



Application Clarification - Strong Start for Mothers and Newborns Funding Opportunity Announcement

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Overview

This document is designed to offer our applicants additional clarifications for completing a competitive application for the Strong Start for Mothers and Newborns (Strong Start) funding opportunity. For complete program descriptions, including selection criteria, we recommend that applicants refer to the Funding Opportunity Announcement (FOA) and this clarification document available on our website at: <http://innovation.cms.gov/initiatives/Strong-Start/index.html>. If applicants continue to have further specific questions that are not addressed by the FOA or frequently asked questions, please email us directly at: StrongStart@cms.hhs.gov.

Types of Enhanced Prenatal Care Funded through Strong Start

CMS Innovation Center funds will be used to pay for the following interventions, but will not duplicate reimbursement if State Medicaid and/ or CHIP programs that already pay for some subset of these services:

1. Enhanced Prenatal Care through Centering/Group Visits – group prenatal care that incorporates peer-to-peer interaction in a facilitated setting for health assessment, education and provides psycho-social support.
2. Enhanced Prenatal Care at Birth Centers – comprehensive prenatal care facilitated by teams of health professionals including peer counselors and doulas. Services include collaborative practice, intensive case management, counseling and psycho-social support.
3. Enhanced Prenatal Care at Maternity Care Homes – enhanced prenatal care including psychosocial support, education, and health promotion in addition to traditional prenatal care. Services provided will expand access to care, improve care coordination and provide a broader array of health services.

Eligible Applicants

The target applicants for this solicitation are providers, States, managed care organizations and conveners.

To be eligible to apply, interested parties must be a State, entity or organization recognized as a single legal entity by the state where it is incorporated, and must have a unique Tax Identification Number (TIN) in order to receive payment. The organization must have a governing body capable of entering into an agreement with CMS on behalf of its members.

Conveners

A “convener” is an entity that brings together multiple participating health care providers. Examples of potential conveners include national trade associations, a collaborative of states, care organizations collaborating with providers or health service organizations. For the purposes of this initiative, a convener may be the applicant, but may be subject to special provisions.

The convener may be a direct applicant, or may convene and facilitate other organizations to become applicants. Conveners must also have a valid Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN) assigned by the Internal Revenue Service. The organization must have a governing body capable of entering into an agreement with CMS on behalf of its members.

Minimum Enrollment

Each applicant should demonstrate that their organization could provide enhanced prenatal care services to at least 500 Medicaid and/or Children’s Health Insurance Program (CHIP) beneficiaries, on average, per year. The expectation for each awardee is that a minimum of 1,500 Medicaid and/or CHIP beneficiaries will be enrolled and receive enhanced prenatal care over the course of the three year intervention period. Centers for Medicare and Medicaid Services (CMS) will require a minimum of 250 births in the first year during Terms and Conditions of the Award. Applicants should indicate their expected enrollment each year and provide attainable benchmarks for enrolling 1,500 Medicaid and/or CHIP beneficiaries over the three year intervention period.

Example. Your entity needs two or three months for program trainings and other administrative start-up before you can enroll the first participant. This start-up time would mean that your enhanced prenatal care approach may only enroll 350 women covered by Medicaid and/or CHIP in the first year of the program. Your application should demonstrate that at least 1,150 additional women enrolled in Medicaid and/or CHIP will receive enhanced prenatal care services in program years two and three combined.

The Innovation Center recognizes that participant attrition is high among populations at high risk for poor outcomes. The Innovation Center seeks to achieve the enrollment of 30,000 women in each of the three approved approaches to enhanced prenatal care. This is necessary for the national evaluation of each of the three approaches. CMS expects applicants to actively engage participants and develop plans to increase participant retention.

Risk Factors for Preterm Birth

Strong Start is particularly interested in reducing the adverse pregnancy outcomes of low birthweight and preterm birth among women at high risk for these outcomes. Applicants should propose target areas for deploying these approaches and present available data to demonstrate that the proposed target areas are those in which there is a greater concentration of risk for preterm births. Applicants should identify the

risk factors for preterm birth present in the areas where they propose to deliver services. Applicants should also present available data to assess and describe the risk factors present. Appendix A of the Funding Opportunity Announcement provides a list of risk factors for preterm birth. Applicants should also clearly demonstrate that women who live in the proposed target areas are at increased risk for preterm births.

Official reporting sources collecting data on indicators of preterm births such as prematurity, low birthweight, infant mortality and other indicators of poor infant outcomes should be used as evidence of high risk in a geographic area. Official reporting sources may include entities like Centers for Disease Control and Prevention, state and county health departments, and the Indian Health Service.

