Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Description: The Head Start Directors Wave 1 survey addresses the grantee's organizational characteristics, how the organization defines and diffuses T/TA, T/TA received and requested in the prior program year, and overall organizational goals and reflections on T/TA efforts for the current year. The Head Start Managers/Coordinators Wave 2 survey addresses four distinct domains of Head Start activity: (1) Program management and fiscal operations; (2) education; (3) parent and family engagement; and (4) health and wellness. The Wave 2 survey addresses how these activity domains are structured and staffed with the grantee organization, the types of T/TA and resources sought and used to improve practice in each domain, perceptions of usefulness of recent T/TA received, and T/TA priorities for the next program year.

Respondents: Head Start Directors, Head Start Managers/Coordinators.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Wave 1 Head Start Director Survey	1,200	1	.75	900
Wave 2 Head Start Managers/Coordinator Survey	860	1	.75	644

Estimated Total Annual Burden Hours: 1,544.

Authority: The Statutory Authority for this data collection is: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–12783 Filed 6–17–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Formative Data Collections for ACF Program Support (New Collection)

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

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), in the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) for a generic clearance to conduct a variety of formative data collections with more than nine respondents. These information collections would not be highly systematic or intended to be statistically representative or otherwise generalizable. ACF programs promote the economic and social well-being of families, children, individuals and communities. Many ACF program offices need to learn more about funded program services so that an understanding of program or grantee processes and potential for improvements can inform ACF decision-making and program support. Information collected under this generic would help address these needs.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Information gathering for program support was originally described under the Formative Data Collections for ACF Research Generic Clearance (0970–0356), but is now being requested as a stand-alone generic clearance. A 60-day comment period was provided as part of the approval process for #0970–0356, which included description of information collections for program support. We are now providing a 30-day comment period specific to this generic clearance for program support.

The goals of the generic information collections under this approval are to obtain information about program and grantee processes or needs, and to inform the following types of activities, among others:

- Delivery of targeted assistance and workflows related to program implementation or the development or refinement of program and grantee processes, and the development and refinement of recordkeeping and communication systems.
- Planning for provision of programmatic or evaluation-related training or technical assistance (T/TA).
- Obtaining grantee or other stakeholder input on the development of program performance measures.
- Use of rapid-cycle testing activities to strengthen programs in preparation for summative evaluation.
- Development of learning agendas and research priorities.

ACF envisions using a variety of techniques such as semi-structured discussions, focus groups, surveys, templates, open-ended requests, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Respondents: Example respondents include: current or prospective service providers, training or technical assistance (T/TA) providers, grantees, contractors, current and potential participants in ACF programs or similar comparison groups, experts in fields

pertaining to ACF programs, key stakeholder groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, or others involved in or prospectively involved in ACF programs.

ANNUAL BURDEN ESTIMATES

Instrument type	Estimated total number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours
Semi-Structured Discussions and Focus Groups	2,000	1	2	4,000
Interviews	1,000	1	1	1,000
Questionnaires/Surveys	1,000	*1.5	.5	750
Templates and Open-ended requests	250	1	10	2,500
Total	.....	.....	.....	8,250

*We have estimated 1.5 responses to account for rapid cycle testing, which will require multiple responses.

Authority: Social Security Act, Sec. 1110. [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–12801 Filed 6–17–19; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request Information Request Title: 340B Drug Pricing Program Reporting Requirements, OMB Number 0915–0176—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than August 19, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Drug Pricing Program Reporting Requirements OMB No. 0915–0176—[Extension].

Abstract: Section 340B of the Public Health Service Act (PHS Act ''Limitation on Prices of Drugs Purchased by Covered Entities'') instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS to comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program) and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS). When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Section 340B(a)(5)(C) of the PHS Act permits the Secretary of HHS and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with procedures established by the Secretary related to the number, duration, and scope of the audits. Manufacturers are permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer notifies the covered entity in writing when it believes the covered entity has violated these provisions of the 340B Program. If the problem cannot be resolved, the manufacturer will then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA, Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) for review. OPA will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General (OIG).

In response to the statutory mandate of section 340B(a)(5)(C) to permit the Secretary or manufacturers to conduct audits of covered entities and because of the potential for disputes involving covered entities and participating drug manufacturers, OPA developed an informal voluntary dispute resolution process for manufacturers and covered entities who, prior to filing a request for resolution of a dispute with OPA,