

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry

Affordable Care Act Program for Early Detection of Certain Medical Conditions Related to Environmental Health Hazards

CDC-RFA-TS15-1501

Application Due Date: 05/11/2015

Affordable Care Act Program for Early Detection of Certain Medical Conditions Related to Environmental Health Hazards

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-TS15-1501. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Agency for Toxic Substances and Disease Registry (ATSDR)

B. Funding Opportunity Title:

Affordable Care Act Program for Early Detection of Certain Medical Conditions Related to Environmental Health Hazards

C. Announcement Type: New - Type 1

This announcement is only for non-research domestic activities supported by ATSDR. If research is proposed, the application will not be considered Research for this purpose is defined at http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-TS15-1501

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.534

F. Dates:

1. Due Date for Letter of Intent (LOI):	**N/A**
2. Due Date for Applications:	**05/11/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.
3. Date for Informational Conference Call:	**N/A**

G. Executive Summary:

1. Summary Paragraph:

This four-year funding opportunity offers, to residents of Libby and Troy, Montana meeting eligibility criteria, health screening for asbestos related disease, health education, and outreach. Libby, Montana was the site of a vermiculite mining and processing operation for much of the twentieth century. Because Libby vermiculite contains asbestos, vermiculite workers and other residents were exposed to asbestos. Community-based health screening for asbestos-related abnormalities has been conducted in Libby under several programs beginning in 2000. The program described in this FOA builds upon previous programs and extends a program begun in 2011 under the Affordable Care Act.

This program will provide screening, health education, and outreach services for residents and former residents of a geographic area subject to declared public health emergencies under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), such

as residents of Libby and Troy, Montana. This is regarding the non-research grant for the next funding cycle or continuation for ACA screening.

a. Eligible Applicants:	Open Competition
b. FOA Type:	Grant
c. Approximate Number of Awards:	1
d. Total Project Period Funding:	$10,000,000
e. Average One Year Award Amount:	$2,500,000
f. Number of Years of Award:	4
g. Estimated Award Date:	05/01/2015
h. Cost Sharing and / or Matching Requirements:	N

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Libby, Montana was the site of a vermiculite mining and processing operation from the early 1920's through 1990. While it was in operation, Libby was the world's largest source of vermiculite. The commercial uses of vermiculite include insulation, fire proofing, and as a soil conditioner. Unfortunately, Libby vermiculite is contaminated with amphibole asbestos. This has resulted in asbestos-related morbidity and mortality in vermiculite workers, their family members, and residents with neither occupational nor para-occupational exposure. In June 2009, the U.S Environmental Protection Administration declared a public health emergency for the Libby Asbestos Site, which includes the cities of Libby and Troy (June 19, 2009 memo from Lisa Jackson, EPA Administrator).

Reports of pervasive asbestos-related health outcomes in Libby prompted a concerted response by the federal government in 1999. A large component of this response was community-based screening conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) in 2000 and 2001 in which 7,307 persons were screened. Additional screening was funded by ATSDR via a grant to the Montana Department of Health and Human Services 2003-2008 and to the Lincoln County Health Department 2009-2011. Language was included in the Affordable Care Act (ACA, Public Law 111-148; http://www.gpo.gov/fdsys/ pkg/PLAW-111publ148/pdf/ PLAW-111publ148.pdf) to continue to make screening available to persons with potential past exposure to vermiculite while they resided in the Libby area. Persons with positive screening results may be eligible for Medicare benefits.

In 2011, a grant was awarded to the Center for Asbestos Related Disease (CARD) to conduct screening activities under ACA. This screening included the use of a standardized health survey, spirometry, and chest radiography as well as high-resolution computed tomography (HRCT) and the fecal occult blood test (FOBT). Screening activities were expanded under ACA to include community outreach and health education. Further, the scope of ACA

screening was expanded from being Libby-based to also include persons who emigrated from Libby.

