provides support for ACYF's personnel administration, including staffing, employee and labor relations, performance management, and employee recognition; manages procurement planning and provides technical assistance regarding procurement; oversees the discretionary grant paneling process; manages ACYF-controlled space and facilities; performs manpower planning and administration; plans for, acquires, distributes and controls ACYF supplies; provides mail and messenger services; maintains duplicating, fax, and computer and computer peripheral equipment; supports and manages automation within ACYF; provides for health and safety; and oversees travel, time and attendance, and other administrative functions for ACYF.

2. Office of Data Analysis, Research and Evaluation provides leadership and direction in program development, innovation, research and in the management of the legislatively mandated information systems used in ACYF. It conducts analysis of national data to inform the policy and program priorities of ACYF and issues regular reports. It oversees ACYF's research and evaluation strategy in support of ACYF's implementation of programs that replicate evidence-based effective program models and efforts to develop an evidence base for innovative practices.

B. The Children's Bureau (CB) is headed by an Associate Commissioner who advises the Commissioner, ACYF, on matters related to child welfare, including child abuse and neglect, child protective services, family preservation and support, adoption, foster care and independent living, and child abuse and neglect prevention. A Deputy Associate Commissioner supports the Associate Commissioner and manages the day-to-day operations of the CB. CB recommends legislative and budgetary proposals, operational planning system objectives and initiatives, and projects

and issue areas for evaluation, research, and demonstration activities.

The Child and Family Services Review Team, housed in the Office of the Associate Commissioner, in partnership with the Administration for Children and Families Regional Offices, carries out reviews of child protective services, foster care, adoption, family preservation, family support, and independent living services provided by the States. CB represents ACYF in initiating and implementing interagency activities and projects affecting children and families and provides leadership and coordination for the programs, activities, and subordinate components of the Bureau. Seven units comprise the CB:

1. The Regional Program Unit is headed by a CB Regional Program Manager who reports to the Associate Commissioner, CB, within ACYF. The CB Regional Program Manager, through subordinate regional staff, in collaboration with program components, is responsible for: (1) Providing program and technical administration of CB formula, entitlement, block, and discretionary programs related to child welfare, including child abuse and neglect prevention, child protective services, family preservation and support, adoption, foster care, and independent living; (2) collaborating with the ACF Central Office, States, and grantees on all program matters for programs or issues that have significant implications for the programs; (3) providing technical assistance to entities responsible for administering CB programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate State and local officials to develop and implement outcome-based performance measures; and (6) monitoring the programs to ensure their efficiency and effectiveness, and ensuring that these entities conform to Federal laws, regulations, policies, and procedures governing the programs.

2. The Office on Child Abuse and Neglect provides leadership and direction on the issues of child maltreatment and the prevention of abuse and neglect under the Child Abuse Prevention and Treatment Act (CAPTA). It is the focal point for interagency collaborative efforts, national conferences and special initiatives related to child abuse and neglect, and for coordinating activities related to the prevention of abuse and neglect and the protection of children at risk of maltreatment. It supports activities to build networks of community-based, prevention-focused

family resource and support programs through the Community-Based Child Abuse Prevention Grants. It supports improvement in the systems which handle child abuse and neglect cases, particularly child sexual abuse and exploitation- and maltreatment-related fatalities, and improvement in the investigation and prosecution of these cases through the Children's Justice Act.

3. The Division of Policy provides leadership and direction in policy development and interpretation of titles IV-B and IV-E of the Social Security Act and the Basic State Grant under CAPTA. It writes regulations and interprets policy for the Bureau's formula and entitlement grant programs, and responds to requests for policy clarification from ACF Regional Offices and other sources.

4. The Division of Program Implementation provides leadership and direction in the operation and review of programs under titles IV-B and IV-E of the Social Security Act and the Basic State Grant under CAPTA. It develops program instructions, information memoranda, and annual reports related to these programs. It analyzes State Plans and develops State profiles and other reports, and it participates in monitoring and reviewing State information systems to ensure the accuracy and relevance of the data. It is responsible for the Monitoring Team, which schedules and coordinates the monitoring of State reviews and ensures effective corrective action if necessary. It works with other agencies and organizations as appropriate on the implementation and oversight of relevant sections of the Indian Child Welfare Act. It is the focal point for financial issues, including disallowances, appeals, and the decisions of the Departmental Appeals Board (DAB). It responds to client and constituent correspondence received electronically or through other channels.

5. The Division of Program Innovation provides leadership and direction in program development, innovation and research. It defines critical issues for investigation and makes recommendations regarding subject areas for research, demonstration and evaluation. It administers the Bureau's discretionary grant programs and awards project grants to State and local agencies and organizations nationwide. It provides direction to the Crisis Nurseries and Abandoned Infants Resource Centers.

