Supporting Statement

Healthy Start Evaluation and Quality Improvement

OMB Control No. 0915-0338

Terms of Clearance: None

A. Justification

1. Circumstances making the collection of information necessary

This statement from the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) requests Office of Management and Budget (OMB) approval for data collection to support monitoring and evaluation of the Healthy Start program. The information collection is a revision to OMB# 091-0338 and is authorized under the Healthy Start Reauthorization Act of 2016 (Public Health Law No. 110-339), which includes appropriations for the Healthy Start initiative (Attachment A).

The revision includes minor updates to the data collection forms that grantees are required to submit. The current OMB approval [OMB# 0915–0338, expiration date 02/28/2023] included three forms: (1) Background Information Form; (2) Prenatal Form; and (3) Parent/Child Form. These changes included only the following: correction of typos, addition of response options (e.g., "don't know", "declined to answer"), and clarification of instructions The purpose of these minor changes is to improve the quality of the instruments and make it easier for the respondents to complete the forms. The improved instructions should reduce confusion in completing the forms. Adding additional response options will eliminate forced responses that do not represent the participant's intent and will increase response accuracy.

The purpose of the ongoing data collection is to assess Healthy Start progress toward meeting its performance goals and other key indicators central to the program's mission. Results from monitoring and evaluation efforts will provide actionable evidence to support the improvement of the program. In addition, monitoring and evaluation of the Healthy Start program are consistent with the needs of HRSA/MCHB to meet its Government Performance and Results Act requirements.

The data collection effort to support monitoring and evaluation is of interest to HRSA/MCHB as the Federal agency for promoting and improving the health of women and children. HRSA/MCHB will use the results of the data collection to improve guidance for Healthy Start grantees funded to serve reproductive age women, their children, and families, and to help reduce health disparities, decrease infant mortality, and improve perinatal health outcomes.

Background of Healthy Start

The national Healthy Start program aims to reduce disparities in infant mortality and other adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and expanded over the past three decades to 101 grantees currently serving communities in 35 states, Washington, D.C., and Puerto Rico. Today, Healthy Start has evolved from a program framework of nine service and systems core components to four approaches to reduce infant mortality through individual services and community support to women, infants, and families: 1) improve women's health, 2) improve family health and wellness, 3) promote systems change, and 4) assure impact and effectiveness.[1]

Need for enhanced data collection of the Healthy Start program

The 2014 transformation of Healthy Start necessitated revised methods for monitoring and program assessment. Information from an ongoing data collection effort will contribute to the program's continued evolution and improvement by informing key programmatic decisions. In addition, results from monitoring and evaluation can be used to meet Government Performance and Results Act requirements.

Healthy Start benefits from more than three decades of experience, including multiple small scale program evaluations; however, program evaluations prior to 2014 were limited by a lack of consistently collected and high-quality data.[2] Although grantees collected administrative data on all of their clients at the individual level, their data collection was not standardized and only reported in the aggregate to HRSA/MCHB.

Considering the lessons learned from the previous funding cycles of the Healthy Start program and its evaluations, HRSA/MCHB seeks to continue to conduct uniform individual-level data collection across grantees for programmatic monitoring purposes, for assessing overall progress towards meeting Healthy Start performance goals, and for improving accuracy and efficiency in reporting. This information can in turn be used to inform future program efforts.

The Revised Client-Level Forms (Background, Prenatal, Parent/Child, Attachments B1 – B3) will collect uniform information at the individual program participant level about women and their partners, their children 0-18 months old, and other caregivers who have primary responsibility for an enrolled child participating in Healthy Start. These data have traditionally been collected by Healthy Start grantees at the individual level within their own administrative data systems and have been reported to HRSA/MCHB only in the aggregate. Data collection using standardized formats began in 2016, and a final report based on analyzed 2017 data was developed in 2020. Also, in January 2020, HRSA received OMB approval to reduce the number and length of the data collection forms submitted by grantees to decrease overall burden while

1 The nine previous Healthy Start components included five service and four systems components. Service components included direct outreach services and client recruitment, case management, health education services, screening and referral for perinatal depression, and interconception continuity of care through the infant's second year of life. Systems components included utilization of community consortia and provider councils to mobilize key stakeholders and advise local grantees, development of a local health system action plan, collaboration and coordination with Title V services, and development of a sustainability plan for continuation of services and project work beyond the grant period.

