

IV. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Meg Sullivan,

Principal Deputy Assistant Secretary for the Administration for Children and Families, performing the delegable duties of the Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number(s): 93.645]

Notice of Allotment Percentages to States for Child Welfare Services State Grants.

AGENCY: Administration on Children, Youth and Families—Children’s Bureau (ACYF–CB), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of biennial publication of allotment percentages for States under the IV–B subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program.

SUMMARY: The Department is publishing the allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program. The allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2026 and 2027.

FOR FURTHER INFORMATION CONTACT: Sona Cook, Grants Management Officer, Family Protection & Resilience Portfolio, Office of Grants Management, Office of Administration, Administration for Children and Families, 330 C Street SW, Washington, DC 20201. Telephone (214) 767-2973, Email: sona.cook@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: As required by section 423(c) of the Social Security Act (42 U.S.C. 623(c)), the Department is publishing the allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program. The allotment percentage for each State is determined on the basis of paragraphs

(b) and (c) of section 423 of the Social Security Act. These figures are available on the ACF internet homepage at http://www.acf.hhs.gov/programs/cb/. The allotment percentage for each State is as follows:

ALLOTMENT **

Table with 2 columns: State, Percentage. Lists states from Alabama to District of Columbia with their respective allotment percentages.

ALLOTMENT **

Table with 2 columns: State, Percentage. Lists states from Florida to N. Mariana Islands with their respective allotment percentages.

ALLOTMENT **—Continued

Table with 2 columns: State, Percentage. Shows Virgin Islands with 70.00.

* State Percentage = 50 percent of year average divided by the National United States 3-year average.

** State Percentage minus 100 percent yields the IV–BI allotment percentage.

* Estimates prior to 1950 are not available for Alaska and Hawaii.

1 Allotment Percentage has been adjusted in accordance with Section 423(b)(1).

Statutory Authority: Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Anthony Petruccelli,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research, and Evaluation Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) has reorganized the Office of Planning, Research, and Evaluation (OPRE). This reorganization creates a new Office of Research and Evaluation (ORE) and an Office of the Chief Data Officer (OCDO). This notice provides the Statement of Organizations, Functions, and Delegations of Authority for the new office of officer.

FOR FURTHER INFORMATION CONTACT: Lauren Supplee, Deputy Assistant Secretary for Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: 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 KM, Office of Planning, Research, and Evaluation (OPRE), as last amended 87 FR 67693-67696 (November 2022).

I. Under Chapter KM, Office of Planning, Research, and Evaluation,

delete in its entirety and replace with the following:

KM.00 Mission

OPRE is the principal advisor to the Assistant Secretary for Children and Families on improving the effectiveness and efficiency of programs designed to make measurable improvements in the economic and social well-being of children and families. OPRE provides guidance, analysis, technical assistance, and oversight to ACF programs and across programs in the agency on strategic planning aimed at measurable results; performance measurement and management; research and evaluation methodologies; demonstration testing and model development; statistical policy and program analysis; synthesis and dissemination of research, evaluation, and demonstration findings; data science; data governance; data use, re-use, and integration; data ethics; data sharing, privacy, and confidentiality; data talent; interoperability; and application of emerging technologies to improve the effectiveness of programs and service delivery.

KM.10 Organization

OPRE is headed by a Deputy Assistant Secretary, who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

- Office of the Deputy Assistant Secretary (KMA)
- Office of Research and Evaluation (KMF)
- Division of Economic Independence (KMB)
- Division of Child and Family Development (KMC)
- Division of Family Strengthening (KMD)
- Office of the Chief Data Officer (KMG)
- Division of Data Governance (KMH)
- Division of Data Capacity (KMI)
- Division of Data Privacy (KMJ)

KM.20 Functions

A. The Office of the Deputy Assistant Secretary provides day-to-day direction and executive leadership to OPRE in administering its responsibilities. It serves as principal advisor to the Assistant Secretary for Children and Families on all matters and directs and coordinates all activities pertaining to improving the effectiveness and efficiency of ACF programs. It represents the Assistant Secretary for Children and Families at various planning, research, evaluation, data, and improvement forums and carries out special Departmental and Administration initiatives.