The target participant for a Strong Start enhanced prenatal care model is a women enrolled in Medicaid and/or CHIP at high-risk for poor outcomes. Applicants should demonstrate that their proposed population is at a higher risk for an adverse pregnancy outcome than other Medicaid-enrolled women.

Emergency Medicaid Recipients

In the three enhanced prenatal care models that Strong Start is testing, prenatal care will be delivered throughout the prenatal period. Enhanced prenatal care services must be completed during Medicaid eligibility because only services provided to Medicaid beneficiaries are reimbursed by Strong Start funds. Therefore, most women eligible for Strong Start will not be receiving Emergency Medicaid, since federal regulations at 42 CFR 440.255 only require States to cover labor and delivery. States, however, have flexibility to define emergency services for which Medicaid payments may be made consistent with federal law and regulations.

Applicants Testing More than One Enhanced Prenatal Care Approach

An awardee may have multiple provider sites within their Strong Start proposal. While an awardee can receive Strong Start funds to administer more than one approach to enhanced prenatal care, individual provider sites can only administer one of the three approaches.

Applicants proposing to implement more than one approach must clearly identify the provider sites and associated enhanced prenatal care packages provided under each approach throughout their application. Medicaid and/or CHIP beneficiaries enrolled in an enhanced prenatal care model should not be enrolled in two approaches to enhanced prenatal care. CMS expects that Strong Start services will be provided *in addition to* current standards of care. Any beneficiary who needs services other than those provided through the enhanced prenatal care approach in which they are enrolled should receive those services. However, for evaluation purposes, the beneficiary will continue to be included in the enhanced prenatal care approach for which she was originally enrolled.

Applicants Submitting More than One Application

Multiple applications will be accepted, by grants.gov, from the same entity. Entities may partner to cover a larger group of women under one proposal. Ultimately, an entity may only receive Innovation Center funds for the Strong Start initiative under one cooperative agreement.

Supplanting or Supplementing Existing Payment for Services:

Supplanting existing payment for services: Innovation Center funds may NOT be used for services currently reimbursed under a State Plan or waiver program.

Supplementing existing payment for services: Innovation Center funds may NOT be used to supplement/improve existing Medicaid and/or CHIP rates for clinical or enhanced prenatal services. Funds may be used to help defray the costs of providing additional services that are not reimbursed but are ancillary activities that support clinical services, such as staff training, coordinating and consulting on care for enrolled women, and minor physical space improvements.

Applicants should provide a detailed description of clinical and enhanced prenatal services currently reimbursed under the state's Medicaid and/or CHIP program, especially detailing special State and/or Managed Care initiatives underway (or conducted in the past) that seek to identify and serve women at high risk for having preterm births. The Innovation Center expects each applicant to include a comprehensive service description, identification of the provider type delivering the service, and the rate and reimbursement methodology for services.

CMS will verify that an applicant's proposed services do not supplement or supplant existing payment for services per the State's Medicaid and/or CHIP plan on file.

Length of the Award

Awardees will receive an initial award for the first year of program implementation to pursue the goals and objectives of the Strong Start initiative. After the initial award, non-competing continuation awards will be awarded for each additional year for two years contingent upon availability of funding, awardee performance, and demonstrated progress toward the goal of reducing premature births. Awardees may also be awarded funds in the fourth year for data collection. CMS is under no obligation to make additional awards under this program.

Feedback on Letters of Intent

CMS is not able to provide feedback on individual LOIs. For specific questions on eligibility and program requirements, please reference the Funding Opportunity Announcement (FOA) and this clarification document.

Verification of Enrollment

CMS will verify Medicaid and/or CHIP enrollment to ensure that women receiving enhanced prenatal care services are Medicaid/CHIP beneficiaries. Every Medicaid/CHIP enrollee has a beneficiary identification number that is used for billing purposes. CMS will require awardees to provide beneficiary identification numbers to CMS and/or its contractor(s) for each woman receiving enhanced prenatal care. CMS will also require beneficiary identification numbers for infants born to women participating in an enhanced prenatal care approach. These beneficiary identification numbers will be used by CMS and/or its contractor(s) for enrollment verification and the national evaluation of each approach to enhanced prenatal care.

Program Start Up

Strong Start funding should be used primarily for the provision of enhanced prenatal care services, rather than for overhead and administrative costs. Proposals are expected to present completion of the infrastructure and capacity-related activities related to implementing the proposed enhanced prenatal care services within three months of the award and start delivering enhanced prenatal care as rapidly as possible.

Funding for training programs for clinical staff may be requested but these activities should be intensive, brief programs connected to the enhanced prenatal care approach being tested.

