

Centers for Disease Control

Office of Public Health Preparedness and Response

Public Health Emergency Preparedness (PHEP) Cooperative Agreement CDC-RFA-TP19-1901
Application Due Date: 05/03/2019

Public Health Emergency Preparedness (PHEP) Cooperative Agreement CDC-RFA-TP19-1901 TABLE OF CONTENTS

Part I. Overview Information

- A. Federal Agency Name
- B. Funding Opportunity Title
- C. Announcement Type
- D. Agency Funding Opportunity Number
- E. Assistance Listings (CFDA) Number
- F. Dates
- G. Executive Summary

Part II. Full Text

- A. Funding Opportunity Description
- B. Award Information
- C. Eligibility Information
- D. Application and Submission Information
- E. Review and Selection Process
- F. Award Administration Information
- G. Agency Contacts
- H. Other Information
- I. Glossary

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-TP19-1901. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Public Health Emergency Preparedness (PHEP) Cooperative Agreement

C. Announcement Type: New - Type 1

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-TP19-1901

E. Assistance Listings (CFDA) Number:

93.069

F. Dates:

1. Due Date for Letter of Intent (LOI): N/A

2. Due Date for Applications: 05/03/2019, 11:59 p.m. U.S. Eastern

Standard Time, at www.grants.gov.

May 3, 2019, 11:59 p.m. EDT (Daylight Savings Time begins March 10, 2019)

3. Date for Informational Conference Call:

Wednesday, March 6, 2019, 2:30 p.m. to 4 p.m. EST

Wednesday, March 13, 2019, 2:30 p.m. to 4 p.m. EDT

Thursday, March 14, 2019, 1:30 p.m. to 3 p.m. EDT

G. Executive Summary:

1. Summary Paragraph:

State, local, tribal, and territorial public health systems must continue to sustain emergency preparedness and response capability and demonstrate operational readiness to respond to public health threats and emergencies. This notice of funding opportunity (NOFO) supports strengthening the capability of public health systems to effectively prepare for and respond to public health threats and emergencies. This announcement provides expectations and priorities for funded recipients to enhance their readiness to save lives during emergency incidents that exceed the day-to-day capacity and capability of public health response agencies. It serves as a roadmap to ensure that PHEP recipients develop strategies and activities that will increase

their ability to be operationally ready to execute plans, respond to, and recover from public health threats and emergencies. PHEP funding will ensure PHEP recipients continue to develop and sustain effective public health emergency management and response capability according to standards described in the *Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health.* These standards provide a framework to ensure that PHEP recipients, based on the PHEP logic model, apply findings from their jurisdictional risk assessments, capability self-assessments, and after-action reports to inform their strategic priorities and direct jurisdictional preparedness investments.

a. Eligible Applicants: Limited

b. NOFO Type:Cooperative Agreement

c. Approximate Number of Awards: 62

d. Total Period of Performance Funding: \$3,061,250,000

e. Average One Year Award Amount: \$10,000,000

f. Total Period of Performance Length: 5

g. Estimated Award Date: 07/01/2019

h. Cost Sharing and / or Matching Requirements: Y

CDC may not award a cooperative agreement to a state or consortium of states under these programs unless the recipient agrees that, with respect to the amount of the cooperative agreements awarded by CDC, the state will make available nonfederal contributions in the amount of 10% (\$1 for each \$10 of federal funds provided in the cooperative agreement) of the award, whether provided through financial or direct assistance. Match may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the federal government or services assisted or subsidized to any significant extent by the federal government may not be included in determining the amount of such nonfederal contributions.

Documentation of match, including methods and sources, must be included in recipient budgets each budget period, include calculations for both financial assistance and direct assistance, follow procedures for generally accepted accounting practices, and meet audit requirements.

Exceptions to Matching Funds Requirement

- The match requirement does not apply to the political subdivisions of New York City, Los Angeles County, or Chicago.
- Pursuant to department grants policy implementing 48 U.S.C. 1469a(d), any required matching (including in-kind contributions) of less than \$200,000 is waived with respect to cooperative agreements to the governments of American Samoa, Guam, the U.S. Virgin Islands, or the Northern Mariana Islands (other than those consolidated under other provisions of 48 U.S.C. 1469)."

Please refer to 45 CFR § 75.306 for more information.

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

Public health emergency preparedness and response capacity continues to be tested at national, state, local, tribal, and territorial levels. Since 9/11, CDC's Public Health Emergency Preparedness (PHEP) program has collaborated with state, local, and territorial health departments to prepare and plan for emergencies, resulting in measurable improvement. However, ongoing risks related to chemical, biological, radiological, and nuclear incidents as well as cyberattacks further underscore the importance of updating and modernizing jurisdictional all-hazards public health preparedness and response strategies to address emerging technologies and new 21st century threats.

To address these challenges, PHEP recipients must increase or maintain their levels of effectiveness across six key public health preparedness domains and focus efforts on strengthening preparedness and response capabilities to prevent or reduce morbidity and mortality. As additional public health threats continue to emerge, CDC must ensure that state, local, tribal, and territorial public health systems remain effectively prepared and ready to respond to the public health consequences of incidents or events whose scale, rapid onset, or unpredictability stresses the public health system.

This 2019-2024 funding opportunity provides fiscal resources to state, local and territorial public health agencies to advance their ability to demonstrate response readiness by the end of the period of performance (performance period). This announcement also includes greater emphasis on programmatic, fiscal, and administrative accountability. Although the PHEP cooperative agreement is no longer aligned with the Hospital Preparedness Program (HPP) within a single funding opportunity, these two distinct federal preparedness programs must continue to be organized to enhance jurisdictional coordination and collaboration between the public health and the health care systems.

This NOFO has been amended to clarify or update requirements. Red type, highlighted in yellow, indicates changes. Please see H. Other Information for more details.

b. Statutory Authorities

Section 319C-1 of the Public Health Service (PHS) Act (47 USC § 247d-3a), as amended.

c. Healthy People 2020

This NOFO addresses the "Healthy People 2020" focus area of Preparedness: https://www.healthypeople.gov/2020/topics-objectives/topic/preparedness

d. Other National Public Health Priorities and Strategies

- HHS Pandemic Influenza Plan
- Homeland Security Presidential Directives (HSPD) <u>5</u> and <u>21</u>
- Presidential Policy Directive 8 (PPD-8): National Preparedness
- National Health Security Strategy's <u>National Health Security Strategy and Implementation</u> Plan
- National Biodefense Strategy 2018
- Center for Medicare &; Medicaid Services Emergency Preparedness Rule (CMS-3178-F)
- Homeland Security Exercise and Evaluation Program (HSEEP)
- National Incident Management System (NIMS)
- National Preparedness Goal (NPG)
- National Response Framework (NRF)
- 2017-2022 Health Care Preparedness and Response Capabilities

e. Relevant Work

This NOFO builds upon relevant current and emergent CDC-supported programmatic priorities, goals, guidance, and recommendations, including, but not limited to:

- <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal and Territorial Public Health</u>
- PHEP ORR Implementation Guidance
- PHEP BP1 (FY 2019) Performance Measures Specifications and Implementation Guida nce
- 2019-2024 PHEP Supplemental Guidance and Resources
- Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness, Version 11