The Office of the Deputy Assistant Secretary manages the formulation and execution of budgets for OPRE

programs; manages correspondence; coordinates the provision of OPRE staff development and training; provides support for OPRE's personnel administration, including staffing, employee and labor relations, and employee recognition; manages OPRE space, facilities, and supplies; and oversees travel, time and attendance, and other administrative functions for OPRE. The Deputy Assistant Secretary for Planning, Research, and Evaluation currently serves as ACF's Chief Evaluation Officer and Scientific Integrity Officer and provides support for and oversight of the ACF Evaluation Policy and ACF's implementation of the Foundations for Evidence-Based Policymaking Act of 2018. The Deputy Assistant Secretary for Planning, Research and Evaluation provides day-to-day executive leadership and direction to the Office of Research and Evaluation and the Office of the Chief Data Officer.

F. The Office of Research and Evaluation (ORE) is directed by ACF's Chief Evaluation Officer, who serves as the principal advisor to the Deputy Assistant Secretary for Planning, Research and Evaluation on all matters related to ACF's evaluation and learning agenda activities. The ORE provides coordination and leadership in implementing Titles I and III of the Foundations for Evidence-Based Policymaking Act of 2018 and oversees and manages the research and evaluation programs under sections 403, 413, 418, 429, 510, 511, 513, 1110, and 2008 of the Social Security Act and section 640 and 649 of the Head Start Act, as well as other research, evaluation, and evidence-building activities authorized by Congress and related to ACF programs and the populations they serve. These activities include priority setting and analysis; developing learning agendas; managing and coordinating major cross-cutting, leading-edge studies and special initiatives; improving ACF capacity to support the development and use of evaluation; and collaborating with federal partners, states, communities, foundations, professional organizations, and others to promote the safety, well-being, and development of children, families, and communities.

The ORE provides strategic direction, focus, and support to the research and evaluation activities that occur within OPRE's three research and evaluation divisions: Division of Economic Independence, Division of Child and Family Development, and Division of Family Strengthening. It serves as principal advisor to the Assistant Secretary for Children and Families on

all matters pertaining to improving the effectiveness and efficiency of ACF programs; strategic planning; research, evaluation, statistical, and analysis methods; program and policy evaluation; research and demonstrations; state and local innovations and progress; and synthesis and dissemination of research and evaluation findings.

B. The Division of Economic Independence, in cooperation with ACF income support programs and others, works with federal counterparts, states, community agencies, and the private sector to understand and overcome barriers to economic independence; promote parental responsibility; and assist in improving the effectiveness of programs that further economic independence. The Division provides guidance, analysis, technical assistance, and oversight in ACF on strategic planning and performance measurement for economic independence; statistical, policy, and program analysis; research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to programs that promote employment, parental responsibility, and economic independence. The Division develops learning agendas and policy-relevant research priorities; conducts, manages, and coordinates major cross-program, leading-edge research, demonstrations, and evaluation studies; manages and conducts statistical, policy, and program analyses on trends in employment, child support payments, and other income supports; and works in partnership with states, communities, and the private sector to promote employment, parental responsibility, and family economic independence. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to employment, parental responsibility, and family economic independence across ACF programs.

C. The Division of Child and Family Development, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness and efficiency of programs, and foster safety and sound growth and development of children and their families. The Division provides guidance, analysis, technical assistance, and oversight in ACF on strategic planning and performance measurement for child and family development; statistical, policy, and

program analysis; surveys, research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to improve the effectiveness of programs and service delivery. The Division conducts, manages, and coordinates major cross-programs, leading-edge research, demonstration and evaluation studies; develops learning agendas and policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to children and families. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to children and families across ACF programs.

D. The Division of Family Strengthening, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness and efficiency of programs; foster the safety, positive growth and development of children, youth, parents, and vulnerable populations; and strengthen families. The Division provides guidance, analysis, technical assistance, and oversight in ACF on parent, child, youth, and family development and dynamics; child safety; statistical, policy, and program analysis; surveys, research, and evaluation methodologies; demonstration testing and model development; synthesis and dissemination of research and evaluation findings; and application of emerging technologies to improve the effectiveness of programs and service delivery. The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation studies; develops learning agendas and policy-relevant research priorities; and manages and conducts statistical, policy, and program analyses related to strengthening families. Division staff also provides consultation, coordination, direction, and support for research and evaluation activities related to strengthening families across ACF programs.

