



Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Childhood Obesity Research Demonstration 2.0

RFA-DP-16-004

Application Due Date: 01/29/2016

Childhood Obesity Research Demonstration 2.0

RFA-DP-16-004

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

Childhood Obesity Research Demonstration 2.0

Activity Code

AMENDMENT I made December 9, 2015

- **Added Figure 1: CORD 2.0 Logic Model to "Evaluation/Performance Measurement" under 2. Approach in Section 1.**

AMENDMENT II made January 7, 2016

- **Appendix A "Questions from Potential Applicants and CDC Responses" added to Section VIII. Other Information.**

U18

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-16-004

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.535

Category of Funding Activity:

Health

FOA Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to test a model of quality clinical care addressing childhood obesity for U.S. low-income children, especially those enrolled in or eligible for health care coverage under the Children's Health Insurance Program (CHIP) or Medicaid. Specifically, the purpose of this FOA is to implement and test the ability of a model of clinical childhood obesity management along with a Electronic Health Record (EHR)-referral-based, family centered pediatric weight management program, to reduce body mass index (BMI) in children with obesity, or overweight with risks (including, e.g., medical and behavioral risks, and family history). Health outcomes of interest include measurable changes in BMI, nutrition and physical activity behaviors, health care satisfaction and service delivery, and quality of life. This will be accomplished through pediatric care and an intensive family centered weight management program in the clinic or community.

Key Dates

Publication Date: To receive notification of any changes to RFA-DP-16-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 12/30/2015

Letter of intent is voluntary.

Application Due Date: 01/29/2016

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 03/22/2016

3/22/2016-3/23/2016

Secondary Review: 04/18/2016

Estimated Start Date: 06/01/2016

Expiration Date: 01/30/2016

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

Executive Summary

The purpose of this FOA is to test a model of quality clinical care addressing childhood obesity for U.S. low-income children, especially those enrolled in or eligible for health care coverage under the Children's Health Insurance Program (CHIP) or Medicaid. Specifically, the purpose of this FOA is to implement and test the ability of a model of clinical childhood obesity management along with a EHR-referral-based, family centered pediatric weight management program, to reduce body mass index (BMI) in children with obesity, or overweight with risks (including, e.g., medical and behavioral risks, and family history). Health outcomes of interest include measurable changes in body mass index (BMI), nutrition and physical activity behaviors, health care satisfaction and service delivery, and quality of life. This will be accomplished through pediatric care including:

Implementing and evaluating a model addressing childhood obesity that includes clinical screening and counseling and a EHR-referral-based, structured, intensive family centered pediatric weight management

program located in the clinic or community;

Collaboration with state CHIP and/or Medicaid offices to advise a state-wide or regional level project and to be part of a stakeholder group that can help generate suitable recommendations for sustainability and program components to be further replicated or scaled.

Mechanism of Support: Applications in response to this FOA will be funded using the U18 cooperative agreement mechanism.

Funds Available and Anticipated Number of Awards: It is anticipated that up to 2 awards of approximately \$4.25M to each recipient will be made. For each awardee, approximately \$1,750,000 will be available for Budget Year 1 and \$2,500,000 available for Budget Year 2. Budget Year 2 will extend from June 1, 2017-September 29, 2018. These estimates include direct and indirect costs. Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Budget and Project Period. The estimated total funding (direct and indirect) for the first year will be \$3,500,000. The estimated total funding (direct and indirect) for the entire project period will be \$8,500,000. The entire 28 month project period will run from 6/1/2016 to 09/29/2018.

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in [Section IV. Application and Submission Information](#) of this announcement.

Eligible Institutions/Organizations. Institutions/organizations listed in Section III, 1 are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

Number of PDs/PIs. Applications may contain more than one PI, however, the first PI listed will be the “contact PI” for all correspondence.

Number of Applications. Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Application Type. New (type 1). **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

[Medicare Access and CHIP Reauthorization Act of 2015](#), Section 304, extends and amends Section 1139A (e)(8) of the Social Security Act (42 U.S.C. 1320b-9a(e)(8))

1. Background and Purpose

Obesity: A Public Health Problem

Childhood obesity prevalence remains high (Ogden 2014). Overall, obesity among our nation’s young people, aged 2 to 19 years, has not changed significantly since 2003-2004 and remains at about 17 percent (or 12.7 million children). Among low-income preschoolers 2-4 years of age in 2011, approximately 14% have obesity (Vital Signs 2013; DNPAO website: [Nutrition, Physical Activity and Obesity: Data, Trends and Maps](#)). Socioeconomic, racial/ethnic and age disparities in obesity prevalence also exist among children and adolescents.

Childhood obesity puts children at greater risk for numerous health consequences, including cardiovascular disease, type-2 diabetes and asthma (Cotes 2013; Freedman 2007; Visness 2010). Childhood obesity is also associated with increased school absenteeism, poorer school performance, and depression (Geier 2007, Taras 2005, Lim 2015). The health care costs associated with childhood obesity may also be significant. Analyses using the Medical Expenditure Panel Survey (MEPS) indicate that obese children and adolescents with overweight or obesity have higher annual medical care and utilization costs compared to children of normal weight (Trasande 2009, Wright 2014). A randomized trial of children with overweight or obesity in a pediatric weight management program with allied professionals identified provider-incurred costs in the intervention group as a major driver of significantly greater costs compared to a usual care group (Wright 2014). Recently, several experts provided a recommendation that all projects addressing childhood obesity should assess and report on cost data such that improvements in health care delivery could be structured in sustainable ways (BPC 2015).

Evidence Base Addressing Clinical Management of Childhood Obesity

The Expert Committee Recommendations of 2007 state that “all physicians and health care providers address weight management and lifestyle issues with all patients, regardless of presenting weight, at least each year” (Barlow 2007) (see Table). According to the Expert Committee, providers should assess medical, behavioral and family history-based risk for obesity for all children and provide behavior counseling on key obesity-related behaviors. Furthermore, providers should initiate a staged multidisciplinary team intervention for treatment for those children with a body mass index (BMI) in the 85th-94th percentile and risks (i.e., overweight with risks), or $\geq 95^{\text{th}}$ percentile (having obesity). Children who are overweight with risks aged 2-18 years of age should receive prevention counseling addressing key obesity-related behaviors. For children with obesity, a staged comprehensive multidisciplinary intervention that increases the intensity of behavior counseling, the frequency of visits, and incorporates specialists, maximizes support for behavior changes.

Included in this comprehensive approach is a multidisciplinary team with experience in childhood obesity and delivering motivational counseling that engages families and incorporates healthy eating and activity goals.

The multidisciplinary team may include a behavioral counselor (such as a social worker, nurse practitioner or mental health care provider), registered dietitian, a team member with knowledge of community resources, and a primary care provider. The Recommendations note that the capacity to support a multidisciplinary team with staged management of obesity risk and counseling is likely beyond the capacity of most pediatric primary care practices and that referrals to family centered structured weight management programs might be necessary.

Table: Assessment and Management of Obesity Risk (adapted from Barlow 2007)

Child BMI Percentile	Risk Assessment	Prevention
5 th -84 th	• Obesity-related behaviors • Child’s growth, history and physical exam • Parental and family history of obesity • Child and family readiness	• Preventive behavioral counseling • Engage family to support healthy behaviors

85th-94th	• Obesity-related behaviors • Child's growth, history and physical exam • Parental and family history of obesity • Child and family readiness • Laboratory testing as indicated	• No risk identified: As above • Risks identified: Begin staged multidisciplinary approach based on age and BMI
>=95th	• Obesity-related behaviors • Child's growth, history and physical exam • Parental and family history of obesity • Child and family readiness • Laboratory testing	• Begin staged multidisciplinary intervention approach for treatment based on age and BMI

The Expert Committee endorsed the use of multi-disciplinary teams of health care providers and allied health professionals such as nurses, registered dietitians to share the responsibility of delivering interventions (Barlow 2007). Allied health professionals can assist children and families by using reminder and access strategies for referrals and motivational interviewing to develop self-monitoring, self-reward and goal-setting techniques. Community health workers (CHWs) and care managers can integrate with and provide outreach to community resources. CHWs have effectively worked within communities in a patient-centered medical home approach (Findley 2013, Raphael 2013) to reduce health disparities and improve health outcomes associated with chronic diseases such as diabetes (Shah 2013). CHWs may also help families to promote healthful behaviors relating to obesity (Ayala 2010). Social workers, CHWs and care managers have the training and skills to address upstream determinants of health while improving outcomes and lowering costs; the evidence is growing for the utility and effectiveness of these team members (Manchanda 2015, Tulloch 2006, Allen 2015).