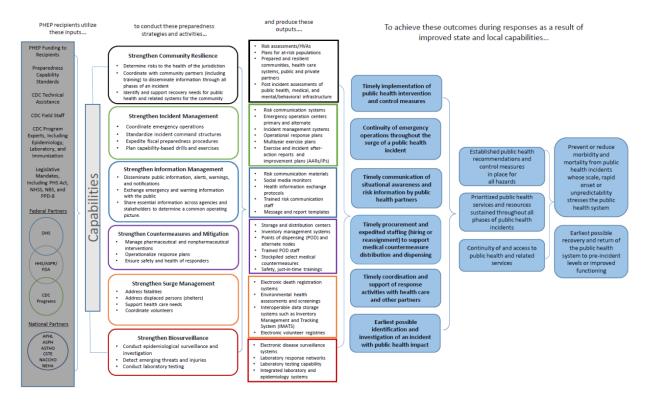
For a detailed listing of relevant work, please visit http://www.cdc.gov/phpr/coopagreement.htm.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

The <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health</u> describes 15 capability standards for PHEP recipients to strengthen during the 2019-2024 performance period. The capability standards inform the PHEP logic model, which is a high-level description of the PHEP program's general approach that displays "if-then" relationships between the program's strategies, activities, and outcomes. The logic model also highlights priority strategies and activities, provides examples of consequent outputs, and characterizes the intended outcomes that will result from building jurisdictional capabilities.



As reflected in the logic model, PHEP recipients are expected to show measurable progress toward achieving the short-term and long-term outcomes during this five-year performance period. CDC will use its Operational Readiness Review (ORR) evaluation process to measure PHEP recipient progress in achieving desired outcomes.

Subject to the availability of funding, CDC may introduce future projects that support advanced development of key public health preparedness capabilities in high population cities during the 2019-2024 performance period. This future project may support high population cities with identifying gaps and strengthening chemical and radiological preparedness.

i. Purpose

The purpose of the 2019-2024 PHEP cooperative agreement is to strengthen state, local, tribal and territorial public health preparedness and response capability through a continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action. An effective public health response will prevent or reduce morbidity and mortality from threats and emergencies whose scale, rapid onset, or unpredictability stresses the public health system and ensure the earliest possible recovery and return of the system to pre-incident levels or improved functioning.

ii. Outcomes

By the end of the performance period, PHEP recipients should build or sustain the elements identified in the <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health. CDC expects recipients to demonstrate measurable progress across the six capability domains, with a goal of achieving "established" operational readiness in all capabilities by the end of the performance period in</u>

2024. CDC will assess jurisdictional operational readiness through the ORR evaluation process, in which PHEP recipients provide specific program information and data regarding their progress in meeting operational readiness criteria.

Recipients should build or sustain their programs' strategies and activities in accordance with the expectations and requirements within this funding opportunity. Ultimately, CDC expects PHEP recipients to achieve the following program outcomes during the 2019-2024 performance period.

- Timely implementation of public health intervention and control measures
- Continuity of emergency operations throughout the surge of an emergency or incident
- Timely communication of situational awareness and risk information by public health partners
- Timely procurement and expedited staffing (hiring or reassignment) to support medical countermeasure distribution and dispensing
- Timely coordination and support of response activities with health care and other partners
- Earliest possible identification and investigation of an incident with public health impact

CDC expects these outcomes to lead to the following outcomes in future performance periods.

- Established public health recommendations and control measures in place for all hazards
- Prioritized public health services and resources sustained throughout all phases of public health incidents
- Continuity of and access to public health and related services

Ultimately, these outcomes will:

- Prevent or reduce morbidity and mortality from public health incidents whose scale, rapid onset or unpredictability stresses the public health system, and
- Result in the earliest possible recovery and return of the public health system to preincident levels or improved functioning.

iii. Strategies and Activities

The goal of the PHEP program is to develop effective public health emergency management and response programs nationwide. By the end of the performance period, PHEP recipients should build and sustain the public health emergency preparedness and response capabilities to achieve substantial, measurable progress across the six domains. Additionally, PHEP recipients are expected to demonstrate operational readiness across all domains by the end of the performance period.

CDC has developed supplemental resources to assist PHEP recipients in developing work plans that address the strategies and activities outlined in the PHEP logic model. The 2019-2024 PHEP Supplemental Guidance and Resources are available at https://www.cdc.gov/cpr/readiness/phep/library.htm.

For the 2019-2024 performance period, all PHEP recipients must address and comply with the following programmatic requirements for the PHEP logic model strategies and activities, building jurisdictional capability with the goal of achieving operational readiness for emerging infectious

diseases (EIDs) such as pandemic influenza, an anthrax event, and other public health threats and hazards. In addition, PHEP recipients must meet all statutory requirements and HHS grant guidance requirements.

CDC has modified programmatic requirements for U.S.-Affiliated Pacific Islands (USAPI) and U.S. Virgin Islands (USVI) recipients. More information is available in the 2019-2024 PHEP Supplemental Guidance and Resources: Modified Requirements for USAPI and USVI Recipients. CDC does not have modified requirements for Puerto Rico. For the purposes of this NOFO, Puerto Rico must meet the same requirements as the 50 states.

Programmatic Requirements

By the end of the performance period, PHEP recipients are expected to show measurable progress toward meeting the outcomes in the PHEP logic model by implementing the following strategies and activities organized by capability domains. CDC will require evidence of domain strategies and activities in various ways, such as work plans and other application documentation; exercise and training plans; annual progress reports; quarterly action plans; ORR documentation; and after-action reports and improvement plans (AARs/IPs).

Domain 1: Strengthen Community Resilience

Community resilience is the ability of a community, through public health agencies, to develop, maintain, and utilize collaborative relationships among government, private, and community organizations to develop and utilize shared plans for responding to and recovering from disasters and public health emergencies.

Associated Capabilities

• Capability 1: Community Preparedness

• Capability 2: Community Recovery

Determine the Risks to the Health of the Jurisdiction

Conduct public health jurisdictional risk assessments (JRA) once every five years, in collaboration with HPP, to identify potential hazards, vulnerabilities, and risks within the community that relate to the public health, medical, and mental/behavioral health systems and the access and functional needs of at-risk individuals. CDC recommends a collaborative and flexible risk assessment process that includes input from existing hazard and vulnerability analyses conducted by emergency management, health care coalitions (HCCs) and other health care organizations, as well as other community partners and stakeholders. PHEP recipients should analyze JRA results, and use diverse data sources such as the HHS Capabilities Planning Guide (CPG), previous risk assessments, jurisdictional incident AARs/IPs), site visit observations, jurisdictional data from the National Health Security Preparedness Index, and other jurisdictional priorities and strategies, to help determine their strategic priorities, identify program gaps, and, ultimately prioritize preparedness investments.

