STRONG START FOR MOTHERS AND NEWBORNS

U.S. Department of Health and Human Services

Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Cooperative Agreement

Second Amended Announcement

Funding Opportunity Number: CMS-1D1-12-001

CFDA: - 93.611

Applicable Dates:

Optional Letter of Intent to Apply: August 08, 2012, by 5:00 p.m. EST

Electronic Cooperative Agreement Application Due Date: August 09, 2012 by 5:00 p.m. EST

Anticipated Notice of Cooperative Agreement Award: October 05, 2012

Cooperative Agreement Period of Performance: The period of performance is four years divided into budget periods that last for 12 months each, beginning on the date of award. This includes three years of service delivery and four years for data reporting **on births of intervention infants**.

Addendum to Strong Start Funding Opportunity

Funding Opportunity Announcement (FOA) No. CMS-1D1-12-001 has been amended based upon the changes outlined in this second amended FOA. This addendum provides a summary of the amendments to the FOA by section. The amended FOA will immediately follow this addendum.

AMENDMENTS TO THE FUNDING OPPORTUNITY ANNOUNCEMENT

This funding opportunity announcement has been amended and is being reissued. Amendments to the cooperative agreement funding opportunity to support *Strong Start for Mothers and Newborns* will be included in the body of the funding opportunity announcement in **bold and underlined text**. This Addendum lists, by section, areas of the funding opportunity announcement that have been amended.

Title Page

- Amended to reflect that this is the second, amended FOA.
- Amended to indicate that the Letter of Intent is optional.
- Amended to reflect extension of the Letter of Intent deadline to August 08, 2012.
- Amended to reflect extension of the Electronic Cooperative Agreement Application Due Date to August 09, 2012.
- Amended to reflect change in Anticipated Notice of Cooperative Agreement Award to October 05, 2012.
- Amended to clarify that data reporting is on births of intervention infants.

Overview Information

- Amended to reflect that this is the second, amended FOA.
- Amended to change Date of Issue to July 03, 2012.
- Amended to indicate that the Letter of Intent is optional.
- Amended to reflect extension of the Letter of Intent deadline to August 08, 2012.
- Amended to reflect extension of the Electronic Cooperative Agreement Application Due Date to August 09, 2012.
- Amended to reflect change in Anticipated Notice of Cooperative Agreement Award to October 05, 2012.
- Amended to clarify data reporting is on births of intervention infants.

Section I. Funding Opportunity Description

A. Purpose

- Amended to delete the word bid in reference to the competitive process.
- Amended to clarify States are eligible applicants and remove specific reference to Medicaid agencies.

D. Program Requirements

- Amended to delete language on providing funds to States for providing necessary data.
- Amended to delete applicant requirement to estimate funds needed for data requirements.
- Amended to delete the word base in regards to funding provided for start-up costs.
- Amended to explain that awardees will be expected to collect gestational age and birthweight and provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.
- Amended to remove state letter of agreement requirement.

- Amended to delete requirement that the State submit a description of relevant Medicaid and/or CHIP covered services, and that the State is responsible for coordinating crossover services.
- Amended to remove state partnership requirements.
- Amended to explain that applicants who state their commitment and demonstrate an ability to provide more than 2 years of historical baseline data upon award and/or are able to provide gestational age and birthweight on a comparison population during the intervention period will be viewed favorably.
- Amended to clarify how CMS will independently work with States (outside of this solicitation).
- Amended to insert the word requirements.
- Amended to clarify Awardee quarterly data reporting on operations, utilization, and outcomes requirements.
- Amended to clarify information pertaining to data sources.
- Amended to eliminate requirement for linking vital statistics information and State Medicaid and/or CHIP data systems through this cooperative agreement funding opportunity.
- Amended to delete reference to comparison entity.
- Amended to delete the word monthly from Continuous provider quality improvement.

Section II. Award Information

B. Award Amount

- Amended to clarify that there is four years of Awardee reporting of data on for intervention infants.

C. Anticipated Award Date

- Amended to reflect change in anticipated award date to October 05, 2012.

D. Period of Performance

- Amended to reflect change in anticipated performance period as October 05, 2012 to October 04, 2016.
- Amended to clarify that there is four years of Awardee reporting of data on intervention infants.

E. Number of Awards

- Amended to reflect that the letter of intent may provide a vehicle to link potential applicants, instead of stating that it will do so (as a result of making letter of intent optional).

Section III. Eligibility Information

A. Eligible Applicants

- Amended to clarify partnership requirements.
- Amended to clarify who must include letters of agreement from provider partners.
- Amended to add the word organizations after managed care.
- Amended to eliminate requirement that awardees provide claims data and vital statistics.
- Amended to explain that awardees are expected to collect gestational age and birthweight and provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.

- Amended to eliminate requirement that Awardees demonstrate engagement with State entities.
- Amended to clarify that CMS foresees providers of proposed interventions responding directly.
- Amended to remove expectation that providers provide evidence of managed care engagement.
- Amended to refer to managed care organizations instead of managed care plans.
- Amended to reflect extension of Application due date to August 09, 2012.
- Amended to clarify that the narrative portions of the application must be double-spaced (i.e. Project Narrative, Budget Narrative, Work Plan and Timeline).
- Amended to clarify that the Project Abstract should be single-spaced.
- Amended to clarify tables, charts and footnotes should be single-spaced and 10 point type font size.

Section IV. Application and Submission Information

A. Address to Request Application Package

- Amended to clarify that the Letter of Intent is optional.
- Amended to clarify that Letter of Intent must be submitted to use Strong Start Platform.
- Amended to insert information on the use of the online platform to facilitate partnerships.
- Amended to reflect extension of the Letter of Intent submission date to August 08, 2012.
- Amended to update requirements on acceptable application file formats.
- Amended to provide clarifying language on grants.gov review and validation process.
- Amended to reflect extension of the Application Due Date to August 09, 2012.
- Amended to Clarify Office of Acquisition & Grants Management

B. Content and Form of Application Submission

- Amended to clarify that font size must be 12-point.
- Amended to clarify which documents are considered part of the narrative portion of the application.
- Amended to clarify tables, charts and footnotes should be single-spaced and 10 point type font size.
- Amended to refer generally to letters of agreement in regards to page limits.
- Amended to insert language on required file format for submission.
- Amended to add the words, if applicable, in regards to LOI identifier.
- Amended to clarify that applicants should indicate the type of applicant (Provider, MCO, convener or State) in the title of the project.
- Amended to eliminate requirement that applicants include documentation from the State outlining State plan services.
- Amended to clarify that applicants should describe relationship with provider partners.
- Amended to explain that applicants must state their commitment and demonstrate their ability to collect gestational age and birthweight for intervention infants during the intervention period.
- Amended to explain that applicants must 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.

- Amended to delete requirement that applicants must work with states and managed care plans.
- Amended to refer to national Strong Start program evaluation.
- Amended to clarify that costs for service delivery must be limited to the first three years, and that costs for Awardee reporting of data on intervention infants can be requested in all four years. The fourth year costs must only reflect awardee reporting costs.
- Amended to clarify that the proportion of the requested funding designated for each activity should be clearly defined and should justify the applicant's readiness to receive funding through 2016. Amended to delete reference to information furnished by the State.
- Amended to eliminate requirement that applicants estimate state costs for reporting requirements.
- Amended to clarify that Awardee reporting of data is on intervention infants.
- Amended to delete language concerning obtaining state level data and compensating States for this data.
- Amended to delete reference to indirect cost rates and just to refer to indirect costs.
- Amended to include waiver program or other Federal program or funding source.
- Amended to delete reference to funds to states for data activities.
- Amended to clarify which entities must provide Letter(s) of Agreement.

C. Submission Dates and Times

- Amended to clarify that Letters of Intent to Apply are optional.
- Amended to reflect extension of the Letter of Intent deadline to August 08, 2012.
- Amended to reflect extension of the Electronic Cooperative Agreement Application Due Date to August 09, 2012.
- Amended to reflect change in anticipated announcement date to October 05, 2012.
- Amended to delete such as targeted case management dental services, and home health.
- Amended to refer to managed care organizations instead of managed care plans.
- Amended to refer to the Code of Federal Regulations in addition to the OMB Circulars.

F. Other Submission Requirements

- Amended to include section F. Other Submission Requirements

Section V. Application Review Information

- Amended to clarify Letters of agreement are only required from provider partners.

A. Criteria

- Amended to include bonus points.
- Amended to delete requirement that applicants demonstrate how they will partner closely with States.
- Amended to insert expectation that the applicant will state their commitment and demonstrate their ability to collect gestational age and birthweight for intervention infants during the intervention period.
- Amended to insert expectation that the applicant will state their commitment and demonstrate their ability to, upon award, provide the same data on births from a baseline period that spans 2 years prior to the start of the intervention.
- Amended to explain that applicants who state their commitment and demonstrate an ability to provide more than 2 years of historical baseline data upon award and/or are able

to provide gestational age and birthweight on a comparison population during the intervention period will be eligible for bonus points.

- Amended to clarify that proposals should show applicants' ability to meet data requirements.
- Amended to refer to applicant's provider partners.
- Amended to delete language about collecting data from States and compensating States for that data.
- Amended to eliminate requirement that applicants estimate the states data costs.

B. Review and Section Process

- Amended to include applicable law (e.g., 2 CFR Parts 180 and 376).
- Amended to include program integrity issues

C. Anticipated Announcement and Award Date.

- Amended to reflect change in anticipated announcement date to October 05, 2012.

Section VI. Award Administration Information

D. Cooperative Agreement and Conditions of Award

- Amended to delete phrase, "including the assigned State."
- Amended to remove state partnership requirement.

Section VIII. Other Information

Appendix C: Measures for Monitoring Quality and Outcomes of Care

- Amended to explain that Awardees will report gestational age and birthweight.
- Amended to explain that awardees must provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.
- Amended to clarify that CMS will independently work (outside of this solicitation) with states to link data.

Appendix E: Maternal & Newborn Health Glossary of Terms

- Amended to include abbreviation for Managed Care Organization (MCO).

Appendix F: Application Check-Off Cover Shee**t**

- Amended to clarify that SF-LLL: Disclosure of Lobbying Activities is only required for organizations engaging in Lobbying Activities
- Amended to remove state Letter of Agreement requirement.
- Amended to clarify that Letters of Agreement are required from provider partners.

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OVERVIEW INFORMATION

Agency Name: Department of Health and Human Services

Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Funding Opportunity Title: STRONG START FOR MOTHERS AND NEWBORNS

Announcement Type: **Second** Amended

Funding Opportunity Number: CMS-1D1-12-001

Catalog of Federal Domestic Assistance (CFDA) Number: 93.611

Key Dates:

Date of Issue: **July 03, 2012**

Optional Letter of Intent **Submission** Date: **August 08**, 2012, by 5:00 p.m. ET

Application Due Date: **August 09**, 2012 by 5:00 p.m. ET

Anticipated Notice of Award: **October 5**, 2012

Period of Performance: The period of performance is four years divided into budget periods that last for 12 months each, beginning on the date of award. This includes three years of service delivery and four years for data reporting requirements **on births of intervention infants.**

I. FUNDING OPPORTUNITY DESCRIPTION

A. Purpose

The Centers for Medicare & Medicaid Services, (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is interested in testing new care and payment models that have the potential to improve perinatal outcomes for women enrolled in Medicaid and/or Children's Health Insurance Program (CHIP) who are at high-risk for adverse pregnancy outcomes. This initiative is a partnership between the Innovation Center and the Center for Medicaid and CHIP Services (CMCS) and part of a larger HHS effort to improve maternal and infant health outcomes.

In this four-year initiative the Innovation Center will offer a funding opportunity to eligible applicants to test the impact of providing enhanced prenatal care interventions for women with Medicaid and/or CHIP coverage who are at high risk for having a preterm birth. The initiative will test 3 distinct approaches to providing enhanced prenatal care delivery. Each approach provides a set of specific and comprehensive interventions to improve current, traditional prenatal care delivery and address additional clinical, behavioral, and psychosocial factors that may be present during pregnancy and contribute to preterm-related poor birth outcomes.

This funding opportunity will award, through a competitive process, cooperative agreements for States, providers, managed care organizations and conveners to test the ability of three such approaches to improve outcomes in approximately 90,000 pregnancies. The Innovation Center proposes to fund the cost of care for 30,000 women in each of the three approved options for enhanced prenatal care.

The ultimate purpose of this initiative is to achieve the three-part aim of better care, improved health and reduced costs by improving outcomes for high-risk pregnant Medicaid and/or CHIP beneficiaries. Specifically, the goal is to determine whether these new approaches to care can increase the gestational age of neonates sufficiently to decrease the anticipated total cost of medical care over the first year of life for children born to high risk mothers. To date, most efforts to address preterm births have focused on clinical interventions delivered in the traditional care delivery sites, in many cases initiated after labor began.[1] There is a growing body of research which suggests interventions that address behavioral and socio-economic dimensions of women's lives may successfully prevent some preterm births. This initiative will focus specifically on the impact of non-medical prenatal interventions that, when provided – *in addition to routine obstetrical medical care* – are believed to reduce rates of preterm births for these women.

Each of the options outlined in this funding opportunity are designed to provide a specific combination of non-medical prenatal interventions that have been found to reduce rates of

preterm births for women particularly at risk for having a preterm birth. These promising approaches are currently being implemented in various forms across the country but are not typically paid for through current reimbursement systems.

The evidenced-based approaches being tested in this initiative are encapsulated in the following 3 options for applicants:

1. Enhanced Prenatal Care through Centering/Group Care – Group prenatal care that incorporates peer-to-peer support in facilitated, face-to-face sessions for three components: health assessment, education, and support occurring within approximately 10 prenatal sessions. This approach focuses on building peer-support relationships.
2. Enhanced Prenatal Care at Birth Centers – Comprehensive prenatal care facilitated by midwives and teams of health professionals including peer counselors and doulas. Services include collaborative practice, intensive case management, counseling and psychosocial support services in addition to traditional prenatal care. This approach focuses on building relationships between caregivers and patients.
3. Enhanced Prenatal Care at Maternity Care Homes – Enhanced prenatal care including psychosocial support, education, and health promotion in addition to traditional prenatal care. In this approach, services are delivered in practices described as maternity care homes.