In 2010, the U.S. Preventive Services Task Force (USPSTF) recommended (Grade B) that clinicians screen all children aged 6-18 years for obesity by measuring body mass index (BMI) and offering or referring obese children for intensive counseling and behavioral interventions to promote improvements in weight status (Whitlock/USPSTF 2010). There was sufficient evidence to recommend that moderate to high intensity comprehensive programs (defined as ≥ 25 hours to < 75 hours of child and/or family contact in a six month period) that incorporate counseling targeting diet and physical activity, and that include behavioral management techniques, lead to modest improvements in weight status within 12 months.

Population Health Focus on Health Care Systems

Experts have also noted that health care systems can be important stakeholders in integrated community frameworks (Hester 2015). New emerging healthcare delivery models are increasing their focus on population health and thereby moving to the inclusion of an integrator. Integrators are macro system level agents that function to address upstream determinants of health across a population to achieve the 'triple aim'-- improve quality of care, and population health and reduce health care costs. In some instances, health care systems might drive the main integrator functions: by convening stakeholders, assessing community resources through existing community coalitions and facilitating stakeholder agreement, gathering and analyzing data to improve health indicators, and working at policy, systems and environment levels to sustain change, integrators can systematically support cross-sector engagement to improve population health (IOM Cross Sector Responses to Obesity, 2015).

Barriers to the Clinical Management of Childhood Obesity

However, there remain barriers to the assessment, counseling and effective management of children with overweight or obesity. National surveys of pediatricians have shown that only half assess BMI (Huang 2009, Klein 2010). The majority of pediatricians also report that they do not have the tools or time to counsel, do not know proper billing and coding procedures, or that families do not want to receive counseling around weight (Klein 2010). In a national survey of parents of children with overweight or obesity, only 22% of parents reported receiving counseling from their child's primary care provider around weight status (Perrin 2012). An analysis using 2005-2009 data from both the National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) showed that of children who are identified with obesity, as few as 7% receive appropriate referrals, regardless of comorbidity status (Walsh 2013). Another analysis of nationally representative surveys showed that of children who are identified with obesity, as few as 7% receive appropriate referrals, regardless of comorbidity status (Walsh 2013). Another analysis of nationally representative data found that children on Medicaid were less likely to receive appropriate clinical obesity prevention counseling than children on private insurance (Branner 2008). Finally, a 2013 survey conducted by the Children's Hospital Association found a number of barriers for families related to referral and participation in weight management programs. More specifically it found that the majority of structured weight management programs were of varying intensity and duration, and had long waiting times, operating costs in excess of revenues and sub-optimal recognition and reimbursement of services rendered by non-physician providers (CHA 2013). Several experts have noted that to make goals relating to weight management and child and family involvement feasible, a number of actions including training and workflow optimization, securing adequate reimbursement for services provided, and familiarity with addressing the upstream determinants of health, such as food security and socioeconomic dynamics, (Daniels 2015, MHCU 2015).

Approaches to Enhance Effective Implementation

The chronic care model, as described by Wagner et al, organizes approaches to support chronic disease management. The obesity chronic care model (Dietz 2007; Barlow 2007 – Figure 2) draws from the Wagner model and includes information systems, decision supports, delivery system design and self-management support that centers on patient self-management. This framework focuses on interventions to improve obesity-related behaviors as taking place in three overlapping arenas: (1) the community and its resources and policies; (2) the health care system and payment structures; and (3) the health care provider.

Advancement in the clinical management of childhood obesity reflect emerging areas that need further research on best practices and on effective and reimbursable models of care delivery (Daniels 2015). Effective childhood obesity weight management programs should include family-tailored, culturally relevant and developmentally appropriate approaches and a dynamic relationship with children and families (Daniels 2015). In some communities providers can refer children to healthy weight clinics based in either a tertiary care center or a free-standing setting. Children and families may also be referred to non-clinical, community based structured weight management programs where nutritional and physical activity counseling are provided. The use of a healthy weight team (including physicians, allied health professionals (e.g., nurses, nurse practitioners, social workers, physician assistants), and CHWs or care managers who collaborate to provide evidence-based quality care is also critical (Barlow 2007). Healthy weight teams can delineate roles and meet multiple family needs such as serving as the [patient centered medical home](#) wherein: (a) the child and family's cultural and linguistic needs are met; and, (b) social determinants of health and barriers to care such as transportation and follow-ups are addressed (Ader 2015).

On-site counseling in the primary care setting has been shown in a few studies to increase consumption of fruits and vegetables, increase physical activity and reduce sedentary time (Kubik 2008, Ford 2002, Taveras 2011). Experts have also noted that effective primary care-based counseling requires that all providers, allied professionals, CHWs and care managers, who are engaging children and families, should be trained in motivational interviewing and effective means of supporting families (Daniels 2015). A study of the effectiveness of motivational interviewing for obesity delivered by intensively trained providers and

registered dietitians showed reductions in BMI compared to a usual care group not utilizing motivational interviewing (Resnicow 2015). This study also demonstrated a dose-response relationship between the number of motivational interviewing sessions attended and BMI reduction, thus interventions improved the quality of care and outcomes for childhood obesity.

Electronic Health Records (EHRs) aid screening of children for growth and healthy weight status through their ability to calculate BMI and chart and display growth trajectories (Barlow 2007). EHRs can also assist providers by providing clinical decision supports (CDS) and counseling recommendations on obesity-specific content to guide the care and management of children's healthy growth, children who are overweight with risks and children with obesity. EHRs can be further augmented by including diagnostic codes, links to further resources, and referrals. An optimized EHR can plot BMI on appropriate growth charts, include evidence-based guidelines for screening, assessment and management of childhood obesity, utilize alerts aligned with these guidelines, and provide obesity-specific note templates (Taveras 2015). EHRs can furthermore provide support for proper billing procedures for overweight and obesity and related diagnostic [codes](#), including [comorbidities](#), and [procedural, evaluation and management](#) codes (Davis 2007).

One study described a childhood obesity treatment intervention based on the use of an enhanced EHR that included two optimized health care information technology components: computerized CDS using enhanced EHR for pediatric clinicians and support for self-guided behavior change for families for children aged 6 to 12 years compared to usual care (Arsenault 2015, Taveras 2015). Supportive strategies, including on-site counseling, educational materials, text messages and follow-up telephone calls by a health coach, increased parental confidence to change behaviors and provided children and families with the information and knowledge needed to improve self-efficacy and change behaviors. At the 12-month follow-up, the intervention resulted in improved childhood BMI compared to usual care practices without the two components and substantially greater rates of BMI assessment and counseling, as measured by the childhood obesity [Healthcare Effectiveness Data and Information Set \(HEDIS\) measures](#), in the CDS arm.

With national population health and healthcare transformation efforts gaining momentum, the U.S. Office of the National Coordinator for Health Information Technology issued Meaningful Use (MU) standards, for childhood obesity specify that in order to qualify for maximal incentive payments, providers must demonstrate that their EHR systems calculate and display BMI for all patients, and plot and display growth charts, including BMI, for all children (CMS 2012). However, a survey of physicians describing EHRs used in their daily practice found that 83% of EHRs could calculate BMI, however only 52% could calculate an age- and gender-specific BMI percentile for children (Bronder 2015). Only 32% of EHRs flagged patients with abnormal BMIs and 36% were reported to provide obesity-related CDSs such as prompts for best practices, counseling or diagnostic codes. Furthermore, only 17% of EHRs suggested additional resources such as referrals to other clinic-based personnel (e.g., dietitians), support staff for case management or community-based resources. Because weight assessment and counseling for nutrition and physical activity are common clinical quality measures linked to payor reimbursement (e.g. [Quality of Child Care Core Set](#) HEDIS), enhanced EHRs with CDS have the potential to increase the frequency of these important activities, as well as increase payor reimbursement to healthcare providers. Further, BMI and obesity-related data collected in EHRs, if transferred to health information exchanges, have broad potential for providing feedback to clinicians and public health practitioners regarding efficacy of interventions, obesity disparities, as well as informing decision makers including Medicaid directors regarding the weight status of children in their community.