G. The Office of the Chief Data Officer (OCDO) is directed by the Chief Data Officer (CDO). The responsibilities of the CDO are to oversee data governance and facilitate the use of data to create evidence to support decision-making. OCDO supports ACF programs in responsibly managing and using data to improve the effectiveness, equity, and efficiency of human services programs; provides coordination, oversight, and

leadership in ACF's implementation of the Government Performance and Results Act Modernization Act, the Paperwork Reduction Act, the Information Quality Act, and the Title II of the Foundations for Evidence-Based Policymaking Act of 2018; and provides expert advice on matters related to data use and reuse, privacy and confidentiality, and the sharing of information. The office coordinates mandated Office of Management and Budget (OMB) information collection approvals and plans and includes ACF's Information Collection Clearance Officer. OCDO works with ACF programs and, in cooperation with ACF programs and others, works with federal counterparts, states, community agencies, and the private sector to improve the effectiveness, efficiency, and equity of programs through improved management and use of data.

The OCDO provides strategic direction, focus, and support to the data activities that occur within OPRE's three data divisions: Division of Data Governance, Division of Data Capacity, and Division of Data Privacy. The OCDO serves as principal advisor to the Deputy Assistant Secretary for Planning, Research, and Evaluation on all matters pertaining to performance measurement and management; supporting ACF programs in responsibly managing and using data to improve the effectiveness, equity, and efficiency of human services programs; data governance; data management, collection, analysis, and use; data sharing, privacy, and confidentiality; data talent; interoperability; and application of emerging technologies to improve the effectiveness of programs and service delivery.

H. The Division of Data Governance provides coordination, consultation, direction, oversight, and technical assistance to ACF on data governance activities, policy, and operational issues. This includes work related to data standards setting, including interoperability and ACF-wide Paperwork Reduction Act policy, coordination, and support; open data initiative work, including ACF data asset cataloging and management; implementation and oversight of the Information Quality Act within ACF; advising on existing and emerging data governance policy issues, such as artificial intelligence; and coordination and support of the ACF Data Governance Council. The Division develops policy-relevant priorities for data collection and analysis and conducts demonstrations and develops tools, policies, and procedures that support the increased accessibility and

reuse of administrative and survey data for statistical purposes.

I. The Division of Data Capacity supports ACF leadership and ACF offices by providing "surge support" and leadership on high-priority campaigns to analyze and use data, including the associated capacity improvements necessary to maintain those activities going forward. Division staff provide guidance, analysis, technical assistance, and oversight on strategic planning and performance measurement and management; statistical policy and program analysis; continuous improvement; surveys, data collection, and analysis methodologies; application of data analyses to program operations and decision-making; and data skill development. Support includes both quantitative and qualitative data efforts. The Division conducts, manages, and coordinates major cross-program, leading-edge research, demonstration, and evaluation activities related to responsible data management and use, and provides consultation, coordination, direction, and support for ACF research and evaluation activities related to responsible data management and use.

J. The Division of Data Privacy provides guidance, technical assistance, and oversight on data ethics, data sharing, data privacy, and data confidentiality. This includes provision of policy analysis to ACF programs on improving program coordination, enhancing information sharing and collaboration, and identifying statutory, regulatory, or policy limitations. Division staff interpret and analyze statutes, bills, reports, and policies relating to data sharing and privacy to determine their effect on ACF and its programs; design, schedule, and execute major projects and studies to analyze interrelated issues of legality, policymaking, and operational need; coordinate and collaborate with the Office of the Chief Technology Officer to evaluate data sharing for potential privacy risks and recommend solutions, coordinate responsibility to ensure implementation of information privacy protections and adherence to federal laws, and support in ACF incident identification, notification, and response activities; develop, oversee, and implement privacy policies, procedures, and compliance across the full range of ACF activities; and advise ACF on data privacy, data confidentiality, and data sharing throughout the full life cycle of information from design, collection, maintenance, disclosure, and archiving or disposition.

IV. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization, are continued in full force and effect.

V. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

VI. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Xavier Becerra,

Secretary, Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-2628]

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.” This guidance demonstrates FDA’s commitment to developing innovative approaches to the regulation of artificial intelligence (AI)-enabled devices. More specifically, this guidance provides recommendations on the information to include in a Predetermined Change Control Plan (PCCP) in a marketing submission for a device that includes one or more AI-enabled device software functions (AI-DSFs). This guidance recommends that a PCCP describe the planned AI-DSF modifications, the associated

methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications. FDA reviews the PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP.

DATES: The announcement of the guidance is published in the **Federal Register** on December 4, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency 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-2022-D-2628 for “Marketing

Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.” 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, 240-402-7500.

- **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, 240-402-7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Marketing