CMS will award, through a competitive process, a set of renewable one-year cooperative agreements to eligible applicants who enter into agreements to implement one of these enhanced prenatal care approaches. CMS will evaluate the potential for these evidence-based approaches to decrease morbidity, mortality and the first year of medical costs of prematurity. The Strong Start Program will operate for four years; including three years for intervention and four years for data collection and submission.

Eligible applicants in this funding opportunity include:

- States;
- Providers of obstetric care (provider groups and/or affiliated providers and facilities);
- Managed care organizations (MCOs); and
- Conveners in partnership with other applicants. The convener may be a direct applicant, or may convene and support other organizations to become applicants. Examples of conveners include states, associations of providers, or other health service related organizations.

Each of the options will present eligible applicants with unique challenges specific to their organizational structure and capability. Applicants should carefully consider each approach and its fit with their organizational structure and capability. Regardless of which option an applicant chooses to pursue, it is required that it clearly identify which, if any, of the specific interventions outlined in each approach it is already being reimbursed or for which reimbursement is already

available. The funding provided by this initiative cannot be used to pay for services for which reimbursement is already available.

B. Authority

This solicitation is being issued under section 1115A of the Social Security Act (added by Section 3021 of the Affordable Care Act), which authorizes the Innovation Center to develop, implement, and evaluate innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and CHIP while preserving or enhancing the quality of care. Pursuant to section 1115A(c), a model being tested by the Innovation Center may, through rulemaking, be expanded or "scaled," including through implementation on a nationwide basis, if certain findings are made regarding the effect of the expansion on program spending and the quality of patient care.

C. Background

Medicaid and Births in the United States

In the United States, approximately 12 percent of infants (more than half a million a year) are born prematurely, with that rate increasing by 36 percent over the last 20 years. The rate of preterm births, medically defined as less than 37 weeks of gestation, is a growing public health problem that has significant consequences for families and has been estimated to cost society at least $26 billion each year.[2] These costs extend beyond the walls of the NICU since infants born preterm are at greater risk for mortality and many endure a lifetime of health and developmental problems. In addition to enormous medical needs, these children often require early intervention services and special education and have conditions that impact their productivity as adults.

Medicaid currently finances about 40% of all births in the United States. Current Federal law requires States to extend eligibility for pregnancy-related care to pregnant women with incomes up to 133% of the federal poverty level and allows States to cover pregnant women with higher incomes as well. In an effort to improve access to prenatal care and birth outcomes, Federal law changed in the mid-1970s to make Medicaid coverage available to pregnant women with incomes up to 133% of the federal poverty level. Yet Medicaid beneficiaries continue to have a rate of preterm birth that is significantly higher than the rate for all other women (11.9% vs. 8.7%).[3] The incidence of preterm births continues to vary significantly depending on geography, race, and ethnic background and is thus a significant source of health disparities across the country. Among Medicaid beneficiaries in 2008, the preterm birth rate for African-American women was 17.5 percent, while the rates were 12.1 percent for Hispanic women and 11.1 percent for white women.[4]

Many different medical interventions have been used to attempt to improve preterm birth rates. Some medical interventions, such as the use of 17 Hydroxy- Progesterone, have been demonstrated to have positive results in select populations. However, in spite of such

interventions, the rate of prematurity has, as noted above, nevertheless increased significantly over the past 20 years, and until a slight improvement recently, had been steadily increasing[5]. Most authorities believe that while the causes of prematurity are multiple and not fully understood, underlying behavioral and socio-economic factors play a meaningful role.

Over the past 15 years, a variety of non-medically based interventions have been explored that focus on addressing psychological and socio-economic issues.[6] Some small studies of these programs have reported significant decreases in preterm rates. To date, however, these models have only been tested in limited settings with small numbers of participants. The impact of these models has not been fully explored and tested among women enrolled in Medicaid and/or CHIP. As a result, many States and managed care plans may be using such enhanced prenatal care models without strong evidence for their ultimate effectiveness. At the same time other States and managed care plans may not be providing these services at all.

Although all State Medicaid programs are required to pay for traditional prenatal care and deliveries, there is great variation in how States cover non-traditional health services under Medicaid. Acknowledging that these additional services require additional time and often additional members in the health care team, the Innovation Center will award funds to eligible states, providers, managed care organizations and conveners who demonstrate plans for incorporating one of the three options of enhanced care into their current prenatal plans.

A fourth approach to evidence-based enhanced prenatal care – structured home visiting during pregnancy – has also demonstrated the potential to reduce preterm births. CMS is interested in learning if this model for enhanced prenatal care also reduces the rate of prematurity, and will work (outside of this solicitation) with the Health Resources and Services Administration (HRSA) and the Administration on Children and Families (ACF) to study this intervention through their existing Maternal, Infant, and Early Childhood Home Visiting program (MIECHV).

Medicaid Beneficiaries are at Increased Risk for Preterm births

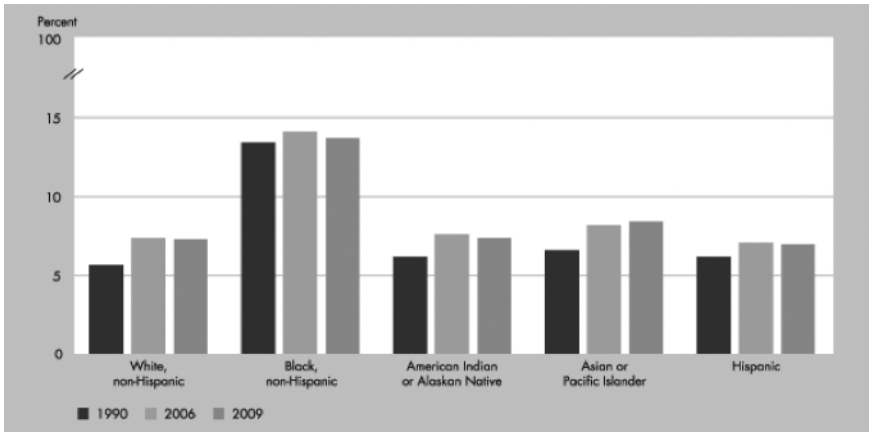
Several risk factors for preterm birth have been well-described in the medical literature. In addition to medical risk factors, research has examined how social and psychosocial factors may influence the risk of preterm birth**.** [7, 8] These factors interact with each other on a multitude of levels. An individual with a constellation of these risk factors is at a higher risk for preterm birth or other poor birth outcome in comparison to an individual without or with fewer of these factors. The chart in Appendix A, modified from the Institute of Medicine Report, shows risk factors associated with preterm birth.[9] Applicants will be asked to identify the risk factors for preterm birth present in the areas they propose to deliver services. Applicants should use available data sources to assess and describe the risk factors present.

The ensuing issues are among those that have been found to be related to the risk for preterm births.

- Prior History of Pre-Term Delivery: Women that have prior medical history involving pre-term delivery and births are an obvious target for improved prenatal care and medical management in subsequent pregnancies.
- Poverty: The relationship between income and health is well-established.[10] Several studies have documented that rates of preterm and low-birthweight are higher among women living in poverty than for higher-income women.[11] Many factors are believed to contribute to income-associated disparities in birth outcomes, some of which may be addressable by the intervention options offered by this program. Women with family incomes below the poverty level are more likely than other women to experience social stressors related to housing, employment, and neighborhood conditions. Additionally, poverty can affect a mother's nutritional intake, which is critical for a healthy newborn, and also can result in financial and other barriers (e.g., lack of transportation) to accessing timely and high-quality prenatal care.

  Race and Ethnicity: Preterm birth rates vary substantially by race and ethnicity. African-American women have the highest rates of preterm births by significant margins. Most studies that have controlled for differences in socio-economic status (SES) continue to find poorer birth outcomes among African-American women as compared to non-Hispanic Whites. African-American, Puerto Rican, and American Indian women at every level of SES have higher rates of poor birth outcomes than their white counterparts.[12] This fact suggests that lower SES alone does not explain fully disparities in birth outcomes. However, there is also substantial evidence that women of lower SES (as defined by education) do indeed have higher rates of poor birth outcomes. For other minority groups, preterm birth rates have increased since 1990. Between 1990 and 2006, preterm birth rates increased for American Indian or Alaskan Native infants (from 6.1 to 7.5 percent) and Asian or Pacific Islander infants (from 6.5 to 8.1 percent).[13] (See Figure 1)

Figure 1. Rates of Preterm Births, by Race/Ethnicity



NOTE: Data for 2009 are preliminary. Race refers to mother's race. The 1977 Office of Management and Budget (OMB) Standards for Data on Race and Ethnicity were used to classify persons into one of the following four racial groups: White, Black, American Indian or Alaskan Native, or Asian or Pacific Islander. Persons of Hispanic origin may be of any race.[14]

- Substance Abuse: Smoking is one of the most important modifiable causes of poor pregnancy outcomes in the United States, and is associated with maternal, fetal, and infant morbidity and mortality. An estimated 5–8% of preterm deliveries, 13–19% of term deliveries of infants with low birthweight, 23–34% cases of sudden infant death syndrome (SIDS), and 5–7% of preterm-related infant deaths can be attributed to prenatal maternal smoking. [15]

  Programs for cessation of tobacco, drug, and alcohol use have been recommended as part of a strategy to reduce spontaneous preterm births. Effective smoking cessation programs have been shown to reduce preterm birth and increase birthweight.[16] In addition, an office-based protocol that systematically identifies pregnant women who smoke and offers treatment or referral has been proven to improve cessation rates. A short counseling session with pregnancy-specific educational materials and a referral to a smokers' quit line has also been found to be an effective smoking cessation strategy.[17]

D. Program Requirements

The solicitation will offer direct funding to applicants for the purpose of providing specific combinations of enhanced prenatal care services, as outlined in the 3 options (approaches) detailed in this document (see Appendix B). Each applicant can propose to implement more than one option but only one option can occur at an individual practice. It will also offer funding to the applicants for start-up and implementation costs associated with developing and implementing the approaches defined in this FOA.

Strong Start funding may not be duplicative of other Federal funding opportunities for information technology capacity building such as assistance provided through Medicaid, ARRA, HITECH, ONC or other CMS initiatives. The intent of this proposal is to complement, not supplant any of these or other Federal programs.

Option 1: Enhanced Prenatal Care through Centering/Group Visits

"Centering" is an approach of care which combines three important components of enhanced prenatal care – medical appointments, education, and support – in group appointments. [18] Pregnant women receive care from health care providers in group settings with other pregnant women with similar gestational ages. The participants meet with their care provider and their cohort approximately 10 times during their pregnancy for a much longer period of time than a usual check-up visit. Through the clinical and psycho-social supportive services provided in this model, women have been found to choose health-promoting behaviors from peer to peer support, which in turn may result in improved birth outcomes and increased maternal satisfaction with the care provided.

This model has been formalized by the Centering Healthcare Institute (CHI), a not-for-profit organization focused on promoting group-based care, as "CenteringPregnancy." CHI provides education and support to practices seeking to adopt their CenteringPregnancy approach and "site approves" practices as CenteringPregnancy locations. The CenteringPregnancy model has shown promise in reducing adverse birth outcomes, including low birthweight and preterm birth.[19,20, 21]

- As per the Centering model, pregnant women will enter the program prior to 18 weeks of pregnancy, and complete eight to ten visits that are approximately 90 to 120 minutes.
- Sessions will include a standard risk assessment, including review of interim history and a physical examination, patient self-monitoring and group discussion facilitated by the health care provider. This discussion includes emphasis on health education, counseling and peer support.

While one goal of this FOA is to test the effectiveness of a group-based, "centered" approach to prenatal care, we are not requiring applicants to seek or receive "site approval" by CHI or demonstrate fidelity to the CenteringPregnancy model as outlined by CHI. However, we do encourage practices that are "site approved" by CHI to apply and demonstrate the effectiveness of the investments and commitment they have already made. Applicants that are not "site approved" or that do not follow the specific CHI model for CenteringPregnancy will need to provide the evidence base for how they will implement "centering" and demonstrate how it has been successful. This FOA does not constitute an endorsement of or effort to endorse the CHI or CenteringPregnancy.

Option 2: Enhanced Prenatal Care at Birth Centers

Birth centers are sources of maternity care facilitated by midwives and other highly qualified professionals from nursing, obstetrics, family medicine, pediatrics, nutrition, social work, physical fitness, childbirth and parenting education disciplines that offer psychosocial support services. Midwives at these centers utilize alternative family-centered techniques to support natural births and provide psychosocial support services during the course of the visits. In most cases, the Birth Center midwives and physicians will attend the delivery in an affiliated hospital, should that become necessary. Generally, there are two models of birth centers—freestanding centers and those that are a unit of or owned by a tertiary care hospital or health system.

Birth centers provide a full range of health and social services including prenatal clinical care, support through labor, delivery and postpartum care. The majority of research done on birth centers has focused on the difference in the labor and delivery for women in birth centers as compared to hospital births. However, some research does suggest that both traditional and enhanced care delivered during pregnancy may account for positive birth outcomes.[22] The enhanced prenatal care package provided at birth centers often includes case management and referral services, improved continuity of care, counseling, and a range of behavioral risk reduction programs.[23,24] Visits tend to be longer, focus on health education, nutrition services,

and psychosocial support and are often provided by a team of licensed and unlicensed professionals including peer counselors, doulas, and lactation consultants.[25]

- Birth Centers can be either free-standing or provider affiliated.
- Birth Centers must be accredited by The Commission for the Accreditation of Birth Centers, licensed, or otherwise approved by the State to provide prenatal labor and delivery or postpartum care and other ambulatory services.
- Funding is available to freestanding birth centers to the extent that they are already recognized for coverage and payment by a State's Medicaid and/or CHIP program.