6. The Division of Child Welfare Capacity Building provides leadership and direction in the areas of training, technical assistance and information

dissemination under titles IV–B and IV–E of the Social Security Act, and under the Child Abuse Prevention and Treatment Act. Either directly or through funded Resource Centers and Implementation Centers, it provides training and technical assistance to assist service providers, State and local governments and tribes, and strengthen headquarters and regional office staff.

It manages discretionary training grants under section 426 of the Social Security Act and title IV–E training and directs the operations and activities of the Child Welfare Information Gateway. The Division identifies best practices for treating vulnerable families and preventing abuse and neglect. It participates in the development of funding opportunity announcements and manages certain discretionary grant projects. It also develops and issues a periodic newsletter, and is the focal point for conference and meeting planning activities for the Bureau.

7. The Division of State Systems (DSS) reviews, assesses, and inspects the planning, design and operation of State management information systems and approves advanced planning documents for automated data systems. The Division provides leadership for the provision of technical assistance to States on information systems projects and advances the use of computer technology in the administration of child welfare and social services programs by States. The Division reviews, analyzes, and approves/disapproves State requests for Federal financial participation for automated systems development and related activities, which support child welfare programs, including foster care and adoption. It provides assistance to States in developing or modifying automation plans to conform to Federal requirements; monitors approved State system development activities; and conducts periodic reviews to assure State compliance with regulatory requirements applicable to automated systems supported by Federal financial participation. It provides guidance to States on functional requirements for these automated information systems.

C. The Family and Youth Services Bureau (FYSB) is headed by an Associate Commissioner who recommends policy direction and programs to address issues involving vulnerable youth and their families to the Commissioner, ACYF. A Deputy Associate Commissioner supports the Associate Commissioner and manages the day-to-day operations of FYSB. The Bureau assesses policies and legislation and develops program initiatives for runaway and homeless youth, family

violence prevention and services, and adolescent pregnancy prevention. It recommends budgetary and legislative proposals and subject areas for research and demonstration activities, and it coordinates efforts with and provides expert advice to departmental and other Federal agencies on issues and programs for vulnerable youth, including runaway and homeless youth; youth at risk of involvement with gangs, violence and drugs; and other youth in at-risk situations. The Bureau represents HHS on various councils, workgroups, and committees and provides leadership and coordination to other HHS programs and agencies. The Bureau is comprised of two divisions.

1. The Division of Adolescent Development and Support promotes a positive youth development approach to program services so that Bureau programs and activities meet the developmental needs of vulnerable populations of young people and their families through administering programs that impact runaway homeless youth, children whose parents are incarcerated, and youth who are pregnant, or who are at risk of becoming pregnant.

The Division administers the runaway and homeless youth program—which incorporates the basic center, street outreach, and transitional living programs. It also includes development and implementation of policy, guidelines and regulations concerning the funding and management of service projects for youth under the Runaway and Homeless Youth Act. The Division designs, develops, funds, and monitors support activities related to these programs, including but not limited to the provision of technical assistance, a monitoring system, a data collection system, the National Clearinghouse on Families and Youth, and the National Runaway Switchboard. The Division oversees the receipt and review of applications for grants in these program areas and monitors the management of these grants through the ACF Regional Offices.

The Division administers a comprehensive array of adolescent pregnancy prevention projects and grant programs that prevent teen pregnancy and the spread of sexually transmitted infections including HIV/AIDS among teens. Grant programs include evidence based comprehensive pregnancy prevention and personal responsibility education (such as maintaining healthy relationships and financial literacy) as well as programs that test innovative approaches to adolescent pregnancy prevention. The Division also administers grants that support

medically accurate abstinence education programs which may include promoting abstinence through mentoring, counseling and adult supervision. The Division develops the conceptual framework for issues pertaining to adolescent pregnancy prevention, monitors funded programs, and ensures the provision of technical assistance.

The Division determines the overall conceptual and policy framework to address issues facing vulnerable families and adolescents in ACYF. It identifies problems, defines critical issues for investigation, and makes recommendations regarding subject areas for research, demonstration, and evaluation activities. Based on the outcomes of these activities, the Division disseminates information through conferences, forums, and written materials; provides assistance to service providers and state and local governments and tribes in planning, developing, implementing and evaluating programs affecting family and youth; and recommends plans and programs to increase public awareness and understanding about activities affecting vulnerable families and youth. Supervision of FYSB's regional staff is also the responsibility of this Division.

The Division of Family Violence Prevention promotes public awareness about domestic violence and its impact and prevention and intervention strategies to address the problem. The Division's programs support the prevention of family violence; provide immediate shelter and related assistance to victims of family violence and their dependents; provide for research into the most effective methods of family violence prevention, identification, and intervention; and provide training and technical assistance to family violence personnel in States, tribes, local public agencies (including law enforcement agencies, courts, social service agencies, and health care providers), and non-profit organizations.

The Division also supports the development of services to address the needs of children exposed to domestic violence. The Division is responsible for developing, updating, and implementing program regulations and policies. The Division oversees the receipt and review of applications for grants and grantee activities. It also provides guidance, review, support and assistance to States and grantees on HHS policies, regulations, procedures, and systems necessary to ensure efficient program operation at the State, territorial, and tribal levels. In addition, the Division coordinates all programs for victims and potential victims of family violence and their dependents.

