

**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). The reorganization has no impact on existing delegations of authority. The reorganization within the ACYF Office of the Commissioner amends the functions of the Office of Management Services and creates the Office of Budget. Within the Children's Bureau (CB), it creates the Division of Performance Measurement and Improvement. It removes the Office of Data Analysis, Research and Evaluation from the Office of the Commissioner and transfers the functions to the Division of Performance Measurement and Improvement. Within the Family and Youth Services Bureau (FYSB), it renames the Division of Adolescent Development and Support to the Division for Optimal Adolescent Development and elevates the Runaway Homeless Youth office to the Division of Runaway and Homeless Youth. It also creates the Division of Evaluation, Data and Policy. Lastly, it renames the Division of Family Violence Prevention to the Division of Family Violence Prevention and Services.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Darling, Commissioner, Administration on Children, Youth and Families, 330 C Street SW, Washington, DC 20201, (202) 401-2761.

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 in 76 FR 81505-81508, December 28, 2011.

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 remediate the effects of trauma, abuse, and/or neglect of children and youth and promote child, adolescent, and family wellbeing.

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 (CAPTA). 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 authorized through Title V of the Social Security Act under Section 510 for Sexual Risk Avoidance Education and Section 513 for Personal Responsibility Education Program.

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 Budget (KBA2)
- 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)
- Division of Performance Measurement and Improvement (KBD7)
- Family and Youth Services Bureau (KBE)
- Division for Optimal Adolescent Development (KBE1)

- Division of Family Violence Prevention and Services (KBE2)

- Division of Evaluation, Data and Policy (KBE3)

- Division of Runaway and Homeless Youth (KBE4)

*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. The Office of the Commissioner is comprised of two offices:

The Office of Management Services functions as Executive Secretariat for the Office of the Commissioner, including managing correspondence, correspondence systems, and electronic mail requests; 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 ACYF-controlled space and facilities; performs manpower planning and administration; plans for, 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 administration, time and attendance, and other administrative functions for ACYF.

The Office of Budget 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, manages procurement planning and provides technical assistance regarding procurement, acquires ACYF supplies, provides oversight and technical assistance on funds planning for travel expenditures and travel administration on obligation and payment issues, monitors the obligation and expenditure of ACYF funds through the lifecycle of the appropriations, and provides leadership and advice on financial policy issues that cut across all the ACYF program and funding mechanisms.

B. The Children's Bureau (CB) is headed by an Associate Commissioner who advises the Commissioner, ACYF,

on matters related to the administration of state and tribal child welfare systems, 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. 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. The Bureau is comprised of eight units:

The Regional Program Unit is headed by the Director of Regional Programs who reports to the Associate Commissioner, CB, within ACYF. The Director of Regional Programs, through subordinate Regional Program Managers and their 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.

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 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 state systems that 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.

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.

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. It is responsible for the Monitoring Team, which schedules and coordinates the monitoring of the state title IV-E reviews and ensures effective corrective action if necessary. It is the focal point for financial issues, including disallowances, appeals, and the decisions of the Departmental Appeals Board (DAB).

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.

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 CAPTA. Either directly or through grants or contracts, it provides training and technical assistance to assist service providers, state and local governments, and tribes. 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 statutorily mandated clearinghouses. 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.

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 that 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 ensure 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.

The Division of Performance Measurement and Improvement provides oversight in the collection, analysis, and reporting of state-level data reported to CB through mandated data collections; oversees an outcomes-oriented review of state child welfare systems; and sets, tracks, and reports on performance indicators in response to the Government Performance and Results Act and other performance oriented mandates. The Division is comprised of two teams. The Data Analytics and Reporting Team collects, analyzes, and disseminates program data from the Adoption and Foster Care Analysis and Reporting System (AFCARS), the National Youth in Transition Database (NYTD), and the National Child Abuse and Neglect Data Systems (NCANDS); ensures accuracy of data reporting; develops systematic methods of measuring the impact and effectiveness of various child welfare programs; and performs statistical sampling functions. The Child and Family Services Review Team, in partnership with CB's Regional Program Units, carries out reviews of child protection, foster care, adoption, family

preservation, family support, and independent living services provided by the states. The Child and Family Services Review Team ensures the accuracy and consistency of the review protocol across all states of the review process and in subsequent program improvement efforts.

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, at-risk youth, survivors of domestic violence and their families to the Commissioner, ACYF. FYSB supports the organizations and communities working to end youth homelessness, youth at risk of trafficking and sexual exploitation, adolescent pregnancy, and domestic violence through programs that provide shelter, community services, and prevention education for youth, adults, and families.

