notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 4, 2023.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 (#37)/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRAListing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* Managed Care Rate Setting Guidance; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* In accordance with 42 CFR 438.7, states must submit to CMS for review and approval all rate certifications for managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs). The rate certification itself is prepared by a state's actuary who certifies the managed care program's capitation rates as actuarially sound for a specific time period, and documents the rate development process and final certified capitation rates.

Our Medicaid Managed Care Rate Development Guide (otherwise referred to as the ''rate guide'') outlines the rate development standards and CMS' expectations for documentation included in rate certifications such as descriptions of base data used, trend factors to base data, projected benefit and non-benefit costs, and any other considerations or adjustments used when setting capitation rates. The information outlined in the rate guide must be included within the rate certification in adequate detail to allow CMS to determine compliance with applicable provisions of 42 CFR part 438, including that the data, assumptions, and methodologies used for rate development are consistent with generally accepted actuarial principles and practices and that the capitation rates are appropriate for the populations and services to be covered. There is no required template that states' actuaries must utilize for the rate certification, but the guidance outlined in the rate guide serves as a resource for states and their actuaries. Adherence by states and their actuaries to the rate development standards and documentation expectations outlined in the rate guide, will aid in ensuring compliance with the regulations and support CMS's review and approval of actuarially sound capitation rates and associated federal financial participation. *Form Number:* CMS–10398 (#37) (OMB control number: 0938–1148); *Frequency:* Annual; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 137; *Total Annual Hours: 753.* For policy questions regarding this collection contact Rebecca Burch-Mack at 303–844–7355.

Dated: November 15, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–25631 Filed 11–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Financing for Early Care and Education: Quality and Access for All (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services seeks approval to collect information to explore the role of Head Start in the early care and education (ECE) financing landscape, as well as how the use of multiple funding sources within a single Head Start program may be associated with the provision of Head Start's comprehensive services and with state-level differences in ECE funding. Survey data will be collected from Head Start program directors and state government administrators.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed data collection seeks to better understand

Head Start's participation in or use of coordinated funding, defined as the piecing together or combining of multiple funding sources. The data collection effort will consist of two surveys: (1) a census survey of Head Start program directors (of any grant recipient with a Head Start grant, Early Head Start grant, or both, or one of their delegate programs), and (2) a census survey of three state government administrative positions in each of the 50 states and Washington, DC (the Head Start Collaboration Office Director, the administrator of state pre-kindergarten funds, and the administrator of the federal Child Care and Development Fund [CCDF]). The surveys will identify the most common approaches to coordinated funding; examine how these approaches relate to the provision of high-quality, comprehensive ECE services in Head Start programs; understand policy levers and conditions that influence Head Start programs' decisions around and ability to coordinate funding; and document how participation in coordinated funding relates to Head Start's engagement with other ECE programs and system efforts. The resulting insights will inform ACF about the prevalence of coordinated funding in Head Start, facilitators and challenges of coordinated funding for Head Start programs, and potential associations with program quality. They will also inform future case studies.

Respondents: Head Start Program Directors, state-based Head Start Collaboration Office Directors, state administrators of state pre-kindergarten funds, and state-based administrators of federal CCDF.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Program Director Survey (Head Start Program Directors or financial administrators)	1,642	1	.83	1,363
ECE State Administrator Survey (State-based Head Start Collaboration Office Directors, administrators of state pre-kindergarten funds, state-based administrators of federal CCDF)	138	1	.67	93

Estimated Total Annual Burden Hours: 1,456.

Comments: 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.

Authority: 42 U.S.C. 9835; 42 U.S.C. 9844.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–25607 Filed 11–17–23; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4806]

Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is publishing this request for information to better understand the status of trading partners' interoperable systems and processes for enhanced drug distribution security as required by the Food, Drug and Cosmetic Act (FD&C Act).

DATES: Although you can comment at any time, submit either electronic or written information and comments by February 20, 2024 to ensure that the Agency considers your comments for potential future actions.

ADDRESSES: You may submit information and comments 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'').