Ensure HPP Coordination

Continue assessing risk, planning, coordinating, and exercising with HPP counterparts, including HCCs. The purpose of this collaboration is to ensure a shared approach to delivering public health services alongside health care services to mitigate the public health consequences of

emergencies. PHEP resources cannot be used to supplant HPP programmatic activities. However, there are areas where coordinated planning and collaboration between the programs are beneficial, including exercising and training. PHEP recipients must conduct one statewide or regional full-scale exercise (FSE) within the five-year performance period to test preparedness capabilities. Exercises must include participation from HCCs and include, at a minimum, hospitals, public health departments, emergency management agencies, emergency medical services (EMS), and public health jurisdictions. To help minimize the burden on exercise planners and participants, CDC recommends meeting multiple program requirements with this exercise, including PHEP, HPP, medical countermeasure (MCM) planning, and Cities Readiness Initiative (CRI) requirements.

Plan for the Whole Community

Working in collaboration with HPP, continue to build and sustain state and community partnerships to ensure that activities have the widest possible reach with the strongest possible ties to the community. PHEP recipients should focus on two activities simultaneously:

- Coordination with state partners and stakeholders to review collaboration efforts with local agencies they represent across the state; and
- Review efforts of local jurisdictions to engage community partners who have established relationships with diverse at-risk populations.

Develop and maintain plans, conduct training and exercises, and respond to public health threats and emergencies using a whole-community approach to preparedness management. Plan for individuals with disabilities and others with access and functional needs. Use a flexible approach to define populations at risk to jurisdictional threats and hazards. Address a broad set of common access and functional needs using the CMIST Framework (Communication, Maintaining Health, Independence, Services and Support, and Transportation). Ultimately, the access and functional needs of individuals must be included within federal, territorial, tribal, state and local emergency and disaster plans.

CDC expects PHEP recipients to work with partners across several sectors to meet the needs of the whole community. PHEP recipients must work with partners and stakeholders on the following activities.

Identify populations at risk of being disproportionately impacted by incidents or events. Have procedures in place to identify individuals with access and functional needs that may be at risk of being disproportionately impacted by incidents with public health consequences. Individuals with access and functional needs are those that are at particular risk of poor physical, psychological or social health after an emergency. Examples of populations with access and functional needs include, but are not limited to, children, pregnant women, postpartum and lactating women, racial and ethnic minorities, older adults, persons with disability, persons with chronic disease, persons with limited English proficiency, persons with limited transportation, persons experiencing homelessness, and disenfranchised populations.

Coordinate with community-based organizations.

Identify community partners and stakeholders with established relationships with diverse at-risk populations, such as social services or faith-based organizations, and use available tools to better anticipate the potential access and functional needs of the community before, during, and after an emergency. Identify and integrate preferred communication messages and strategies for

populations with access and functional needs.

Engage with key community organizations to plan and implement preparedness and response activities tailored to that community's needs. Key community partners include public health, medical, and mental/behavioral health social networks, as well as organizations representing citizens and at-risk populations. Recipients should convene partners and stakeholders and establish clearly delineated roles and responsibilities for each partner across all hazards.

Integrate access and functional needs of individuals.

Describe the structure or processes in place to integrate the access and functional needs of individuals during a public health emergency. Use available tools to better anticipate the potential access and functional needs of at-risk community members before, during, and after an emergency.

Develop or expand child-focused planning and partnerships.

In coordination with HPP, ensure emergency preparedness and response planning and coordination with designated educational agencies and lead childcare agencies in the jurisdictions. Collaborate with child-serving institutions such as schools and daycare centers to ensure crisis preparedness plans are in place.

Consider family reunification plans for schools and day care centers, either as part of crisis preparedness plans or as separate plans for reunification. Coordinate messages and plans for reunification and for identifying the public health role in addressing children's mental health needs following emergencies.

Engage the state office on aging.

Engage the state office on aging or an equivalent office in addressing the public health emergency preparedness, response, and recovery needs of older adults.

Engage mental/behavioral health partners and stakeholders.

Engage with state, health care, and community mental/behavioral health organizations to plan and implement preparedness and response activities tailored to that community's needs. PHEP recipients should convene partners and stakeholders, and establish clearly delineated roles and responsibilities for each partner across all hazards.

Focus on Tribal Planning and Engagement

Federally recognized American Indian and Alaska Native tribes are sovereign nations having a unique legal and political trust relationship with the United States, serving as key partners in the states and communities in which they live. In the area of public health emergency preparedness and response, state and local health departments must engage with tribes in a meaningful and mutually beneficial way to ensure that all tribes and their members are fully served, while also recognizing the inherent responsibility of those nations to support their members in a culturally appropriate manner. Further, tribal nations can provide unique resources to their neighboring states and communities in many emergency situations.

The PHEP program awards federal funds to states whose boundaries include tribal reservations and tribal communities. States have a responsibility to work with tribes to ensure appropriate efforts are made to develop public health preparedness and response capability.

At a minimum, this NOFO requires joint planning with federally recognized American Indian and Alaska Native tribes within applicable PHEP jurisdictions. Recipients must describe joint

planning effort in their project narratives, work plans, and as appropriate, budgets, to include:

- How each tribe within the state participates in planning activities and exercises.
- How the state manages this engagement, such as through a tribal liaison or committee.
- How funding or support for tribal preparedness activities is determined; for instance, do tribes get direct funding from the state or does the state provide services in lieu of funding?
- How tribal preparedness activities are monitored.
- How technical assistance is provided, including training related to the public health preparedness and response capability standards.
- How tribes funded by PHEP-recipients are held accountable for preparedness activities, including financial or administrative reports, plans, or AARs.
- How states are planning for tribal populations when engagement is limited.

Ensure Emergency Support Function (ESF) Cross-Discipline Coordination and Partner and Stakeholder Collaboration

Coordinate with ESF partners and stakeholders to include, but not limited to, other public health and health care programs, HCCs, emergency management agencies, EMS providers, behavioral/mental health agencies, community organizations, older adult-serving organizations, and educational agencies and state child care lead agencies as applicable.

Establish and Maintain Senior Advisory Committee

Maintain advisory committee(s) comprised of senior officials from governmental and nongovernmental partners to integrate preparedness efforts across jurisdictions and to leverage funding streams. CDC strongly encourages PHEP recipients to broaden advisory committee membership to include senior representatives from multiple disciplines and partner organizations including, but not limited to:

- State administrative agency (SAA)
- State office on aging
- Jurisdictional HPP director, principal investigator, or coordinator
- Jurisdictional PHEP director or principal investigator
- Jurisdictional emergency management agency representative
- Jurisdictional EMS representative
- Jurisdictional medical examiner
- Jurisdictional hospital representative
- Jurisdictional immunization representative
- Tribal representatives
- Jurisdictional HCC coordinator(s)
- Jurisdictional mental/behavioral health representative
- Local health department governing board representative, local jurisdictions and associations, or regional working groups
- Community-based partners representing at-risk populations serving individuals with disabilities and others with access and functional needs
- Citizen representation to obtain public input and comment on emergency preparedness

planning

Strengthen and Implement Plans through Training and Exercising

Consistent with the Homeland Security and Evaluation Program (HSEEP) approach to exercise planning, PHEP recipients are expected to create a progressive, multiyear training and exercise program with increasingly complex exercises to improve operational readiness across multiple hazards. HSEEP guidance is available at https://www.fema.gov/media-library/assets/documents/32326.