Option 3: Enhanced Prenatal Care at Maternity Care Homes

The Maternity Care Home model integrates a comprehensive set of non-clinical services into the current offering of traditional prenatal care. Although many maternity care models have been implemented around the nation, no single stand-alone intervention has shown to be effective in reducing preterm birth.[26] However, literature has shown promising success when a set of prenatal services is collectively implemented throughout the course of a woman's prenatal care. These successful interventions provide an evidence base for testing enhanced maternity home models.[27,28] Services in a maternity care home include clinical aspects of prenatal care, as well as services that address behavioral, psychological, and social factors that a woman may face during a pregnancy. These enhanced services could be provided by both licensed and unlicensed professionals, offering services that include but are not limited to nutritional and psychosocial counseling, health education, and case management.

Applicants applying for the Maternity Care Home approach must describe how they intend to provide the following elements of care:

1. Access and Continuity: Critical first steps of a successful comprehensive maternity care model are to get pregnant women into care and help them stay in care. Markers of successful enhanced prenatal care include enrolling women into Medicaid and/or CHIP services[29] and providing nurse outreach to patients during visits and between visits.[30,31] Health providers should be easily accessible when a patient needs care including after usual business hours by offering expanded office hours, a 24-hour nurse support line, direct access to prenatal providers, or other comparable access. Services must be culturally and linguistically appropriate. Therefore, applicants must demonstrate activities to enroll pregnant women who are eligible, but are not currently enrolled in Medicaid, demonstrate how patients have direct access to providers between scheduled visits, and demonstrate capacity to have patients receive care consistently from the same primary provider.

2. Care Coordination: Patient care must be organized and coordinated both within the practice and with outside consultants. Markers of success include having a care navigator

create a mutually agreed-upon care plan with patients[32] and having patients referred to and enrolled in community support services, such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). [33,34, 35, 36] In consultation with their patients, providers should create a care plan/birth plan to assure that patients understand the plan of care and that the plan is congruent with patient choices and values. Practices must demonstrate the ability to provide key information to other services and providers, and to receive it in return.

Enhanced Content: During a prenatal visit, providers must make enhanced prenatal services and education available to all patients, as necessary. Markers of success include integrating smoking cessation interventions[37] into prenatal care and providing health education to women during prenatal care visits.[38] Providers shall describe the package of enhanced prenatal services they will provide, specifying how it goes beyond traditional, clinical prenatal care. Psychosocial services must be integrated into the prenatal practice.

For all approaches

The solicitation will offer direct funding for the provision of enhanced prenatal care in each of the specified care models. Funding should be calculated as a particular amount per pregnant woman who completes the pregnancy at the relevant site (see example in Budget Narrative). In addition, a portion of this funding will be available for start-up costs associated with developing the models and for on-going administrative costs. **Awardees will be expected to collect gestational age and birthweight for the infants of the mothers participating in the proposed intervention. These infants (referred to throughout as intervention infants) are born during the intervention period to mothers who participated in the enhanced prenatal care approach proposed by the applicant. Awardees must also be able to provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.** This funding shall not supplant existing payment for services that may already be provided under current State Plans and waiver programs. Funding is not available to supplement payment for services that are currently offered. Funds may, however, 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 physical space improvements. Applicants will be required as part of their applications to detail current Medicaid, CHIP and federally covered perinatal services in their State, as well as describe the proposed enhanced services or benefits. CMS will verify applicant information regarding service description, identification of the provider type, and the rate and reimbursement methodology by way of state plans and waivers on record.

MONITORING AND EVALUATION

1. Monitoring

The purpose of monitoring is to ensure that implementation is occurring safely and appropriately at the practice level, and that adequate patient protections are in place. CMS will monitor awardees participating in this initiative to ensure that access to care is not being compromised.

The awardees will be expected to collect and report, on a quarterly basis, metrics that are consistent with the goals of the model. The specific metrics will be detailed and affirmed as part of the terms and conditions for the cooperative agreement. Measures will be determined based on measures such as those compiled as part of the Physician Consortium for Performance Improvement® (PCPI).[39] This set of measures aims to assess the improvement of care for women during pregnancy, delivery, and post-partum (Appendix C). The PCPI was convened by The American Congress of Obstetricians and Gynecologists (ACOG), the National Committee for Quality Assurance (NCQA) and the American Medical Association.

These measures are consistent with the goals and objectives of the Strong Start program and specifically meant to be used at the clinician level. They include measures that will help monitor the quality and success of the delivery of enhanced prenatal care services.

Awardees will also be expected to report on their outreach and targeting activities and on their success in engaging at-risk populations. The information provided in the self-reported progress reports will be augmented with analyses by the CMS support contractor. **Awardees will be expected to collect gestational age and birthweight for the infants of the mothers participating in the proposed intervention. The awardee must also be able to 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.**

CMS will independently work (outside of this solicitation) with states to collect vital statistics and Medicaid and/or CHIP claims and encounter data. CMS seeks to link vital records and Medicaid and/or CHIP data, as possible, and provide this data, linked at the individual level, to the CMS evaluator. These data will supplement the comparison of gestational age and birthweight in the baseline and intervention periods as reported by the Strong Start awardees. CMS will also independently work with States to collect data on the Medicaid Maternity Core Set of Quality measures (Appendix D). Health system utilization data such as inpatient length of stay for mother and baby, NICU use, type of birth (vaginal or C-section), cost of care, and health care utilization and cost of care during pregnancy and for the infant's first year of life obtained through this independent work with states will support a broader evaluation of the Strong Start models.

States that are primary applicants under this funding opportunity announcement should report gestational age and birthweight for intervention infants, as well as, upon award, historical data on births from a baseline period that spans at least 2 years prior to the start

of the intervention. Collection of vital records, Medicaid/CHIP claims, and Medicaid/CHIP encounter data and the required data linkages beyond those described in section VI, Award Administration Information, will be pursued independently with States. Agreements between States and CMS for these additional data, and compensation for providing such data, will also be pursued independently of this solicitation.

Progress Report: The awardee is required to submit quarterly, semi-annual (every six months), annual, and final reports to the CMS Project Officer. These reports are to be submitted online, through CMS' web-based system. Content **requirements** of the progress reports will be detailed in the Standard and Special Terms and Conditions, but will at a minimum include information such as:

- The specific use(s) of the cooperative agreement funds.
- An assessment of overall project implementation, including lessons learned and best practices.
- An assessment of quality improvements and clinical outcomes of Medicaid and/or CHIP beneficiaries.
- Estimates of cost savings resulting from the cooperative agreement-funded activities.
- An evaluation of the degree to which the intervention is achieving its purposes, aims, goals, objectives, and quantified performance targets.
- An account of barriers that were encountered and how were they addressed.
- A discussion of lessons that were learned as a result of the intervention and recommendations for others who might be interested in implementing a similar approach.

Quarterly Data Reporting on Operations, Utilization, and Outcomes: Awardees must submit quarterly data as needed for monitoring and evaluation of the project. The format and details of this data reporting will be determined at the start of the project in collaboration with the monitoring and independent evaluation teams. For planning purposes, the applicants should expect to provide the following types of information:

> Operations **and Utilization**: **The awardees will report information regarding the operations** of the project **as well as certain aspects of utilization, which may include** staffing, number of women identified for **the** project, number of educational and support sessions with women, types of sessions, etc.
>
> **Outcomes: The awardees will report gestational age and birthweight for intervention infants. Awardees must also be able to provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.**

2. Measurement and Evaluation Plan

CMS' evaluation will inform policy makers about the impact of each of the initiative's prenatal care models on reducing the rate and degree of pre-term births and on reducing adverse pregnancy outcomes. Health improvement and expenditure outcomes to be described and evaluated may include:

- Type of delivery system – including whether Medicaid/CHIP is FFS or managed care
- Gestational age at delivery
- Frequency of ongoing prenatal care
- Timeliness of prenatal care
- Delivery method (cesarean, vaginal)
- Elective delivery prior to 39 weeks versus completed gestation
- Appropriate use of antenatal steroids
- Appropriately timed postpartum care
- Frequency of low birthweight
- Average length of stay for delivery
- Unplanned maternal admission to ICU
- NICU admission, length of stay and associated costs
- Medical costs of infants first year of life
- Total cost of care (cost of pregnancy, delivery and first year medical costs for infant)

Data Sources and Possible Evaluation Frameworks

Data availability and program designs are expected to vary by awardee. As a result, several designs will be employed to evaluate program effectiveness. CMS' third-party evaluators will employ the most rigorous set of evaluation designs, as proves feasible, for the awarded projects.

Data Sources: CMS will work closely with the awardees to establish the best possible baseline and trends **to assess the outcomes of intervention infants**. **Awardees will be expected to provide historical data on gestational age and birthweight for a baseline period that spans at least 2 years prior to the start of the intervention.** The evaluation contractor will design the evaluation and include primary data collection where necessary. **CMS will work with** an independent evaluator **to identify a baseline and trends** for the Strong Start evaluation. The health outcomes of these women and their infants **in the base period** will be compared to women receiving enhanced prenatal care as part of this initiative and their infants.

Collaboration with the evaluation contractor is required, in order for data collection to provide rapid-cycle feedback about performance and promote continuous quality improvement in the intervention. Surveys of various participants, including patients and program staff, are envisioned, in order to compare the intervention's plans and goals to the reality of what has been implemented and achieved. The evaluators will perform on-site visits to allow for direct observation of program implementation. Multiple cycles of interviews may be necessary, due to the changing nature of the approaches used by the awardees in response to rapid-cycle feedback.

3. Evaluation Questions

The CMS evaluation will assess the impact of the models on the three-part aim of better care, better health, and lower costs through improvement. This process will include assessments of patient experience of care, utilization, outcomes, quality, and access. We will plan for certain uniform data collection elements to be part of monitoring for all of the different models, and these monitoring and surveillance elements will feed into the evaluation.

4. Continuous provider quality improvement

In addition to these external checks on quality and outcomes, all applicants should provide a proposal for continuous quality improvement in the standard prenatal care that enrolled women receive. The proposal should describe a plan for quality monitoring, including selection of quality benchmarks and the use of "real-time" data from reports to assure fidelity in implementation of standards of care for the selected model and standard prenatal care and to drive quality improvement. Providers, as part of the terms and conditions of the cooperative agreement, will establish a set of measures drawn in part from the PCPI maternity care workgroup recommended measures and State Medicaid maternity care measures (see Appendices C and D), but may choose additional measures appropriate to improve the quality of the enhanced and standard prenatal care at their practices.

LEARNING AND DIFFUSION

Successful introduction of these specific approaches to enhanced prenatal care will require each participating group to actively and continuously analyze its performance and take part in learning networks that will facilitate and accelerate the exchange of effective ideas and practices. CMS-supported learning networks will be grouped by geography or option (care approach), and will provide for regular consultation between awardees and content-area experts, support for ongoing submission and study of data on progress, and face-to-face and virtual meetings with peers. Relevant activities may include:

- Use of a shared learning platform to submit data on progress and share new ideas on a frequent basis;
- In-person and virtual meetings to better understand known practice, deepen shared accountability, and build engagement and confidence;
- Collaborative improvement activities (e.g., 12-18 months of regular meetings and virtual exchanges of questions, solutions, and new practices), which will allow providers to work together to adapt the same (or a similar) model to their settings;
- Topic-specific webinars with faculty experts providing an in-depth curriculum related to perinatal models of care;

- Affinity groups based on common provider characteristics, under the premise that working with other providers with common characteristics accelerates progress;
- Site visits by CMS and support contractors to study and document positive results and offer strategies for overcoming barriers to practice.

E. Technical Assistance

CMS will provide technical assistance, analytic support, and assistance with program coordination to help awardees launch their interventions to reduce premature births. Awardees will also have access to CMS technical assistance to facilitate collection, reporting, and use of the Medicaid quality measures. Awardees should plan to participate in opportunities for shared learning and dissemination with other sites through regular phone conferences and other learning opportunities.

II. AWARD INFORMATION

A. Total Funding

Up to $41.4 million is available to fund this initiative. Applicants will be selected with consideration to: (1) available funding; (2) geographic diversity, defined as States representing regions of the United States with poor birth outcomes as determined by Centers for Disease Control and Prevention data on prematurity and low birthweight; and (3) the quality of each application, including the cost effectiveness of the proposal and the evidence presented to support the applicant's ability to meet the goals of the project. Awardees might not receive the total award requested and may be asked to revise the work plan and budget to reflect the amount awarded.

B. Award Amount

Awards will be made for a four-year period of performance including a three year period for service delivery and four years for **awardee reporting of data on intervention infants**. The number of awards will depend upon the number of women that applicants propose they can enroll in each of the three options. The Innovation Center intends to fund the cost of care for 30,000 women in each of the three approved options.

As described in detail in the budget narrative section, applicants will propose an aggregate payment amount they expect will be required to cover the cost of the specific combination of enhanced prenatal care services as defined in their selected option as well as provide a detail of the costs associated with each service include in the aggregate payment amount. The total amount of this expected expenditure 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 data submission. Applications that propose the most efficient use of funds, in addition to meeting the other goals of the project, will achieve the highest evaluation scores in the budget category.

The payment schedule and associated metrics will be detailed and affirmed as part of the terms and conditions for the cooperative agreement. As a result of this agreement, awardees may receive partial payments for provision of services, as outlined in the terms and conditions of their cooperative agreement. The balance of the potential payment will be awarded based on achievement of specific performance metrics. The specific metrics will vary based on the approach but are intended generally to encourage and reward those applicants that achieve high levels of beneficiary participation and engagement in their respective approach.

In the absence of funding, CMS is under no obligation to make awards under this program.

C. Anticipated Award Date

The anticipated award date is **October 05**, 2012. The period of performance will begin on the day of the cooperative agreement award notice.

D. Period of Performance

Upon notification of the award, awardees will receive initial funding for the first year or 12-months of their program, to be used for implementation of the proposed intervention. Non-competing continuation awards will be awarded for each additional year of the award, contingent upon availability of funding, awardee performance, and demonstrated progress toward the goal of reducing premature births. The anticipated period of performance for the 4-year project period is **October 05**, 2012 through October **04**, 2016, including a three year period for service delivery and four years for **awardee reporting of data on intervention infants**. Funds shall not be used to cover Strong Start service delivery operations after the third year.