2OMB numbers for the previous national evaluations are 0915-0287 and 0915-0300 for the first national evaluation and 0915–0338 for the second national evaluation.

focusing greater attention on quality improvement and on grantee progress in relation to program performance measures and other key indicators central to Heathy Start's mission. The current request focuses on minor quality improvements to the form used by grantees since early 2020.

2. Purpose and use of information collection

The purposes of this data collection are aligned with Healthy Start program needs and goals for accountability, programmatic decision making, and ongoing quality assessment at the grantee and national levels. The monitoring and evaluation of the Healthy Start program are focused on the goal of providing information to enable identification of issues at the earliest possible stages to help allow for midcourse corrections among individual grantees and for the program as a whole. In addition, the extent to which individual grantees and the program as a whole are meeting and/or improving their progress towards number of clients served, and other program goals and key indicators is essential to data collection.

The revised client-level forms (Attachments B1-B3) are intended to collect information about Healthy Start participants/clients across all Healthy Start grantee sites. Additionally, the forms include items that prompt provision of staff records that are designed to bring client-level data directly into alignment with grantee reporting requirements. The revised forms also continue to facilitate rough benchmarking and comparison with national databases on various health behaviors and perinatal outcomes. The wording of individual items was standardized to align with existing national surveys, including the Health Resources and Services Administration's (HRSA) National Survey of Children's Health (NSCH) and CDC's Pregnancy Risk Assessment Monitoring System (PRAMS).

3. Use of improved information technology and burden reduction

These three data collection forms comply with the Government Paperwork Elimination Act (Public Law 105-277, Title XVII) by efficiently employing technology in an effort to reduce burden on respondents. Grantees create a reporting file that is submitted in XML or CSV format via the Healthy Start Monitoring and Evaluation Data System (HSMED). HSMED was developed with quality assurance features, such as the incorporation of data validation and verification capabilities, to facilitate collection of high-quality data.

4. Efforts to identify duplication and use of similar information

These three revised forms constitute a smaller and more focused extension of the currently authorized (0915-0338) HRSA/MCHB data collection activities for monitoring and evaluating the Healthy Start program. Aside from this current effort, the client-level information proposed for collection in this OMB package is not available elsewhere.

5. Impact on small businesses or other small entities

Healthy Start grantee staff will collect information from Healthy Start participants. Some of the Healthy Start grantee organizations may be small businesses. Additionally, some of the Healthy Start grantees may have contracts with small businesses to provide additional staff or services. Because information collection may involve small businesses, the information being requested has been held to the absolute minimum necessary for the intended use of the data and to demonstrate programmatically important outputs and outcomes.

6. Consequences of collecting the information less frequently

The requested data collection activity does not result in less frequent collection of data. The Background Information form will be administered to all clients upon enrollment in the program and updated when the enrolled participant enters a new reproductive phase (e.g., preconception to prenatal, or prenatal to postpartum, etc.), or annually, as long as the client is enrolled in Healthy Start. The Prenatal form will be administered when an enrolled woman is pregnant, and the Parent/Child form will be administered when a program participant has a live birth, updated when the enrolled child is 6 months old, and/or when the child exits the program (if that exit is at least 3 months beyond the previous data collection point). This will facilitate tracking participant outcomes across the full time horizon of the Healthy Start program.

7. Special circumstances relating to the guidelines of 5 CFR 1320.5

This request fully complies with 5 CFR 1320.5. There are no special circumstances.

8. Comments in response to the Federal Register Notice/outside consultation

The 60-day Federal Register Notice required in 5 CFR 1320.8(d) was published in the Federal Register on Oct 21, 2022, Volume 87, Number 203, Page Numbers 64065-64066. No public comments were received.