The present funding opportunity announcement (FOA) is for the continuation of the activities begun under the previous FOA by CARD. This program is expected to result in improved survival of participants with asbestos-related cancers, reduced rates of smoking-related diseases, and improved quality of life for participants.

b. Statutory Authorities

Affordable Care Act (ACA) Section 10323(b) amends Title XX of the Social Security Act (42 U.S.C 1397 et seq.) to establish a "Program for Early Detection of Certain Medical Conditions Related to Environmental Health Hazards." (Section 2009 of the Social Security Act, as amended) (42 U.S.C. 1397h).

c. Healthy People 2020

This program addresses the “Healthy People 2020” focus area of Environmental Health available at http://www.healthypeople.gov.

d. Other National Public Health Priorities and Strategies

Measurable outcomes of the program will be in alignment with the following performance for ATSDR: Determine human health effects associated with exposures to priority hazardous substances.

e. Relevant Work

The present FOA was immediately preceded by a similar one in which community-based health screening, community outreach, and health education was offered to current and past resident of Libby and Troy, Montana. In addition, ATSDR conducted health screening in Libby in 2000 and 2001, and the Montana Department of Public Health and Human Services also offered health screening 2003–2008 under an ATSDR grant.

2. CDC Project Description

a. Approach

Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Community outreach - Media campaign - Community events Screening - Standardized health surveys	Target audience aware of screening services* Target audience aware of Medicare eligibility* Individuals with qualifying diagnosis enrolled in Medicare*	Target population enrolled in disease management programs* Target population enrolled in treatment (for lung cancer or other asbestos- related	Increased survival from lung cancer Increased survival from mesothe- lioma Increased

- Spirometry - Chest radiography - High-resolution computed tomography - Fecal occult blood test - Quality control processes Health Education/ Materials for Community and Physicians - Asbestos- related disease education - Exposure risk education - Smoking cessation programs	Increased knowledge of the following among target community and physicians*: - Exposure prevention - Risks of smoking - Asbestos-related disease - Disease management	cancers)* Target population reduce their exposure to asbestos* Target population reduce their rate of smoking* Providers improve smoking reduction/ cessation programs* Improved treatment/ management of individuals with asbestos- related disease* Community members with negative results seek continued screening*	survival from other asbestos-related cancers Reduced rate of smoking- related diseases Improved quality of life

* indicates project period outcome

i. Purpose

The purpose of the program is to (1) provide medical screening to persons with possible exposure to amphiboles that occurred in Libby and Troy, Montana; (2) conduct nationwide outreach to raise awareness of the screening program among persons eligible to participate and of the availability of certain Medicare benefits; and (3) provide health education to detect, prevent, and treat environmental health conditions. The three components of this project (screening, outreach and education) will be conducted in an integrated manner.

ii. Outcomes

As shown in the Logic Model, a series of short and intermediate-term outcomes are expected to be achieved as a result of awardee efforts.
Short-term Outcomes:

- Target audience aware of screening services: Awareness of the screening program among current and former residents of Libby and Troy will be increased.
- Target audience aware of Medicare eligibility: Awareness of the Medicare benefit eligibility among current and former residents of Libby and Troy will be increased.
- Individuals with qualifying diagnosis enrolled in Medicare: Screening participants with an asbestos-related disease are enrolled in Medicare.
- Increased knowledge of the following among target community and physicians:
    - Exposure prevention: Recognition of potential asbestos exposure pathways.

- Risks of smoking: Recognition of the health risks associated with smoking.
- Asbestos-related disease: Recognition of disease associated with asbestos exposure.
- Disease management: How to diagnose and treat asbestos-related diseases.

Intermediate Outcomes:

- Target population enrolled in disease management programs: Participants with a positive screening are referred for treatment and diagnosis.
- Target population enrolled in treatment (for cancer or other asbestos-related, nonmalignant disease).
- Target population reduces their exposure to asbestos.
- Target population reduces their rate of smoking.
- Provider improves smoking reduction cessation programs.
- Improved treatment/management of individuals with asbestos-related diseases.
- Community members with negative results seek continued screening.

iii. Strategies and Activities

In general, the grantee should conduct community outreach using various media (e.g., the internet, press releases and advertisements) to increase awareness of the federal screening and health benefit programs among residents of Libby and Troy, MT, as well as among former residents who no longer live in those communities. After screening candidates complete pre-screening questions to demonstrate eligibility to the grantee, the grantee should conduct screening via chest radiography, high-resolution computed tomography, and the fecal occult blood test. If additional tests become available during the project (e.g., testing for mesothelin), the grantee should consider adding them to the screening routine, if supported by the scientific literature and approved by ATSDR. The grantee should communicate the screening result with individual candidates and their physicians as well as organize and manage all screening data in a database. The grantee should also conduct health education via community meetings and an annual newsletter.

Some specifications for carrying out activities under this grant, which are described in the ACA legislation (http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf) are summarized below, and should be followed to ensure consistency of the program:

1. Community Outreach.

a. Goal: To increase awareness of new federal screening and health services programs, including Medicare benefits, among current and former Libby residents.

b. Outreach activities:

i. Internet: The grantee should establish a web site containing program information.

ii. Traditional mail: The grantee should communicate with screening candidates via letters and other mailed materials.

iii. In Libby: The grantee should use the local media (newspaper and radio advertisements) and community meetings.

iv. Outside of Libby: The grantee should use press releases and advertisements in

national newspapers and magazines and other resources such as social media.

v. Phone center: The grantee should establish a toll-free phone number staffed with persons who can answer questions about federal screening and health services and receive calls from screening candidates.

2. Screening.

a. Goal: To provide asbestos-related disease (ARD) screening to at-risk individuals for environmental health conditions (as defined below).

b. Eligibility for screening: An at-risk individual is defined as having been present for an aggregate total of 6 months in the geographic area subject to an emergency declaration (the towns of Libby and Troy, in Lincoln County, Montana), as specified by ACA, during a period ending:

i. not less than 10 years prior to the date of an individual's application for screening under this program; and

ii. prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7.

The grantee should insure each participant furnishes documentation (e.g., mail delivered to a Libby address during the time period specified above, or a letter from ATSDR containing results from a previous screening) to demonstrate eligibility for screening.

c. Screening components: Each candidate will be evaluated with radiologic testing (posterior-anterior (PA) chest radiograph and possibly chest high-resolution computed tomography (HRCT)). All candidates should be evaluated initially via a PA radiograph; if the radiograph results obtained through a B-reading are judged to be equivocal by the screening participant's physician, then the candidate may also be evaluated via HRCT. Screening for colorectal cancer should be conducted in accordance with applicable guidelines1 and should include screening with a high sensitivity fecal occult blood test (FOBT) in adults aged 50 to 75 years.

d. Locations:

i. Libby and surrounding areas: If expertise does not reside within the applicant's organization, it may subcontract with local provider entities in the immediate area or reimburse individual provider entities according to a predetermined fee schedule to conduct screening. ATSDR anticipates fewer than 4,000 persons in Libby and surrounding areas would be eligible for screening based on previous screening programs. In order to maintain continuity with the current screening program, the grantee should implement the screening program for the Libby area prior to initiating the screening program outside of Libby.

ii. Outside of Libby: After implementing the Libby area screening program, the grantee should expand screening to areas outside of Libby: The grantee may reimburse individual provider entities according to a predetermined fee schedule or subcontract with local provider entities if feasible to screen candidates no longer living in Libby. ATSDR anticipates the universe of screening candidates no longer

residing in Libby is fewer than 8,000 based on U.S. Census data.

iii. All radiographs and HRCT scans should be read within one business day by an onsite radiologist (i.e., a radiologist reporting to the local provider entity). If an urgent abnormality (e.g., breast or lung cancer) is detected, those results should be immediately communicated to the screening participant and his/her primary care physician.

e. Positive screening result definition: The screening candidate will be deemed positive if one of the following conditions is present:

i. Asbestosis, pleural thickening, or pleural plaques as established by

1. Interpretation by a single 'B Reader' qualified physician of a plain chest x-ray or

2. Interpretation of a computed tomography of the chest by a qualified physician (a physician with board certification in radiology or pulmonary medicine or an interpretation provided by the Center for Asbestos-Related Diseases (CARD) Clinic, for patients in the Libby area).

Note: This clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses.

ii. Mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by:

1. Pathologic examination of biopsy tissue or

2. Cytology from bronchioalveolar lavage.

f. Follow-up: If a patient has an initial negative B-reading, he or she may be entitled to a second and last reading by another B-reader in the panel described below. Since asbestos-related diseases require a sufficient latency between exposure and the actual development of disease, and considering that the sensitivity and specificity of screening procedures are not perfect, candidates that are not initially eligible for screening, may be entitled to additional screening, as described in the table below. The schedule for additional screening should take into consideration age and the risk of developing asbestos-related disease, according to categories of exposure, as follows:

Category	Retesting Frequency
Workers <= 35 years old	Every 3 years
Workers 36-45 years old	Every other year
Workers >= 46 years old	Every year
Non-workers <= 35 years old	Every 5 years
Non-workers 36-45 years old	Every 3 years
Non-workers <= 46 years old	Every other year

g. Quality control: To assure the consistency of screening activities, the grantee will implement the following strategies:

i. Form a panel of B-readers to serve as "acceptable B-readers" for the purposes of screening ARD under this program, to be approved by ATSDR. ATSDR anticipates that the panel will consist of at least 5 B-readers, three of which will also be board-certified radiologists. The grantee should select panel members based on the following criteria:

1. NIOSH B reader certification.

2. Active in reading at least 20 films for asbestos B reading per month as indicated on the Interpreting Physician Certification Document (CDC/NIOSH(M)2.12).

3. Board certification in radiology or pulmonary medicine.

4. Experience with asbestos-related disease.

5. Preference will be given to readers holding an academic appointment at a medical school in the U.S.

ii. Create a repository of program radiograph and HRCT images.

iii. Randomly sample radiographs held in the repository periodically for review by the entire panel of B-readers. This review will have no influence on already established status of patient benefits under the program, but will serve solely to bring consistency to the screening program.

iv. Randomly sample HRCTs held in the repository for review by the radiologists sitting on the panel. Again, this review will have no influence on already established status of patient benefits under the program, but will serve solely to bring consistency to the screening program.

h. Screening flow: The grantee should coordinate the flow of screening participants through the system. Steps in screening flow may include:

i. Pre-screening to confirm eligibility for screening according to ACA language, as described above in Section b., Eligibility for screening.

ii. Initial enrollment and obtaining participant's consent (Prior to screening, the grantee will obtain consent from each participant. The grantee will also invite each participant to participate in ATSDR's Tremolite Asbestos Registry).

iii. Prior to screening, mailing information to each screening participant about the screening program (including an overall program description, list of affiliated providers in the area, letter to personal physician or affiliated provider explaining screening requirements, and instructions for how to send radiographic exams to the grantee).

iv. Appointment scheduling.

v. Administration of screening components (radiography (radiograph and HRCT) and

FOBT, as appropriate).

vi. Onsite radiology reading. vii. Dissemination of urgent results from onsite radiology reading, if necessary.

viii. Routing radiographs to B-readers and HRCT scans to radiologists.

ix. Collecting B-reader/radiologist interpretations and disseminating to the screening physician along with a blank final diagnosis letter (to be completed by the screening physician). One copy of the final diagnosis letter will be returned to the grantee and one will be sent to the screening participant.

x. Creating a disposition for each screening participant (i.e., ARD positive or negative).

xi. Storing all screening data in a database.

xii. Reporting results to ATSDR.

xiii. According to screening results, mailing a letter to participant with instructions for how to contact SSA, if necessary, and pertinent education materials.

i. Data storage: The grantee should create and maintain a database containing survey and clinical data as well as the disposition of participants. Data elements for this database should include: number of calls received via the program's toll-free number, number of individuals eligible for screening, screening results (including B readings, HRCT readings, and final diagnosis), and number of individuals with follow-up screenings.

j. National network of providers: The grantee should establish a national network of health care providers to administer the screenings, including providers that administer the required radiologic tests (radiographs and HRCT).

k. Participant disposition, reporting, and radiologic image access:

i. The grantee should create a database to track the screening disposition for all participants.

ii. Using this database, the grantee should provide a written quarterly report to ATSDR summarizing the results of screening including number of people screened, as well as costs for administrative and outreach activities.

iii. While all screening data will reside with and be owned by the grantee, the grantee should provide ATSDR with access to all radiograph and HRCT images and other screening data collected for this program for quality control, reporting, and research purposes.

3. Health education.

a. Goal: To educate persons with possible asbestos exposure and their physicians in actions that can detect, prevent, and treat environmental health conditions. Because most of the health outcomes associated with exposure to Libby amphibole is pulmonary, smoking cessation should be one of the main areas of focus.

b. Activities:

i. Newsletter to participants: An annual newsletter should contain topics related to asbestos exposure and resulting health outcomes and ways participants can improve their health (e.g., smoking cessation).

ii. Physician education: Pamphlets describing ATSDR educational resources available to physicians, such as Case Studies in Environmental Medicine and Grand Rounds in Environmental Medicine, may be disseminated to physicians who are likely to provide care for ARD patients.

References

U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. AHRQ Publication 08-05124-EF-3. Rockville: Agency for Healthcare Research and Quality, 2008. Available: www.ahrq.gov

Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: A joint guideline from the American Cancer Society, the U.S. Multi-Society Task force on Colorectal Cancer, and the American College of Radiology. Gastroenterology 2008;134:1570–95.

Rex DK, Johnson DA, Lieberman DA, Burt RW, Sonnenberg A. Colorectal cancer prevention 2000: screening recommendations of the American College of Gastroenterology. Am J Gastroenterol 2000;95:868–77.

Davila RE, Rajan E, Baron TH, et al. ASGE guideline: Colorectal cancer screening and surveillance. Gastrointent Endosc 2006;63:546–57.

U.S. Preventive Services Task Force. Guide to Clinical Preventive Services. http://www.ahrq.gov/CLINIC/cps3dix.htm#cancer.

1.Collaborations

N/A

a. With CDC-funded programs:

The grantee will be expected to collaborate with ATSDR to optimize program reports.

b. With organizations external to CDC:

N/A

2. Target Populations

The target populations, as specified in the ACA legislation, are at-risk individuals for environmental health conditions, as defined below. An at-risk individual is defined as having been present for an aggregate total of 6 months in the geographic area subject to an emergency declaration (the towns of Libby and Troy, in Lincoln County, Montana), as specified by ACA, during a period ending:

i. not less than 10 years prior to the date of an individual's application for screening under this program; and
ii. prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7.

Environmental health conditions are defined as:

i. Asbestosis, pleural thickening, or pleural plaques as established by

1. Interpretation by a single 'B Reader' qualified physician of a plain chest x-ray or
2. Interpretation of a computed tomography of the chest by a qualified physician (a physician with board certification in radiology or pulmonary medicine or an interpretation provided by the Center for Asbestos-Related Diseases (CARD) Clinic, for patients in the Libby area). Note: This clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses.

ii. Mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by:

1. Pathologic examination of biopsy tissue or
2. Cytology from bronchioalveolar lavage.

a. Inclusion

N/A

iv. Funding Strategy (for multi-component FOAs only)

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

The grantee will track and report on appropriate process measures for the strategies/activities they have undertaken. These measures are to help track the implementation of strategies and their component activities. ATSDR will work with the awardee in the 6 months following award to finalize these measures.

Strategy/Activities	Process Measures/Indicators
Community Outreach Media campaign Community events	Types of outreach events Number of outreach events (by type)

Screening Standardized health surveys Spirometry Chest radiography High Resolution Computed Tomography Fecal occult blood test Quality control processes	Number of tests run (by test type) Number of peer review reading conducted, by type
Health Education for Community and Physicians Asbestos-related disease education Exposure risk education Smoking cessation programs	Number and type of education materials produced Methods for disseminating education materials Demographics of health education participants

Outcome Measures

As noted in the logic model and narrative, awardees are being held accountable for the short-term and intermediate outcomes in the project period. The tables below show some potential outcome measures for all relevant outcomes. These measures are to help track progress on achievement of the accountable outcomes. ATSDR will work with awardees in the 6 months following award to finalize these measures for all relevant outcomes.

Short-Term Outcomes	Potential Outcome Measures
Target audience aware of screening services Target audience aware of Medicare eligibility Individuals with correct diagnosis enrolled in Medicare Increased knowledge of the following among target community and physicians: Exposure prevention Risks of smoking Asbestos-related diseases Disease management	Number of target population residing outside of Libby that are aware of screening services Number of target population aware of Medicare benefits prior to outreach Percent of target audience who heard about screening through different outreach methods Reasons people come in for screening Percent of target population that can correctly identify: Exposure prevention Risks of smoking Asbestos-related diseases Disease management

Intermediate Outcomes	Potential Outcome Measures
Target population enrolled in disease management programs Target population enrolled in treatment (for cancer or other asbestos-related cancers) Target population reduce their exposure to asbestos Target population reduce their rate of smoking Providers improve smoking cessation programs Improved treatment/management of individuals with asbestos-related diseases Community members with negative result seek continued screening	Number of people with positive diagnosis who enroll in follow-up care Reasons that people with a positive diagnosis choose to seek care for providers other than grantee Reasons that people with positive diagnosis choose not to seek care for their condition Percent decrease in incidence of pleural plaque among those with sufficient latency Smoking frequency among target population Percent of persons newly diagnosed at earlier stage Number of persons who receive treatment for symptoms that may not have otherwise been treated Number of people with initial negative screening that report back for additional screening

ii. Applicant Evaluation and Performance Measurement Plan

c. Organizational Capacity of Awardees to Execute the Approach

d. Work Plan

Workplans must include, at a minimum:

1. A descriptive detailed year-one workplan, including objectives, activities and timelines to support the achievement of FOA outcomes. These activities must be in alignment with the FOA Logic Model and should have appropriate performance measures or milestones for accomplishing tasks. A high-level workplan for years two through four should address how progress will continue.
2. Staff and administrative roles and functions to support the implementation of the award. Awardee should identify and assign staff, contractors, and/or consultants, sufficient in number and expertise, to carry out the activities of the FOA.
3. A description of administration and assessment processes to ensure successful implementation and quality assurance.

e. CDC Monitoring and Accountability Approach
Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the
- intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.

These activities may include monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

B. Award Information

1. Funding Instrument Type:	Grant
2. Award Mechanism:	
3. Fiscal Year:	2015
Estimated Total Funding:	$2,500,000
4. Approximate Total Fiscal Year Funding:	$2,500,000
5. Approximate Project Period Funding:	$10,000,000
6. Total Project Period Length:	4 year(s)
7. Expected Number of Awards:	1
8. Approximate Average Award:	$2,500,000 Per Budget Period
9. Award Ceiling:	$2,500,000 Per Budget Period
10. Award Floor:	None
11. Estimated Award Date:	05/01/2015

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

Direct Assistance (DA) is not available through this FOA.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
State governments
County governments
City or township 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
Others (see text field entitled "Additional Information on Eligibility" for clarification)

2. Additional Information on Eligibility

From the preceding FOA elibility section:

Eligible applicants that can apply for this funding opportunity are listed below according to the authorizing legislation:

- A hospital or community health center.
- A Federally qualified health center.
- A facility of the Indian Health Service.
- A National Cancer Institute-designated cancer center.
- An agency of any State or local government.
- A nonprofit organization

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application.

The award ceiling for this FOA is $2,500,000. CDC will consider any application requesting an award higher than this amount as non- responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf)

3. Justification for Less than Maximum Competition

NA

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:	No

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

Additional materials that may be helpful to applicants: http://www.cdc.gov/od/pgo/funding/docs/Financial ReferenceGuide.pdf.

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System: All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or Internet at http:// fedgov.dnb.com/webform/displayHomePage.do. The DUNS number will be provided at no charge.If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM): The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process usually requires not more than five business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

c. Grants.gov: The first step in submitting an application online is registering your

organization through www.grants.gov, the official HHS E-grant website. Registration information is located at the "Get Registered" option at www.grants.gov.

All applicant organizations must register with www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by PGO.

a. Letter of Intent Deadline (must be emailed or postmarked by)

N/A

b. Application Deadline

Due Date for Applications: **05/11/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://www.cdc.gov/grants/interestedinapplying/applicationprocess.html.

- Complete the applicable assurances and certifications on an annual basis, name the file "Assurances and Certifications" and upload it as a PDF file at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

  Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

LOI is not requested or required as part of the application for this FOA.

8. Table of Contents

(No page limit and not included in Project Narrative limit): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Maximum of 20 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 20 pages will not be considered. The 20 page limit includes the work plan. For a multi-component FOA, maximum page limit is 25.)

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes
Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities
Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations
Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

2. Target Populations
Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. Refer back to the CDC Project Description section – Approach: Target Population.

c. Applicant Evaluation and Performance Measurement Plan
Applicants must provide an overall evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Affirm the ability to collect the performance measures and respond to the evaluation questions specified in the CDC strategy. (For guidance regarding the Paperwork Reduction Act, please visit http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html)
- Describe how key program partners will participate in the evaluation and performance measurement planning processes.
- Describe how evaluation findings will be used for continuous program quality improvement.

Where the applicant chooses to, or is expected to, take on specific evaluation studies:

- Describe the type of evaluation(s) (i.e., process, outcome, or both) to be conducted.
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information relevant to the evaluation (e.g., measures, data sources)

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's 20 page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov.

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). The CDC will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at:http://www.cdc.gov/grants/interestedinapplying/applicationresources.html .

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Grantees under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

N/A

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

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 recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care,or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.

2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/ graphics/pbs/Guidelines_for__Federal_Concessions_and_Vending__Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm

http://www. thecommunityguide.org/ tobacco/index.html

http:// www.cdc.gov /obesity /strategies /food-serv-guide.html

14. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review

Executive Order 12372 does not apply to this program.

16. Pilot Program for Enhancement of Employee Whistleblower Protections

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.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel,

travel, supplies, and services.

- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See http://www.cdc.gov/grants/additionalrequirements/index.html#ar12 for detailed guidance on this prohibition and http:// www.cdc.gov/od/pgo / funding / grants / Anti-Lobbying _ Restrictions_for_CDC_Grantees_July _2012 .pdf.

N/A

18. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A

second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Applicant User Guide, Version 1.1, page 102.

http:// www.grants.gov /documents /19/18243 /Grantsgov ApplicantUserGuide .pdf /ce754626 -c2aa-44bc- b701 -30a75bf428c8

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail or call CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC ATSDR and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review
A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach

i. Approach	**Maximum Points: 50**

Evaluate the extent to which the applicant:

Presents outcomes that are consistent with the project period outcomes described in the CDC Project Description and logic model. (10 points)

Describes an overall strategy and activities consistent with the CDC Project Description and logic model. (10 points)

Describes strategies and activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable). (10 points)

Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the project period outcomes. (10 points)

Presents a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and formatproposed by CDC. (10 points)

ii. Evaluation and Performance Measurement	**Maximum Points: 25**

Evaluate the extent to which the applicant:

Shows/affirms the ability to collect data on the process and outcome performance measures specified by CDC in the project description and presented by the applicant in their approach. (5 points)

Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities. (5 points)

Describes how performance measurement and evaluation findings will be reported, and used to demonstrate the outcomes of the FOA and for continuous program quality improvement. (5 points)

Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base. (5 points)

Describes any evaluation studies they are to undertake. Describe in sufficient detail to identify the key evaluation questions, and data sources and analysis methods. (5 points)

iii. Applicants Organizational Capacity to Implement the Approach	**Maximum Points: 25**

Evaluate the extent to which the applicant addresses the items below.

Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes. (10 points)

Demonstrates experience and capacity to implement the evaluation plan. (5 points)

Provides a staffing plan and project management structure that will be sufficient to achieve the project outcomes and which clearly defines staff roles. Provides anorganizational chart. (5 points)

Budget: When scoring budgets, CDC programs must assess whether the budget aligns with the proposed work plan. (5 points)

Is the description of why the project has a strong probability of success reasonable? Are anticipated challenges in completing the recipient activities reasonable? Do the applicant and key staff have experience with conducting outreach, screening, managing data, and education for individuals with asbestos-related diseases? Does the applicant have demonstrated access to public health data, resources, and contacts within the Libby Community?

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

c. Phase III Review

2. Announcement and Anticipated Award Dates

TBD

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC PGO. The NOA shall be the only binding, authorizing document between the awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA)

requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administrative and public policy requirements outlined in 45 C.F.R. Part 74 or Part 92 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html

The HHS Grants Policy Statement is available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

*Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Successful applicants must comply with the administrative requirements outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. The following additional requirements apply to this project:

- AR-7 Executive Order 12372
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-16 Security Clearance Requirement
- AR-19 Third Party Agreements-ATSDR
- AR-24 Health Insurance Portability and Accountability Act Requirements
- AR-25 Release and Sharing of Data
- AR-29 Compliance with E.O. 13513 Federal Leadership on Reducing Text Messaging While Driving, October 1, 2009.

For more information on the C.F.R. visit http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the FOA copying the CDC Project Officer.

Report	**When?**	**Required?**
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

Activities involving information collections (e.g., surveys, questionnaires) from 10 or more individuals/entities are subject to OMB/PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.

a. Awardee Evaluation and Performance Measurement Plan (required)
With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award.

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.

- How data will be reported.
- How evaluation findings will be used for continuous quality and program improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the FOA (e.g., improved public health outcomes, effectiveness of FOA, cost-effectiveness or cost benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

b. Annual Performance Report (APR) (required)
The awardee must submit the APR via www.grants.gov 120 days before the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.

This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
    - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
    - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Awardees must describe success stories.
- **Challenges**
    - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.
    - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Awardees**
    - Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.
    - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
    - Indirect Cost Rate Agreement.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

c. Performance Measure Reporting (optional)
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)
The annual FFR form (SF-425) is required and must be submitted through eRA Commons 90 days after the end of the calendar quarter in which the budget period ends. The report must include only 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 by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to PGO and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)
This report is due 90 days after the end of the project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

N/A

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)
The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible website, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than $25,000. For the full text of these requirements, see: http://www.gpo.gov /fdsys/browse/

collection.action?collectionCode= BILLS.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Theodore Larson, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Email: THL3@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance,** contact:

Terrian Dixon, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
Email: thd4@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:
Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: pgotim@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative

- CDC Assurances and Certifications
- Table of Contents for Entire Submission

Optional attachments, as determined by CDC programs

- Resumes/CVs
- Position descriptions
- Letters of Support
- Organizational Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate , if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additionalrequirements/index.html

. Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period.Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs

administered by the Federal Government.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the "life" of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http:// www.cdc.gov /grants /additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at

http://fedgov.dnb.com/ webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The FOA evaluation plan is used to describe how the awardee and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: http://www.whitehouse.gov/omb/ grants_spoc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to,

proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activites; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of

program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA's funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development,

implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of project period outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.