At a minimum, PHEP recipients are expected to strengthen their training and exercising efforts through the following activities.

Develop and maintain plans.

Develop and maintain training and exercise plans for building and/or sustaining public health preparedness and response capability. PHEP recipients should identify gaps in preparedness through their JRA and CPG, determine their priorities, and develop plans for building and sustaining capabilities.

Develop and maintain current versions of the following plans (may be included as annexes or components in larger plans):

- All-hazards preparedness and response plan
- Infectious disease response plan
- Pandemic influenza plan
- Medical countermeasure distribution and dispensing plans
- Continuity of operations (COOP) plans
- Chemical, biological, radiological, and nuclear (CBRN) threat response plans
- Plan(s) that support the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) or volunteer management plan
- Communications plan

Listed plans must be reviewed, updated, and signed by the respective partners at least once every three years. Additionally, all plans must be accessible to CDC upon request and made available for review prior to site visits and ORRs.

Coordinate training, exercise planning, and implementation.

Participate in the jurisdictional annual training, exercise, and planning workshop (TEPW).

Develop and provide multiyear training and exercise plans (MYTEPs) that specify at least two years of trainings and exercises. The MYTEP should address the needs and priorities identified in previous AARs/IPs; demonstrate coordination with applicable entities, partners, and stakeholders; and describe methods to leverage and allocate resources to the maximum extent possible. MYTEPs must be submitted in DCIPHER no later than May 3, 2019.

Plan and participate in, at a minimum, one joint exercises with HPP and emergency management at least once every five years. Recipients can meet this requirement with a functional exercise (FE), an FSE, or a real incident.

Training and planning templates can be found in the in the FEMA HSEEP preparedness toolkit at https://preptoolkit.fema.gov/web/hseep-resources.

Conduct evaluation and improvement planning.

Develop evaluative processes to review, revise, and maintain plans based on the resulting priorities, needs, findings, and corrective actions of exercises, real incidents, trainings, or needs assessments. These processes must be used to develop and inform AARs/IPs.

Complete and submit AARs/IPs within 120 days after every FE, FSE, or incident involving public health. To ensure compliance with exercise requirements, PHEP recipients must submit AAR/IP forms as well as upload a copy of the AAR/IP file.

Obtain Public Comment and Input

Obtain public comment and input on public health emergency preparedness and response plans and their implementation, using existing advisory committees or a similar mechanism, to ensure continuous input from other state, local, and tribal stakeholders and the general public, including members of at-risk populations.

See Capability 1: Community Preparedness and Capability 2: Community Recovery in <u>Public</u> <u>Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health for more information.</u>

Domain 2: Strengthen Incident Management

Incident management is the ability to activate, coordinate, and manage public health emergency operations throughout all phases of an incident through use of a flexible and scalable incident command structure that is consistent with the NIMS and coordinated with the jurisdictional incident, unified, or area command structure.

Associated Capability

• Capability 3: Emergency Operations Coordination

Activate and Coordinate Public Health Emergency Operations

Have written plans and procedures in place to activate, coordinate, manage, sustain, and demobilize public health emergency operations throughout all phases of an emergency. To meet this expectation, PHEP recipients should conduct the following activities to strengthen incident management.

Update critical contact information.

Update jurisdictional points of contact twice during each budget period (December 31 and June 30), or as changes occur, to facilitate time-sensitive, accurate information sharing within the jurisdiction and between CDC and the jurisdiction.

Maintain updated all-hazards preparedness and response plans.

Maintain a current all-hazards public health preparedness and response plan, with applicable annexes. Such plans, which should be developed in conjunction with HPP, should include activities to be conducted to meet the preparedness goals described in sections 2802(b)(1), (2), (4), (5), and (6) of the PHS Act (42 U.S.C. § 300hh-1). Plans must also include descriptions of activities that address chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate and describe how jurisdictions will partner with relevant public and private partners and stakeholders during responses. PHEP recipients also should include provisions for mobilizing other state and local personnel from their jurisdictions when reassigned to preparedness and response activities during a public health emergency.

Updated all-hazards preparedness and response plans should include but not be limited to:

- Procedures for how preliminary assessments are conducted to determine the need for activation of public health emergency operations;
- Process for establishing a flexible and scalable public health incident management structure that is consistent with NIMS and jurisdictional standards and authorities;
- Procedures for activating, operating, managing, and staffing the public health emergency operations center or implementing public health functions within another emergency operations center;
- Designation of primary and alternate locations, including virtual communication structures, for the public health emergency operations center;
- Procedures for demobilizing public health emergency operations; and
- A description of how the jurisdiction will use Emergency Management Assistance Compact (EMAC) or other mutual aid agreements for public health and medical mutual aid to support coordinated activities and to share resources, facilities, services, and other potential support required when responding to emergencies that impact the public's health. At minimum, this plan should include the following:
 - Procedures for evaluating, responding to, and seeking reimbursement for resources deployed under EMAC;
 - Description of how information will be shared between relevant partners for a resource request;
 - o Processes, procedures, and threshold(s) for deploying a requested resource;
 - Documented roles and responsibilities during a resource request within the state public health agency;
 - Redundant points of contact for all state's public health and medical Mission Ready Packages (MRPs) as applicable; and
 - o Description of reimbursement processes following a deployment for both the deployed personnel and the key internal staff.

For more information see <u>FEMA Comprehensive Preparedness Guide 101: Developing and Maint aining Emergence Operations Plans.</u>

Maintain and exercise continuity of operations (COOP) plans. Maintain a current COOP plan that includes the following elements.

- Definitions, identification, and prioritization of essential services needed to sustain public health agency mission and operations, including laboratory services that ensure the ability to conduct ongoing testing of routine and emerging public health threats
- Procedures to sustain essential services regardless of the nature of the incident (all-hazards planning);
- Positions, skills, and personnel needed to continue essential services and functions (human capital management);
- Identification of public health agency and personnel roles and responsibilities in support of ESF #8;
- Scalable workforce expansion and reduction, in response to needs of the incident;
- Limited access to facilities due to issues such as structural safety or security concerns;

- Broad-based implementation of social distancing policies;
- Identification of agency vital records (such as legal documents, payroll, personnel assignments) that must be preserved to support essential functions or for other reasons;
- Alternate and virtual work sites:
- Devolution of uninterruptible services for scaled down operations;
- Reconstitution of uninterruptible services; and
- Cost of additional services to augment recovery.

PHEP recipients must test their COOP plans, including their jurisdictional public health laboratory COOP plans, during a real incident, a tabletop exercise (TTX), an FE, or an FSE at least once every five years. CDC strongly encourages recipients to coordinate with HPP to complete this requirement, either separately or as part of a broader exercise.

Maintain personnel lists.

Maintain a list of personnel with necessary skills to fulfill required incident command and public health incident management roles. Test staff assembly processes for notifying personnel to report physically or virtually to the public health emergency operations center or jurisdictional emergency operations center during a drill or real-time incidents at least once during the budget period.

