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: 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Healthy Start Evaluation and Quality Improvement, OMB No. 0915-0338 - Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement

OMB No. 0915-0338 – Revision

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. § 254c-8 (§ 330H of the Public Health Service Act), seeks to improve maternal and infant health outcomes and reduce infant mortality and other adverse perinatal outcomes. Established in 1991 as a demonstration project with 15 grantees, the program has expanded to 114 grantees serving communities in 37 states, the District of Columbia, and Puerto Rico. Healthy Start operates in communities experiencing disproportionately high rates of infant mortality and adverse birth outcomes and provides outreach, case management, care coordination, health education, and other supportive services to women, infants, children up to 18 months of age, fathers, and families. Healthy Start programs tailor services to meet the unique needs of their communities. Serving as comprehensive care hubs, they provide outreach, one-on-one case management, care coordination, clinical services (e.g., behavioral health care, midwifery care), and individual and group-based health and parenting education. Programs work across health care and social service systems to help pregnant women and families access prenatal and postpartum care, mental health therapy, substance use treatment, nutrition and breastfeeding support, transportation, and other essential resources that contribute to healthier pregnancies and improved infant and maternal health outcomes.

Over the past few years, HRSA has sought to implement a uniform set of data elements for monitoring and conducting an evaluation to assess grantees' progress towards these program goals. Under the previously approved OMB collection, the data collection instruments for the program's reporting requirements include four participant-level screening tools: (1) Demographic, (2) Background Information, (3) Prenatal, and (4) Parent/Child forms. The primary purpose of this information collection request is to reinstate the four data collection forms included in the information collection that expired on September 30, 2026. HRSA is proposing a limited number of minor revisions to the forms for the purposes described below.

HRSA also anticipates seeking OMB approval for additional revisions to the information

collection in advance of the 2029–2034 Healthy Start grant cycle. Consistent with recommendations from the U.S. Government Accountability Office (GAO), HRSA plans to revise certain Healthy Start measures to better align with measures used by other Maternal and Child Health Bureau programs, including the Title V Maternal and Child Health Services Block Grant and the Maternal, Infant, and Early Childhood Home Visiting Program. GAO also recommended that changes to Healthy Start measures and related data collection materials be completed prior to the start of a new grant cycle. To inform the future revisions, HRSA plans to solicit input from internal and external interested parties beginning in late 2026 as part of the process for updating the data collection forms for the 2029–2034 grant cycle. HRSA has also compiled comments received in response to the 60-day notice for consideration in developing the future information collection request.

In this reinstatement with change, HRSA plans to retain the participant-level tools as approved by OMB in 2020 and updated in 2024, with minor changes to: (1) clarify instructions, (2) update select response options to improve accuracy in reporting, and (3) add fields to capture the month of infant birth and/or death. These revisions are intended to improve the quality and usability of the data collection instruments and enhance the accuracy of tracking infant birth and death outcomes. The revised instructions were developed in response to grantee feedback and are expected to reduce confusion and improve consistency in form completion.

The 60-day notice described four categories of proposed changes to the data collection instruments. Following publication of that notice, HRSA further reviewed the proposed revisions and determined that certain changes should be deferred. Specifically, HRSA is no longer proposing changes to separate response options to reflect current program priorities and has narrowed the proposed updates to select response options to those needed to improve reporting accuracy. Consistent with the GAO recommendation to limit changes to data collection measures during a grant cycle, HRSA determined that more substantive revisions would be more appropriately considered as part of the planned update to the information

collection for the 2029–2034 Healthy Start grant cycle. The 60-day notice also identified reducing respondent burden as one purpose of the proposed revisions. Because the revisions proposed in this notice are limited in scope and are not expected to result in a meaningful reduction in respondent burden, HRSA has removed that description from the stated purposes of the revisions.