Current Opportunity

This funding opportunity will emphasize the primary care sector's role in childhood obesity prevention and treatment, specifically the implementation of quality clinical pediatric primary care and use of weight management programs based in either the clinic or community. There are 31 million children covered by either CHIP or Medicaid (Medicaid.gov), and Medicaid bears a significant portion of the cost burden associated with obesity (Trasande 2010). Thus, developing quality clinical strategies and weight management programs that are acceptable to payors is critical and timely.

Healthy People 2020 and other National Strategic Priorities

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of CDC, within the Department of Health and Human Services (HHS) is committed to achieving the objectives of “Healthy People 2020.” This funding opportunity addresses the following Healthy People 2020 priorities: Focus Area 19: Nutrition and Overweight and Focus Area 22: Physical Activity and Fitness.

This FOA is also in alignment with performance Goal 6, Performance Measure 1 (HHS FY 2008 Congressional Justification). For more information go to <http://www.healthypeople.gov/> and <https://www.whitehouse.gov/omb/mgmt-gpra/index-gpra>. The FOA evaluation measures align with the [2015 Medicaid child core set of quality measures](#), and the [Healthcare Effectiveness Data and Information Set \(HEDIS\)](#) measures for BMI assessment and counseling.

This FOA is also aligned with the following activities under NCCDPHP’s Domains 3 and 4:

Domain 3

1. Health system interventions to improve the effective delivery and use of clinical and other preventive services in order to prevent disease, detect diseases early, and reduce or eliminate risk factors and mitigate or manage complications.
2. Increase EHR adoption and the use of health IT to improve performance
3. Increase use of team-based care in health systems-Increase engagement of patient navigators in the health care system-Increase use of self-management plans monitoring tied with clinical support

Domain 4: Strategies to improve community-clinical linkages ensuring that communities support and clinics refer patients to programs that improve management of chronic conditions. Such interventions ensure those with or at high risk for chronic diseases have access to quality community resources to best manage their conditions or disease risk.

1. Increase the use of effective community interventions such as chronic disease self-management programs by making them widely available, ensuring that doctors refer their patients to them, and helping to insure that they are covered by health insurance
2. Link existing public health services to health care systems
3. Encourage a broader spectrum of health care workers-including pharmacists, patient navigators, and community health workers-to help people manage their own health.

Public Health Impact

This research opportunity has the potential to demonstrate effective models in addressing child obesity through the delivery of quality clinical services and family centered pediatric weight management programs for millions of at-risk children, especially for CHIP and Medicaid eligible children. This work will expand on a limited research base on how to implement and evaluate a model for operationalizing the US Preventive Services child obesity recommendations among low income children, including a pediatric weight management program. Strategies and recommendations derived from this research can be offered to state and federal agencies and adapted and scaled to local circumstances and a variety of payors.

Relevant Work

The Division of Nutrition, Physical Activity and Obesity (DNPAO) at the Centers for Disease Control and Prevention (CDC) aims to:

1. Increase health-related physical activity through population-based approaches;
2. Improve those aspects of dietary quality most related to population burden of chronic disease and unhealthy child development;

3. Decrease prevalence of obesity through prevention of excess weight gain and maintenance of healthy weight loss;
4. Reduce health disparities.

DNPAO is currently overseeing the 4-year [CORD project](#). CORD is testing whether a coordinated approach to address childhood obesity between primary care and public health strategies including efforts in early care and education, schools and communities can improve health behaviors and weight status for lower-income children 2-12 years of age eligible for, or on CHIP. A comprehensive evaluation report of this project will be made available to grantees by Fall 2016. DNPAO is also currently supporting work to standardize how obesity data collected for clinical purposes in electronic health records can be transmitted to local public health agencies, provider groups or other communities of clinical/public health practice for the purpose of child obesity surveillance to improve primary care and community-level public health child obesity interventions ([HL7 International 2013](#); [Integrating the Healthcare Enterprise 2013](#)). Standards, implementation tools, lessons and experience from this work will be shared with grantees to inform their work in this area.

2. Approach

The project goal is to implement and evaluate a model addressing childhood obesity among low-income children that includes pediatric clinical care (on-site assessment, counseling) and an affordable, EHR-referral-based, family centered intensive weight management program. To meet this goal, grantees will answer the following quantitative research question: Does an affordable referral-based family centered intensive weight management program reduce BMI in low-income children who are overweight with risks or who have obesity versus usual clinical care?

Objectives/Outcomes

Implementation and Evaluation

1. Readiness of Existing Intervention: Applicants must identify an existing family-centered pediatric weight management program intervention that is implementation ready (or that can be readily adapted), and has process data including number of children/families enrolled and retained in the program, program staff trained, and evidence of program effectiveness, but that has not been rigorously evaluated in low-income children. Applications must include a summary of the intervention, a logic model, and target population selected for recruitment and program delivery.
2. Intervention Design: As part of the proposed applicant work, the pediatric primary care center and proposed family centered pediatric weight management program are to follow expert recommendations to screen, assess and manage overweight and obesity. The applicant should use an EHR with clinical decision supports, a multi-disciplinary team, and a program that delivers a minimum of moderate intensity nutrition and physical activity education and behavior modification (i.e. at least 25 hours of contact time over 6 months) for children and families. The proposed intervention program should be tested in low-income children aged 6 to 12 years of age, with the option of also including low-income children 2-5 years. If a control group consisting of usual care is planned, it must be clearly described.

The family-centered pediatric weight management program can be delivered in either the primary care or community setting and may include a combination of group and individual/family sessions, and in-person or virtual (telephone or web-based) health coaches. The delivery of the program, including a description of the theoretical base, the content (nutrition and physical activity and other behavior goals), and intensity and frequency of counseling and educational engagement of children and families should be provided. The program should be able to be delivered at a cost not to exceed \$1000 per family. Applicants should demonstrate capacity and experience accessing and working with the proposed target age range and program setting, including evidence of successful enrollment in programs, intervention studies or trials, and the

expertise to implement the intervention with fidelity.

In addition to the proposed program intervention component:

- The intervention pediatric primary care office that offers or refers children and families to the program needs to have the following capacities and resources in place:
 - Utilization of an EHR system that calculates BMI and flags at-risk children and, with minimal improvements, provides decision supports and referrals to a weight-management program for children who are overweight with risks or who have obesity. This enhanced EHR will assist the clinician in implementing expert recommendations and improve achievement of measurable relevant clinical quality measures including:
 - Documenting and coding for BMI percentile,
 - Placing referrals for ongoing weight management activities (either onsite at the clinic or to a separate community program).
- A primary care site that utilizes counseling and/or motivational interviewing in order to assist children and families with education, remove barriers to access to programs and referrals, support enrollment and retention in the family-centered pediatric weight management program, and aid with identification of other community resources.

3. Stakeholders

Recipients are also expected to engage key stakeholders that support preventive care for low-income children including the state CHIP or Medicaid offices to advise on a state-wide or regional level project, as well as local or state health departments. These stakeholders are encouraged to partner with the grantee including but not limited to:

- Regularly take part in advisory meetings in order to aid the grantee in development of appropriate information and data collection in order to help develop sustainable delivery strategies that align with clinical quality measures, flexible delivery approaches, and/or value-based care.
- Provide recommendations on study design that increase the chance for widespread, sustainable coverage for the program if it is found to be effective.

Objectives

Objective 1: Develop the proposed intervention for a rigorous evaluation. Below are some of the activities anticipated for Objective 1.