E. Number of Awards

The number of awards will depend upon the number of women that applicants propose to enroll in each of the three models. The Innovation Center intends to fund the cost of care for 30,000 women in each of the three approved options of enhanced prenatal care, or 90,000 women total over three years. Each applicant should have the capacity to serve at least 500 pregnant Medicaid and/or CHIP beneficiaries each year. The expectation is that for each awardee a minimum of 1500 Medicaid / CHIP beneficiaries will be enrolled and receive enhanced prenatal care over the course of the three year intervention period.

Small practices are encouraged to apply by partnering with similar providers, with their States, with MCOs or with a convener. The Letter of Intent **may** provide a vehicle to link potential

applicants; see additional information in Section IV: Application and Submission Information - Letter of Intent to Apply. Applicants must indicate their preference to share contact information with potential partners on their Letter of Intent.

F. Type of Award

Awards will be made through cooperative agreements.

III. ELIGIBILITY INFORMATION

A. Eligible Applicants

The intent of this FOA is to engage with a wide variety of interested parties who have developed innovations that will drive significant improvement in three-part aim outcomes. The target applicants for this solicitation are providers (e.g., specific service providers, clinician groups and/or hospitals); States applying in partnership with providers; managed care **organizations (MCOs) applying in partnership with providers;** and conveners **applying** in partnership with providers. **All applicants not directly providing prenatal care services (i.e. States, MCOs, and conveners) are expected to partner with providers of obstetrical care services and proposed enhanced prenatal care services.** Included within the definition of State, for the purposes of this FOA are the District of Columbia and the 5 U.S. Territories: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. Faith-based organizations, Community-based organizations, and Tribal organizations are also eligible to apply.

States, managed care **organizations,** and conveners must include letters of agreement from their provider partners who will be carrying out the intervention as described in the proposal. Partnerships with public health organizations are encouraged, as are multi-state collaborations.

All awardees should be able to:

- Ensure the availability and oversee the delivery of one or more of these approaches for high risk patients. While an awardee can receive funds to administer more than one option of enhanced prenatal care, individual practices must enroll in only 1 of the 3 approaches – the one that best describes their practice.
- Demonstrate that implementation of the selected enhanced model will be coordinated closely with the provision of evidence-based prenatal medical care.
- Accept and distribute funding from the Innovation Center, ensuring that only services provided to Medicaid and/or CHIP beneficiaries are reimbursed.
- **Collect and report to CMS gestational age and birthweight for intervention infants. Awardees must be able to provide the same data on births from a baseline period that spans at least 2 years prior to the start of the intervention.**

- Demonstrate their ability to deliver the proposed enhanced prenatal care model.
- Demonstrate their ability to provide services to at least 500 pregnant Medicaid and/or CHIP beneficiaries each year. The expectation is that for each awardee a minimum of 1500 Medicaid beneficiaries will be enrolled and receive enhanced prenatal care over the course of the three year intervention period.

Given these requirements and the implications noted above, we foresee the following types of responses:

1. States respond directly, working in partnership with Fee for Service (FFS) providers and/or relevant managed care plans. States must demonstrate a working partnership with the providers who are agreeing to provide the proposed interventions.

2. Providers **of proposed interventions** respond directly.

3. Managed care **organizations** respond directly, partnering with eligible providers.

4. Conveners respond directly in partnership with other providers, serving either as a facilitator or a co-applicant. 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, or care organizations collaborating with providers. For the purposes of this initiative, a convener may be the applicant, but may be subject to special provisions.

Eligibility Threshold Criteria

- Application deadline: Applications are due by **August 09**, 2012 by 5:00 PM EST. Applications not received electronically through www.grants.gov by the application deadline will not be reviewed.

- Application requirements: Applications will be considered for funding only if the application meets the requirements as outlined in, Section III, Eligibility Information, and Section IV, Application and Submission Information.

- Page limit: Applications must not be more than 40 pages in length, including the project abstract, the project and budget narratives, and the work plan and timeline. Supporting materials are limited to 30 pages in length. These include documentation related to financial projections and profiles of participating organizations. Standard forms and letters of agreement are not included in this page limit. **The narrative portions of the application must be double-spaced (i.e. Project Narrative, Budget Narrative, Work**

Plan and Timeline). The Project Abstract should be single-spaced. Type font size must be 12 point. **Tables, charts and footnotes should be single-spaced and 10 point type font size.** For more information, see Section IV.B, Content and Form of Application Submission.

Applicants are strongly encouraged to use the review criteria information provided in Section V, Application Review Information, to help ensure that the proposal adequately addresses all the criteria that will be used in evaluating the proposals.

Legal Status: To be eligible, an applicant must be a State, entity or organization recognized as a single legal entity by the state where it is incorporated. All applicants, includ**ing** States, providers, managed care **organizations** and conveners, must 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.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS number): All applicants must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number in order to apply. The DUNS number is a nine-digit identification number that uniquely identifies business entities. Obtaining a DUNS number is easy and free. To obtain a DUNS number, access the following website: www.dunandbradstreet.com or call 1-866-705-5711. See Section IV, Application and Submission Information, for more information on obtaining a DUNS number.

Central Contractor Registration (CCR) Requirement: All awardees must provide DUNS and EIN/TIN numbers in order to be able to register in the Central Contractor Registration (CCR) database at www.ccr.gov. Applicants must successfully register with CCR prior to submitting an application or registering in the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS) as a prime awardee user. See Section IV, Application and Submission Information, for more guidance on CCR registration. Prime awardees must maintain a current registration with the CCR database, and **may make subawards only to entities that have DUNS numbers**. Organizations must report executive compensation as part of the registration profile at www.ccr.gov by the end of the month following the month in which this award is made, and annually thereafter (based on the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109-282), as amended by section 6202 of Public Law 110-252 and implemented by 2 CFR Part 170)). See Section VI, Award Administration Information, for more information on FFATA.

The Grants Management Specialist assigned to monitor the sub-award and executive compensation reporting requirements is Iris Grady, who can be reached at **divisionofgrantsmanagement@cms.hhs.gov**.

B. Cost Sharing/Matching

Cost sharing is not required.

C. Foreign and International Organizations

Foreign and international organizations are ineligible to apply.

D. Faith-Based Organizations

Faith-based organizations are eligible to apply, as specified in item III.A of this section, Eligibility Information.

E. Community-Based Organizations

Community-based organizations are eligible to apply, as specified in III.A of this section, Eligibility Information.

F. Tribal Organizations

American Indian and Alaskan Native Tribal Organizations are eligible to apply, as specified in III.A of this section, Eligibility Information.

IV. APPLICATION AND SUBMISSION INFORMATION

A. Address to Request Application Package

This Funding Opportunity Announcement serves as the application package for this cooperative agreement and contains all the instructions to enable a potential applicant to apply. The application should be written primarily as a narrative, accompanied by the standard forms required by the Federal government for all cooperative agreements.

Letter of Intent to Apply

Applicants **may** submit a non-binding Letter of Intent to Apply. Receipt of such notices enables CMS to better plan for the application review process. The Letter of Intent **may** provide a vehicle to link applicants**. CMS has established an online platform for potential applicants who are interested in partnering with others in a Strong Start program. The online platform is a website that is intended to facilitate such partnerships, and allows potential applicants to share information on the secure website. Applicants interested in sharing their organization's location, contact information and the approach(es) to enhanced prenatal care services** may indicate their consent to share information on their Letter of Intent. Applicants who consent will gain access to a password protected site, which provides information on all applicants who have consented, to share **their** information. All potential applicants interested in partnering will have access to this **site** if they have submitted a Letter of Intent and indicated **their** consent to share information **on their Letter of Intent**. Although the Letter of Intent is otherwise optional, all potential applicants interested in using the online platform must submit a Letter of Intent as documentation of their consent to share information.

Letters of Intent to Apply **may be submitted by August 08,** 2012 5:00 pm Eastern Time. The Letter of Intent **must** be submitted via the Letter of Intent form on the Innovation Center website, http://innovations.cms.gov.

Letters of Intent submissions form will ask for the following information:

- Name and type of applicant organization
- Address of applicant organization
- Point of contact for applicant organization
- Estimated funding request
- Brief summary of the proposal
- Description of geographic region(s) where proposal activity will occur
- Primary state where proposal activity will occur
- Names of provider partners.
- Explain why the proposed area is at higher risk for pre-term births
- For each option being proposed, indicate how many pregnant Medicaid and/or CHIP women will be served in year 1, year 2, and year 3
- Optional consent to share contact and other information with others who have submitted a Letter of Intent and also want to share information.

Form and accompanying instructions for submitting Letters of Intent to Apply are posted on the Innovation Center website at http://innovations.cms.gov.

Application Materials

Application materials will be available for download at http://www.grants.gov. Please note that HHS requires applications for all announcements to be submitted electronically through http://www.grants.gov. For assistance with grants.gov, contact support@grants.gov or call 1-800-518-4726. At http://www.grants.gov, applicants will be able to download a copy of the application packet, complete it off-line, and then upload and submit the application via the Grants.gov website. The Funding Opportunity Announcement can also be viewed on HHS's website at http://www.hhs.gov/.

Specific instructions for applications submitted via http://www.grants.gov:

- You can access the electronic application for this project at grants.gov. You must search the downloadable application page by the CFDA number 93.611.
- At the grants.gov website, you will find information about submitting an application electronically through the site, including the hours of operation. HHS strongly recommends that you do not wait until the application due date to begin the application process through http://www.grants.gov, because of the time needed to complete the required registration steps.

- All applicants under this announcement must have an Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN), to apply. **Please note, the time needed to complete the EIN/TIN registration process is substantial, and applicants should therefore begin the process of obtaining an EIN/TIN immediately upon posting of this FOA to ensure this information is received in advance of application deadlines.**
- All applicants, as well as sub-recipients must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number at the time of application in order to be considered for a grant or cooperative agreement. A DUNS number is required whether an applicant is submitting a paper application (only applicable if a waiver is granted) or using the Government-wide electronic portal, www.Grants.gov. The DUNS number is a nine-digit identification number that uniquely identifies business entities. Obtaining a DUNS number is easy and free. To obtain a DUNS number, access the following website: www.dunandbradstreet.com or call 1-866-705-5711. This number should be entered in the block with the applicant's name and address on the cover page of the application (Item 8c on the Form SF 424, Application for Federal Assistance). The name and address in the application should be exactly as given for the DUNS number. **Applicants should obtain this DUNS number as soon as possible after the announcement is posted to ensure all registration steps are completed in time.**
- The applicant must also register in the Central Contractor Registration (CCR) database in order to be able to submit the application. Applicants are encouraged to register early, and must have their DUNS and EIN/TIN number in order to do so. Information about CCR is available at http://www.ccr.gov. The Central Contractor Registration process is a separate process from submitting an application. **You should allow a minimum of five business days to complete CCR registration; however, in some cases, the registration process can take approximately two weeks or longer to be completed. Therefore, applicants should begin the CCR registration process as soon as possible after the announcement is posted to ensure that it does not impair your ability to meet required submission deadlines.**
- Authorized Organizational Representative: The Authorized Organizational Representative (AOR) who will officially submit an application on behalf of the organization must register with grants.gov for a username and password. AORs must complete a profile with Grants.gov using their organization's DUNS Number to obtain their username and password, at http://grants.gov/applicants/get_registered.jsp. AORs must wait one business day after successful registration in CCR before entering their profiles in Grants.gov. **Applicants should complete this process as soon as possible after successful registration in CCR to ensure this step is completed in time to apply before application deadlines.**
- When an AOR registers with Grants.gov to submit applications on behalf of an organization, that organization's E-Biz POC will receive an e-mail notification. The e-mail address provided in the profile will be the e-mail used to send the notification from Grants.gov to the E-Biz POC with the AOR copied on the correspondence.

- The E-Biz POC must then login to Grants.gov (using the organization's DUNS number for the username and the special password called "M-PIN") and approve the AOR, thereby providing permission to submit applications.
- Any files uploaded or attached to the Grants.Gov application must be **PDF file format** and must contain a valid file format extension in the filename. Even though Grants.gov allows applicants to attach any file format as part of their application, CMS restricts this practice and only accepts **PDF** file formats. Any file submitted as part of the Grants.gov application that is not in a **PDF** file format, or contains password protection, will not be accepted for processing and will be excluded from the application during the review process. In addition, the use of compressed file formats such as ZIP, RAR, **or Adobe Portfolio** will not be accepted. The application must be submitted in a file format that can easily be copied and read by reviewers. It is recommended that scanned copies not be submitted through Grants.gov unless the applicant confirms the clarity of the documents. Pages cannot be reduced in size, **resulting in** multiple pages on a single sheet, to avoid exceeding the page limitation. All documents that do not conform to the above constraints will be excluded from the application materials during the review process.
- After you electronically submit your application, you will receive an **automatic email** from http://www.grants.gov that contains a Grants.gov tracking number. **Please be aware that this notice does not guarantee that the application will be accepted by Grants.gov. Rather, this email is only an acknowledgement of receipt of the application by Grants.gov. All applications must be validated by Grants.gov before they will be accepted. Please note, applicants may incur a time delay before they receive acknowledgement that the application has been validated and accepted by the Grants.gov system. In some cases, the validation process could take up to 48 hours. If for some reason the application is not accepted, then the applicant will receive a subsequent notice from Grants.gov indicating that the application submission has been rejected. Applicants should not wait until the application deadline to apply because notification by Grants.gov that the application is incomplete may not be received until close to or after the application deadline, eliminating the opportunity to correct errors and resubmit the application. Applications submitted after the deadline because the original submission failed validation and is therefore rejected by Grants.gov, as a result of errors on the part of the applicant, will not be accepted by CMS and/or granted a waiver. For this reason, CMS recommends that applicants apply in advance of the application due date and time.**
- After HHS retrieves your application package from Grants.gov, a return receipt will be e-mailed to the applicant contact. This return receipt will be in addition to the tracking number sent by Grants.gov.
- Each year organizations and entities registered to apply for Federal grants through http://www.grants.gov will need to renew their registration with the Central Contractor Registration (CCR). You can register with the CCR online; registration will take about

30 minutes to complete (http://www.ccr.gov). **Failure to renew CCR registration prior to application submission will prevent an applicant from successfully applying.**

Applications cannot be accepted through any e-mail address. Full applications can only be accepted through http://www.grants.gov. Full applications cannot be received via paper mail, courier, or delivery service, unless a waiver is granted per the instructions below.

All agreement applications must be submitted electronically and be received through http://www.grants.gov on **August 09**, 2012 by 5:00 pm Eastern Standard Time.

All applications will receive an automatic time stamp upon submission and applicants will receive an e-mail reply acknowledging the application's receipt.

The applicant must seek a waiver **at least** ten days prior to the application deadline if the applicant wishes to submit a paper application. Applicants that receive a waiver to submit paper application documents must follow the rules and timelines that are noted below.

In order to be considered for a waiver application, an applicant **must** have adhered to the timelines for obtaining a DUNS number, registering with the Central Contractor Registration (CCR), registering as an Authorized Organizational Representative (AOR), obtaining an Employer/Taxpayer Identification Number (EIN/TIN), completing Grants.gov registration, as well as requested timely assistance with technical problems. Applicants that do not adhere to timelines and/or do not demonstrate timely action with regards to these steps will not be considered for waivers based on the inability to receive this information in advance of application deadlines.

Please be aware of the following:

- Search for the application package in Grants.gov by entering the CFDA number. This number is located on the first page of this announcement.
- Paper applications are not the preferred method for submitting applications. However, if you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: www.grants.gov/customersupport or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, you must submit a request in writing (e-mails are acceptable) to Michelle.Feagins@cms.hhs.gov with a clear justification for the need to deviate from our standard electronic submission process.

- If the waiver is approved, the application should be sent directly to the Office of Acquisition & Grants Management and received by the application due date.

To be considered timely, applications must be received by the published deadline date. However, a general extension of a published application deadline that affects all applicants or only those applicants in a defined geographical area may be authorized by circumstances that affect the public at large, such as natural disasters (e.g., floods or hurricanes) or a disruption of electronic or other services (e.g., application receipt services), such as a prolonged blackout.

Grants.gov complies with Section 508 of the Rehabilitation Act of 1973. If an individual uses assistive technology and is unable to access any material on the site including forms contained with an application package, they can email the Grants.gov contact center at support@grants.gov or call 1-800-518-4726.

B. Content and Form of Application Submission

1. Form of Application Submission

Each application shall include all contents described below, in the order indicated, and in compliance with the following specifications:

- Use 8.5" x 11" letter-size pages (one side only) with 1" margins (top, bottom, and sides). Other paper sizes will not be accepted. This is particularly important because it is often not possible to reproduce copies in a size other than 8.5" x 11".
- All pages of the project narrative must be paginated in a single sequence.
- Font size **must be** 12-point with an average character density no greater than 14 characters per inch.
- The narrative portions of the application **(i.e. project narrative, budget narrative, work plan and timeline)** must be DOUBLE-SPACED. **Tables, charts and footnotes should be single-spaced and 10 point type font size.**
- The project abstract is restricted to a one-page summary, which should be single-spaced.
- Applications must not be more than 40 pages in length (including the project abstract, the project and budget narratives, and the work plan and timeline), and should include not more than 30 pages of supporting material (e.g., documentation related to financial projections, profiles of participating hospitals and/or practices). The total size of all uploaded files may not exceed the equivalent of 70 pages when printed by HHS, or a total file size of 13 MB. Standard forms and letters of agreement are NOT included in the page limits.

Any files uploaded or attached to the Grants.Gov application must be PDF file format and must contain a valid file format extension in the filename. Even though Grants.gov allows applicants to attach any file formats as part of their application, CMS restricts this practice

and only accepts PDF file formats. Any file submitted as part of the Grants.gov application that is not in a PDF file format, or contains password protection, will not be accepted for processing and will be excluded from the application during the review process. In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. The application must be submitted in a file format that can easily be copied and read by reviewers. It is recommended that scanned copies not be submitted through Grants.gov unless the applicant confirms the clarity of the documents. Pages cannot be reduced in size, resulting in with multiple pages on a single sheet, to avoid exceeding the page limitation. All documents that do not conform to the above constraints will be excluded from the application materials during the review process.

2. Overview of Cooperative Agreement Application Structure and Content

a. Standard Forms

The following standard forms must be completed with an original signature and enclosed as part of the proposal:

SF 424: Official Application for Federal Assistance (see note below)
SF 424A: Budget Information Non-Construction
SF 424B: Assurances-Non-Construction Programs
SF LLL: Disclosure of Lobbying Activities
Project Site Location Form(s)
Project abstract summary

Note: On SF 424 "Application for Federal Assistance": State the specific agreement opportunity for which you are applying – Strong Start for Mothers and Newborns – on Item 15 "Descriptive Title of Applicant's Project" and enter the tracking number from your Letter of Intent submission on Field 4, Applicant Identifier**, if applicable**.

b. Cover Letter

A letter from the Applicant's Authorized Organizational Representative, indicating the title of the project, the principal contact person, amount of funding requested, and the name of the agency that will administer the cooperative agreement, and all major partners, departments, divisions, services, and organizations actively collaborating in the project is required. **Also, indicate the type of applicant (Provider, MCO, convener or State) in the title of the project.** This letter should be addressed to:

Michelle Feagins
Grants Management Officer
Centers for Medicare and Medicaid Services
Office of Acquisition and Grants Management
200 Independence Ave., S.W.
Room 733H-02
Washington, DC 20201

c. Project Narrative

The application is expected to address how the awardee will design, implement, and ultimately meet the objectives of the Strong Start for Mothers and Newborn program. The required elements (sections) of the application are listed below. Also provided is a brief description of the type of information that must be included in each specific section. The application must be organized using the specified headings for the operational element sections, as outlined below.

Section One: Project Design

1. Background, Goals, and Design of Program

1.1 Background: The application shall describe the background of the program, its goals, and the need for the program in the proposed geographic area. It should include detailed background information on existing efforts already in place in the State and region that pertain to the initiative. Provide State and/or provider information and statistics about prenatal care, preterm births, maternal and infant health characteristics, and any supporting information that will provide a basis for establishing the need for the intervention.

Applicants will propose target areas for deploying these approaches and will utilize available data to demonstrate that the proposed target area is one in which there is a greater concentration of risk for pre-term births. Applicants will be asked to identify the risk factors for preterm birth present in the areas they propose to deliver services. Applicants should use available data sources to assess and describe the risk factors present. The application will also clearly demonstrate that women who live in the proposed target area are at increased risk for preterm births.

Describe current State plan and/or waiver program coverage and benefits for pregnant women, 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.

1.2 Identify the Proposed Option: The application must describe the design of the selected care model/s and explain how the applicant will meet the program requirements. Review the design and evidence basis for each model selected and explain why each is suitable for the specific practice/s involved and the population/s served. The organizations that would implement the project must be identified and described. Explain how, in your project, care would be delivered and describe your experience in each of the proposed model/s.

Describe in detail the specific enhancement benefit and/or services and option type requested for implementation. Explain how the proposed enhancement connects within the continuum of services that are currently available and why the proposed enhancements will strengthen the coverage and lead to improved participant care, better health outcomes, and lower overall costs for women and infants.

Describe how applicants will provide clinical obstetrical services to ensure that each patient receives optimal medical care as well as proposed enhanced prenatal care.

The applicant should also identify the primary challenges to successful implementation of the project and explain how these anticipated risks will be mitigated.

1.3 Education and Outreach: The application must describe plans for recruiting women into the proposed option/s. Explain how prior experience and outreach will inform this effort. The applicant must describe plans to address language and literacy issues that may cause recruitment or implementation problems.

1.4 Enrollment: The application must describe the enrollment process for expectant mothers, demonstrate capacity to enroll individuals into the initiative, and explain how the applicant will address breaks in Medicaid and/or CHIP eligibility while the woman is pregnant.

1.5 Stakeholder Involvement: Please list consumer/advocacy groups, community-based organizations, providers, and others consulted while developing the proposal and explain how the applicant will continue to engage stakeholders in the program during implementation and operation. Please also describe the relationship **with all providers** in the application **who are partnering with States**, MCOs and conveners as outlined in the attached letters of agreement (subsection e below).

2. Implementation and Operations.

2.1 ***Relevant Experience*****.** The applicant must provide a history of any activities that demonstrate their ability to implement and/or expand an existing capability to deliver one of the three options. This must include a summary of the plans for implementation and operations, describing major

activities, major milestones, and the staff or organization that will carry out the activities. Applications should clearly and in detail describe current capacity and explain how quickly the first patient will be enrolled, how long it will take to reach full capacity, and what expansion plans are under consideration, if applicable.

2.2 Monitoring and continuous quality improvement: Explain how the applicant will monitor project operations and outcomes in order to provide immediate knowledge about problems and issues related to both project operations and progress toward project objectives. Describe how these data will be used to assure the quality of standard care, implement rapid-cycle quality improvements, and meet project goals. Explain how the use of funds will be monitored to ensure that only services provided to Medicaid and/or CHIP enrollees are reimbursed. Describe how Medicaid and/or CHIP eligibility will be monitored. Applicants must describe how they will use these data to quickly solve problems, implement operational improvements, and meet project goals.

2.3 Data collection and reporting: The applicants will be required to provide data needed for an independent national evaluation of the project, in addition to data for monitoring 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.**

2.4 ***Cooperation with Evaluation:*** The application must demonstrate a commitment to cooperate and collaborate with CMS and the **national Strong Start program evaluation**.

3. Applicant Organization

3.1. Organization Experience and Capacity: Describe the applicant organization and explain how it has the ability and experience needed to implement and/or expand the existing capability to offer one or more of the care options. Show examples of operating experience with large scale projects that provide evidence that the organization can operate the project. Describe the organization's and its partners' financial strength and provide evidence and support showing its stability and its resolve to operate the project for the specified period of performance. Demonstrate the organization's understanding of the needs of the community that it will serve in this project. The applicant should describe any involvement in or activity related to maternity and newborn health care grants and programs, including Maternal and Child Block Grants, Pregnancy and Risk Assessment Monitoring System Grants, Home Visiting Program Grants, etc.

3.2 Proposed staffing: Provide information on the proposed project director and his/her background, showing appropriate operational ability. Give information about other key staff and

their management and leadership skills. Specify and explain what proportion of their time will be dedicated to the project.

d. Budget and Budget Narrative

i. Budget SF 424A

All applicants must submit an SF 424A. To fill out the budget information requested on form SF 424A, review the general instructions provided for the SF 424A and follow the instructions outlined below.

Section A – Budget Summary

- *Grant Program Function or Activity* (column a) = Enter "Strong Start for Mothers and Newborns" in row 1.

- *New or Revised Budget, Federal* (column e) = Enter the Total Federal Budget Requested for the 4-year project period **(i.e. three years for service delivery and four years for awardee reporting of data on intervention infants)** in rows 1 and 5. The fourth **year** may **only include costs** for **awardee reporting of data on intervention infants**.

- *New or Revised Budget, Non-Federal* (column f) = Enter Total Amount of any Non-Federal Funds Contributed (if applicable) in rows 1 and 5.

- *New or Revised Budget, Total* (column g) = Enter Total Budget Proposed in rows 1 and 5, reflecting the sum of the amount for the Federal and Non-Federal Totals.

Section B – Budget Categories

- Enter the total costs requested for each Object Class Category (Section B, number 6) for each year of the 3-year project period. A fourth budget period may be included for data reporting.
- Column (1) = Enter the heading for this column as Year 1. Enter Year 1 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges should be reflected in row j. The total for direct and indirect charges for all year 1 line items should be entered in column 1, row k (sum of row i and j).
- Column (2) = Enter the heading for this column as Year 2. Enter Year 2 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect

charges should be reflected in row j. The total for direct and indirect charges for all year 2 line items should be entered in column 2, row k (sum of row i and j).

- Column (3) = Enter the heading for this column as Year 3. Enter Year 3 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges should be reflected in row j. The total for all year 3 line items should be entered in column 3, row k (sum of row i and j).
- Column (4) = Enter the heading for this column as Year 4. Year 4 costs may only include costs related to data reporting. Enter Year 4 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges should be reflected in row j. The total for all year 4 line items should be entered in column 4, row k (sum of row i and j).
- Column 5 = Enter total costs for the project period for each line item (rows a-h), direct total costs (row i), and indirect costs (row j). The total costs for all line items for the three years should be entered in row k (sum of row i and j). The total in column 5, row k should match the total provided in Section A – Budget Summary, New or Revised Budget, column g, row 5.

ii. Budget Narrative

Applicants must supplement Form SF 424A with a Budget Narrative. **The Budget Narrative must include a yearly breakdown of costs for the 4-year project period (three years of service delivery and four years for awardee reporting of data on intervention infants).** The applicant must also include a clear description of the proposed set of services that would be covered with Innovation Center funds. The Budget Narrative should provide a detailed cost breakdown for each line item outlined in the SF 424A by cooperative agreement year, including a breakdown of costs for each activity/cost within the line item. The proportion of the requested funding designated for each activity should be clearly defined and should justify the applicant's readiness to receive funding through 201**6**. This will include providing complete explanations and justifications for the proposed agreement activities.

All applicants must provide information about any component(s) of the service models that are currently authorized for payment and coverage. The Innovation Center expects each applicant to include a comprehensive service description, identification of the provider type it represents, and the rate and reimbursement methodology in effect per the current State Plan, waiver program or other Federal program or funding source.

For the model selected, the applicant must describe the services within the model of care it proposes will be provided using Innovation Center funds. In doing so the applicant must provide a service description, provider type associated with the service provided, and the rate and reimbursement methodology.

Only funding for **awardee reporting of data on intervention infants** can be requested for all four years of the performance period. Service delivery costs are limited to the first three years.

The applicant should clearly justify funding needs and explain why the requested funding is the most cost-effective way to implement the model. This includes indirect costs. The budget must separate out funding that is administered directly by the prime awardee from funding that will be subcontracted to other partners.

The following budget categories should be addressed (as applicable), and match the budget stated in Section B of Form SF 424A:

- Personnel
- Fringe benefits
- Travel
- Equipment
- Supplies
- Contractual costs, including subcontract contracts
- Construction costs
- Other costs
- Indirect charges, in compliance with the appropriate Code of Federal Regulations Circulars. If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required.

iii. Additional Cost Considerations

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 must include travel funds for at least 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. Successful applicants will also be required to participate in regular webinars and conference calls to share information about their projects with other sites, and to learn from experts on how to further improve operations and outcomes.

e. Letter(s) of Agreement

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/CHIP beneficiaries to be served, and the enhanced prenatal approach the partner has committed to provide.

f. Work Plan and Timeline

The applicant must provide a work plan and timeline that details benchmarks and milestones consistent with those outlined in the project narrative. The timeline should provide a sequential representation of project activities. The work plan submitted with the application should document reasonable milestones with associated timeframes, and identify by name and title the individual responsible for accomplishing the goals of the project. Benchmarks and milestones included in the work plan and timeline are project actives such as: education and outreach; project enrollment targets; project enrollment start and end dates; service delivery start date; and if adding new or additional services, service implementation dates.

C. Submission Dates and Times

Optional Letters of Intent to Apply may be submitted by August 08, 2012 on-line via Letter of Intent form at innovation.cms.gov. Submission of a Letter of Intent to Apply does not bind the applicant to apply.

Agreement Applications

All cooperative agreement applications are due August 09, 2012 by 5:00 p.m. Eastern time throughhttp://www.grants.gov. All applications will receive an automatic time stamp upon submission and applicants will receive an e-mail reply acknowledging the application's receipt.

The anticipated announcement date for all agreement awards will be October 05, 2012. All awards will have an initial budget period of 12 months.

D. Intergovernmental Review

Applications for these awards are not subject to review by States under Executive Order 12372, "Intergovernmental Review of Federal Programs" (45 CFR 100). Please check box "C" on item 19 of the SF 424 (Application for Federal Assistance) as Review by State Executive Order 12372 does not apply to these awards.

E. Funding Restrictions Interaction with Medicaid and/or CHIP Payment Policy

Although all State Medicaid programs are required to pay for traditional prenatal care and deliveries, there is great variation as to which services are covered. Many States already provide

Extended Services to Pregnant Women (see 42 CFR 440.250(p)). Under this benefit, a State may provide a greater amount, duration, or scope of services to pregnant women than it provides under its plan to other individuals who are eligible for Medicaid. Under this authority, States offer a variety of services for this particular population.

Through funding for new services, the Innovation Center will assist States, providers, and managed care **organizations** in making more robust their offering of perinatal services. All funding will be targeted to services and activities that reduce the risk of an adverse birth outcome. Funding is not available to supplement payment for services that are currently offered. Funds may, however, 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 physical space improvements.

In compliance with the OMB Circulars **and the Code of Federal Regulations**, which define allowed costs, funding from the Innovation Center may not supplant funding for services that are currently authorized through the Medicaid and/or CHIP State Plan. This also applies to funding provided through waivers or other grants, including Federal grants. A State currently reimbursing perinatal services would continue to receive federal matching funds at the established rate for those services authorized through the State's approved Medicaid and/or CHIP program.

Indirect Costs

If requesting indirect costs, a currently effective Indirect Cost Rate Agreement will be required. Applicants are required to use the rate agreed to in the Indirect Cost Rate Agreement. However, if there is not an agreed upon rate, the award (if the applicant is selected) may not include an amount for indirect costs unless the organization has never established an indirect cost rate (usually a new recipient) and intends to establish one. In such cases, the award shall include a provisional amount equaling one-half of the amount of indirect costs requested by the applicant, up to a maximum of 10 percent of direct salaries and wages (exclusive of fringe benefits). If the recipient fails to provide a timely proposal, indirect costs paid in anticipation of establishment of a rate will be disallowed. See the Health and Human Services Grants Policy Statement at http://www.hhs.gov/grantsnet/adminis/gpd/ for more information.

Note that indirect costs will be considered as part of the total proposed budget for the purposes of evaluating the cost effectiveness of applications. Applicants with an effective Indirect Cost Rate Agreement may modify their request to lower their total proposed budget.

The provisions of 2 CFR Part 225 (previously OMB Circular A-87), 2 CFR Part 220 (previously OMB Circular A-21), 2 CFR Part 230 (previously OMB Circular A-122), and 48 CFR subpart

31.2 govern reimbursement of indirect costs under this solicitation (based upon the applicable entity).

Reimbursement of Pre-Award Costs
No cooperative agreement funds awarded under this solicitation may be used to reimburse pre-award costs.

Prohibited Uses of Agreement Funds

1. To match any other Federal funds.

2. To provide services, equipment, or support that are the legal responsibility of another party under Federal or State law (e.g., vocational rehabilitation or education services) or under any civil rights laws. Such legal responsibilities include, but are not limited to, modifications of a workplace or other reasonable accommodations that are a specific obligation of the employer or other party.

3. To supplant existing State, local, or private funding of infrastructure or services, such as staff salaries, etc.

4. Funding for data collection and reporting may not be duplicative of other CMS or HHS funding opportunities for information technology capacity building, such as assistance provided through ARRA, HITECH, or other ONC initiatives.

F. Other Submission Requirements

a. Letter of Intent
Applicants may submit a non-binding optional Letter of Intent to Apply. Letters of Intent to Apply may be submitted by August 08, 2012 5:00 pm Eastern Time. The Letter of Intent must be submitted via the Letter of Intent form on the Innovation Center website, http://innovation.cms.gov. The form and accompanying instructions for submitting Letters of Intent to Apply are posted on the Innovation Center website at http://innovation.cms.gov.

b. Additional requirements for online submission through grants.gov APPLY

(1) The applicant will be required to have a DUNS number in order to apply. To obtain a DUNS number, access the following website www.dunandbradstreet.com or call 1-866-705-5711.

(2) The applicant will be required to register in the Central Contractor Registry (CRR) database in order to be able to submit the application. One element of the

CCR is the DUNS number (see section IV.A.), which must be obtained separately from CCR registration. Information about CCR is available at http://www.ccr.gov.

(3) The applicant is required to register with the Authorized Organization Representative (AOR) for Grants.gov. Information about this requirement is available at http://grants.gov/applicants/get_registered.jsp.

c. Point of Contact for difficulties with electronic application submission

If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: www.grants.gov/customersupport or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on federal holidays). Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained. If it is determined that a waiver is needed you must submit a request in writing (e-mails are acceptable to Michelle.Feagins@cms.hhs.gov with a clear justification for the need to deviate from our standard electronic submission process.

V. APPLICATION REVIEW INFORMATION

In order to receive an agreement under this funding opportunity announcement, applicants must submit an application, in the required format, no later than the deadline dates published in this FOA.

If an applicant does not submit all of the required documents and does not address each of the topics described below, the applicant risks not being awarded.

As indicated in Section IV, *Application and Submission Information*, all applicants must submit the following:

1. Standard Forms
2. Cover Letter
3. Project Abstract
4. Project Narrative
5. Budget and Budget Narrative
6. Letter(s) of agreement **from provider** partners **when applicant is a State, MCO, or convener**
7. Work Plan and Timeline

A. Criteria

This section fully describes the evaluation criteria for this cooperative agreement program. Applicants are strongly encouraged to review the programmatic requirements detailed in Section I, Funding Opportunity Description. The application must be organized as detailed in Section IV, Application and Submission Information, of this solicitation. The following criteria will be used to evaluate applications received in response to this solicitation. Applications will be scored with a total of 100 points available. **A maximum of five (5) bonus points may be earned in the Design of Project category. These bonus points will be added to the applicant's total score. Applicants earning bonus points may earn a total score of 105 points.**

1) Design of Project (35 points) and (5 bonus points)

The proposed cooperative agreement project is appropriately selected, well-designed, and likely to succeed in improving the health status of beneficiaries with regard to improving the prenatal care and maternal and neonatal outcomes resulting from these improvements. The application presents well-described goals and applicant's history in regard to the type of prenatal care currently provided, presents the numbers of deliveries, outlines their plan to identify the high-risk patients, and describes their operational experience and ability to report data. The proposed cooperative agreement program is based on evidence-based approaches to improve prenatal care and resulting maternal and neonatal outcomes, and on collaborative approaches for quality improvement. The applicant can provide services to a significant number (500 annually – 1500 or more during the three year intervention period) of mothers and babies in the program over three years.

The application describes a proposed intervention using enhanced prenatal services as defined in the FOA option/s chosen. The applicant describes the ability of the providers to deliver enhanced prenatal care through the selected approach and demonstrates a track record of providing this type of enhanced care. The application outlines how the practices will deliver the services in a manner consistent with the specific proposed option and identifies how the practice will demonstrate and maintain the ability to provide care consistent with the distinct approach.

The application provides an assessment of the particular need for the initiative based on the needs of the covered population and the need for new or enhanced service delivery options as identified in the solicitation. The application clearly describes the proposed service delivery area and uses data to describe the factors that define the area as one in which there is an increased risk for preterm birth.

The applicant should indicate how they will integrate the project with area hospitals, local health care providers, other publicly financed health programs, Public Health Departments and relevant community-based organizations. It will explain how the awardee will integrate the project with other medical care being provided to participants and relevant support services being provided to

them by community-based organizations, in order to implement the project in a manner that ensures best practice medical care, in addition to enhanced support under this intervention.

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 should 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. Applicants who state their commitment and demonstrate an ability to provide more than 2 years of historical baseline data on infant gestational age and birthweight, upon award, may earn up to two and a half (2.5) bonus points. Applicants who state their commitment and demonstrate an ability to provide gestational age and birthweight on a comparison population during the intervention period may also earn up to two and a half (2.5) bonus points.

The application should show that the applicant has a plan and the capacity, data, and analytic infrastructure to provide the data required in a standardized format for the Strong Start initiative. This includes, but is not limited to, gestational age and birthweight for intervention infants during the intervention period and historical data for births in a baseline period, upon award, as well as clinical quality measures during the intervention period.

2) Administration, Organization and Staffing (40 points)

The proposed awardee has a documented ability and the necessary infrastructure to successfully implement the proposed program. The applicant's **provider** partner**(s)** also have the administrative capacity and infrastructure to carry out the tasks required to support the program as proposed. Tasks for implementation and the organizations responsible for these tasks should be fully described and explained.

The proposal shall be comprehensive and feasible; define specific milestones; assign all tasks to a task owner or party accountable for accomplishing the task; and establish the administrator's qualifications to perform the task. The staff proposed to carry out the care delivery model has the skills and experience needed to assure smooth and effective implementation. The work plan and timeline will be evaluated based on reasonableness and feasibility of project bench marks and milestones and task accountability.

If the applicant is not the provider, the application demonstrates a strong partnership with the providers who will deliver the enhanced prenatal care services. The applicant clearly defines how they will coordinate project-related services with medical care and provide best practice medical care to mothers and babies.

The proposing organization demonstrates that it has the ability to work with the program staff to conduct a self-assessment of the project, with the goal of understanding its progress toward project goals and making rapid mid-course corrections to project implementation in order to improve performance. The applicant provides examples of experience with continuous improvement and/or quality improvement outcomes, and has a demonstrated record of positive results.

3) Budget (25 points)

The proposed budget is carefully developed, with plans for an efficient use of funds. The applicant clearly justifies funding needs and demonstrates that the requested funding is the most cost-effective way to implement the model. The funding will be used primarily for the provision of services rather than for overhead and administrative costs. The requested budget fits within the expectations of CMS for service delivery and data collection costs – and will be verified by CMS.

B. Review and Selection Process

A team consisting of staff from CMS and other outside experts will review all applications. The review process will include the following:

1. Applications will be screened to determine eligibility for further review using the criteria detailed in this solicitation and applicable law (e.g., 2 CFR Parts 180 and 376). Applications received late or that fail to meet the eligibility requirements as detailed in the solicitation or do not include the required forms will not be reviewed.

   The results of the objective review of the applications by quality experts will be used to advise the approving CMS official. Final award decisions will be made by a CMS program official. In making these decisions, the CMS program official will take into consideration: recommendations of the review panel; the geographic diversity of awardees, defined as including regions of the United States with poor birth outcomes as determined by official reporting sources, such as Centers for Disease Control and Prevention, states and county data on prematurity, low birthweight, and IMR; reviews for programmatic and grants management compliance; the reasonableness of the estimated cost to the government and anticipated results; the likelihood that the proposed project will result in the benefits expected; and program integrity issues. CMS reserves the right to conduct pre-award Budget Negotiations with potential awardees.

C. Anticipated Announcement and Award Date

The anticipated announcement date for agreement awards will be **October 05**, 2012.

VI. AWARD ADMINISTRATION INFORMATION

A. Award Notices

Successful applicants will receive a Notice of Award (NoA) signed and dated by the CMS Grants Management Officer. The NoA is the document authorizing the cooperative agreement award and will be sent through electronic mail to the applicant organization as listed on the SF 424. Any communication between CMS and applicants prior to issuance of the NoA is not an authorization to begin performance of a project.

Unsuccessful applicants are notified within 30 days of the final funding decision and will receive a disapproval letter via the U.S. Postal Service or electronic mail.

Federal Funding Accountability and Transparency (FFATA) subaward Reporting Requirement: New awards issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252 and implemented by 2 CFR Part 170. Cooperative agreement recipients must report information for each first-tier subaward of $25,000 or more in Federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (available online at www.fsrs.gov).