9. Explanation of any payment/gift to respondents

Healthy Start participants will not be compensated for completing the three revised forms, as information will be collected as part of the enrollment and participation process and will be essential for providing, targeting, and improving services for these participants.

10. Assurance of confidentiality provided to respondents

The information collection will fully comply with all aspects of the Privacy Act I and agencies will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). All participants will be told that the information they provide will be treated in a secure manner to the extent allowed by law. Participants also will be informed that they may refuse to answer any question, and that they can stop at any time without risk to any Healthy Start benefits or services they receive. In addition, participant names and dates of birth will not be provided to the Federal Government, nor will any other PII be uploaded to HRSA/MCHB during the data collection process. Thus, HRSA/MCHB will not be collecting any PII from these data collection forms. A unique ID will be assigned to each participating woman as well as participating children and fathers/partners.

At Healthy Start sites, individuals must have a form recorded in the data collection system to be considered a program participant. The form can be incomplete if the individual refuses to provide all information requested; however, without a form in the data collection system, grantees will not have a means of accounting for individuals recruited (and Healthy Start services provided) in reporting to HRSA/MCHB. If a field is required to be completed for upload into the HSMED system, “Don’t know” or “Declined to answer” response options may be selected.

In addition, any/all contractor employees will sign a pledge that data will be kept private to the extent allowed by law and respondent identity. Breaking that pledge is grounds for immediate dismissal and possible legal action.

11. Justification for sensitive questions

The revised forms are designed to provide data on individual-level socio-demographics (e.g., education, race, ethnicity), and to track outcomes and progress at the subgroup and participant levels. The forms also facilitate aggregate benchmarking and comparison with national databases on various health behaviors and perinatal outcomes.

While numerous potentially sensitive questions have been eliminated from the three revised forms, in addition to socio-demographic information, several items remain that refer to behaviors and/or circumstances that may be of a personal nature for respondents. Examples of potentially sensitive questions include: those related to behaviors including smoking, alcohol, and drug use; family planning goals; and, pregnancy loss or infant death. As Healthy Start provides services to promote healthy behaviors and link participants to critical resources in the face of challenging circumstances, it is necessary to collect information on related topics given the association between these factors and perinatal outcomes. Finally, as noted in #10 above, participants will be assured that they do not have to respond to any questions that they do not want to answer, and that all information they provide will be kept confidential and private. No PII will be uploaded to HRSA/MCHB.

12. Estimates of annualized hour and cost burden

Section 12A:

This information collection request contains three forms: the Background Information form (see Attachment B1); the Prenatal Form (see Attachment B2); and the Parent/Child form (see Attachment B3). The Background Information form will be administered to each Healthy Start participant upon enrollment and updated with each reproductive phase change. The Prenatal form will be administered to pregnant women, and the Parent/Child form will be administered to participants who have a child 0-18 months enrolled in Healthy Start.

The annualized frequency of the data collection will include one response per respondent for each data collection form. Respondents include pregnant women, women of reproductive age, and the primary custodial parent of children who are served by the Healthy Start program, as well as any fathers/partners who are linked to either an enrolled woman or an enrolled child in relevant Healthy Start activities. HRSA funds 101 Healthy Start grantees and requires that the grantees serve 700 participants per year in the following manner: 300 pregnant women; 300 non-pregnant (i.e., never pregnant, postpartum, or interconception) women, infants, and children up to 18 months of age; and 100 men. Based on these numbers, HRSA expects each grantee to serve approximately 450 adults, 300 pregnant women, and 300 parents of enrolled children per year, and estimates 106,050 total responses with an average time per response ranging from 0.10-0.30 hours per form (based on form type). Given that the forms must be administered to participants by Healthy Start staff, the overall average burden per response doubles the average time per response (i.e., ranging from 0.2-0.60 hours per form). The estimated annualized burden hours is

48,480 hours. Table A1 presents the annual burden hour estimates for this data collection. The original estimates in 2020 were derived through nine pilot administrations conducted with Healthy Start clients across nine Healthy Start sites and represented the longer end of the range of times found in these administrations; as such, the original time estimates were conservative in that they are more likely to over than to underestimate the actual time burden. Given that the grantees have been using the forms since 2020, and are familiar with both the data collection process and form contents, it is likely that the estimated amount of time to complete the collections has remained the same or decreased since the last OMB submission. However, the average burden per response will double to account for the time needed by the Healthy Start grantee staff to administer the surveys.