Maintain and Exercise Fiscal and Administrative Preparedness Plans

The fiscal, legal, and administrative authorities and practices that govern funding, procurement, contracting, and hiring must be appropriately integrated into all stages of emergency preparedness and response. Identifying and removing barriers that prevent the timely implementation of response activities will speed the acquisition of goods and services, the hiring or assignment of response personnel, the disposition of emergency funds, and legal determinations needed to implement protective health measures during a public health response.

Describe standard fiscal operating procedures.

Document the time it takes to move funds from the state public health agency to local public health agencies, both during emergencies and during routine grant administration.

Submit administrative preparedness plans to speed hiring and contracting during emergencies. Update and submit a plan to speed hiring, contracting, and dispensing funds during emergencies to CDC at least once every five years. At minimum, the plan should include the following elements and processes.

Fiscal Planning: Alignment of the PHEP administrative processes to describe how funds will be managed, including processes for:

- Streamlining and consolidating contracting procedures; and
- Tracking PHEP and other CDC grants or cooperative agreements separately as, according to federal appropriations law and HHS grant guidance, PHEP funds must maintain their unique identity and must be used for their intended purposes.

Emergency Legal Authority: Describe and provide PHEP recipient citations (as applicable) for emergency legal authorities applicable to the Public Health Emergency Law Competency Model, including authorities addressing:

- Procedures for the declaration of disasters or emergencies and accompanying emergency authorities for designated officials;
- Expedited procedures for receiving, allocating, and spending emergency funds, including the ability to quickly move emergency funds from the state level to local governments;
- Powers and procedures for the use of public health interventions including isolation, quarantine, and the seizure and reallocation of supplies;
- Emergency suspensions, waivers, or similar legal processes that can be used to minimize the potential conflicts between federal authorities applicable to medical countermeasures and state-based pharmaceutical, prescribing, labeling, and other drug-related laws; if no waivers or similar legal processes exist, PHEP recipients must describe laws that may potentially conflict with emergency use authorizations (EUAs), emergency use instructions (EUI), and investigational new drug (IND) and investigational device exemptions;
- Protocol or formal memoranda of understanding or agreement (MOU/MOA) between health authorities and other preparedness partners including law enforcement for implementation of public health activities, such as joint investigations of intentional threats or incidents that impact the public's health, signed and executed between state public health departments, including local public health departments where relevant, such as in home rule states; and
- Protection of volunteers against tort liability and licensure penalties, and the provision of
 workers' compensation claims, excluding federal mechanisms such as the Public
 Readiness and Emergency Preparedness Act. PHEP recipients should distinguish between
 in-state and out-of-state volunteers and indicate whether the state can use EMAC to send
 or receive volunteers.

Fiscal and Administrative Emergency Processes: Describe expedited fiscal and other administrative processes and identify procedures to test fiscal preparedness planning for such activities, including:

- Emergency procurement and contracting authorities and processes and how they differ from day-to-day business processes;
- Receiving emergency funds during a real incident or exercise, as well as reducing the cycle time for contracting or procurement during a real incident or exercise;
- Emergency hiring processes (workforce surge) and how they differ from customary hiring processes;
- Reporting and monitoring methodology to ensure payment efficiency and funding accountability;
- Emergency procedures for allocating funds to local and tribal health departments and other subrecipients;
- Internal controls related to subrecipient monitoring and any negative audit findings resulting from suboptimal internal controls; and
- Internal controls that allow recipients to receive other federal preparedness and response grant funding without the potential for supplanting or commingling of funds.

Conduct a fiscal and administrative preparedness tabletop exercise.

Test fiscal and administrative preparedness processes during a real incident or tabletop exercise (TTX) at least once every five years. CDC strongly encourages recipients to coordinate with HPP to complete this requirement

See Capability 3: Emergency Operations Coordination in <u>Public Health Emergency Preparedness</u> <u>and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public</u> <u>Health</u> for more information.

Domain 3: Strengthen Information Management

Information management is the ability to develop and maintain systems and procedures that facilitate the communication of timely, accurate, and accessible information, alerts, and warnings using a whole community approach. It also includes the ability to exchange health information and situational awareness with federal, state, local, territorial, and tribal governments and partners.

Associated Capabilities

- Capability 4: Emergency Public Information and Warning
- Capability 6: Information Sharing

Maintain Situational Awareness during Incidents

Establish a common operating picture (COP), or situational awareness tool, that facilitates coordinated information sharing among all public health, health care, and necessary partners and stakeholders. This includes state, local, tribal, and territorial public health agencies and their respective preparedness programs, public health laboratories, communicable disease programs, and programs addressing health care-acquired infections. Information sharing is the ability to share real-time information related to the emergency, such as capacity, capability, and stress on health care facilities and situational awareness across the various response organizations and different levels of government. Accomplishing these activities will enable public health and other organizations and responders to contribute to responses to coordinate efforts before, during, and after emergencies; maintain situational awareness; and effectively communicate with the public.

To reduce undue burden on PHEP and HPP recipients, CDC and ASPR will coordinate both within HHS and with interagency federal partners to reduce duplicative requests for information. Recipients and subrecipients may provide requested information in any format used by their organizations, such as a situation report (SITREP) or a spot report (SPOTREP).

Coordinate Information Sharing

Have or have access to communication systems that maintain or improve reliable, resilient, interoperable, and redundant information and communication systems and platforms, including those for bed availability, EMS data, and patient tracking, and provide access to HCC members and other partners and stakeholders. Such systems, whether they are internally managed or externally hosted on shared platforms, must be capable of supporting syndromic surveillance, integrated surveillance, active and/or passive mortality surveillance, public health registries, situational awareness dashboards, and other public health and preparedness activities. CDC recommends that PHEP recipients conduct training on coordinated information sharing to develop competent personnel to manage and support these systems.

Have plans in place that identify redundant communication platforms (primary and secondary)

and a cycle of maintenance and testing of these platforms every six months.

Provide situational awareness data to CDC during emergency response operations and at other times, as requested.

See the 2019-2024 PHEP Supplemental Guidance and Resources: Public Health Informatics for more information.

Coordinate Emergency Information and Warning

In conjunction with HPP, develop, coordinate, and disseminate information, alerts, warnings, and notifications to the public.

Have plans in place to stand up joint information communication centers when needed. Have plans in place that demonstrate ability to monitor jurisdictional media, conduct press briefings, and provide rumor control for media outlets, using the principles of the NIMS for organizing and coordinating incident-related communications.

Complete the following:

- Have a communication plan that identifies the public information officer (PIO) and supporting personnel responsible for implementing jurisdictional public information and communication strategies. Plans must outline requirements and duties; roles and responsibilities; and required qualifications or skills for PIO personnel.
- Use crisis and emergency risk emergency communication (CERC) principles to disseminate critical health and safety information to alert the media, public, community-based organizations, and other stakeholders to potential health risks and reduce the risk of exposure. Develop message templates based on planning or risk scenarios identified in risk assessments and incorporate these into the communication plans as applicable.
- Ensure that PIOs, or other personnel, receive training in topics including, but not limited to: CERC, health communication, and cultural competency; and are able to employ these principles in an emergency.
- Ensure that communication plans have processes for coordinating public messaging during infectious disease outbreaks and information sharing regarding monitoring and tracking of cases of persons under investigation to ensure maximum coordination and consistency of messaging.
- Ensure communication plans have a process for coordinating messages for government officials, first responders, and community leaders during highly infectious disease responses.