B. Administrative and National Policy Requirements

The following standard requirements apply to applications and awards under this FOA:

1. Specific cost principles, as outlined in 2 CFR Part 225 (previously OMB Circular A-87), 2 CFR Part 220 (previously OMB Circular A-21), 2 CFR Part 230 (previously OMB Circular A-122), 48 CFR subpart 31.2, as well as the administrative requirements outlined in 45 CFR Parts 74 and 92, apply to cooperative agreements awarded under this announcement.

2. All awardees receiving awards under this agreement project must comply with all applicable Federal statutes relating to nondiscrimination including, but not limited to:
    a. Title VI of the Civil Rights Act of 1964,
    b. Section 504 of the Rehabilitation Act of 1973,
    c. The Age Discrimination Act of 1975, and
    d. Title II Subtitle A of the Americans with Disabilities Act of 1990.

3. All equipment, staff, other budgeted resources, and expenses must be used exclusively for the project identified in the applicant's original agreement application or agreed upon subsequently with CMS, and may not be used for any prohibited uses.

4. Consumers and other stakeholders must have meaningful input into the planning and implementation of the project. All grant budgets must include some funding to facilitate participation on the part of individuals who have a disability or long term illness in their families. Appropriate budget justification to support the request for these funds must be included. Awardees must coordinate their project activities with other State, local and Federal agencies that serve the population targeted by their application.

C. Terms and Conditions

Cooperative Agreements issued under this FOA are subject to the *Health and Human Services Grants Policy Statement (HHS GPS)* at http://www.hhs.gov/grantsnet/adminis/gpd/. Standard terms and special terms of award will accompany the Notice of Award. Potential applicants should be aware that special requirements could apply to cooperative agreement awards based on the particular circumstances of the effort to be supported and/or deficiencies identified in the application by the HHS review panel. The general terms and conditions that are outlined in Section II of the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary. Awardees must also agree to respond to requests that are necessary for the evaluation of the national efforts and provide data on key elements of their own cooperative agreement activities.

Subaward Reporting and Executive Compensation: New awards issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252 and implemented by 2 CFR Part 170. Cooperative agreement recipients must report information for each first-tier subaward of $25,000 or more in Federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (available online at www.fsrs.gov).

Once an award is made, the funds are posted in recipient accounts established in the Department of Health and Human Services, Division of Payment Management, Payment Management System (PMS). Grantees may then access their funds by using the PMS funds request process. Upon notification of award, recipients under this announcement will be able to drawdown funds for approved start-up costs. The remaining funds will be reimbursable upon meeting specific performance measures. More details on the start-up costs and performance measures will be outlined in the terms and conditions of award for each Grantee.

HHS may terminate any CMS award for material noncompliance. Material non compliance includes, but is not limited to, violation of the terms and conditions of the award; failure to

perform award activities in a satisfactory manner; improper management or use of award funds; or fraud, waste, abuse mismanagement, or criminal activity.

D. Cooperative Agreement and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations, and other HHS and PHS grant/cooperative agreement administration policies.

The administrative and funding instrument used for this program will be a Cooperative Agreement, an assistance mechanism in which substantial HHS programmatic involvement with the recipient is anticipated during the performance of the activities. Under each Cooperative Agreement, HHS' purpose is to support and stimulate the recipient's activities by involvement in and otherwise working jointly with the award recipient in a partnership role. To facilitate appropriate involvement during the period of this Cooperative Agreement, HHS and the recipient will be in contact monthly and more frequently when appropriate. Additional information on the cooperative agreement terms and conditions of award will be outlined in the Notice of Award.

Recipients

Recipients and assigned points of contact retain the primary responsibility and dominant role for planning, directing and executing the proposed project as outlined in the terms and conditions of the Cooperative Agreement and with substantial HHS involvement. Recipients shall engage in the following activities:

- Collaboration and Sharing – collaborate with the critical stakeholders listed in this funding opportunity and the HHS team.
- Reporting – comply with all reporting requirements outlined in this funding opportunity and the terms and conditions of the Cooperative Agreement to ensure the timely release of funds.
- Program Evaluation – cooperate with HHS-directed national program evaluations.
- Participate in user groups and other technical assistance venues as appropriate.
- Participate in site visits as appropriate.

E. Reporting

1. Progress Reports

Awardees must agree to cooperate with any Federal evaluation of the program and must provide required quarterly, semi-annual (every six months), annual, and final (at the end of the cooperative agreement period) reports in a form prescribed by CMS. Reports will be submitted electronically. These reports will outline how cooperative agreement funds were used, describe program progress, describe any barriers encountered, and detail measurable outcomes. CMS will

provide the format for program reporting and the technical assistance necessary to complete program reporting requirements.

2. Quarterly Data Reporting on Operations, Utilization, and Outcomes

Awardees must agree to cooperate with any Federal monitoring and evaluation of the program and must provide quarterly reports in a form prescribed by CMS. Reports will be submitted electronically. The format and details of this data reporting on operations, utilization, and outcomes will be determined at the start of the project in collaboration with the monitoring and independent evaluation teams. CMS will provide the format for program reporting and the technical assistance necessary to complete program reporting requirements.

3. Federal Financial Report (FFR)

The Federal Financial Report (FFR or Standard Form 425) has replaced the SF-269, SF-269A, SF-272, and SF-272A financial reporting forms. All grantees must utilize the FFR to report cash transaction data, expenditures, and any program income generated.

Grantees must report on a quarterly basis cash transaction data via the Payment Management System (PMS) using the FFR in lieu of completing a SF-272/SF272A. The FFR, containing cash transaction data, is due within 30 days after the end of each quarter. The quarterly reporting due dates are as follows: 4/30, 7/30, 10/30, 1/30. A Quick Reference Guide for completing the FFR in PMS is at: www.dpm.psc.gov/grant_recipient/guides_forms/ffr_quick_reference.aspx.

In addition to submitting the quarterly FFR to PMS, Grantees must also provide, on an annual basis, a hard copy FFR to CMS which includes their expenditures and any program income generated in lieu of completing a Financial Status Report (FSR) (SF269/269A). Expenditures and any program income generated should only be included on the annually submitted FFR, as well as the final FFR. Annual hard-copy FFRs should be mailed and received within 30 calendar days of the applicable year end date. The final FFR should be mailed and received within 90 calendar days of the project period end date.

More details will be outlined in the Notice of Award.

4. Transparency Act Reporting Requirements

New awards issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252 and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier sub-award of $25,000 or more in Federal funds and also report executive total compensation for the

recipient's and sub-recipient's five most highly compensated executives, as outlined in Appendix A to 2 CFR Part 170 (available online at www.fsrs.gov). Competing Continuation awardees may be subject to this requirement and will be so notified in the Notice of Award.

5. Audit Requirements

Awardees must comply with the audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at www.whitehouse.gov/omb/circulars.

6. Payment Management Requirements

Awardees must submit a quarterly electronic SF 425 via the Payment Management System. The report identifies cash expenditures against the authorized funds for the award. Failure to submit the report may result in the inability to access award funds. The SF 425 Certification page should be faxed to the PMS contact at the fax number listed on the SF 425, or it may be submitted to:

Division of Payment Management
HHS/ASAM/PSC/FMS/DPM
PO Box 6021
Rockville, MD 20852
Telephone: (877) 614-5533

VII. AGENCY CONTACTS

A. Programmatic Questions

Programmatic questions about the Strong Start for Mothers and Newborns cooperative agreement award program should be directed by e-mail to our program staff at: StrongStart@cms.hhs.gov.

B. Administrative Questions

Administrative questions about the Strong Start for Mothers and Newborns cooperative agreement award program may be directed to:

Michelle Feagins, Grants Management Officer
Center for Medicare and Medicaid Services
Office of Acquisition and Grants Management
200 Independence Ave., S.W.
Room 733H-02
Washington, DC 20201

Phone: 301-492-4312 or Email: Michelle.Feagins@cms.hhs.gov

VIII. OTHER INFORMATION

APPENDIX A: INSTITUTE OF MEDICINE RISK FACTORS FOR PRETERM BIRTH[40]

Medical Risk Factors	Demographic Risk Factors	Social Risk Factors
• Previous low birthweight or preterm delivery • Multiple 2nd trimester spontaneous abortion • Prior first trimester induced abortion • Familial and intergenerational factors • History of infertility • Nulliparity • Placental abnormalities • Cervical and uterine anomalies • Gestational bleeding • Intrauterine growth restriction • In utero diethylstilbestrol exposure • Multiple gestations • Short stature • Low pregnancy weight/low body mass index • Urogenital infections • Preeclampsia	• Race/ethnicity • Single marital status • Low socioeconomic status • Seasonality of pregnancy and birth (birth rate by time of year) • Maternal age • Employment-related physical activity • Occupational exposures • Environment exposures	• No or inadequate prenatal care usage • Cigarette smoking • Use of marijuana and other illicit drugs • Cocaine use • Alcohol consumption • Caffeine intake • Maternal weight gain (both excessive or insufficient) • Poor dietary intake • Sexual activity during late pregnancy • Leisure-time physical activities

APPENDIX B: COMPARISON OF ENHANCED PRENATAL CARE APPROACHES

	Centering/Group Care	Enhanced Prenatal care package at Birth Centers	Enhanced Prenatal care package at Maternity Care Homes
Examples of types of services that could be included in enhanced Prenatal Care Service Packages for each approach	A group of pregnant women (with similar gestational ages) receive: • health assessments, • education • support in group settings Meet approximately 10 times during their pregnancy Much longer visits (usually 90-120 minutes) • clinical and psycho-social supportive services • peer support	The enhanced prenatal care package provided at birth centers often includes: • case management and referral services, • improved continuity of care, counseling, and • a range of behavioral risk reduction programs.[41,42] Visits tend to be: • longer, • focus on health education, nutrition services, • psychosocial support, • are often provided by a team of health providers • Including peer counselors, doulas, and lactation consultants.[43]	All Practices must demonstrate the ability to: 1. Expand access and provide continuity 2. Assure care coordination 3. Provide enhanced content of care during visits Enhanced services could be provided by both licensed and unlicensed professionals. Include but are not limited to: • expanded office hours, • greater use of health IT, • nutritional and • psychosocial counseling, • health education, • case management, • Periodic home visiting.
Criteria	• May be approved by the Centering Healthcare Institute (CHI) • Approved or evidence-based curriculum • Experience with centering group care • Providers trained in group counseling	• Must be accredited by The Commission for the Accreditation of Birth Centers, licensed, or otherwise approved by the State to provide prenatal labor and delivery or postpartum care and other ambulatory services • Assures the center is in compliance with applicable federal, state, and local laws and regulations.	Applicant must describe how they provide services in each of the following categories: 1. Access and Continuity - demonstrates timely prenatal care and access between scheduled visits 2. Care Coordination – including ability to track patients and integrate appropriate staff 3. Enhanced Content - including details of how care expands standard prenatal care

APPENDIX C: MEASURES FOR MONITORING QUALITY AND OUTCOMES OF CARE

I. Gestational age and birthweight (primary outcomes):

- Gestational age **and birthweight for intervention infants will be reported by the awardee. The Awardee will also 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 also independently work with** States **to** link the birth certificate data from vital records with individual level Medicaid and/or CHIP data **as possible**, and provide these linked individual-level data to the evaluator **to supplement the comparison of gestational age in the baseline and intervention periods as reported by the awardee.**

II. Additional Measures to be decided as part of terms and conditions (will be based on the following types of measures):

- **PCPI Maternity Care Work Group Recommendations[44]**

The PCPI Maternity Care Work Group proposed ten draft measures for consideration. These draft measures support the efficient delivery of high quality health care in each of the Institute of Medicine's (IOM) six aims for quality improvement as described in the following table:

IOM Domains of Health Care Quality		Safe	Effective		Patient Centered	Timely	Efficient	Equitable
			Underuse	Overuse				
Draft Measures								
1	Prenatal Care Screening and Accurate Gestational Age	√	√		√	√	√	√
2	Behavioral Health Risk Assessment	√	√		√	√	√	√
3a; 3b	BMI Assessment and Plan of Care for Patients with BMI >30	√	√		√	√		√
4	Elective Delivery Before 39 Weeks	√		√	√	√		√
5	Cesarean Delivery for Low-Risk Nulliparous Women	√		√	√	√	√	√
6	Episiotomy	√		√	√			√
7	Spontaneous Labor and Birth	√	√		√			√
8	Incidence of Maternal Serious Adverse Events During Hospital Stay	√	√		√			√
9	Care Coordination: Prenatal Record Present at Time of Delivery	√	√		√	√	√	√
10	Post-Partum Follow-up		√		√	√	√	√

APPENDIX D: STATE MEDICAID MATERNITY CORE SET OF MEASURES

Measure	Measure Steward/Owner	Description
Frequency of Ongoing Prenatal Care	NCQA/HEDIS	Percentage of Medicaid deliveries between November 6 of the year prior to the measurement year and November 5 of the measurement year that received the following number of visits: < 21 percent of expected visits 21 percent – 40 percent of expected visits 41 percent – 60 percent of expected visits 61 percent – 80 percent of expected visits ≥ 81 percent of expected visits
Pediatric central-line associated blood stream infections – Neonatal Intensive Care Unit and Pediatric Intensive Care Unit	Centers for Disease Control and Prevention	Rate of central line-associated blood stream infections (CLABSI) identified during periods selected for surveillance as a function of the number of central line catheter days selected for surveillance in pediatric and neonatal intensive care units
Prenatal and Postpartum Care: Timeliness of Prenatal Care	NCQA/HEDIS	The percentage of deliveries of live births between November 6 of the year prior to the measurement year and November 5 of the measurement year that received a prenatal care visit in the first trimester or within 42 days of enrollment in the organization.
Percent of live births weighing less than 2,500 grams	Centers for Disease Control and Prevention	The measure assesses the number of resident live births less than 2,500 grams as a percent of the number of resident live births in the State reporting period.
Prenatal and Postpartum Care: Postpartum Care Rate	NCQA/HEDIS	The percentage of deliveries of live births between November 6 of the year prior to the measurement year and November 5 of the measurement year that had a postpartum visit on or between 21 and 56 days after delivery.
Cesarean rate for nulliparous singleton vertex	California Maternal Quality Care Collaborative	Percentage of women who had a cesarean section among women with first live singleton births [also known as nulliparous term singleton vertex (NTSV) births] at 37 weeks of gestation or later.
Appropriate Use of Antenatal Steroids	Providence St. Vincent Medical Center	Mothers receiving antenatal steroids during pregnancy at any time prior to delivery of a preterm infant
Elective delivery prior to 39 completed weeks	Hospital Corporation of America	Percentage of babies electively delivered prior to 39 completed weeks gestation

APPENDIX E: MATERNAL & NEWBORN HEALTH GLOSSARY OF TERMS

Birth Center: Physical locations where healthy, low-risk mothers can give birth naturally with minimal clinical interventions. Birthing centers may also provide a complement of psychosocial support services including WIC, breastfeeding support, child support, and laundry facilities for women.

Centering: Health care delivery method through which pregnant women receive health assessments, education, and support in a group setting.

Convener: An entity that can bring together multiple participating health care providers, such as a professional association or a collaborative of providers.

Maternity Care Home: Service model that integrates clinical prenatal care with behavioral, psychological, and social services such as nutritional and psychosocial counseling, health education, case management and home visiting.

High Risk Pregnancy: Pregnancy in which medical, behavioral, genetic or social risk factors are present that have the potential to adversely impact maternal, fetal and/or newborn health.

Low Birthweight: Newborn weight at birth of less than 2500 grams.

Managed Care Organization (MCO): Entity under contract with State to manage Medicaid and/or CHIP population.

Newborn Care: Care provided to an infant from the time of birth through the first year of life.

Prenatal Care: Clinical care provided to an expectant mother prior to the delivery the infant.

Post-Partum Care: Medical care provided to a woman after delivering an infant that is related to the prior pregnancy and delivery.

Preterm Birth: Births taking place less than 37 weeks of gestation.

Timely Post-Partum Care: Postpartum visit occurring within 56 days of delivery.

Timely Prenatal Care: First prenatal visit occurring within first trimester.

APPENDIX F: APPLICATION CHECK-OFF COVER SHEET

Strong Start for Mothers and Newborns

REQUIRED CONTENTS

A complete application consists of the following materials organized in the sequence below. Please ensure that the project narrative is page-numbered. The sequence is:

- ☐ Forms/Mandatory Documents (Grants.gov) (with an electronic signature)
  - ☐ SF 424: Application for Federal Assistance
  - ☐ SF-424A: Budget Information
  - ☐ SF-424B: Assurances-Non-Construction Programs
  - ☐ SF-LLL: Disclosure of Lobbying Activities (required for organizations engaging in Lobbying Activities)
  - ☐ Project Site Location Form(s)
  - ☐ Project Abstract Summary

- ☐ **Letter(s) of agreement from provider partners when applicant is a State, MCO, or convener (not included in page limit).**

- ☐ Cover Letter

- ☐ Project Narrative

- ☐ Work Plan and Timeline

- ☐ Budget Narrative

APPENDIX G: GUIDANCE FOR PREPARING A BUDGET REQUEST AND NARRATIVE IN RESPONSE TO SF 424A

INTRODUCTION

This guidance is offered for the preparation of a budget request. Following this guidance will facilitate the review and approval of a requested budget by ensuring that the required or needed information is provided. This is to be for done for each 12 month period of the agreement project period. Applicants should be careful to only request funding for activities that will be funded by the Strong Start for Mothers and Newborns cooperative agreement award program. Any other agreement funding provided by CMS, should not be supplanted by this Strong Start for Mothers and Newborns cooperative agreement award program funding. In the budget request, awardees should distinguish between activities that will be funded under this agreement and activities funded with other sources. Other funding sources include other HHS agreement programs, and other funding sources as applicable.

Please refer to Section IV of this FOA for more information on the Budget and Budget Narrative.

A. Salaries and Wages

For each requested position, provide the following information: name of staff member occupying the position, if available; annual salary; percentage of time budgeted for this program; total months of salary budgeted; and total salary requested. Also, provide a justification and describe the scope of responsibility for each position, relating it to the accomplishment of program objectives.

Sample budget

Personnel

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

Position Title and Name	*Annual*	*Time*	*Months*	*Amount Requested*
Project Coordinator Susan Taylor	*$45,000*	*100%*	*12 months*	*$45,000*
Finance Administrator John Johnson	*$28,500*	*50%*	*12 months*	*$14,250*
Outreach Supervisor (Vacant)*	*$27,000*	*100%*	*12 months*	*$27,000*

Sample Justification

The format may vary, but the description of responsibilities should be directly related to specific program objectives.

Job Description: Project Coordinator - (Name)

This position directs the overall operation of the project; responsible for overseeing the implementation of project activities, coordination with other agencies, development of materials, provisions of in service and training, conducting meetings; designs and directs

the gathering, tabulating and interpreting of required data, responsible for overall program evaluation and for staff performance evaluation; and is the responsible authority for ensuring necessary reports/documentation are submitted to HHS. This position relates to all program objectives.

B. Fringe Benefits

Fringe benefits are usually applicable to direct salaries and wages. Provide information on the rate of fringe benefits used and the basis for their calculation. If a fringe benefit rate is not used, itemize how the fringe benefit amount is computed.

Sample Budget
Fringe Benefits

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

25% of Total salaries = Fringe Benefits

If fringe benefits are not computed by using a percentage of salaries, itemize how the amount is determined.

Example: Project Coordinator — Salary $45,000

Retirement 5% of $45,000	=	*$2,250*
FICA 7.65% of $45,000	=	*3,443*
Insurance	=	*2,000*
Workers' Compensation	=	_____
	Total:	

C. Consultant Costs

This category is appropriate when hiring an individual to give professional advice or services (e.g., training, expert consultant, etc.) for a fee but not as an employee of the awardee organization. Hiring a consultant requires submission of the following information to HHS **(see Required Reporting Information for Consultant Hiring later in this Appendix)**:

1. Name of Consultant;
2. Organizational Affiliation (if applicable);
3. Nature of Services to be Rendered;
4. Relevance of Service to the Project;
5. The Number of Days of Consultation (basis for fee); and
6. The Expected Rate of Compensation (travel, per diem, other related expenses)—list a subtotal for each consultant in this category.

If the above information is unknown for any consultant at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. In

the body of the budget request, a summary should be provided of the proposed consultants and amounts for each.

D. Equipment

Provide justification for the use of each item and relate it to specific program objectives. Maintenance or rental fees for equipment should be shown in the "Other" category. All IT equipment should be uniquely identified. As an example, we should not see a single line item for "software." Show the unit cost of each item, number needed, and total amount.

Sample Budget

Equipment

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

Item Requested	*How Many*	*Unit Cost*	*Amount*
Computer Workstation	*2 ea.*	*$2,500*	*$5,000*
Fax Machine	*1 ea.*	*600*	*600*
			Total $5,600

Sample Justification

Provide complete justification for all requested equipment, including a description of how it will be used in the program. For equipment and tools which are shared among programs, please cost allocate as appropriate. States should provide a list of hardware, software and IT equipment which will be required to complete this effort. Additionally, they should provide a list of non-IT equipment which will be required to complete this effort.

E. Supplies

Individually list each item requested. Show the unit cost of each item, number needed, and total amount. Provide justification for each item and relate it to specific program objectives. If appropriate, General Office Supplies may be shown by an estimated amount per month times the number of months in the budget category.

Sample Budget

Supplies

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

General office supplies (pens, pencils, paper, etc.)		
12 months x $240/year x 10 staff	*=*	*$2,400*
Educational Pamphlets (3,000 copies @) $1 each)	*=*	*$3,000*
Educational Videos (10 copies @ $150 each)	*=*	*$1,500*
Word Processing Software (@ $400—specify type)	*=*	*$ 400*

Sample Justification
General office supplies will be used by staff members to carry out daily activities of the program. The education pamphlets and videos will be purchased from XXX and used to illustrate and promote safe and healthy activities. Word Processing Software will be used to document program activities, process progress reports, etc.

F. Travel

Dollars requested in the travel category should be for **staff travel only**. Travel for consultants should be shown in the consultant category. Travel for other participants, advisory committees, review panel, etc. should be itemized in the same way specified below and placed in the **"Other"** category.

In-State Travel—Provide a narrative justification describing the travel staff members will perform. List where travel will be undertaken, number of trips planned, who will be making the trip, and approximate dates. If mileage is to be paid, provide the number of miles and the cost per mile. If travel is by air, provide the estimated cost of airfare. If per diem/lodging is to be paid, indicate the number of days and amount of daily per diem as well as the number of nights and estimated cost of lodging. Include the cost of ground transportation when applicable.

Out-of-State Travel—Provide a narrative justification describing the same information requested above. Include HHS meetings, conferences, and workshops, if required by HHS. Itemize out-of-state travel in the format described above.

Sample Budget
Travel (in-State and out-of-State)

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

In-State Travel:

1 trip x 2 people x 500 miles r/t x .27/mile	=	*$ 270*
2 days per diem x $37/day x 2 people	=	*148*
1 nights lodging x $67/night x 2 people	=	*134*
25 trips x 1 person x 300 miles avg. x .27/mile	=	*2,025*
Total		*$ 2,577*

Sample Justification
The Project Coordinator and the Outreach Supervisor will travel to (location) to attend an eligibility conference. The Project Coordinator will make an estimated 25 trips to local outreach sites to monitor program implementation.

Sample Budget

Out-of-State Travel:

1 trip x 1 person x $500 r/t airfare	=	*$500*
3 days per diem x $45/day x 1 person	=	*135*
1 night's lodging x $88/night x 1 person	=	*88*
Ground transportation 1 person	=	*50*
Total		*$773*

Sample Justification

The Project Coordinator will travel to HHS, in Atlanta, GA, to attend the HHS Conference.

G. Other

This category contains items not included in the previous budget categories. Individually list each item requested and provide appropriate justification related to the program objectives.

Sample Budget

Other

Total $_____
Strong Start Cooperative agreement $_____
Funding other than Cooperative agreement $_____
Sources of Funding_____

Telephone	
($ ___ per month x ___ months x #staff)	*= $ Subtotal*
Postage	
($ ___ per month x ___ months x #staff)	*= $ Subtotal*
Printing	
($ ___ per x ___ documents)	*= $ Subtotal*
Equipment Rental (describe)	
($ ___ per month x ___ months)	*= $ Subtotal*
Internet Provider Service	
($___ per month x ___ months)	*= $ Subtotal*

Sample Justification

Some items are self-explanatory (telephone, postage, rent) unless the unit rate or total amount requested is excessive. If the item is not self-explanatory or is excessive, include additional justification. For printing costs, identify the types and number of copies of documents to be printed (e.g., procedure manuals, annual reports, materials for media campaign).

H. Contractual Costs

Cooperative Agreement recipients must submit to HHS the required information establishing a third-party contract to perform program activities **(see Required Information for Contract Approval later in this Appendix)**.

1. Name of Contractor;
2. Method of Selection;
3. Period of Performance;
4. Scope of Work;
5. Method of Accountability; and
6. Itemized Budget and Justification.

If the above information is unknown for any contractor at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. Copies of the actual contracts should not be sent to HHS, unless specifically requested. In the body of the budget request, a summary should be provided of the proposed contracts and amounts for each.

I. Total Direct Costs $_____

Show total direct costs by listing totals of each category.

J. Indirect Costs $_____

To claim indirect costs, the applicant organization must have a current approved indirect cost rate agreement established with the Cognizant Federal agency. A copy of the most recent indirect cost rate agreement must be provided with the application.

Sample Budget

The rate is ___% and is computed on the following direct cost base of $_____.

Personnel		*$*
Fringe		*$*
Travel		*$*
Supplies		*$*
Other$_____		
Total	*$*	*x ___% = Total Indirect Costs*

If the applicant organization does not have an approved indirect cost rate agreement, costs normally identified as indirect costs (overhead costs) can be budgeted and identified as direct costs.

REQUIRED REPORTING INFORMATION FOR CONSULTANT HIRING

This category is appropriate when hiring an individual who gives professional advice or provides services for a fee and who is not an employee of the awardee organization. Submit the following required information for consultants:

1. Name of Consultant: Identify the name of the consultant and describe his or her qualifications.
2. Organizational Affiliation: Identify the organization affiliation of the consultant, if applicable.
3. Nature of Services to be Rendered: Describe in outcome terms the consultation to be provided including the specific tasks to be completed and specific deliverables. A copy of the actual consultant agreement should not be sent to HHS.
4. Relevance of Service to the Project: Describe how the consultant services relate to the accomplishment of specific program objectives.
5. Number of Days of Consultation: Specify the total number of days of consultation.
6. Expected Rate of Compensation: Specify the rate of compensation for the consultant (e.g., rate per hour, rate per day). Include a budget showing other costs such as travel, per diem, and supplies.
7. Method of Accountability: Describe how the progress and performance of the consultant will be monitored. Identify who is responsible for supervising the consultant agreement.

REQUIRED INFORMATION FOR CONTRACT APPROVAL

All contracts require reporting the following information to HHS.

1. Name of Contractor: Who is the contractor? Identify the name of the proposed contractor and indicate whether the contract is with an institution or organization.
2. Method of Selection: How was the contractor selected? State whether the contract is sole source or competitive bid. If an organization is the sole source for the contract, include an explanation as to why this institution is the only one able to perform contract services.
3. Period of Performance: How long is the contract period? Specify the beginning and ending dates of the contract.
4. Scope of Work: What will the contractor do? Describe in outcome terms, the specific services/tasks to be performed by the contractor as related to the accomplishment of program objectives. Deliverables should be clearly defined.
5. Method of Accountability: How will the contractor be monitored? Describe how the progress and performance of the contractor will be monitored during and on close of the contract period. Identify who will be responsible for supervising the contract.
6. Itemized Budget and Justification: Provide an itemized budget with appropriate justification. If applicable, include any indirect cost paid under the contract and the indirect cost rate used

---------- For Administrative Purposes Only ----------

Completeness check:

Panel Assignment:

Primary Panel Reviewer:

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