A 60-day notice published in the **Federal Register** on July 10, 2026, vol. 91, No. 131; pp. 42,737 - 42,739 (91 FR 42737). HRSA received six comments: four from current Healthy Start grantees, one from a company that provides data system services to Healthy Start grantees, and one from a national coalition that works to advance policies and practices supporting breastfeeding and human milk feeding in the United States. The following summarizes the key themes raised by commenters and the responses that HRSA provided directly to the commenters prior to the publication of this 30-day notice:

- **Data collection forms and reporting guidance:** Five commenters, including the four Healthy Start grantees and the data system representative, recommended changes to specific items in the proposed data collection forms and related guidance. Recommendations included clarifying instructions in the reporting system implementation guide; providing greater flexibility in administering data collection forms to Group-Based Education participants; incorporating skip logic where appropriate; considering alternatives to certain sensitive questions (e.g., using participation in the Supplemental Nutrition Assistance Program as a proxy for financial information rather than household income); and relocating certain questions to forms where the information may be more likely to be collected before a participant is lost to follow-up. Commenters also suggested adding administrative elements, such as an indicator for participants lost to follow-up, and developing a mechanism to document the history of participant screenings and updates. Such a mechanism could help identify when information was last verified, track changes over time, and support interpretation of longitudinal data. HRSA expressed appreciation for these recommendations and noted plans to consider them with internal and external interested parties beginning in late fall/winter 2026 as part of the process for updating the data collection forms for the 2029–2034 grant cycle.

- **Estimated burden and data collection processes:** One grantee recommended reassessing the estimated burden to more fully account for the workload associated with the information collection. The commenter noted that participant records may require updates after the initial screening and that staff time is also required for quality assurance, data management, and preparation for reporting. The commenter also recommended the use of automated collection techniques to reduce burden and improve system functionality. HRSA acknowledged these recommendations and expressed plans to reassess burden estimates beginning in late fall/winter 2026 as part of the process for updating the data collection forms for the 2029–2034 grant cycle. This assessment will consider the time associated with form administration, participant record updates, data management, and reporting activities.
- **Federal data coordination on lactation and infant feeding:** A national breastfeeding coalition recommended strengthening Healthy Start data on lactation, infant feeding, and postpartum support and improving alignment of relevant Healthy Start data elements with Centers for Disease Control and Prevention (CDC) maternal mortality review data. Specific recommendations included collecting more structured information on lactation and infant feeding at key postpartum intervals, lactation-related clinical conditions and other maternal health circumstances, and postpartum support and referral pathways. The coalition also recommended coordinating with CDC to align relevant definitions and data elements across programs, where appropriate, to improve data utility and comparability while minimizing unnecessary respondent burden. HRSA expressed appreciation for these recommendations and noted plans to consider them with internal and external interested parties beginning in late fall/winter 2026 as part of the process for updating the data collection forms for the 2029–2034 grant cycle.

Need and Proposed Use of the Information: The purpose of the revised data collection instruments will be to assess grantee and participant-level progress towards meeting Healthy Start program performance measures and other key indicators central to the program's mission. Findings from monitoring and evaluation efforts will provide actionable evidence to support continuous program improvement and inform decision-making. The data will also enhance understanding of participant characteristics, behaviors, and health outcomes, enabling assessment

of how these factors, in combination with Healthy Start interventions, influence program outcomes.

Likely Respondents: For the Demographic, Background Information, Prenatal, and Parent/Child participant-level forms respondents include preconceptive, pregnant, and postpartum women, as well as fathers/partners. Additionally, a small number of forms may be completed by non-enrolled guardians (e.g., foster parents, grandparents) of children in the program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Demographic Form	76,975	1	76,975	0.17	13,086
Background Form	44,600	1	44,600	0.42	18,732
Prenatal Form	31,500	1	31,500	0.25	7,875
Parent/Child Form	39,100	1	39,100	0.42	16,422
Total	192,175		192,175		56,115

Note: Total Burden Hours are rounded up to the nearest whole number.

Maria G. Button,

Director, Executive Secretariat.

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