Table A1 – Estimates of annualized burden hours:

Type of Collection	**Number of Respondents**	**Number of Responses per Respondent**	**Total Responses**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Background Information Form	45,450*	1	45,450*	.60**	27,270
Prenatal Form	30,300*	1	30,300*	.20**	6,060
Parent/Child Form	30,300*	1	30,300*	.50**	15,150
Total	106,050		106,050		48,480

*All adult participants (45,450) complete the General Background form, and a subset of these same individuals (30,300) also complete the Prenatal or Parenting forms for total of 106,050 responses.
** Healthy Start staff administer the surveys to all adult participants; therefore, the average burden per response and the total burden hours will be doubled to account for the staff persons' time.

Section 12B:

For each data collection effort, we use dollar per hour estimates to generate the estimated annualized burden costs. For Healthy Start participants, we used the Federal minimum wage ($7.25) provided by the Department of Labor, Bureau of Labor Statistics (BLS), 2022. (https://www.bls.gov/opub/reports/minimum-wage/2022/home.htm#:~:text=In%202022%2C%2078.7%20million%20workers,wage%20of%20%247.25%20per%20hour.). For Healthy Start staff administering the forms (typically Community Health Workers), we used the median wage ($22.21) estimated by the Department of Labor, Bureau of Labor (BLS), Occupational

Employment and Wages for Community Health Workers in 2022. (https://www.bls.gov/oes/current/oes211094.htm)

Table A2 – Estimates of annualized burden costs:

Type of Collection	Total Burden Hours	Wage Rate Participants	Total Burden Cost
Background Information Form	Participants: 13,635	$7.25	$98,854
	Program Staff: 13,635	$22.21	$302,833
Prenatal Form	Participants: 3,030	$7.25	$21,968
	Program Staff: 3,030	$22.21	$67,296
Parent/Child Form	Participants: 7,575	$7.25	$54,919
	Program Staff: 7,575	$22.21	$168,241
Total	48,480		$714,111

13. Estimates of other total annual cost burden to respondents or record keepers/capital costs

Other than their time, there is no cost to Healthy Start program participants. Healthy Start program grantees devote time and resources to the development and/or update of management information systems used to collect, aggregate, and report performance data in order to align with the information requested under this request. HRSA will provide technical assistance to awardees in order to promote efficiencies in this development work. Grantees use grant funds to pay for these developments/updates.

14. Annualized cost to Federal government

The approximate annualized cost to the government for this data collection effort is $204,806. These costs are comprised of: Federal employee salaries, contractor staff salaries, and operational expenses (e.g., equipment, printing, and postage). Table A3 below provides the cost breakdown for the annualized cost to the Federal Government based on 2022 salaries (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/html/DCB.aspx).

Table A3. Estimates of annualized cost to the Federal Government

Item	Grade/Salary	Percent Effort	Annualized Cost
HRSA/MCHB Healthy Start Project Staff/Oversight	GS-14-5 ($143,064)	30%	**$64,378.5****

HRSA/MCHB Healthy Start Project Staff/Oversight	GS-13-5 ($121,065)	50%	**$90,799.5****
Contract Staff (Operations & Maintenance Analyst/Programmer)	$95/hr	n/a (148 hrs/yr)	$14,060*
Contract Staff (Tableau Analyst)	$117/hr (cost based on # of support hours provided with a max of 120 hrs)	n/a (120 hrs/yr)	$14,068*
Contract Staff (Operations & Maintenance Engineer)	$117/hr	n/a (100 hrs/yr)	$11,700*
Contract Staff (Operations & Maintenance Solutions Specialist)	$98/hr	n/a (100 hrs/yr)	$9,800*
Total			**$204,806**

*Contractor salaries are loaded and include fringe benefits (e.g., costs for health insurance, travel, paid vacation). The fringe rate is 38% for full-time staff.
**Federal staff salaries include overhead and benefits.

15. Explanation for program changes or adjustments

Piloting occurred with participants across nine Healthy Start grantees in August 2019. HRSA/MCHB incorporated key feedback from these pilots into the three revised forms. Based on the feedback obtained through the piloting, HRSA/MCHB was able to better ensure that the questions used were understandable to the intended population, and allowed grantees an opportunity to provide input into whether the content of the questions was aligned with grantee reporting requirements.

Furthermore, the forms have been in use since early 2020, and the need for additional corrections was noted by the grantees. The revision includes minor updates to the data collection forms that grantees are required to submit. The current OMB approval [OMB# 0915–0338, expiration date 02/28/2023] included three forms: (1) Background Information Form; (2) Prenatal Form; and (3) Parent/Child Form. These changes included only the following: correction of typos, addition of response options (e.g., “don’t know”, “declined to answer”), and clarification of instructions. The purpose of these minor changes is to improve the quality of the instruments and make it easier for the respondents to complete the forms. The improved instructions should reduce confusion in completing the forms. Providing additional response options will eliminate forced responses that do not represent the participant’s intent and will increase response accuracy.

16. Plans for tabulation, publication, and project time schedule

Analysis plan

The analyses of data will vary based on the data collected by the specific form and the analytical approach and methods proposed by the data sources. The analyses will be primarily descriptive at the participant and grantee levels as well as exploring associations at these levels.

Reports

Results from monitoring will be synthesized annually to assess trends and changes in participant characteristics and outcomes, allowing for program adjustments throughout the grant period. The data is also used in Healthy Start's national evaluation effort; it is estimated that final data collection results from the evaluation will become available in Fall 2025.

Analyses of program progress spanning five years will allow HRSA/MCHB to examine short- and long-term outcomes as the program matures throughout the grant cycle. It is important to assess the program effects on outcomes at multiple points in time to identify when the changes in outcomes occur and link the changes to the maturity of the program; information that can be used in program improvement and replication. In addition, it is important to assess progress towards performance goals over a relatively long period of time (in this case, five years) to give the program time to affect long-term gains, which are typically difficult to change and observe at the population-level in a short period of time.

Schedule

Funding for the Healthy Start grantees began in April 2019 and will end in March 2024. After the receipt of funding, grantees began recruiting and/or providing services. HRSA/MCHB's HSMED data system was launched in November 2020 to collect information via the Healthy Start Data Collection Forms. The estimated schedule for the project is presented in Table A.5 for key data collection, analysis, and reporting tasks relevant to this request for OMB approval. The maximum three years of clearance is requested with the intent that an extension for OMB clearance will be requested to continue data collection if needed.

Table A5. Estimated time schedule for data collection, analysis, and reports

Task	Time Schedule
Prepare data collection tools	January 2019 – August 2019
Receive OMB approval	February 2020
• Receive OMB approval for continued effort	• Estimated September 2023
Update data collection systems	February 2020 – November 2020
Administer Background Information, Prenatal, Parent/Child Forms	
Train staff on data collection/new data collection system	February 2020– November 2020
Collect individual-level data for monitoring (Healthy Start grantees)	November 2020–June 2024*
Conduct Analyses and Reporting	
Analyze and synthesize data annually and at project end	January 2022–June 2024

Task	Time Schedule
Develop Final report	June 2024–December 2024
Final study briefing	December 2024

* Includes extended data submission for full program close out

17. Reason(s) display of OMB expiration date is inappropriate

There are no exceptions to the certification; the expiration date will be displayed. To continue data collection in the last two years of the grant, an extension or revision to this package will be submitted for OMB clearance.

18. Exceptions to certification for paperwork reduction act submissions

There are no exceptions to the certification.