See Capability 4: Emergency Public information and Warning and Capability 6: Information Sharing in <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health for more information.</u>

Domain 4: Strengthen Countermeasures and Mitigation

Countermeasures and mitigation is the ability to distribute, dispense, and administer medical countermeasures (MCMs) to reduce morbidity and mortality and to implement appropriate nonpharmaceutical and responder safety and health measures during response to a public health incident.

Associated Capabilities

- Capability 8: Medical Countermeasure Dispensing and Administration
- Capability 9: Medical Materiel Management and Distribution
- Capability 11: Nonpharmaceutical Interventions
- Capability 14: Responder Safety and Health

Develop and Test Plans for MCM Distribution, Dispensing, and Vaccine Administration Operationalize MCM distribution, dispensing, and vaccine administration plans through development, training, exercising, and evaluating these MCM plans. Managing access to and administration of countermeasures and ensuring the safety and health of clinical and other personnel are important priorities for preparedness and continuity of operations. Jurisdictions participating in the CHEMPACK program, Cities Readiness Initiative (CRI), or other planning for maintaining treatment or prophylaxis caches must be engaged in the development, training, and exercising of plans for MCM distribution, dispensing, and vaccine administration and work closely with HPP to ensure effective care is delivered following an emergency. This includes open and closed points of dispensing (POD) plans and plans to leverage community vaccine providers in large pandemic influenza-like responses. For more information, see the *Public Healt h Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health*.

Recommendation: Award 75% of CRI Funding to Improve Local Capability CDC strongly encourages that PHEP recipients make 75% of their CRI funds available to their CRI jurisdictions within 90 days of the start of the budget period to improve all-hazards MCM distribution and dispensing planning and response capabilities. CDC will review local MCM ORR data for evidence of improved local capabilities.

Demonstrate Operational Readiness for Multiple Risks

Historically, all 62 PHEP jurisdictions and their local planning jurisdictions have been required to plan and exercise around a common planning scenario: an intentional release of anthrax. CDC subject matter experts, state and local preparedness directors, and other national experts agree that jurisdictions should also more broadly incorporate EID scenarios into their MCM planning. For the 2019- 2024 performance period, CDC will require all PHEP recipients and local CRI planning jurisdictions to ensure elements of planning and operational readiness for two specific threats: the intentional release of a Category A agent, such as anthrax, and an EID, such as pandemic influenza. CDC has determined key operational readiness elements for both planning scenarios. All PHEP recipients and their local CRI planning jurisdictions must have in place these essential planning elements to respond to both an intentional release of anthrax and pandemic influenza. A jurisdiction that is able to demonstrate these key components is likely to be in an improved state of readiness for all hazards. See the 2019-2024 PHEP Supplemental Guidance and Resources: Key Components of Pandemic Influenza Operational Readiness and Key Components of Anthrax Operational Readiness for more information.

While PHEP jurisdictions must continue to prepare for all potential threats, only those at higher risk must demonstrate readiness for an intentional release of anthrax. Using a variety of federal risk assessments and other data, CDC identified the metropolitan statistical areas (MSAs) that must focus on an intentional release of anthrax as their primary planning scenario. The following MSAs must demonstrate operational readiness by conducting an anthrax distribution FSE once

every five years.

- o Atlanta- Sandy Springs-Roswell, GA
- o Baltimore-Columbia-Towson, MD
- o Boston-Cambridge-Newton, MA-NH
- o Chicago-Naperville-Elgin, IL-IN-WI
- o Cleveland-Elyria, OH
- o Dallas-Fort Worth-Arlington, TX
- o Detroit-Warren-Dearborn, MI
- o Houston-The Woodlands-Sugar Land, TX
- o Las Vegas-Henderson-Paradise, NV
- Los Angeles-Long Beach-Anaheim, CA
- o Miami-Fort Lauderdale- West Palm Beach, FL
- o New York-Newark-Jersey City, NY-NJ-PA
- o Orlando-Kissimmee-Sanford, FL
- o Philadelphia-Camden-Wilmington, PA-NJ-DE
- o San Diego-Carlsbad, CA
- o San Francisco-Oakland-Hayward, CA
- o Tampa-St. Petersburg-Clearwater, FL
- o Washington-Arlington-Alexandria, DC-VA-MD

The remaining CRI jurisdictions must demonstrate operational readiness for an influenza pandemic through an FSE conducted once every five years. For pandemic influenza preparedness planning, all PHEP recipients and CRI jurisdictions must collaborate with immunization programs to develop, maintain, and exercise their pandemic influenza plans to prevent, control, and mitigate the impact of pandemic influenza on the public's health and to help meet pandemic vaccination goals for the general population.

Maintain Preparedness Plans Based on Risks

All PHEP recipients must have in place essential planning elements to respond to both an intentional release of anthrax and a pandemic influenza.

Maintain and update anthrax plans.

For a public health response to an intentional release of anthrax, all PHEP recipients and CRI jurisdictions must have updated plans that outline how the jurisdiction will provide MCMs, including antibiotics and vaccines for post-exposure prophylaxis and antibiotics and antitoxin for treatment, to the potentially infected populations within 48 hours. Plans should be effectively coordinated with CRI and local jurisdictional MCM dispensing plans.

Maintain and update pandemic influenza plans.

All recipients and CRI jurisdictions must seek subject matter expertise and collaborate with health department programs including immunization programs and other subject matter experts to update pandemic influenza plans to prevent, control, and mitigate the impact on the public's health. Plans should address ways to help meet pandemic vaccination goals for the general population and goals targeting vaccination of critical workforce personnel:

• Address multiple capabilities, drawing on a wide spectrum of subject matter expertise in surveillance, epidemiology, laboratory testing, community mitigation measures, MCMs

(both vaccines, antiviral drugs, and others), health care system preparedness and response activities, communications and public outreach, scientific infrastructure preparedness, regulatory and legal considerations, and domestic response policy and incident management;

- Determine jurisdictional readiness to vaccinate critical workforce personnel with two doses of pandemic influenza vaccine, separated by 21 days, within four weeks of influenza vaccine availability;
- Determine readiness of the jurisdiction's vaccine providers and partners to vaccinate at least 80% of the jurisdiction's population with two doses of pandemic influenza vaccine, separated by 21 days, within 12 weeks of pandemic influenza vaccine availability; and
- Estimate pandemic vaccine administration capacity based on potential number, types, participation rate, and throughput of vaccine providers and settings. This includes health care provider offices, pharmacies, school-based health centers, worksites and occupational health clinics, hospitals, federal facilities with vaccine administration capabilities, and PODs or dispensing and vaccination clinics that would participate in a pandemic vaccine response.

See the <u>Pandemic Influenza Guidance for State and Local Planning</u> and the 2019-2024 PHEP Supplemental Guidance and Resources: Key Components of Pandemic Influenza Operational Readiness and Key Components of Anthrax Operational Readiness for more information.

Ensure Scalable Staffing Plans

Ensure, to the greatest extent possible, that staffing plans are scalable to adapt to changing requirements based on the incident size, scope and complexity. The number, type, and sources of resources must be able to quickly mobilize or demobilize. Plans should be able to guide the mobilization of large numbers of resources including staff, volunteers, equipment, and facilities during a large response. Plans should also provide flexibility to guide responses to smaller incidents that pose a serious public health threat.

Recipients should consider inclusion of the following strategies in their MCM plans, in addition to local support from community organizations, businesses, and other entities.

- Using the National Guard as a potential resource for MCM distribution and dispensing operations or vaccine administration operations.
- Explore the eligibility of federal workers assigned to state or regional offices to serve temporarily to staff state and local MCM dispensing or vaccine administration operations in their jurisdiction.
- In addition to state-funded personnel, Sections 319C-1 of the PHS Act provides the HHS Secretary with discretion to authorize the temporary reassignment of certain federally funded state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization; the temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction.

Conduct Required MCM Exercises

The following information details CDC's expectations for MCM exercises. Recipients must meet

these exercise requirements once every five years unless noted otherwise. In addition, there are exercise requirements outside of Domain 4; these are included in the Administrative Requirements and Assurances section.

CDC requires PHEP recipients to adopt an HSEEP framework in their planning and exercising to ensure a consistent and interoperable approach to improvement planning. This progressive exercise program management approach includes exercises anchored to a common set of objectives, built toward an increasing level of complexity over time, and involves the participation of partners and stakeholders. Because exercises should adopt a "crawl, walk, run" approach and include various stakeholders and partners, CDC requires the following progressive exercises in the 2019-2024 performance period. A real incident that incorporates the same operational elements fulfills any level of exercise requirement for the same operational period.

- Higher-risk CRI planning jurisdictions (anthrax focus)
 - Complete three annual dispensing drills (facility setup, staff notification and assembly, and site activation), alternating each year between anthrax and pandemic influenza scenarios.
 - o Complete two TTXs every five years, one to demonstrate readiness for an anthrax scenario and one for a pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.
 - Demonstrate operational readiness for the intentional release of anthrax through the completion of a dispensing FSE (including dispensing throughput drill) once every five years.
- All other CRI planning jurisdictions (pandemic influenza focus)
 - Complete three annual dispensing drills (facility setup, staff notification and assembly, and site activation), alternating each year between anthrax and pandemic influenza scenarios.
 - o Complete two TTXs every five years, one to demonstrate readiness for an anthrax scenario and one for a pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.
 - o Demonstrate operational readiness for a pandemic influenza scenario through the completion of an FSE once every five years.
- Directly funded localities (both scenarios)
 - Complete three annual dispensing drills (facility setup, staff notification and assembly, and site activation), alternating each year between anthrax and pandemic influenza scenarios.
 - o Complete two TTXs every five years, one to demonstrate readiness for an anthrax scenario and one for a pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.

- Demonstrate operational readiness for the intentional release of anthrax through the completion of a dispensing FSE (including dispensing throughput drill) once every five years.
- o Demonstrate operational readiness for the intentional release of anthrax through the completion of a distribution FSE once every five years.
- US-affiliated Pacific Island jurisdictions and the U.S. Virgin Islands (pandemic influenza focus)
 - Complete one TTX every five years to demonstrate readiness for a pandemic influenza scenario.
 - o Optional/not required: Demonstrate operational readiness for a pandemic influenza scenario through the completion of an FSE once every five years.
- State recipients with higher-risk CRI planning jurisdictions
 - o Complete two TTXs every five years, one to demonstrate readiness for the anthrax scenario and one for the pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.
 - Demonstrate operational readiness for the intentional release of anthrax through the completion of a distribution FSE once every five years.
- State recipients without higher-risk CRI planning jurisdictions and Puerto Rico (pandemic influenza focus)
 - o Complete two TTXs every five years, one to demonstrate readiness for the anthrax scenario and one for the pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.
 - o Demonstrate operational readiness for a pandemic influenza scenario through the completion of an FSE once every five years.
- State recipients with both categories of CRI planning jurisdictions (both scenarios)
 - o Complete two TTXs every five years, one to demonstrate readiness for the anthrax scenario and one for the pandemic influenza scenario.
 - Complete an FE once every five years, focusing on vaccination of at least one critical workforce group, to demonstrate readiness for a pandemic influenza scenario.
 - o Demonstrate operational readiness for the intentional release of anthrax through the completion of a distribution FSE once every five years *or* demonstrate operational readiness for a pandemic influenza scenario through the completion of an FSE once every five years.

Participate in ORRs

All 62 PHEP recipients are required to participate in an ORR and must meet all requirements outlined in the <u>Public Health Emergency Preparedness (PHEP) Operational Readiness Review Guidance</u>. Historically, the ORR focused solely on MCM planning and operations. During

Budget Period 1, the ORR will maintain an MCM focus for the 62 PHEP recipients and their CRI jurisdictions but will also include pandemic influenza planning and response elements. Beginning in July 2020, the start of Budget Period 2, CDC plans to expand the ORR to include a comprehensive evaluation of planning and operational readiness based on elements across all 15 public health preparedness and response capabilities.

CDC will conduct, within a two-year cycle, ORRs in all 62 PHEP recipient jurisdictions and will collaborate on the ORR process with the states that have the higher risk CRI jurisdictions. At least 20 business days prior to the CDC ORR site visit, PHEP recipients must submit ORR forms and supporting documentation into the ORR online system.

PHEP recipients are required to conduct operational reviews for all remaining CRI planning jurisdictions within a two-year period. CDC recommends PHEP recipients review 50% of the CRI planning jurisdictions every other year. States must submit the resulting ORR data from their CRI reviews to CDC using the ORR online system. CDC may attend one or more ORRs per CRI MSA to ensure consistency and provide feedback.

Local health departments that have successfully achieved Project Public Health Ready (PPHR) recognition (or re-recognition) status will qualify for exemption from the planning elements of the ORR process. Successful and active PPHR recognition will fulfill the local ORR planning requirements for the duration of the five-year recognition period. Similar to accreditation, local jurisdictions that have a role in public health response activities may apply for PPHR recognition through a state-supported model. States unfamiliar with the PPHR process should contact the National Association of County and City Health Officials (NACCHO), which administers the PPHR program.

Through a cooperative agreement with CDC, NACCHO established Project Public Health Ready (PPHR) in 2002. Project Public Health Ready (PPHR) is a criteria-based training and recognition program that assesses local health department capacity and capability to plan for, respond to, and recover from public health emergencies. Application fees for the PPHR program are PHEP-eligible expenses. The PPHR application and review process occurs on a yearly basis beginning in October and concluding 18 months later in June. Visit www.naccho.org/pphr for more information on PPHR application and recognition requirements.

CDC and PHEP recipients will address identified improvement areas based on the most recent ORR findings. To help jurisdictions move toward "established" status levels for MCM operational readiness on or before June 30, 2022, CDC will work with all 62 PHEP recipients and higher-risk CRI MSAs to complete activities designed to address identified planning and operational opportunities for improvement.