1. Identify and convene a Study Team.
2. Identify and convene a consultative advisory group that includes the State CHIP office, Medicaid off and other relevant healthcare stakeholders.
3. Refine and enhance the electronic health record system.
4. Provider refresher training to the existing usual care primary care staff regarding referral to the family centered pediatric weight management program and appropriate follow-up.
5. Refine and finalize program intervention materials (as applicable) to prepare for the implementation and evaluation, including but not limited to a logic model, data collection instruments and processes, training materials, educational and behavioral modification curricula and materials.
6. Determine approach for rapidly identifying a pool of children eligible for the study. This could include a review of EHR information or a data registry.

Objective 2. Implement the Intervention Below are some of the activities anticipated for Objective 2, as previously described.

1. The pediatric primary care center is to follow expert recommendations to screen, assess and manage overweight and obesity.
2. The applicant should use an EHR with clinical decision supports and ability for referral.

3. Deliver the program, including a minimum of moderate intensity nutrition and physical activity education and behavior modification (i.e. at least 25 hours of contact time over 6 months) for children and families. The family centered pediatric weight management program can be delivered in either the primary care or community setting and may include a combination of group and individual/family sessions, and in-person or virtual (telephone or web-based) health coaches.

Objective 3: Evaluate the intervention. There will be two evaluation elements: a quantitative efficacy evaluation and a qualitative evaluation. Below are the parameters for the evaluation design and some of the anticipated activities for Objective 2.

1. Develop and implement a quantitative efficacy evaluation of the intervention.
2. The proposed evaluation plan should be accompanied by a logic model and address key activities and outcomes. Evaluations implementing randomized controlled trials (RCTs) including cluster RCTs are preferred, though rigorous evaluations with non-randomized designs are also acceptable with justification. The comparison usual care group needs to be described and justified.
3. Applicants should provide a power analysis that demonstrates the proposed sample size after anticipated attrition is sufficient to detect an intervention effect.
 - Evaluation outcomes: The primary outcomes to be assessed are BMI/weight status, nutrition and physical activity behaviors, quality of life, satisfaction with care, and cost to carry out the components of the FOA as well as other costs such as parent/caregiver time-costs.
 - Key intermediate outcomes based on the logic model should be assessed including electronic health record use including CDS audits, documentation of staff training and competencies, metrics that capture that referrals were appropriate, and clinical quality measures.
 - Implementation of the evaluation should include process monitoring and quality assurance activities; protection of human subjects; baseline and follow-up data collection for intervention and comparison groups; and data security, cleaning and analysis activities.
4. Develop and implement qualitative evaluation of the intervention
 - The purpose of the qualitative evaluation element is to provide context to the quantitative results and enhance understanding of the intervention, such as components that resonate with participants and mediate behavior change, barriers to behavior change and intervention program attendance. This evaluation element should also assess facilitators and barriers to program implementation and provide information for replication of the intervention package.

Objective 4: Develop and implement a plan to summarize efficacious interventions and disseminate study results and products for stakeholders. Below are some of the activities anticipated for Objective 3.

1. Prepare a manuscript(s) that report results from the quantitative and qualitative including effects on BMI, cost and other key outcomes.
2. Use lessons learned from the quantitative and qualitative evaluations, including but not limited to, information on the intervention's logistics, team member roles, training, referral flow, and cost. Report this information as part of the evaluation.
3. Provide sustainability plans based on these findings and their discussions with their stakeholders, including state CHIP or Medicaid offices. These plans may include aspects of replication of optimal pediatric care and weight management program implementation, staff certification and reimbursable components.

Target Population

Target population

1. The target population is low-income children aged 6-12 years for this FOA. The applicant should document their ability to reach this population through appropriate data sources, such as:
 - Documenting eligibility for services under titles XIX (Medicaid) or XXI (CHIP) of the Social Security Act; income eligibility levels for Medicaid and CHIP are available at: <http://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/medicaid-and-chip-eligibility-levels-table.pdf>
- OR
- Establishing catchment areas where 50% of students are in schools eligible for free or reduced meals in the National School Lunch Program, and come from families at or below 185% of the federal poverty level. See Census Bureau's American Fact Finder page: <http://factfinder.census.gov>
- OR,
- Providing documentation of the proportion of children (using chart audits, EHR data pulls or administrative data), seen in the clinic office who are covered by CHIP, Medicaid, or Medicaid managed care plans

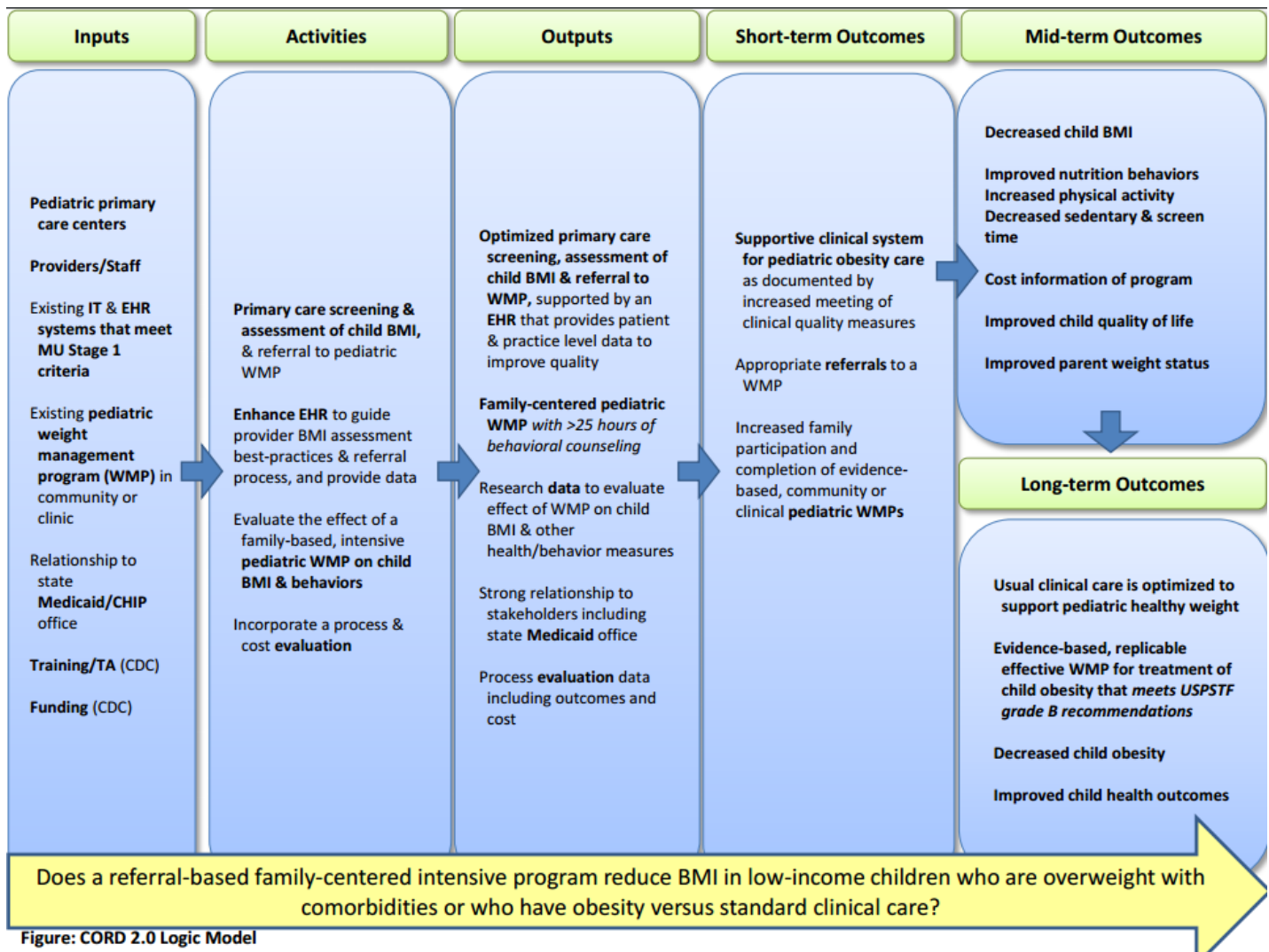
Collaboration/Partnerships

Grantees are expected to develop a Study Team to fulfill the capacity needs for successfully completing the project (e.g. team member(s) within a primary care center collaborating with intervention program staff). Grantees should work to ensure that the intervention tested is feasible and sustainable. Grantees are also expected to collaborate with the CHIP or Medicaid office in the state. In addition to the CHIP or Medicaid office, grantees should collaborate when appropriate with community organizations that can provide resources for children and families, and state and local health departments. Grantees will be expected to collaborate closely with the other investigators funded under this announcement and CDC.

Evaluation/Performance Measurement

All funded grantees are expected to complete a rigorous evaluation designed to address the elements in the logic model. Applicants should include a preliminary evaluation plan that includes the following evaluation components: outcome evaluation, process evaluation and cost evaluation. The outcome evaluation will include a plan for measurement and evaluation of the primary FOA outcomes, see Objective 3.

Figure 1: CORD 2.0 Logic Model



Translation Plan

All funded grantees are expected to prepare an intervention outcome-related manuscript. Applicants are expected to create additional written and verbal products as part of the project including costs. These include but are not limited to presentations, toolkits, meetings with CDC and key partners and stakeholders.

OMB/PRA not expected to be required

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Section II. Award Information

Funding Instrument Type: Cooperative Agreement
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: \$8,500,000

- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year will be 1,750,000 . The estimated funding for the second year which extend for 16 months is 2,500,000. The estimated total funding (direct and indirect) for the entire project period will be \$8,500,000. The entire 28 month project period will run from 6/1/2016 to 09/29/2018.

Anticipated Number of Awards: 2

Budget and Project Period. The estimated total funding (direct and indirect) for the first year will be 1,750,000. Estimated funding for the second year which extend for 16 months is 2,500,000. The estimated total funding (direct and indirect) for the entire project period will be \$8,500,000. The entire 28 month project period will run from 6/1/2016 to 09/29/2018.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: \$1,750,000 Per Budget Period

Award Floor: \$0 Per Budget Period

Total Project Period Length: 2.3 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

- State governments
- County governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public housing authorities/Indian housing authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
- Private institutions of higher education
- For profit organizations other than small businesses
- Small businesses
- Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter the review process.

Applicants must:

1. Provide a letter of support from the weight management program director specifying their participation in the intervention.

2. Provide a letter of support from the state CHIP or Medicaid agency indicating that they agree to provide guidance on the project.

These items can be referenced in the application. The documentation should be provided in the Appendix of your application.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

An application must address all requirements of this FOA listed in the Special Eligibility Requirements Section in order to be considered responsive. An application that exceeds the ceiling amount for Year 1 will be considered non-responsive and will not receive further review.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](https://www.Grants.gov)
- [eRA Commons](https://www.eRA Commons)

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is

submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at <https://www.sam.gov/index.html>.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf),

except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional.

Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit

additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from <http://grants.nih.gov/grants/forms.htm>

3. Letter of Intent

Due Date for Letter of Intent: **12/30/2015**

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent electronically to:

Natalie J. Darling, MPH

NCCDPHP and NCBDDD

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-5740

Email: ndarling@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

- 1. Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.

2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health. **3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline. **4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY) **5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects **7. Inclusion of Women and Minorities** **8. Targeted/Planned Enrollment Table** (for New Application ONLY) **9. Inclusion of Children**

Other Research Plan Sections

10. Vertebrate Animals **11. Select Agent Research** **12. Multiple PD/PI Leadership Plan.** **13. Consortium/Contractual Arrangements** **14. Letters of Support** **15. Resource Sharing Plan(s)** **16. Appendix**

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide

(http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Research Plan

The applicant's research plan should address activities that will be conducted over the entire project period and should include the following items.

Introduction/background

1. Describe previous experience.
2. Explain the importance of involving families in the intervention program, including how to address barriers to family engagement.

Specific Aims

Specify overall aims or objectives of intervention adaptation, implementation and evaluation.

Research Strategy

1. Describe the use of the electronic health record system including flagging of at-risk children and the referral system processes.
2. Describe the program components of the family-centered pediatric weight management program including how the program follows the USPSTF recommendation of ≥ 25 contact hours of both nutrition and physical activity counseling.
3. Describe the clinical team that will support the intervention.
4. Describe plan for enrolling sufficient amounts of low-income children (e.g., through BMI reports, obesity registries, or rolling recruitment).
5. Describe the process to encourage participant and retention in the family centered weight management program.
6. Describe how the intervention addresses developmentally appropriate materials aimed at behavior change in children ages 6-12 years of age and ages 2-5 years if included in the proposal.
7. Describe past implementation of the intervention (whether implemented by the applicant or other persons) including but not limited to how long it has been implemented, the sociodemographic characteristics of the population enrolled, the number of participants have enrolled in the program, the

number of participants that completed the program, and costs of the intervention.

8. Describe plans to form collaborations such as an advisory group including State CHIP office representation.

Study Design

1. Describe the target population and proposed intervention site(s).
2. Describe the evaluation design, including whether the proposed study will include a RCT, cluster-RCT, or quasi-experimental design.
3. Describe power analyses conducted to detect improvements in BMI change in children.
4. Describe plan to reduce bias in the evaluation.
5. Provide a timeline for conducting assessments at baseline and at subsequent time points during a minimum follow-up period of 6 months.

Study implementation

1. Describe plan to recruit the target group into the study:
2. Describe the agencies, clinics, venues from which participants will be referred who are eligible for the weight management program. If a community site is the proposed site, provide a letter of commitment to participate in the research study.
3. Describe method of data collection, security, and data management including issues of privacy and confidentiality.
4. Describe plans to retain sample across the follow-up period.
5. Describe the standard care control arm and how participants will be assigned to condition.
6. Describe plans for ongoing process evaluation and quality assurance throughout the project period.
7. Describe what steps will be taken to ensure fidelity to the program and measures to assess adherences to fidelity of program implementation.
8. Describe the plan to document and track the insurance coverage, including CHIP, Medicaid and Medicaid managed care coverage, of children and families enrolled in the intervention.
9. Describe the plan for clinical measure data collection including measurable relevant clinical quality measures (e.g. Medicaid child core set, HEDIS)
10. Describe plans to expeditiously provide refresher training and to measure existing competencies of a primary care team (may be comprised of providers, allied professionals (including, but not limited to, nurses, social workers, physician assistants), and CHWs or care managers.
11. Describe plans for measurement of key FOA outcomes including child BMI, behavior change (e.g. improvements in physical activity, sleep, fruit and vegetable intake, and reduced television and screen time viewing, high energy dense foods and sugary drink consumption), quality of life, satisfaction with care; additional outcomes including parent BMI.
12. Describe plans to assess the cost of the major components of the FOA relative to informing the design of sustainable fiscal models for stakeholders such as CHIP or Medicaid.

Study Dissemination

Describe plan to disseminate findings

Study Management

Describe the study team's capacity to design, implement and evaluate the intervention.

Describe how the study team plans to work with CDC.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Applicants must provide a logic model that frames the intervention and serves as a basis of the evaluation plan. A sample logic model is included (see Figure 1: CORD 2.0 Logic Model) under "Evaluation/Performance Measurement" in Part 2. Full Text, Section 1. Funding Opportunity Description, 2. Approach of this FOA.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, *the applicant* must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **01/29/2016**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review ([http:// www. whitehouse.gov/ omb/ grants_ spoc](http://www.whitehouse.gov/omb/grants_spoc)).

11. Funding Restrictions

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.
- Human Subjects Education Requirement documentation is provided.