A Deputy Associate Commissioner supports the Associate Commissioner and manages the day-to-day operations of FYSB. The Bureau assesses and recommends policies and legislation and develops program initiatives for runaway and homeless youth, family violence prevention and services (*i.e.*, services addressing domestic violence, and dating violence and to provide immediate shelter and supportive services for adult and youth victims), adolescent pregnancy prevention, and trafficking prevention services. FYSB recommends budgetary and legislative proposals, operational planning initiatives, and projects and subject areas for research, evaluation, and demonstration activities. FYSB coordinates efforts with and provides expert advice to departmental and other federal agencies on addressing and preventing family violence, domestic violence, and dating violence and for implementing programs for vulnerable youth, including runaway and homeless youth; youth at risk of trafficking, sexual exploitation, or violent crime victimization; youth at risk of unplanned pregnancy or becoming teen parents; and any 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 working to address runaway and homeless youth, youth at risk of severe forms of trafficking and sexual exploitation, domestic and dating violence prevention and services, and adolescent pregnancy prevention. The Bureau is comprised of four Divisions:

The Division of Family Violence Prevention and Services promotes

public awareness about family violence, domestic violence, and dating violence. The Division also promotes awareness about the impact of family violence, and effective prevention and intervention strategies to address the problem. The Division's programs 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 and domestic violence programs including states, tribes, local public agencies (such as law enforcement agencies, courts, social service agencies, child welfare programs, mental health and substance abuse treatment programs, and health care providers), and non-profit organizations. The Division provides support for the National Domestic Violence Hotline, which operates 24 hours a day, 7 days a week and is available in 200 languages, including services in Spanish, video and/or text chat for Deaf and Hard of Hearing survivors, and culturally specific response to Native American victims by Native advocates. The Division supports the development of services to address the needs of children exposed to domestic violence and their abused parents. 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, tribes, discretionary grantees and sub awardees 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.

The Division of Evaluation, Data and Policy provides leadership and direction for FYSB, informing program and policy development and innovation through evaluation strategies and data analysis for runaway and homeless youth, youth at risk of severe forms of trafficking, adolescent pregnancy prevention, and family violence prevention and services. The Division leads the management of the legislatively mandated data information systems and all evaluation efforts within FYSB. The Division directs evaluation efforts to include study design; instrument development; and rigorous, methodological approaches; and conducts analysis of data (*e.g.*,

regression, ANOVA, predictive modeling) to inform the policy and program priorities of FYSB programs. It oversees FYSB's performance standards and performance measurement process, evaluation strategies, program outcome development, and the synthesis of data to inform and support innovation in the implementation of each program and demonstration projects' best and emerging practices. The Division provides leadership and direction in policy development, responds to requests for policy clarification, and analyzes the implementation of FYSB's authorizing legislations. The Division provides recommendations to the Commissioner and Associate Commissioner on strategic priorities, policy direction, and programmatic improvements to address issues involving vulnerable youth and their families, adolescent pregnancy prevention, and victims of domestic violence. The Division also recommends legislative and budgetary proposals, strategic partnerships, and identifies issue areas for evaluation, research, and demonstration initiatives.

The Division for Optimal Adolescent Development administers an array of adolescent pregnancy prevention projects to states, tribes, and community-based organizations that provide education to youth on how to prevent teen pregnancy and the spread of sexually transmitted infections, including HIV/AIDS, and provides education on healthy relationships and refraining from non-marital sexual activity. The Division supports the inclusion of evidence-based, age-appropriate, and medically accurate strategies and models that support the successful transition of youth through adolescence and into adulthood with a holistic approach to teaching the benefits of personal responsibility, healthy decision-making, goal setting, and normalizing the optimal behavior of avoiding non-marital sexual activity. There is a subset of grant programs that test innovative approaches to adolescent pregnancy prevention through rigorous evaluations conducted at local and national levels. The collection of performance measurement data provides information to support program improvement and to track program outcomes. The Division provides technical support to ensure compliance with programmatic and fiscal requirements of programs across all funding streams, as directed by the application of federal policy, regulations, and laws. The Division develops the conceptual framework for issues pertaining to adolescent

pregnancy prevention, monitors funded programs, and ensures the provision of technical assistance and training through contracts, cooperative agreements, and Interagency Agreements. This includes the development and management of a social media marketing campaign to provide messaging to youth that normalize the optimal behavior of avoiding non-marital sexual activity.

The Division of Runaway and Homeless Youth serves as the national leader for the provision of shelter and supportive services to unaccompanied homeless youth and administers the runaway and homeless youth program that incorporates the basic center, street outreach, and transitional living programs. The Division also conducts development and implementation of policy, guidelines, and regulations concerning the funding and management of service projects for youth in compliance with the Runaway and Homeless Youth Act. The Division designs, develops, funds, and monitors support activities related to RHY programs including, but not limited to, the provision of technical assistance, executing a monitoring system, maintaining a requisite data collection system, the National Clearinghouse on Homeless Youth and Families, and the National Runaway Safeline. The Division oversees the receipt and review of applications for discretionary grants in these program areas and monitors the management of these grants through monthly contacts and on-site visits through the ACF Regional Offices.

**Authority:** 44 U.S.C. 3101.

Dated: February 28, 2020.

**Alex M. Azar II,**  
Secretary.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1041]

#### Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry; Availability; Reopening of Comment Period

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

**ACTION:** Notice of availability; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is

reopening the comment period for the notice entitled “Development of a Shared System REMS; Draft Guidance for Industry; Availability” that appeared in the **Federal Register** of June 1, 2018. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening the comment period for the notice published on June 1, 2018 (83 FR 25468). Submit either electronic or written comments on the draft guidance by May 18, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-

2018-D-1041 for “Development of Shared System REMS.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics