**Supporting Statement A**

**Healthy Start Evaluation and Capacity Building Support**

**OMB Control No. xxxx-xxxx**

**Terms of Clearance:** **None**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this submission requests Office of Management and Budget (OMB) approval of a 3-year clearance for the Health Resources and Services Administration (HRSA) to conduct an evaluation of the Healthy Start Program. The goal of the Healthy Start Program, funded through HRSA’s Maternal and Child Health Bureau (MCHB), is to reduce disparities in maternal and infant health. Using a life course approach, the program has focused on improving the health of mothers, infants, and families in those communities with the highest rates of infant mortality, maternal morbidity and mortality, and other adverse birth outcomes such as prematurity and low birth weight, with an emphasis on racial, ethnic, social, and economic disparities. Changes made to the program in 2019 added an increased focus on maternal health and strengthened activities for fathers/partners. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 3 decades to 101 grantees across 35 states, Washington, D.C., and Puerto Rico. In October 2019, a bill to amend the Public Health Service Act to reauthorize the Healthy Start program (Healthy Start Reauthorization Act of 2016) for FY2020-FY2024 was enacted. The collection of information for this evaluation is authorized by 42 U.S.C. § 254c-8 (Title III, Part D, § 330H of the Public Health Service Act).

MCHB has long recognized the importance of addressing health disparities and inequitable access to health services and has continuously conducted assessment and evaluation of the program. Evaluation data are key to the identification of strengths and successes of the Healthy Start programs, as well as opportunities for improvement and development. Evaluation data can be used to improve the programs at the grantee and national levels; data can also demonstrate the value and importance of Healthy Start and provide evidence for the need for continued funding, thus ensuring a stable resource within high-risk communities. For the next cycle of evaluation, MCHB has partnered with Westat (contract # 75R60219D00021) to develop a feasible, cost-effective evaluation design that can show the HS programs’ association with measurable changes in infant and maternal health outcomes in areas serviced by the HS program. In the design process, the Westat team has closely collaborated with MCHB to carefully consider and address those questions most relevant to MCHB and the future success of the Healthy Start program, including consideration of methods to address confounding of outcomes. Further, as conversations on health equity have been elevated to center stage in this country, we recognize that Healthy Start is at the forefront of addressing prevalent, persistent flaws in our nation’s systems and social structures that negatively impact social determinants of health and outcomes. Health equity requires addressing obstacles to health such as poverty and discrimination and their consequences.

The current evaluation is assessing program implementation, service utilization, health outcomes, and transformational changes in HS communities and will involve the following analyses and data sources:

* HS program data (from all 101 grantees) will be used to analyze the program’s dosage (referring to the duration or amount of program exposure)[[1]](#footnote-2),[[2]](#footnote-3), and measure the association between program dosage and individual-level health outcomes such as birth outcomes, women’s health, and the health and well-being of infants, as well as disparities in health outcomes, with additional participant data obtained from (up to 9) select grantees and vital records data (from one state) to support the basic dosage analysis;
* Program data (from all 101 grantees) will also be used to assess participant characteristics, utilization of services, duration of participation in HS, and progress towards HS program benchmarks;
* A survey of all 101 HS Program Directors will be used to assess organization-level factors such as the types of services and referrals provided by HS sites, implementation challenges and successes, data collection, quality improvement and performance monitoring;
* Case studies, which will enable a deeper dive to examine program implementation strategies, will be conducted with up to 15 grantees and include staff interviews, a Network survey, and a Participant survey to assess organizational, community and individual level factors such as implementation barriers and facilitators, types of collaborative activities, network membership, workforce development, and participant satisfaction.

More detailed information regarding the evaluation questions, data sources and the analytic approach can be found below in Table A.1.

1. **Purpose and Use of Information Collected**

The goal of this evaluation, as stated above, is to provide MCHB with information to guide future program and policy decisions related to infant and maternal health in high-risk communities. MCHB seeks to implement a mixed-methods evaluation to assess association between the program and individual-level outcomes and examine the role of organizational and community-level factors on the successes and challenges of HS activities noted above. The evaluation centers on four components – implementation, utilization, outcome, and transformative. The implementation component will assess program activities/services directed at Healthy Start (HS) participants, including facilitators and barriers faced by local HS programs. For example, a descriptive statistical analysis will be conducted of the data from each of the surveys to examine the types of services to which the Healthy Start programs refer participants, and the extent to which participants enroll in services for which they are eligible. The utilization component will assess HS participants’ uptake of HS services, particularly by type of HS participant subgroup characterized by demographics and risk level. The outcome component will assess the HS programs’ association with improved maternal and child health outcomes. The transformative component will examine how local HS programs engage with health systems and with other programs and policies at the local and state level to impact positive change in their community, such as the number and types of local community efforts that the HS programs participate in to address health equity and social determinants of health (SDoH).

The transformative evaluation framework uses mixed methods, engages stakeholders, includes research questions based on community needs, and develops collaborations based on trust and respect to help identify, understand, and reveal multiple, unique experiences with a program. The transformative evaluation framework is aimed at improving responsiveness to marginalized communities’ needs and to respect the multiple cultural positions that rest therein while working for positive transformation.[[3]](#footnote-4) The questions in the new data collection instruments are designed to address such issues.

New data collection instruments will include: 1) Healthy Start Program Survey, 2) Healthy Start Network Survey, 3) Healthy Start Participant Survey, and 4) Healthy Start Stakeholder Interview Guide. These instruments have been specifically designed to be non-duplicative. In addition, secondary data will be used for the overall evaluation. The secondary data sources include performance measures reported by HS grantees to HRSA’s Discretionary Grants Information System (DGIS); de-identified HS participant data reported by HS grantees to HRSA’s Healthy Start Monitoring and Evaluation Data System (HSMED); data from up to nine HS grantees that collect, but do not report to HSMED, on the types and quantities of HS services received by HS participants; and vital records data obtained from one state. HSMED data includes information about participant demographics; health care access and utilization; personal well-being; health behaviors; pregnancy and childbirth history; mother and child health history; home life; parenting practices; and pregnancy outcomes such as low birthweight, preterm birth, and infant mortality for all participants across all 101 grantees. HSMED will be used to examine associations between exposure to the HS program and pregnancy outcomes and to analyze black/white disparities in outcomes. OMB clearance is not requested for these secondary data. Together, the primary data collection instruments and the secondary data will be used to address the evaluation questions. These evaluation questions are listed in Table A.1 below, along with the data sources and a brief description of the associated analysis for a clearer understanding of the overall evaluation.

All 101 HS grantees will be asked to complete the new Program Survey, and all 101 grantees already contribute data to HSMED and DGIS, which will be used for the evaluation. From these 101 grantees, a convenience sample of 15 grantees will be selected as case study sites where data from the Network Survey, Participant Survey, and the Stakeholder Interview Guide will be collected.

The sample of 15 grantees selected will serve as illustrative case studies to provide more context about the implementation of program activities and evidence-based programs, and about strategies, practices, and processes that contribute to outcomes. This approach of a collective case study of 15 grantees is undertaken to elicit common findings from different HS programs that have performed well, have higher levels of participation, in a diversity of settings, and may have more lessons learned regarding implementation successes and challenges than less experienced programs. Therefore, case study sites will be selected to represent experienced grantees with established Community Action Networks (CANs) and sufficient numbers of current HS participants to provide the data needed for the evaluation. Priority will be given to select grantees that have attained at least 70 percent of the HS benchmarks in the previous year and, in particular, attained the benchmarks related to the CANs as reported in the DGIS. Grantees from both urban and rural locations and from organizations that are both health departments and non-health departments will be selected. Recent 2021 data from the DGIS and HSMED will be used to ensure that sites selected have the targeted sample sizes of respondents for the two surveys. Grantees with 50 or more CAN members reported in the DGIS and those with 250 or more currently enrolled women participants and 20 or more male participants reported in HSMED will be used for the inclusion criteria of the case study sites.

 This collective case study approach of 15 more developed programs will allow the evaluation to obtain data to examine patterns of similarities and differences across grantees and enhance the understanding of conditions that facilitate program activities and services. This is an efficient, cost-effective approach for identifying strategies from successful programs, but it is subject to survivorship bias. Although it will not be representative of the full cohort, it will provide insights into the functioning of grantees with higher levels of CAN participation and higher numbers of participants, a goal which all sites are working towards. By only sampling from successful programs, and not the general population of HS grantees, these strategies may not be generalizable to all HS grantees. While this approach may limit generalizability, the goal is to identify successful strategies and processes of addressing challenges in program implementation that can be shared and adopted by less experienced grantees.

A list of grantees meeting the criteria will be generated, and further input from the MCHB HS project officers will be obtained on these grantees to learn about their performance and responsiveness before selecting the 15 sites to request participation. Once the grantees agree to participate, they will be asked to provide a list of their currently active CAN members with their email addresses and currently enrolled participants with their phone numbers and email addresses to which web survey links can be sent. From these lists, the number of potential respondents identified for each survey will be randomly selected and contacted by email to complete the web surveys, with weekly reminders sent for survey completion. More potential respondents from the lists will be randomly selected and contacted and similar process followed to reach the targeted numbers for completion of each survey.

For the Participant Survey, if potential respondents have difficulty completing the survey over the web, the evaluation contractor will offer assistance to help them complete the survey over email or by telephone. For those who are non-responsive, the contractor will attempt to reach them by phone and will also ask the HS case managers for assistance with contacting the participants about the survey as needed. The contractor will also ask the HS program staff to allow participants to use computers at their site to access the web survey when they come in for services, if needed.

An initial, basic dosage analysis will use HSMED data to measure the association of the HS program with health outcomes such as preterm birth, low birthweight, and infant death. Basic dosage will be represented by the duration of exposure to the interaction and /or services the HS program supplies to a participant. A regression analysis will be used to capture changes in outcomes among participants with high doses relative to mothers with lower doses (see Statement B for more details regarding the dosage analysis). In addition, as mentioned above, secondary data will be collected from up to 9 grantees who are able to regularly collect additional data on the types and quantities of HS services received by HS participants. These additional data on the quantity of services represent amount of program exposure. These grantees will be selected and asked to participate based on their data systems, including the availability of the data and ease of access, as well as on input from the MCHB HS project officers. This sample of approximately 10% of all grantees will be sufficient to support the basic dosage model based on duration of exposure with additional data on the amount of program exposure. Furthermore, vital records data will be collected from one state, which will be selected based on criteria developed with MCHB. These data are already being collected by the grantees and the state, and the contractor will ask for access to these data to be used in the outcome evaluation component to support the dosage analysis conducted with data from HSMED. The previous evaluation taught us that it is not feasible to obtain data use agreements with all states. This parallel analysis limits the number of data use agreements required while helping to ensure the consistency of the basic dosage model. If both analyses show a positive effect of participating in the program, our confidence in the dosage analysis results is strengthened.

Information collected through these activities together will be used to evaluate improvements in perinatal health among disadvantaged populations served by the Healthy Start program. The mixed-methods data collection approach will capture both quantitative measures of program activities, outputs, and outcomes as well as qualitative impressions of program implementation and lessons learned. This data collection approach will generate results useful to policymakers and practitioners, informing them about the implementation and value of Healthy Start as an intervention working at multiple levels in diverse communities to reduce infant mortality, and maternal mortality and morbidity.

**Table A.1. Data Sources and Analytic Approach for the Healthy Start (HS) Evaluation Questions**

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| --- | --- | --- | --- |
| Type of Evaluation | Evaluation Sub-Question | Data Sources  | Analytic Approaches  |
| 1. Evaluation Question: To what extent is HS associated with improved health status among participants served by HS programs?
 |
| Outcome | 1a. To what extent did infant health and perinatal outcomes improve in communities served by HS?1a i. To what extent were disparities in infant health and perinatal outcomes reduced in communities served by HS?1b. To what extent did maternal health indicators improve in communities served by HS?1c. To what extent did child health indicators improve in communities served by HS? | HSMED(*secondary data*) – all 101 granteesAdditional participant data from (up to 9) select grantees for enhanced dosage analysis (*secondary data*)Vital Records from 1 state (*secondary data*) | Dosage analysis (basic and enhanced) that projects how outcomes (e.g., prematurity, birthweight) differ from what they would have been absent HS. Dosage analysis uses HS participants as their own comparison group to avoid the selection bias issues inherent in many quasi-experimental impact analysis designs. Baseline data is less crucial when HS participants serve as their own comparison group. Basic dosage model will use duration in HS as a proxy for program dosage (i.e., duration of exposure to HS services) and enhanced dosage model will strengthen inferences of associations of HS services with outcomes using additional data on quantities of services (i.e., amount of exposure to HS services) received.Propensity score matching (PSM) analysis to support dosage analysis results (1 state). Comparison group analyses based on PSM check the robustness of the dosage analysis findings and guide selection of the best dosage model specifications. |
| 1. Evaluation Question: To what extent do local HS programs reach women who are high-risk for poor reproductive health outcomes?
 |
| Implementation | 2 a. How do local HS programs define “high-risk?” | Program Survey - all 101 grantees | Descriptive statistical analysis of the data from the survey to examine the high-risk criteria (e.g., medical and social risk) used and the variation in the criteria across the HS programs.  |
| **Utilization** | 2 b i. What are the characteristics of HS women overall?2 b ii. To what extent do local HS programs reach high-risk women as intended?2 b iii. What are the risk profiles of participants served?2 b iv. How long does each subgroup (based on risk status) stay in the HS program? | HSMED (*secondary data*) - all 101 grantees | Descriptive statistical analysis to identify demographic (e.g., age, race/ethnicity, education, income) and high risk characteristics (substance use, poor prior pregnancy outcomes, chronic medical conditions, depression, domestic violence, late prenatal care entry) of HS women to develop risk profiles. |
| 1. **Evaluation Question: In providing a set of core HS services, how are HS programs addressing participants needs?**
 |
| **Utilization** | 3 a. What types of HS services does each subgroup use?  | HSMED (*secondary data*) – all 101 grantees | Descriptive statistical analysis to identify health services (e.g., usual sources of care, preventive care, prenatal/postpartum visits, screening and referral for depression) used by HS participants. |
| **Implementation** | 3 b. To which services/ programs do HS programs refer and assist participants?3 b i. To what extent are HS participants enrolled in services for which they are eligible? | Program Survey – all 101 granteesParticipant Survey – up to 15 grantees | Descriptive statistical analysis of the data from each of the surveys to examine the types of services to which the Healthy Start programs refer and assist participants, and the extent to which participants enroll in services for which they are eligible (e.g., behavioral health, housing, WIC, employment)?  |
| 1. **Evaluation Question: To what extent are HS programs meeting HS benchmarks? What activities are associated with improving HS benchmarks?**

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| **Implementation (performance measures)** | 4 a. To what extent do HS grantees reach all the national program benchmarks? | DGIS (*secondary data*) – all 101 grantees | Descriptive statistical analysis of secondary data to identify annual benchmarks met/not met by grantees. |
| **Implementation**  | 4 b. What are the barriers/challenges to implementing program activities?4 b i. What are the challenges for specific targeted initiatives?  | Program Survey – all 101 granteesParticipant Survey – up to 15 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of data from each of the surveys to identify the barriers/challenges to implementing program activities.Content analysis of interview data to examine the specific challenges/barriers for targeted initiatives (e.g., fatherhood initiative, maternal health, Community Action Network (CAN)) and other barriers/challenges identified in open-ended questions. |
| **Implementation** | 4 c. What specific activities, including quality improvement, did HS programs conduct to improve benchmarks overall and for each specific benchmark? | Program Survey – all 101 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of data from the survey to identify and rank (by how well they work) the activities conducted to improve the HS benchmarks overall.Content analysis of interview data to examine activities that worked well to improve specific benchmarks.  |
| 1. **Evaluation Question: To what extent do local HS programs, including the Community Action Networks (CANs), engage in activities with collaborators to advance the goals of HS?**
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| **Implementation** | 5 a. What are the facilitators and barriers to the implementation of the CANs?  | Program Survey – all 101 granteesNetwork Survey – up to 15 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of data from each survey to identify overall facilitators/barriers of CAN activities undertaken to advance HS goals? Content analysis of data from interviews to examine specific facilitators/barriers to the implementation of CAN activities. |
| **Implementation**  | 5 b. How do local HS programs, including the CANs, coordinate, collaborate and integrate with reproductive, child, and family health activities in their community to provide services from preconception through early childhood care and education? | Program Survey – all 101 granteesNetwork Survey – up to 15 grantees | Descriptive statistical analysis of data from the two surveys to identify the types of coordinated/ collaborative community activities that the HS programs and the CANs participate in and their patterns of referrals.Network analysis from the Network Survey data to identify the number and types of organizations with established HS partnerships, the volume of interactions on specific program activities (i.e., sharing of resources, improving access to services, building capacity), and the level of cohesion and centralization across the activities.  |
| **Implementation** | 5 b i. To what extent are local HS programs part of/drivers of their local community development agencies?5 b ii. How does the CAN contribute to the local HS program?5 b iii. What are the characteristics of a CAN? | Program Survey – all 101 granteesNetwork Survey – up to 15 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of data from the two surveys to identify HS staff’s memberships/ affiliations on community boards and other collaboratives (e.g., health, social service, religious, philanthropy).Network analysis of data from the Network Survey to identify key network players (e.g., brokers, leaders) and their contributions to HS, and examine how well CANs function (e.g., low, medium, high).Content analysis of data from the interviews to identify types of specific community efforts and contributions of the CAN to HS. |
| **Implementation** | 5 c. How extensively do local HS programs actively participate in, engage with, and contribute to their state public health and other programs, policies, and how sustainable are these efforts? | Program Survey – all 101 grantees | Descriptive statistical analysis of the data from the survey to identify the maternal and child programs, services and policies in the HS communities (e.g., fetal, infant and maternal mortality review committees, Title V, Medicaid), how HS is represented in these initiatives (e.g., committee memberships and attendance at meetings), and how data are shared and used across these initiatives.  |
| 1. **Evaluation Question: To what extent do local HS programs engage in activities aimed at advancing health equity and addressing the social determinants of health in their communities?**
 |
| **Transformative**  | 6 a. How do local HS programs define health equity?6 a i. What do HS sites do to address health equity for their staff, clients, and communities? | Program Survey – all 101 granteesParticipant Survey – up to 15 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of data from each of the surveys to identify healthy equity definitions used by the HS programs, the variation in the definitions used across the HS programs, HS efforts to address health equity (e.g., equity trainings; diverse HS workforce; program policies/procedures; participant services; efforts to increase participants’ perceptions/ satisfaction with respectful, non-discriminatory care from HS and the community) and other health equity efforts raised by respondents. Content analysis of data from the interviews to identify HS efforts to address health equity (See examples above).  |
| **Transformative** | 6 b. To what extent do local HS programs participate organizationally in local community efforts that address health equity? 6 b i. To what extent do HS programs participate organizationally in local community efforts that address social determinants of health?  | Program Survey – all 101 granteesNetwork Survey – up to 15 granteesStakeholder Interviews – up to 15 grantees | Descriptive statistical analysis of the surveys to identify the number and types of local community efforts that the HS programs participate in that address health equity topics (e.g., structural and implicit bias and unequal treatment), SDoH topics (e.g., transportation, housing, food, recreation, environmental issues, immigration, and new federal programs such as the Rescue Plan), and satisfaction with participation in these efforts. Content analysis of data from the interviews to to identify the number and types of local community efforts that the HS programs participate in that address health equity and SDoH topics (See examples above), and satisfaction with participation in these efforts. |

The four new data collection instruments included in this statement and submitted for OMB clearance reflect feedback from MCHB and the information collected in pilot testing. Further information about the instruments is described below, and information about their sampling methodologies are described in Table A.2.

**The Healthy Start Program Survey** was designed to collect information about program implementation and transformation from all 101 grantee programs. For the implementation component of the programs, the following information will be collected: capacity and staffing; services provided; activities related to targeted Healthy Start initiatives, including fatherhood, maternal health, and the Community Action Network (CAN); programs’ definitions of high-risk status for Healthy Start participants; staff, participant, and community challenges; benchmark quality improvement activities; referrals to community services; and local and state collaborations with Healthy Start and in the Healthy Start communities. For the transformative program component, information will be collected about how Healthy Start programs address health equity and social determinants of health for their staff and participants, as well as within the CANs; other community and state health equity-related activities in which the programs participate; and perceptions of the program and clinical services related to respectful, non-discriminatory care for Healthy Start participants. The survey will be sent to the Healthy Start program directors, but it is expected that the directors may delegate sections of the survey to other Healthy Start staff members. The survey is designed for self-administration. The survey tool will allow the respondents to complete the survey over multiple sessions. Healthy Start programs will be asked to complete the survey once in Year 2 of the evaluation. The information collected in the survey will enable assessment of grantee activities such that efforts can be initiated to assist them in improving assessment of risk, identification of needed services, provision of needed services and activities to program participants, and overall service delivery and strengthen the programs’ activities.

**The Healthy Start Network Survey** focuses on understanding the participation of community organizations/ groups in the Healthy Start CANs and collaborations within the CANs and Healthy Start communities to improve maternal, infant, and family health outcomes. The survey will be administered to up to 600 active CAN members in 15 Healthy Start programs that will constitute case study sites. The evaluation team, comprising MCHB’s evaluation project managers, the Contracting Officer Representative (COR), and the Westat contractors, will develop criteria to identify which programs will be surveyed. Like the Program Survey, the Network Survey questions will focus on implementation and transformation. The implementation topics covered will include: the types of organizations partnering with Healthy Start; frequency of communication within and outside of CAN meetings; relationships between grantees and CAN members; shared program events; trust and value in the Healthy Start community collaborations; and balance of power and leadership. The transformative questions asked will include: the role of Healthy Start and the CAN in fostering health equity through collaborations with community organizations and providers, improvements in equitable access to care and services, and joint training and capacity building on equitable service. The survey is designed for self-administration. The survey tool will allow the respondents to complete the survey in multiple sessions. Healthy Start CAN members will be asked to complete the survey once in Year 3 of the evaluation. Results from the survey will be used to help the Healthy Start programs and their CANs identify areas of strength and opportunities for further collaborations, understand how well the CAN members are working together to serve women and their families, and whether they are supporting the programs in addressing the participants’ greatest needs.

**The Healthy Start Participant Survey** was designed to collect information from the Healthy Start participants about their experiences with the program before, during and after pregnancy, and whether the programs are meeting their needs. The survey will be administered to up to 750 current participants in 15 Healthy Start programs that will constitute case study sites. The criteria and process for reaching out to Healthy Start participants will be determined by the evaluation team, as described above. Questions related to the utilization of services and program implementation will include: the services received by the participants from the Healthy Start staff, including those related to maternal health and fatherhood, and organizations the participants were referred to by Healthy Start staff; other Healthy Start activities; and satisfaction with the program. In looking at transformation, the participants also will be asked about their experiences with Healthy Start and their broader communities related to health equity, including racism and respectful, non-discriminatory care. The survey is designed for self-administration. The survey tool will allow the respondents to complete the survey in multiple sessions. Healthy Start participants will be asked to complete the survey once in Year 3 of the evaluation. The Healthy Start program will use this information to identify areas to strengthen the services provided to the participants and respond to participant input.

**The Healthy Start Stakeholder Interview Guide** was designed to collect more in-depth qualitative data about the Healthy Start services, the new or enhanced maternal health and fatherhood initiatives, CAN activities, and activities developed to improve the Healthy Start benchmarks and achieve health equity. The information collected will also give context to quantitative outcomes and help identify best practices. These interviews will be done in-person or by telephone with up to 150 key stakeholders at 15 Healthy Start programs that will constitute case study sites, and will include Healthy Start directors, case managers, fatherhood coordinators, CAN coordinators and data/evaluation team members. The data will be collected in Years 2 and 3.

**Table A.2. Potential Respondent Universe and Sample**

|  |  |
| --- | --- |
| **Form Name** | **Number of Entities in the Universe** |
| Healthy Start Program Survey | **101** individuals (1 from each of the 101Healthy Start-funded projects) who are in the Program Director role are eligible to be surveyed. Based on similar surveys in previous evaluations, we expect a response rate of 95%. |
| Healthy Start Network Survey | Convenience sample of up to **600** active members that constitute the Community Action Networks (CAN) in the 15 case study sites are eligible to be surveyed. Healthy Start programs across the country vary in the members who constitute the CAN, but they are typically composed of diverse membership and represent different sectors of the community, including 25% of members who are HS participants or people with lived experience similar to that of HS participants. We estimate that including members who have actively participated in the CAN in the past year by attending at least two meetings will result in approximately 40 eligible members at each of the 15 case study sites. Based on experience with other network surveys, we expect a response rate between 50% to 70%. |
| Healthy Start Participant Survey | Convenience sample of up to **750** potential participants who currently receive services in the 15 case study sites will be eligible for this survey. Each Healthy Start program is expected to serve 300 pregnant women; 300 infants/children up to 18 months, preconception women, and interconception women (combined); and 100 fathers/male partners affiliated with Healthy Start women/ infants/ children, per calendar year. We have restricted eligibility to include only adult participants who are currently enrolled in the program. This leads us to estimate approximately 50 eligible participants in each of the 15 case study sites. Based on our proposed multi-method approach to assisting participants via email or telephone if they are unable to use the web survey, we expect a response rate of 40-60%. |
| Healthy Start Stakeholder Interview Guide | Convenience sample of up to **150** key informants will be eligible for interviews involving 5-10 administrative and service staff in each of the 15 sites. Based on experience with similar activities and a typically high level of motivation among Healthy Start staff with heavy workloads, we expect a response rate of 70-80%. |

### 3. Use of Improved Information Technology and Burden Reduction

The Healthy Start Program Survey, Healthy Start Network Survey, Healthy Start Participant Survey, and Stakeholder Interview Guide will comply with the Government Paperwork Elimination Act (Public Law 105-277, Title XVII) by employing technology efficiently to reduce burden on respondents. The contractor will use an online, web-based application to obtain information from respondents for all three survey instruments. The application will include automated range checks and branching logic, and will enforce consistency among critical questions to optimize resources and facilitate collection of high-quality data. The programming will allow the collection of information specific to each respondent by permitting respondents to skip over questions not pertinent to them, thereby eliminating undue time burden on respondents. The application will also allow respondents to stop and return to the instrument so that they can complete it at their convenience. The instruments will solicit only information that corresponds to the specific research areas described in Section 2 above.

### 4. Efforts to Identify Duplication and Use of Similar Information

The information in this OMB package that we are requesting to collect is not available elsewhere. We developed a crosswalk (Attachment A8) between the evaluation questions and questions in the four primary data collection instruments and the secondary data sources to ensure that the instrument questions were relevant and not duplicative. To address some evaluation questions for this project, as mentioned above, we will also use data that Healthy Start grantees regularly report on their participants and program performance to HRSA’s Healthy Start Monitoring and Evaluation Data System (HSMED) and the Discretionary Grants Information System (DGIS), respectively. However, the instruments submitted in this OMB package are not collecting information that is available from HSMED and DGIS; hence there is no duplication of efforts.

### 5. Impact on Small Businesses or Other Small Entities

This project does not impact small business or entities.

### 6. Consequences of Collecting the Information Less Frequently

Table A.3below summarizes the data collection efforts, including the frequency of the information collection. In the table, we describe the consequences of collecting the information less frequently for each data collection activity.

**Table A.3. Summary of Data Collection Efforts**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Data Collection Method** | **Data Collected** | **Respondents** | **Administration** | **Rounds of Data Collection** | **Consequences of Less Frequent Data Collection** |
| Healthy Start Program Survey | Program implementation and aggregate outcomes data | All Healthy Start projects (101) | Web-based survey self-administered by Healthy Start director and staff | One round during Year 2 of the evaluation  | Would limit the ability to link changes in outcomes to the implementation of program components and identify the best and promising practices associated with better outcomes. |
| Healthy Start Network Survey | Organizational-level data | Up to 600 CAN members in 15 Healthy Start programs | Web-based survey self-administered by CAN members | One round during Year 3 of the evaluation  | Would limit the ability to assess changes in community-level and systems outcomes of the program and link them to changes in individual-level outcomes.  |
| Healthy Start Participant Survey  | Participants’ perspectives of utilization and implementation | Up to 750 participants in 15 Healthy Start programs | Web-based survey self-administered by participants (or by phone if requested) | One round during Year 3 of the evaluation  | Would limit the ability to assess participants’ experiences with the program, including services received.  |
| Stakeholder Interviews  | Qualitative program implementation information | Up to 150 key stakeholders in 15 Healthy Start programs | In-person or telephone Interviews with Healthy Start project directors, and core service staff and providers | One round during Years 2 and 3 of the evaluation  | Would limit the ability to link changes in outcomes to the program and identify the best and promising practices associated with better outcomes. |

### 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

**Section 8A:**

A 60-day Federal Register Notice was published in the *Federal Register,* 87 Fed. Reg. 43535 (July 21, 2022) (Attachment A1). There was a request for a copy of the draft information collection tools, but no other public comments were submitted. In response to this request, the draft instruments were shared.

**Section 8B:**

 The evaluation contractor presented a description of the planned Healthy Start evaluation to Healthy Start grantees at the annual grantee meeting. In addition, HRSA/MCHB staff reviewed and provided feedback on the instruments during a number of meetings and conference calls.

 The evaluation contractor pilot tested the four data collection instruments with nine respondents for each instrument between 01/10/2021 and 03/08/2022. The pilot test was conducted with the electronic version of the surveys programmed on the web. The pilot test of the interview guide was conducted using the virtual platform Zoom or Microsoft Teams. The respondents represented Healthy Start program directors for the Program Survey, CAN members from one grantee site for the Network Survey, Healthy Start participants from one grantee site for the Participant Survey, and a combination of Healthy Start staff and CAN members for the Stakeholder Interview Guide.

 The results of the pilot tests and recommendations for finalizing the instruments are described in Supporting Statement B. The pilot test allowed us to validate the length of the instruments and to refine and clarify the instructions and language.

The instruments were revised based on the results of the pilot test and feedback from HRSA/MCHB staff.

### 9. Explanation of Any Payment/Gift to Respondents

Those completing the Healthy Start Program Survey, Network Survey and Participant Survey, and those participating in the Stakeholder Interviews will not receive any payments or gifts.

### 10. Assurance of Confidentiality Provided to Respondents

The current project will fully comply with the Privacy Act of 1974 (5 U.S.C. Section 552a, 1998; <https://www.justice.gov/opcl/privacy-act-1974>). The Privacy Act may apply to some data collection activities (e.g., the study will collect email addresses from some respondents).

All respondents will be assured that their data will be kept private to the extent allowed by law. In addition, emails to inform participants about the data collection and any other introductory materials about the data collection will indicate HRSA’s Federal status and the purpose of the data collection. Please see Attachments A2‒A6 for email invitations. Section B contains additional information on study procedures and the data collection instruments. For all the data collection instruments, potential participants will be sent information about the study and what is required for participation. For the web-based surveys, the elements of consent will be explained before beginning the survey, and we will include a box that the potential respondents can check to show their consent to participate in the survey. Participants for the Stakeholder Interviews will be invited to participate and asked for a convenient time to schedule the interview. Interviews will be scheduled and conducted with those who agree to participate. In addition, all participants 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.

The Westat Institutional Review Board (IRB) determined that per 45 CFR 46.104(d) (4) (see Attachment A7), this project is exempt from further IRB review as it includes a research and demonstration project (conducted or supported by a Federal department or agency), and is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. The Westat IRB requires that data collected are kept secure. HRSA will receive de-identified analytic datasets, and reports will only include aggregated data and summary of responses. To protect the subjects’ privacy, each subject will be assigned a unique study ID number. All databases related to the study will, therefore, not contain subjects’ names or other personal identification (e.g., email addresses). This information will be stored in password-protected databases with well-established security systems to prevent unauthorized access.

 In addition to specific security procedures for the various data collection activities, all contractor employees involved in the work will sign a pledge that the data will be kept private to the extent allowed by law and that the respondents will not be identified. Breaking this pledge is grounds for immediate dismissal and possible legal action.

### 11. Justification for Sensitive Questions

 Personally identifiable information (PII) including participants’ names and email addresses will be collected for administration of the surveys and interviews. Collection of these data are necessary for the evaluation in order to contact potential respondents by email to send them the web link to complete the survey or arrange a time for an interview, and this information will enable us to track non-responders to send them reminders. HRSA will provide the contact information for the Healthy Start program directors to the contractor, and the contractor will contact the Healthy Start program directors to provide the list of names and email addresses of the members of their CANs and their currently enrolled participants. The surveys and interviews do not ask for information of a sensitive nature (e.g., sexual practices, religious preference) other than race/ethnicity in the Participant Survey. This race/ethnicity information will allow us to better understand the demographics of the Healthy Start participants who take the survey. For all instruments, respondents will have the option to skip any questions they do not feel comfortable answering. We will not include any information in the reports that can identify anyone who takes part in the evaluation, and only aggregate results will be included in these reports. All data and information from participants will be stored in secure locations for 3 years after the study is completed, and we will adhere to Federal requirements regarding collection and storage of PII. The contractor will not share materials containing PII with HRSA.

### 12. Estimates of Annualized Hour and Cost Burden

 The Healthy Start evaluation will include the four data collection instruments described in Section 2 above: 1) Healthy Start Program Survey, 2) Healthy Start Network Survey, 3) Healthy Start Participant Survey, and 4) Healthy Start Stakeholder Interview Guide. There will be 1,601 respondents across all four instruments, and there will be one response per respondent for each data collection form. We calculated the average burden per response in hours by determining the average (median) completion time based on pilot testing of the instruments (see Attachment B6). The time to complete each instrument ranged as follows: 23-44 minutes (Program Survey); 8-16 minutes (Participant Survey); 16-45 minutes (Network Survey); and 30-80 minutes (Stakeholder Interview Guide). For the Program Survey, pilot test respondents indicated they would need to consult other staff and need additional time to extract data from their records to complete some of the questions. We, therefore, added 30 minutes to the average time of 30 minutes for an average burden of 1 hour for this survey. For each instrument, the total number of responses was multiplied by the average burden per response and summed to produce the total annualized burden hours, which is estimated to be 600 hours. A break-down of these hours is detailed in Table A.4 below.

**Table A.4. 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** |
| Healthy Start Program Survey | 101 (across 101 grantee programs) | 1 | 101 | 1.00 | 101 |
| Healthy Start Network Survey | [[4]](#footnote-5)600 (across 15 grantee programs) | 1 | 600 | 0.33 | 198 |
| Healthy Start Participant Survey | [[5]](#footnote-6)750 (across 15 grantee programs)  | 1 | 750 | 0.25 | 188 |
| Healthy Start Stakeholder Interview Guide | [[6]](#footnote-7)150 (across 15 grantee programs) | 1 | 150 | 0.75 | 113 |
| Total | 1,601 | \_\_\_\_\_ | 1,601 | \_\_\_\_\_ | 600 |

 For each data collection effort, we determined the type of respondent expected to complete each survey and multiplied the total burden hours by hourly wage rate estimates to generate the estimated burden costs. We used the 2022 median rates provided by the Department of Labor, Bureau of Labor Statistics (BLS) national occupational employment and wage estimates (<http://www.bls.gov/oes/current/oes_nat.htm>) to generate the hourly wage estimates.

 For the Program Survey, we used the median hourly wage for the occupational group 19-3099: social scientists and related workers for the program directors who will oversee and answer the survey questions. This rate per the BLS is $42.74 per hour. For the Network Survey, community partners will complete the instrument. We estimated their wage rates at $23.74 based on the BLS's median hourly wage for the occupational group 21-0000: community and social service occupations. For the participants completing the Participant Survey, we used the BLS’s median hourly wage across all occupations, estimated at $22.26 per hour. In addition, we will be involving social workers (e.g., case managers, health educators) to complete the Stakeholder Interviews; their wage rates are estimated at $26.61 based on BLS's median hourly wage for occupational group 21-1020: social workers. We totaled the respondent costs to produce the total burden cost of $16,209.07 for this evaluation. A break-down of these costs is detailed in Table A.5 below.

**Table A.5. Estimated Annualized Burden Costs**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Respondent** | **Total Burden Hours** | **Hourly Wage Rate ($/hour)** | **Total Respondent Costs** |
| Program Directors | 101 | $42.74  | $4,316.74 |
| Community Partners  | 198 | $23.74  | $4,700.52 |
| Participants  | 188 | $22.26  | $4,184.88 |
| Social Workers  | 113 | $26.61  | $3,006.93 |
| Total  | 600 |  | $16,209.07 |

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

Other than time, there is no cost to respondents.

### 14. Annualized Cost to Federal Government

 The costs to the Federal government are comprised of contractor staff salaries, federal employee salaries, and operational expenses (e.g., equipment, printing, telephone calls).

Contractor salaries include fringe benefits (e.g., costs for health insurance, travel, paid vacation). The cost, including operational expenses, incurred by the contractor for this data collection effort as part of the 4-year evaluation is $2,068,608 or $517,152 per year. The contractor’s total average cost for the project is $517,152 over a 1-year period. This cost covers tasks that include Federal staff trainings, project management, instrument design and development, web survey programming, testing, data collection, analysis, and reporting.

Federal staff supporting this effort include the following (along with their salary and time estimates): one full-time equivalent HRSA staff member will spend 30% of his or her time (576 hours) to manage and administer the project, the COR will spend 15% of his or her time (288 hours) overseeing contractual matters, one staff member will spend 25% of his or her time (480 hours) providing subject matter expertise and management support, one staff member will spend 10% of his or her time (192 hours) providing subject matter expertise support, and one staff member will spend 5% (96 hours) of his or her time providing higher-level consultative services. Assuming that these staff are all approximately in the Grade 13, Step 5 category with an annual salary of $121,065, government personnel costs will be $102,905 over a 1-year period.

The total approximate annualized cost to the government for this data collection effort is $620,057.

### 15. Explanation for Program Changes or Adjustments

 This is a new information collection effort.

### 16. Plans for Tabulation, Publication, and Time Schedule

 Although information from the various data collection efforts will be combined to answer the evaluation questions, the analyses of data will vary based on the specific questions. The type of evaluation, evaluation questions, and analytic approaches for the instruments included in this Statement A are described in Table A.1 above. Both quantitative and qualitative data analysis will be conducted to address the evaluation questions.

**Quantitative Analyses**

 Descriptive statistical analysis will be conducted on the data collected from the Program Survey, Network Survey, and Participant Survey and will be used to produce frequencies, measures of central tendency, and standard deviations for each survey. The analyses will be used to describe program services for Healthy Start participants (screenings, referrals, health education and case management); participant characteristics and experiences with the program (involvement and satisfaction); and the community members, networks, agencies, and programs working with Healthy Start (including the Healthy Start Community Action Networks (CANs)) and in the Healthy Start communities. These analyses will also describe the efforts of the Healthy Start programs to advance health equity in their programs and communities and improve their program benchmarks.

 The quantitative information collected can be used to make crude comparisons between programs, such as the proportion of participants from multiple programs who report receiving referrals for specific services. The results from the surveys can be combined across all sites into one pooled analytic sample to further explore relationships between participant demographics (such as gender identity, age, race/ethnicity, etc.), length of time in Healthy Start and evaluation measures. This will allow for a larger sample for the descriptive statistics described above (frequencies, proportions, etc.). Depending upon the sample size for the demographics and heterogeneity of the programs in which the data are collected, bivariate analyses may also be used to test for statistically significant differences in the implementation of program activities, referrals, or participant perceptions of their experiences with respectful care, among other evaluation measures. This type of statistical analysis would rely on assumptions of the pooled data being from comparable programs and would need large enough samples for the demographics of interest but could allow for the identification of statistically significant differences between groups. The usefulness of conducting bivariate analyses can be determined after data collection, once the number of completed surveys is known.

**Network Analysis**

 The Network Survey data, in addition to the analyses described above, will be used to conduct a network analysis to discover linkages among the Healthy Start programs, CAN members and other local organizations. This analysis will include quantitative metrics to characterize the structure of the network and centrality of each network participant and will assess how centralized or fragmented the relationships are between those in the network. Graphic representations will also be used in this analysis to depict the linkages across the organizations.

**Qualitative Analyses**

 The qualitative analyses will use the data collected from the interviews with Healthy Start project and administrative staff to examine in-depth information about five Healthy Start areas (Maternal Health, Fatherhood, CAN, Health Equity and Benchmarks), including facilitators and barriers to the efforts in these areas. The interview data will be analyzed to identify salient themes and common patterns that emerge to address the related evaluation questions.

 As the first step in the data-cleaning process, audio recordings of the interviews will be transcribed, de-identified, and cleaned of any transcription mistakes; these transcriptions will serve as the qualitative data used for the study. To analyze the data, we will use the software package NVivo (Version 11). A codebook containing the descriptive codes and their operational definitions will be developed based on the specific evaluation question under investigation, which are covered in the discussion topics of the Stakeholder Interview Guide. The descriptive codes in the codebook will be applied to text passages of the interview transcripts to conduct a thematic analysis. The thematic analysis will first identify lower order themes, which will then be grouped into higher order themes, which in turn will finally be grouped into major categories. Consensus among evaluation team members conducting the analyses will be reached at each step of the analytical process (i.e., lower order themes, higher order themes, major categories) before proceeding to the next step to achieve inter-coder reliability. This process ensures a consistent understanding and interpretation of the data.

#### Reports

Annual reports of the evaluation findings-to-date will be produced and submitted to MCHB. A final report will be submitted at the end of Year 4. Study briefings/presentations will be made to key HRSA/MCHB staff, the Secretary’s Advisory Committee on Infant Mortality, grantees, and other program stakeholders upon request. Additional publications may include peer-reviewed journal articles and issue briefs to disseminate results to the broader community of maternal and child health (MCH) policymakers and practitioners.

#### Schedule

Funding for the Healthy Start evaluation began in September 2021 and will end in September 2025. The estimated schedule for key data collection, analysis, and reporting tasks relevant to this request for OMB approval is presented in Table A.6 below. 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 A.6. Estimated Time Schedule for Data Collection, Analysis, and Reports**

|  |  |
| --- | --- |
|  Task | Time Schedule |
| Healthy Start Participant Survey  |
|  Administer the survey to grantees  | September – November 2023 |
|  Analyze survey data | December 2023 – January 2024  |
|  Prepare report and brief stakeholders | February – March 2024 |
| Healthy Start Network Survey |
|  Administer the survey  | October 2023 – January 2024 |
|  Analyze survey data | February – April 2024 |
|  Prepare report and brief stakeholders | May – June 2024 |
| Healthy Start Program Survey |
|  Administer survey | January 2024 – February 2024  |
|  Analyze survey data | March – May 2024 |
|  Prepare report and brief stakeholders | June – July 2024 |
| Healthy Start Stakeholder Interviews  |
|  Conduct key stakeholder interviews  | September 2023 – April 2024 |
|  Analyze interview data  | September 2023 – June 2024 |
|  Prepare report and brief stakeholders | July – August 2024 |
| Final Report  |
|  Prepare and submit final report  | September 2024 |
|  Presentation of final report to HSRA  | September 2024 |

### 17. Reason Display of OMB Expiration Date is Inappropriate

 The OMB number and expiration date will be displayed on every page of every instrument.

### 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

1. Goyal NK, Hall ES, Meinzen-Derr JK, Kahn RS, Short JA, Van Ginkel JB, Ammerman RT. Dosage effect of prenatal home visiting on pregnancy outcomes in at-risk, first-time mothers. Pediatrics. 2013 Nov;132 Suppl 2(Suppl 2):S118-25. doi: 10.1542/peds.2013-1021J. PMID: 24187113; PMCID: PMC3943375. [↑](#footnote-ref-2)
2. Manian, N, Wagner, CA, Placzek, H, Darby, BA, Kaiser, TJ, Rog, DJ. Relationship between intervention dosage and success of resource connections in a social needs intervention. Public Health. 2020; 185, 324-331. <https://pubmed.ncbi.nlm.nih.gov/32726729/> [↑](#footnote-ref-3)
3. Mertens, D. M. (2009). Transformative research & evaluation. NY: Guilford [↑](#footnote-ref-4)
4. This is the maximum number of responses for this data collection instrument. [↑](#footnote-ref-5)
5. Ibid. [↑](#footnote-ref-6)
6. Ibid. [↑](#footnote-ref-7)