12. Other Submission Requirements and Information

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in

the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide. If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<http://www.cdc.gov/about/organization/mission.htm>), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

1. Has the applicant shown how it will reduce barriers to successful completion of the weight management program by low-income children and their families?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

1. Is their evidence of successful past collaborations with the proposed Study Team or with similar partners?
2. Does the study team have significant experience developing, implementing, and evaluating interventions aimed at childhood obesity?
3. Does the applicant describe their plans for a refresher training of all clinic staff?
4. To what extent do the PI or study team members have experience in being part of an intervention involving public health, community and clinical settings that required buy-in and collaboration with state payors?
5. Is the time commitment of key research study team members adequate to successfully design and implement the project?
6. To what extent does the applicant provide a management plan, a detailed time line, and delineation of roles?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

1. To what extent does the applicant demonstrate reach into the eligible pool of low-income children 6-12 years of age and enroll them in the intervention?
2. Does the applicant describe their ability to ensure retention of target children and families in the intervention?
3. To what extent does the applicant demonstrate partnerships with the state CHIP or Medicaid offices to work toward increased access to counseling and management for children with overweight and risk factors or obese children? Are Memoranda of Agreement, or Understanding, other governance documents, or letters of support provided?
4. Does the applicant provide evidence of sign-on by a primary care system or systems that are ready to participate in the study?
5. Does the applicant include plans to measure/capture and report clinical quality measures such as the Medicaid Child Core Set or HEDIS measures?
6. Does the applicant describe the plan to document and track the insurance coverage, including CHIP, Medicaid and Medicaid managed care coverage, of children and families enrolled in the

intervention?

7. Does the applicant provide evidence that an existing family-centered weight management program has evidence of effectiveness or promising evidence and can be delivered at a cost of less than \$1000/family (including proprietary costs)? Do results provided from previous process and/or outcome evaluations provide a compelling case for rigorously evaluating the intervention with this target population?
8. How well does the applicant demonstrate the ability to expeditiously collaborate with a sufficient network of providers, allied health professionals, community health workers or care managers to perform the research project including the weight management program?
9. Does the applicant propose a strong evaluation design and justification for the design?
10. Does the applicant includes plans to measure SMART outcomes and objectives including BMI, behavior change, quality of life, satisfaction with care, process measures of pediatric care as well as costs?
11. Does the applicant provide power calculations demonstrating proposed sample size, taking into account anticipated attrition and the unit of randomization is sufficient to detect intervention effects on BMI in the target population?
12. Does the applicant provide an appropriate statistical approach to determine the efficacy of the intervention?
13. How well does the applicant describe the control group(s)?
14. To what extent does the applicant address the ability to have a robust clinical data acquisition process to aid process and quantitative outcomes including clinical quality measures?
15. Does the applicant specify use of the Obesity Chronic Care Model in their design and implementation plan showing linkage between activities and program elements to outcomes?
16. Does the applicant describe the multi-disciplinary primary care team that will be part of usual care capacity and roles?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

1. Is there adequate infrastructure for the coordination of the project across the various sites, including description of information exchange and data collection at the primary care center and/or community venue if that is the proposed program intervention site?
2. Does the applicant describe how child and family progress will be sent to the primary care team to be recorded in the EHR as part of feedback from the intervention?
3. Does the applicant have access to qualified personnel and partners with realistic and sufficient percentage-time commitments relative to the study's activities?
4. Does the application describe the target setting(s) and explain how the physical infrastructure, organizational infrastructure, and typical staff workload will contribute to and be affected by the implementation of the project, including the intervention itself, data collection, and evaluation?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#), the committee will evaluate the justification for involvement of human

subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(<http://www.cdc.gov/grants/additionalrequirements/index.html>).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research ([http:// www.cdc.gov /maso Policy /Policy_women.pdf](http://www.cdc.gov/maso/Policy/Policy_women.pdf) and [http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1](http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1)) and the policy on the Inclusion of Persons Under 21 in Research ([http:// www.cdc.gov /maso /Policy /policy496.pdf](http://www.cdc.gov/maso/Policy/policy496.pdf)).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern

Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: <http://www.phe.gov/s3/dualuse>. Tools and guidance for assessing DURC potential may be found at:

<http://www.phe.gov/s3/dual-use/Pages/companion-guide.aspx>.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication.

Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Awardees are expected to comply with all applicable CDC and federal policies on public access to publication and data collected with federal funds. CDC/ATSDR Policy on Releasing and Sharing Data is available at <http://www.cdc.gov/maso/Policy/ReleasingData.pdf>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Resource Sharing Plans HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/grants/additionalrequirements/index.html>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Geographic diversity of study sites.
- Diversity in populations disproportionately impacted by obesity-related risk factor and obesity (e.g., racial and ethnic minorities or low socioeconomic status populations).
- Diversity in intervention approaches.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement ([http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award ([http://www.hhs.gov/ asfr/ogapa/aboutog/hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)

[AR-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”; October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR 32 –; FY 2015 Enacted General Provisions](#)

[AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website

at: <http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html>.

Federal Funding Accountability and Transparency Act of 2006

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: <https://www.fsrs.gov/>.

Plain Writing Act

The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: <http://www.plainlanguage.gov/plLaw/index.cfm>.

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.

- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- [http://www.gsa.gov/graphics/pbs/ Guidelines for Federal Concessions and Vending Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)
- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

Pilot Program for Enhancement of Employee Whistleblower Protections

All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency

Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs

without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern

On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at <http://www.phe.gov/s3/dualuse>.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

1. Designing, conducting and implementing the intervention demonstration project research plan to address the described research objectives of this cooperative agreement.
2. Guiding and coordinating the work of the coalition and ensuring effective linkage, communication, and accountability.
3. Sharing outcome information with the CDC.
4. Obtaining the appropriate Institutional Review Board approvals for research involving human subjects.
5. Participating in CDC-sponsored meetings as scheduled by CDC.
6. Conducting analyses, interpreting results, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conferences

and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.

7. Make use of local analytic support, center-specific and shared datasets and local resources related to the project.
8. The Principal Investigator will attend at least one in-person meeting per year and televideo conference calls regularly, as scheduled in consultation with CDC.
9. Other members of the research team will participate in appropriate sub-committees and CDC-sponsored meetings.
10. Ensure adequate management, staffing, oversight, and mentoring of research team members in support of the project activities.

Awardees

are expected to comply with all applicable CDC and federal policies on public access to publication and data collected with federal funds. CDC/ATSDR Policy on Releasing and Sharing Data is available at <http://www.cdc.gov/maso/Policy/ReleasingData.pdf>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

HHS/CDC Responsibilities

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

There are two CDC scientific roles – the Scientific Consultant (SC) and the Scientific Program Official (SPO).

In this cooperative agreement NCCDPHP SC will provide technical assistance for scientific and programmatic aspects during the conduct of the project through technical assistance, advice, and coordination.

At the awardees request, the SPO will provide technical assistance and consultation in the development and/or refinement of the intervention and the design of research protocols; monitor and evaluate scientific and operational accomplishments of this project through frequent telephone contact, review of technical reports, and review of interim data analyses. Based on this, CDC will make recommendations aimed at solving problems and improving the quality and timeliness of the research activities.

NCCDPHP SC and additional scientific consultants will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

1. At the awardees request, provide expertise and guidance on the project-developed protocol including use of evidence-informed strategies and implementation approaches.
2. At the awardees request, provide expertise related to data collection methods, instruments and tools including electronic health records.
3. Support awardee activities in intervention design, data management, data analysis and interpretation, formats for presenting research findings, and in comparing project-developed evaluation formats with other research projects and activities known to CDC.
4. At the awardees request, assist in the analyses, interpretation, and reporting of findings in the literature, summary and policy briefs, and professional presentations.

The SPO will:

- Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award.
- Monitor performance against approved project objectives.
- Assure assessment of the public health impact of the research conducted under this funding

opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

The Demonstration Project Research Network Committee will be formed after grantees are awarded and made up of a Principal Investigator from each funded Demonstration Project, and the lead HHS/CDC Project Scientist and Project Administrator. Other federal agency liaisons such as a Senior Advisors from HHS (CMS, NIH, AHRQ, HRSA) may be appointed as members. This Committee will work together on common issues of funded projects.