Dated: November 1, 2011.

**George H. Sheldon,**

*Acting Assistant Secretary for Children and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0912]

#### Communications and Activities Related to Off-Label Uses of Marketed Products and Use of Products Not Yet Legally Marketed; Request for Information and Comments

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

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a docket to assist with our evaluation of our policies on communications and activities related to off-label uses of marketed products, as well as communications and activities related to use of products that are not yet legally marketed for any use, we would like to obtain comments and information related to scientific exchange. FDA is interested in obtaining comments and information regarding scientific exchange about both unapproved new uses of products already legally marketed (“off-label” use) and use of products not yet legally marketed for any use.

**DATES:** Submit either electronic or written information and comments by March 27, 2012.

**ADDRESSES:** Submit electronic information and comments to <http://www.regulations.gov>. Submit written information and comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane Rm. 1061, Rockville, MD 20852. Identify both electronic and written comments and any supporting documents with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

#### For the Center for Drug Evaluation and Research

Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6312, Silver Spring, MD 20993-0002, (301) 796-3601.

#### For the Center for Biologics Evaluation and Research

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, (301) 827-6210.

#### For the Center for Devices and Radiological Health

Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 3414, Silver Spring, MD 20993-0002, (301) 796-5732.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 5, 2011, a citizen petition was submitted by Ropes & Gray and Sidley Austin LLP on behalf of seven product manufacturers (Petitioners): Allergan, Inc.; Eli Lilly and Co.; Johnson & Johnson; Novartis Pharmaceuticals Corp.; Novo Nordisk, Inc.; Pfizer, Inc.; and sanofi-aventis U.S. LLC under 21 CFR 10.30. The citizen petition requested that FDA clarify its policies for drug products and devices governing certain communications and activities related to off-label uses of marketed products and use of products that are not yet legally marketed for any use.<sup>1</sup> Specifically, the petition requests clarification in the following areas:

1. Manufacturer responses to unsolicited requests;
2. Scientific exchange;
3. Interactions with formulary committees, payors, and similar entities; and
4. Dissemination of third-party clinical practice guidelines.

For some time, FDA has been considering these issues and is currently evaluating our policies on sponsor or investigator communications and activities related to off-label uses of marketed products and use of products that are not yet legally marketed for any use. We have been considering what actions to take in the areas specified by the petitioners with respect to manufacturer responses to unsolicited requests; interactions with formulary committees, payors, and similar entities; and the dissemination of third-party clinical practice guidelines. To assist with our evaluation of our policies on communications and activities related to off-label uses of marketed products, as well as communications and activities related to use of products that are not yet legally marketed for any use, we would like to obtain comments and

information related to scientific exchange.

Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service Act (PHS Act), any person who wishes to introduce or deliver for introduction into interstate commerce any new drug (including a biological drug product) must demonstrate that the product is safe and effective for its intended uses (see sections 505(a) and 512(a) of the FD&C Act (21 U.S.C. 355(a) and 360b(a)) and section 351 of the PHS Act (42 U.S.C. 262)). Any person who wishes to introduce or deliver for introduction into interstate commerce a new medical device (including a biological device product) must either demonstrate that the device has a reasonable assurance of safety and effectiveness for its intended uses or that it is substantially equivalent to a legally marketed predicate device (see sections 510(k), 513(f), and 515(a) of the FD&C Act (21 U.S.C. 360(k), 360c(f), 360e(a)) and section 351 of the PHS Act (42 U.S.C. 262)).

The demonstrations of product safety and efficacy usually consist of data and information derived from clinical investigations and presented as part of a marketing application. The marketing application also contains information regarding the product’s intended uses, the patient population (including any special conditions, restrictions, or limitations for segments of the population, such as children, pregnant women, or the elderly), potential adverse events associated with the product’s use, and technical information about the product (see, e.g., 21 CFR 314.50, 514.1, 601.25, and 814.20). If FDA agrees that a product is safe and effective for its intended uses, as reflected in the marketing application, it approves the application and certain required product labeling. For devices subject to clearance through the 510(k) process, the clearance establishes the intended use(s) for which it is legal to market the product. The uses that are approved or cleared by the Agency are sometimes referred to as “labeled” uses because they appear in the product’s required labeling. Uses that do not appear in the labeling and are not approved or cleared by the Agency are referred to as “unapproved,” “unlabeled,” “off-label,” or “extra-label” uses.

As explained previously in this document, under section 505 of the FD&C Act, a new drug (which includes a marketed drug intended for a new use) may not be introduced or delivered for introduction into interstate commerce without approval by FDA, but FDA is authorized to create regulations

<sup>1</sup> See Docket No. FDA-2011-P-0512 at <http://www.regulations.gov> for a copy of the citizen petition.