The Innovation Center recognizes that some applicants will need time for administrative start-up activities, participant recruitment, participant enrollment, and program implementation. These activities should be built into the applicant's work plan and timeline. Applicants are expected to demonstrate how they will enroll 1,500 pregnant Medicaid and/or CHIP beneficiaries over the three-year intervention period. Enrollment benchmarks will be detailed and defined in the Terms and Conditions of the award.

Letters of Agreement

A letter of agreement indicates programmatic collaboration among partners, both providers and nonclinical organizations, represented in a Strong Start application. All partners must have an active role in the implementation of a Strong Start award. For the purposes of the Strong Start initiative, letter(s) of agreement should explain the relationship and roles of the entities agreeing to collaborate.

State, managed care organizations, and convener proposals must include letters of agreement from provider partners outlining their experience, willingness to participate in the program, expected number of Medicaid and/or CHIP beneficiaries to be served, and the enhanced prenatal care approach the partner has committed to providing.

Travel to CMS-Sponsored Meetings

All awardees will be required to travel to Washington, DC or Baltimore, MD for two meetings each year for the first three years. The purpose of the meetings will include opportunities for collaborative learning and sharing of experiences among the community of awardees. Therefore, applicants' budgets should include travel funds for two people to attend these CMS-sponsored meetings. Additionally, applicants should budget for two people to attend an initial technical assistance meeting to be held in the Washington, DC or Baltimore, MD area during the first year of the agreement. CMS-sponsored meeting attendees should budget for two full days of meeting events. Specific travel logistics will be determined post award.

Total Payment per Expected Beneficiary Served

Applicants should propose an aggregate funding request for enhanced prenatal services that covers the cost of the specific combination of enhanced prenatal care services as described in their selected approach. Applicants should specify the cost of each specific service included in the aggregate funding request. The total amount of this request should be described as a total payment per expected beneficiary

served. This amount should include total costs for service delivery, administration and data collection and submission.

“Learning and Diffusion” Activities

CMS will be responsible for the creation of learning networks and designing the Learning and Diffusion activities. CMS will work with awardees to ensure that all activities are relevant and useful for the awardees. Awardees are expected to participate in the learning network and to work with each other and with CMS toward the goal of continuous quality improvement throughout the performance period.

Institutional Review Board (IRB) and Approval Requirements

Cooperative agreements awarded under the Strong Start initiative are exempt from IRB review and approval requirements under section 45 CFR 46.101(b)(5).

Section 45 CFR 46.101(b)(5) states:

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs (45 CFR 46.101(b)(5)).

Central Contracting Registration (CCR) Number

The Strong Start application must be submitted through <http://www.grants.gov>. A Central Contracting Registration (CCR) and Data Universal Numbering System (DUNS) number will be required to complete the application process; however, it is not necessary to include a CCR number when submitting a Letter of Intent. CMS encourages all organizations to register in the CCR and obtain a DUNS number as soon as possible. Organizations must have a CCR and DUNS number in place in order to submit an application. CMS recommends allowing at least two weeks to complete the Grants.gov application process. For more information about the application process through grants.gov, the CCR and/or DUNS number, please refer to the FOA (pages 28-34).

Required Data for Evaluation and Monitoring

CMS will be conducting a national evaluation of the Strong Start for Mothers and Newborns enhanced prenatal care approaches. Awardees will be required to report data necessary for the CMS national evaluation and programmatic monitoring of their own operations. The applicant should state their commitment and demonstrate their ability to collect gestational age and birthweight for intervention

infants during the intervention period. The applicant must also state their commitment and demonstrate their ability to, upon award, provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention. CMS will look favorably upon applicants who state their commitment and demonstrate an ability to provide more than 2 years of historical baseline data upon award. CMS will also look favorably upon applicants who state their commitment and demonstrate an ability to provide gestational age and birthweight on a comparison population during the intervention period. Applicants demonstrating an ability to provide more than 2 years of baseline data will receive 2.5 extra points in the review of their application. Applicants demonstrating an ability to provide a comparison group during the intervention will also receive 2.5 extra points in the review of their application. Applicants who are unable to demonstrate their ability to provide at least 2 years of baseline data are ineligible for award.

The following organizations that do not have two years of their own baseline data on the population they will serve under the Strong Start initiative may propose an alternative data source:

- Start-ups
- Organizations with less than two years of service provision history
- Organizations that are already providing the proposed model, but to a population that is different from the population that will be served under Strong Start

The applicant must be able to demonstrate that these alternative data represent a population that is similar from a socio-demographic perspective to the population they will be serving under Strong Start.

Other Data for Evaluation and Monitoring

Applicants must be prepared to provide quarterly reports on a variety of quality metrics for the women and infants served by Strong Start. Variables in addition to gestational age and birthweight that may be reported include information collected on the 2003 version of the U.S. Standard Certificate of Live Birth. Other relevant data may include the identification of cases involving elective inductions, elective cesareans, and cesareans scheduled before onset of labor.