Funded Demonstration Sites should seek the review and input from their state CHIP and/or Medicaid agency, as well as technical input from CDC when identifying and considering the adoption of innovative interventions that have long-term financial and operational implications.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrc.gov on all subawards over \$25,000. See the HHS Grants Policy Statement ([http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

In addition to the reporting requirements outlined above

1. Provide certification, for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects, that they have completed an educational program in the protection of human subjects.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm), is due 90

to 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 ([http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm))
[http:// grants.nih.gov/grants/ funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm): Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*
 - How will the scientific findings be translated into public health practice or inform public health policy?
 - How will the project improve or effect the translation of research findings into public health practice or inform policy?
 - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
 - How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:
 - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
 - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.
- Additional Reporting Requirements:

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress

report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at [http:// grants.nih.gov/ grants/forms.htm](http://grants.nih.gov/grants/forms.htm). For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https:// commons. era.nih.gov/ commons/](https://commons.era.nih.gov/commons/)). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to [https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp](https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp) for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: [http:// era.nih.gov/ commons /index.cfm](http://era.nih.gov/commons/index.cfm).

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee’s final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- **Publications; Presentations; Media Coverage:** Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Natalie J. Darling, MPH

NCCDPHP and NCBDDD

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

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Email: ndh6@cdc.gov

Peer Review Contact(s)

Jayalakshmi (Jaya) Raman, PhD

NCCDPHP and NCBDDD

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-6511

Email: kva5@cdc.gov

Financial/Grants Management Contact(s)

Monique McEwen

Grants Management Specialist

Office of Grant Services (OGC)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention

2920 Brandywine Road, M/S E-09
Atlanta, GA 30341

Telephone: 770-488- 2617

Email: mmcewen@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Medicare Access and CHIP Reauthorization Act of 2015, Section 304, extends and amends Section 1139A (e)(8) of the Social Security Act (42 U.S.C. 1320b-9a(e)(8)[CUI]).

Appendix A. Questions from Potential Applicants and CDC Responses

Q1 (A): On page 9 in the FOA it states, "The program should be able to be delivered at a cost not to exceed \$1000 per family." What exactly is this figure in reference to? It seems that it refers to the family-centered pediatric weight management program only and not any services provided by primary care. Is this correct?

Relatedly, is this figure a cost for the program when it's delivered in the proposed project period (that is, a behavioral health specialist's time to deliver the program costs less than \$1000) or when the program is delivered at scale in a real-world system (that is, the cost to a healthcare agency, a private or federal payor (Medicaid) to deliver the program)?

A1 (A): Yes, the program refers to the "family-centered pediatric weight management program" as stated on page 11 of the FOA. The cost of \$1000/family per treatment program excludes research costs, but includes costs relating to the program's delivery, including existing staff training and time, material and resources in the context of the demonstration project *and* currently available reimbursable services. The program can be delivered in either a primary care or community setting.

If the applicant intends to propose a program that is more than \$1000/family, then in order to be considered for the review process the applicant must describe a process by which a real-world (i.e., post demonstration project) application can be developed at less than \$1000/family per treatment program.

Q1 (B): Also on page 9, it states that the proposal use "a program that delivers a minimum of moderate intensity nutrition and physical activity education and behavior modification (i.e. at least 25 hours of contact time over 6 months) for children and families." I understand this number comes from the USPSTF report in 2010 but can you clarify what types of "contact" is included in this 25 hour benchmark? If contact is defined as time with a provider, then even a community health worker with a bachelor's degree will cost well beyond \$1000 to deliver 25 hours of intervention time—even if these are group-based sessions. Relatedly, the 25 to 75 hour window from the USPSTF would only be applicable to children who are already overweight, correct? Those whose weight falls within the selective or indicated prevention criteria (Barlow's table on page 4—second row) would not require this level of intervention. It's unclear to me what then the target of the proposed program is supposed to be as there is some inconsistencies in the announcement. If the 25 hour minimum is accurate, then the announcement is really only applicable to children who are already obese (BMI 95th and above).

The root of my questions is that I am having a difficult time envisioning a prevention program meeting these parameters that is tied into primary care.

A1 (B): The types of contact may include provider, community health worker, registered dietitians, behavioral specialists, exercise specialists or health coaches. The format for the contacts may include in-person, group, telephone follow-ups or other virtual means.

Please see the Intervention Design section of the FOA: “Intervention Design: As part of the proposed applicant work, the pediatric primary care center and proposed family centered pediatric weight management program are to follow expert recommendations to screen, assess and manage overweight and obesity (Barlow, 2007). The applicant should use an EHR with clinical decision supports, a multi-disciplinary team, and a program that delivers a minimum of moderate intensity nutrition and physical activity education and behavior modification (i.e. at least 25 hours of contact time over 6 months USPSTF, 2010) for children and families. The proposed intervention program should be tested in low-income children aged 6 to 12 years of age, with the option of also including low-income children 2-5 years. If a control group consisting of usual care is planned, it must be clearly described.”

Q2: The UPSTF recommended number of hours would apply to only children who are obese, but the FOA seems to allow for selected prevention for children in the 75th–95th percentile range; in which case the 25–75 hours of contact guideline would NOT apply. This is critical to have clear [for applicants] proposing to work with children that are in the overweight range but not yet obese.

A2: CORD is a research demonstration project meant to fill in gaps in the evidence. USPSTF found that there was insufficient evidence to recommend moderate to high intensity interventions for children with overweight. Thus, in order to strengthen the evidence base, this FOA intends to include children >85th percentile with risk factors for obesity (see page 4 of the FOA) as part of the study population. Children with overweight will receive the same moderate to high intensity intervention (26-75 hours in a 6 month period, as per the USPSTF recommendation) as children with obesity.

Q3 (A): On page 9, under ‘Implementation and Evaluation’ and “Readiness of Existing Intervention”, it states that the program “...has not been rigorously evaluated in low-income children.” Does that mean that we can’t use MEND/CATCH as we used in CORD? Could we use a modified version of MEND/CATCH? What is meant by ‘has not been rigorously evaluated’? This is confusing, as under ‘Research Strategy’ on page 22, it states that we should ‘...describe past implementation of the intervention...’

A3 (A): The intent of the statement is to emphasize evaluation in a new population group of low income children, for example, a specific sub-group or ethnic group not studied in CORD 1.0 to add to the evidence base. The applicant should describe the past experience and evidence base behind the chosen intervention.

Q3 (B): One of the criteria of the program used is that it needs to not exceed \$1000/family (page 9). Does that include program material costs, or material plus personnel implementation costs (e.g., total costs)?

A3 (B): The cost of \$1000/family per treatment program excludes research costs, but includes costs relating to the program’s delivery, including existing staff training and time, material and resources in the context of the demonstration project. The program can be delivered in either a primary care or community setting.

If the applicant intends to propose a program that is more than \$1000/family, then in order to be considered for the review process the applicant must describe a process by which a real-world (i.e., post demonstration project) application can be developed at less than \$1000/family per treatment program.

Q3 (C): The RFA states that the intervention must be a minimum of 6 months long and at least 25 contact hours. It also mentions that there must be follow up of at least 6 months. Does that mean that the intervention should be at least 6 months, with a 6-month follow up time (e.g., measurements at baseline, 6 months and 12 months)? Or can it be just 6 months (e.g., baseline and 6 month)? Also, for the 6 month follow-up, is it a ‘do nothing’ time period (e.g., no contact with the participants) or would it be OK to provide some sort of research or clinic contact (e.g., social media or follow up visits with their provider). As you can see, we are unclear about what is meant by the 6 month follow up period.

A3 (C): The intervention must deliver the USPSTF recommendation of moderate to high intensity comprehensive programs (defined as 26-75 hours of child and/or family contact) in a six month period.

There must be a 6 month follow-up period *after the end* of that intervention period (which MUST include measurements at 6 months and 12 months). During the 6 month follow up period, the intervention may continue and the applicant can choose the method of contact, frequency and duration. If the applicant proposes interventions past the initial 6 month period a description of the method of contact, frequency and duration should be included in the application and evaluation plan.

Q4: I'm writing to inquire about the scope of this project. Is there an expectation that the project should be statewide or regional (versus local)? Thank you.

A4: The applicant must decide on the scope of the project as well as determining sustainability plans.

Q5: We are planning a response to the Childhood Obesity Research Demonstration 2.0 (RFA-DP-16-004), and have a few questions about key portions of the RFA.

- What costs should we attribute to the \$1000/family cost cap in the intervention?
- The RFA reads "\$1000/family." If there are multiple children in a family who qualify, do they each have allowable expenses up to \$1000?
- Superiority vs. non-inferiority to standard of care?
- Standard of care comparison group: would like to discuss details of what is most appropriate

A5: The cost of \$1000/family per treatment program excludes research costs, but includes costs relating to the program's delivery, including existing staff training and time, material and resources *in the context* of the demonstration project. The program can be delivered in either a primary care or community setting.

If the applicant intends to propose a program that is more than \$1000/family, then in order to be considered for the review process the applicant **must** describe a process by which a real-world (i.e., post demonstration project) application can be developed at less than \$1000/family per treatment program.

The study design and analyses are determined by the investigators. The investigators must propose a study design that is robust and an analysis plan, with an appropriate comparison group that can determine whether the intervention represents a model of quality clinical care that is effective.

Q6: Two quick follow ups from Q5:

- Laboratory tests recommended by AAP – I'm assuming these costs are included
- The well-visit when the patient is identified for the intervention and referred – I'm thinking this is NOT included b/c not part of the actual intervention?
- The 1000/family – if more than one child in a family qualifies (has high BMI) is it 1000 per child or still capped at 1000 per family?

A6: Services that would routinely be covered by insurance cannot be paid for by this funding opportunity announcement (FOA) such as laboratory tests and well-child visits that would normally be covered.

If there is more than one child per family enrolled in the intervention, then the cost cap would become \$1000/child.

Q7: My team is interested in applying for the FOA on the CORD project. We have a question about page limits. Can you please clarify what page limit is expected. We are a little confused as the research strategy of the research plan is stated as 25 pages which does not include sections on background/introduction, previous experience, or specific aim.

A7: The Research Strategy is limited to 25 pages. You may also have up to 10 pdf attachments in your appendix which is explained In **Section IV. Application and Submission Information, 6. Appendix** and **7. Page Limitations** on page 26 of FOA. There is a maximum of 35 pages for appendices.

Please follow page limits stated in the **SF 424 (R&R) Application Guide** unless otherwise stated in the FOA (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf). The SF424 (R&R) link can also be found in the FOA in **Section IV. Application and Submission Information, 2. Content**

and Form of Application Submission. The SF424 (R&R) Forms Version C Application Guide has instructions and detailed information on the biographical sketch and Research Plan components including the specific aims and Research Strategy in **Part 1, Section 5.5 PHS “398 Research Plan Form”** which begins on about page 138 of the SF424 (R&R) Application Guide referenced in the link above.

Q8: I'm writing to request a phone call to discuss the RFA for CORD 2.0. I find both your contacts associated with the RFA. If one of you are the appropriate program officer, please let me know when some of your available times and dates might be.

A8: RFA-DP-16-004 is a new and open competitive funding opportunity announcement (FOA). Childhood Obesity Research Demonstration (CORD) 2.0 is an FOA that is open to the list of eligible entities listed in the FOA (**Section III. Eligibility Information, 1. Eligible Applicants**). That is any applicant, regardless of whether or not they participated in previous cooperative agreements may apply so long as they meet the eligibility criteria.

Q9: I am writing to clarify whether healthcare organizations are eligible to apply for the CDC RFA DP-16-004 - specifically, [name of organization].

A9: RFA- DP-16-004 is an open competitive funding opportunity announcement (FOA) which means any eligible applicant listed in **Section III. Eligibility Information, 1. Eligible Applicants** of the FOA may apply.

Q10 (A): Just to clarify, does the \$1000 cost of the program include just the 6 month intervention period, or the combined intervention and follow up periods? In other words, if we do any follow up intervention components, should they be included as part of the \$1000 program costs?

A10 (A): The \$1000 should cover all services to deliver the weight management program. If a follow-up period is being provided as part of a clinical service it would be included under the \$1000 cap.

Q10 (B): Does the \$1000 include any provider visits as part of the program, e.g., provider visits that would not normally be covered under Medicaid/CHIP?

A10 (B): The \$1000 includes any provider visits that are part of an intervention and are not currently being covered by insurance.

Q10 (C): In the RFA, an Introduction should be included for resubmissions and revisions only. Since we had a CORD grant, do we need to complete an Introduction section? I'm not sure of our status here.

A10 (C): RFA-DP-16-004 Childhood Obesity Research Demonstration (CORD) 2.0 is a new and open competitive funding opportunity announcement (FOA). All potential applicants that are eligible to apply for this FOA (see **Section III. Eligibility Information, 1. Eligible Applicants**) should complete a new application, regardless of whether or not they participated in any previous cooperative agreements.

Resubmissions and revisions are not applicable to this FOA.

Q10 (D): In the RFA, an Inclusion Enrollment Report is needed for renewal and revision applications only. Is this something we should include?

A10 (D): RFA-DP-16-004 Childhood Obesity Research Demonstration (CORD) 2.0 is a new and open competitive funding opportunity announcement (FOA). All potential applicants that are eligible to apply for this FOA (see **Section III. Eligibility Information, 1. Eligible Applicants**) should complete a new application, regardless of whether or not they participated in any previous cooperative agreements.

An Inclusion Enrollment Report is not required for this FOA.

Q10 (E): In the RFA, a Progress Report Publication List is required for Continuations only. I am assuming that we should include this – is that correct?

A10 (E): RFA-DP-16-004 Childhood Obesity Research Demonstration (CORD) 2.0 is a new and open competitive funding opportunity announcement (FOA). All potential applicants that are eligible to apply for

this FOA (see **Section III. Eligibility Information, 1. Eligible Applicants**) should complete a new application, regardless of whether or not they participated in any previous cooperative agreements.

A Progress Report Publication is not required nor applicable for this FOA.

Q10 (F): In the RFA, a logic model is required, and one is provided. Can we adapt that logic model to our specific work plan? I am assuming that we should use the logic model that is provided, correct?

A10 (F): The applicant should provide a logic model that is relevant to their intervention.

Q10 (G): In the RFA, we had several questions about the Research Plan. Does the Research Plan include the Research Strategy section, plus the additional components? Should the Introduction/Background be included in the Research Strategy part of the grant, or should it be an additional section? Does the Introduction/Background count as part of the 25-page Research Strategy? Just to clarify, the Specific Aims should be one page, in addition to the Research Strategy (for a total of 26 pages)? Under Research Strategy, should we include study design, study implementation, etc. (see below)?

A10 (G): **Section IV. Application and Submission Information, 5. PHS 398 Research Plan Component** of the FOA states “Part 1, Section 5.5 of the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)” includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components; however, not all 16 components of the Research Plan apply to every funding opportunity announcement (FOA). Specifically some components are used only for revisions, resubmissions, or continuations which are not applicable to this FOA.

For this announcement, RFA-DP-16-004, the Research Plan should include the following components: 2. Specific Aims, 3. Research Strategy, 5. Protection of Human Subjects, 6. Inclusion of Women and Minorities, 7. Inclusion of Children, 8. Other Research Plan Sections (Letters of Support, Resource Sharing Plan, etc.), and 14. Appendix.

The Research Strategy should be subdivided into 3 parts: 1) Significance 2) Innovation and 3) Approach and is limited to 25 pages in length (see “**Part 1. Overview Information**”, “**Required Application Instructions**” in FOA). The applicant should determine how to address the bulleted activities listed in each subheading (e.g., introduction, background, study design, study implementation, etc...). If the applicant addresses these selected activities in the Research Strategy component of their application, then it would count towards the Research Strategy’s 25 page limit. Applicants should follow the page limits stated in the SF424 (R&R) unless otherwise specified in the FOA.

Q11: I understand that we wouldn't charge clinical costs to the FOA; I guess what I'm trying to ask is whether those costs count toward the \$1000 cap on the actual intervention cost? This is becoming important as we are layering on elements of the proposed intervention; if we are to account for lab costs in the overall cap, we would have to be more frugal with other aspects of the intervention. Since the labs are typically part of the PCP screening visit rather than an intervention, we thought perhaps this cost would NOT "count;" however it may change management depending on the results so in that sense I would understand if it WOULD "count" toward the cost.

A11: Clinical costs that are normally covered by insurance (that will not be “charged” to the grant) will not count toward the \$1000/family cost cap of the intervention.