Ideally, additional variables collected and reported by the awardees, in quarterly reports, will address maternal as well as infant outcomes. Maternal outcomes may include psychosocial factors and health outcomes extending six weeks postpartum or longer. Such variables may include compliance with postnatal care instruction, breastfeeding practices, post-partum complications, incidence of post-partum depression, and other maternal health concerns. The detailed requirements for quarterly reports will be further specified later.

Methodology for Data Collection

Women may only be enrolled in one of the three Strong Start approaches for each pregnancy. Applicants should consider methodologies for data collection that are best suited to their circumstances, which may include qualitative evaluation (e.g. open-ended maternal interviews) in addition to collection of gestational age and birthweight data and other quantitative variables. The costs of administrative activities related to collecting gestational age and birthweight for intervention women and their infants; gestational age and birthweight for an applicant's own baseline period; gestational age and birthweight for

a comparison group during the intervention (if applicable); and quality metrics for quarterly reports may be included in the application budget.

State Data Linkages for Intervention and Comparison Mothers and Infants

Partnering with states to link vital statistics with Medicaid and/or CHIP claims and encounter data for intervention and comparison mothers and infants is no longer a requirement for funding. Ultimately CMS plans to link vital statistics and Medicaid utilization and encounter data for the women and their infants served by Strong Start. Therefore, if applicants have an internal capacity or have established relationships with their states to accomplish this objective, they should describe this in their application (see Section A below), although the costs of these activities should not be included in the applicant's budget.

CMS will be working independently with states or other entities (outside of the solicitation) to link vital statistics with Medicaid and/or CHIP claims and encounter data as part of the national program evaluation. In cases in which the awardee does not have the internal capacity and does not independently develop a state partnership to make these linkages during the award period, the awardee will be required to provide identifiable data that will facilitate CMS's ability to independently make the linkages in partnership with states or other entities (see Section B below). The costs for linking vital statistics and Medicaid utilization and encounter data should not be included as part of an applicant's budget. Agreements between States, awardees, or other entities and CMS with respect to these data, and compensation for providing such data, will also be pursued independently of this solicitation.

Section A:

Applicants, including States, which have an internal capacity to link data or have established the necessary relationships with their states, should describe this capacity in their application. Specifically, applicants should address their access to person-level Medicaid and/or CHIP administrative data (e.g., eligibility, demographics, service claims, encounters under managed care, drugs, payments/expenditures) and to person-level Vital Records data for Strong Start participants and comparison samples.

CMS expects that the following data files will be required for the appropriate linkages:

1. Medicaid and/or CHIP record for woman's prenatal care, delivery, and one-year post-partum
2. Medicaid and/or CHIP record for infant from birth through the first year of life
3. Infant's vital records (i.e., birth, and death certificate)
4. Medicaid and/or CHIP enrollment records for woman and infant

Ultimately, CMS expects that the following linkages will be required to address the evaluation objectives of the national evaluation:

1. Women's pregnancy-related Medicaid and/or CHIP records with infants' Medicaid and/or CHIP records through first year of life (e.g. prenatal visits, delivery hospitalization, and postpartum visits for three months)

2. Infants' vital records to linked maternal-infant Medicaid and/or CHIP records
3. For the intervention participants, beneficiary-level documentation of enhanced benefits linked to participants' Medicaid and/or CHIP information
4. Medicaid and/or CHIP monthly *enrollment* for women during pregnancy, and infants through the first year of life

Section B

CMS will need the following data elements to link mothers' and infants' Medicaid and/or CHIP claims:

1. Family Case Identification Number (or other State identified method to link mother to infant through administrative data)
2. Medicaid and/or CHIP Identification Number
3. Mother's First and Last Name
4. Mother's Date of Birth
5. Mother's Race/Ethnicity
6. Mother's Residence (street name, city, county, or zip code)
7. Mother's Delivery Date
8. Infant's First and Last Name
9. Infant's Date of Birth
10. Infant's Sex
11. Healthcare Provider Identification Number

Ideally, CMS will need the following data elements to link Medicaid and/or CHIP claims to Vital Records:

1. Birth Certificate number
2. Medicaid and/or CHIP Identification Number
3. Mother's Social Security Number (except in States where this information is unavailable by law)
4. Mother's First and Last Name and name prior to first marriage
5. Mother's Date of Birth
6. Mother's Race/Ethnicity
7. Mother's Address (e.g., street name, city, zip code, county)
8. Infant's First and Last Name
9. Infant's Date of Birth
10. Infant's Sex
11. Healthcare Provider Identification Number
12. Name of Facility for Birth
13. County of Birth