CDC may publicly release data collected during the ORR in CDC state-based and other reports.

Submit ORR Forms and Documentation

The ORR has three sections: 1) descriptive and demographic, 2) planning, and 3) operational. Each section collects information to allow CDC to evaluate a jurisdiction's ability to execute a large response during a public health emergency. Detailed guidance on specific data requirements for each section of the ORR is located in the <u>Public Health Emergency Preparedness (PHEP)</u>
Operational Readiness Review Guidance.

Submit Updated MCM Action Plans

Submit updated MCM action plans and participate in quarterly conference calls with CDC to

discuss action plan activities. The action plans focus on activities designed to address prioritized MCM planning and operational gaps identified during a jurisdiction's most recent ORR.

In addition, states must obtain or develop MCM action plans for all of their CRI local planning jurisdictions, conduct quarterly conference calls with the CRI jurisdictions, and submit updated MCM action plans to CDC biannually. Each action plan must summarize activities based on areas for improvement identified in the jurisdiction's most recent ORR.

Conduct Inventory Management Tracking System and Data Exchange Annual Tests
Provide inventory counts to CDC during a public health emergency. PHEP recipients may use either CDC's Inventory Management and Tracking System (IMATS) with built-in reporting functionality or configure their own inventory management systems using CDC's Inventory Data Exchange Specification guide, enabling them to receive and respond to an inventory request from CDC. The chosen system must be IMATs-compatible. PHEP recipients must participate in annual tests that provide MCM inventory counts to the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) to ensure data reports of inventory levels are reliable.

Update Receipt, Stage, and Store (RSS) Site Surveys

Complete the RSS site survey form annually. RSS site information is required for the primary and backup RSS sites, a minimum of at least two locations, and all potential RSS sites in the jurisdiction. PHEP recipients are required to validate each RSS site, with CDC and a U.S. Marshals Service representative, at least once every three years.

Coordinate Nonpharmaceutical Interventions

Coordinate with and support partner agencies to plan and implement nonpharmaceutical interventions (NPIs) by developing and updating plans for isolation, quarantine, temporary school and child care closures and dismissals, mass gathering (large event) cancellations and restrictions on movement, including border control measures. Plans must:

- Document applicable jurisdictional, legal, and regulatory authorities necessary for implementation of NPIs in routine and incident-specific situations.
- Delineate roles and responsibilities of health, law enforcement, emergency management, chief executive, and other relevant agencies and partners.
- Define procedures, triggers, and necessary authorizations to implement NPIs, whether addressing individuals, groups, facilities, animals, food products, public works/utilities, or travelers passing through ports of entry.
- Determine occupational and exposure prevention measures, such as decontamination or evacuation strategies.

Ensure Safety and Health of Responders

In coordination with HPP, PHEP recipients must assist, train, and provide resources necessary to protect public health first responders, critical workforce personnel, and critical infrastructure workforce from hazards during response and recovery operations. Assistance may include personal protective equipment (PPE), MCMs, workplace violence training, psychological first aid training, and other resources specific to an emergency that would protect responders and health care workers from illness or injury at the state and local levels. This may include developing clearance goals for contaminated areas based on guidance from a committee of subject matter experts. It may also include a stand-up team, trained and properly equipped to conduct

environmental sampling according to CDC-recommended methods.

See the Glossary for definitions of critical workforce personnel and critical infrastructure workforce.

Demonstrate MCM Operational Readiness - PHEP Benchmark

PHEP recipients must demonstrate readiness to receive, stage, store, distribute, and dispense or administer MCMs during a public health emergency. This benchmark applies to all 62 PHEP recipients. On or before the end of Budget Period 3, June 30, 2022, 100% of PHEP recipients must achieve an overall status level of "established" for MCM operational readiness. In Budget Period 1, PHEP recipients must complete and submit:

- MCM operational readiness review data;
- Reports demonstrating significant annual progress in mitigating MCM gaps identified through the MCM ORR process, including gaps in pandemic influenza preparedness; and
- Review approximately 50% of their local CRI planning jurisdictions and provide ORR data for each review, with the remaining CRI jurisdictions reviewed during the following budget period. Such updates are required to track progress on addressing identified gaps. In subsequent budget periods, all PHEP recipients must submit quarterly action plans and annual progress reports that demonstrate they continue to make measurable improvements in mitigating MCM gaps identified through their most recent MCM ORR findings, including gaps in pandemic influenza preparedness, to ensure that PHEP recipients meet the CDC standard of achieving an overall status level of "established" on or before June 30, 2022.

See the Evaluation and Performance Measurement section for more information on PHEP benchmarks.

See Capability 8: Medical Countermeasure Dispensing and Administration, Capability 9: Medical Materiel Management and Distribution, Capability 11: Nonpharmaceutical Interventions, and Capability 14: Responder Safety and Health in Public Health for more information.

Domain 5: Strengthen Surge Management

Surge management is the ability to coordinate jurisdictional partners and stakeholders to ensure adequate public health, health care, and behavioral services and resources are available during events that exceed the limits of the normal public health and medical infrastructure of an affected community. This includes coordinating expansion of access to public health, health care and behavioral services; mobilizing medical and other volunteers as surge personnel; conducting ongoing surveillance and public health assessments at congregate locations; and coordinating with organizations and agencies to provide fatality management services.

Associated Capabilities

- Capability 5: Fatality Management
- Capability 7: Mass Care
- Capability 10: Medical Surge

• Capability 15: Volunteer Management

Coordinate Activities to Manage Public Health and Medical Surge

Coordinate with HPP, HCCs, health care organizations, emergency management, and other relevant partners and stakeholders to assess the public health and medical surge needs of the affected community. At minimum, PHEP recipients must have written plans in place that clearly define the public health roles and responsibilities during surge operations and outline procedures on how public health will engage the health care system to provide and receive situational awareness throughout the surge event.

<u>Coordinate Public Health, Health Care, Mental/Behavioral Health, and Human Services Needs</u> <u>during Mass Care Operations</u>

In collaboration with HPP, recipients should coordinate with and support partner agencies to address, within congregate locations (excluding shelter-in-place locations), the public health, health care, mental/behavioral health, and human services needs of those impacted by an incident. In collaboration with ESF #6, #8, and #11 partners, health care, emergency management, and other pertinent stakeholders, PHEP recipients should develop, refine, or maintain written plans that identify the public health roles and responsibilities in supporting mass care operations. At minimum, these plans should address:

- Procedures on how ongoing surveillance and public health assessments will be coordinated to ensure that the public health, health care, mental/behavioral health and human services needs of those impacted by the incident continue to be met while at congregate locations; and
- Procedures to support or implement family reunification, including any special considerations for children.

<u>Coordinate with Partners to Address Public Health Needs during Fatality Management</u> Operations

Coordinate with and support partner agencies to address fatality management needs resulting from an incident. In collaboration with jurisdictional partners and stakeholders, PHEP recipients should conduct the following activities.

- Coordinate with subject matter experts and cross-disciplinary partners and stakeholders to clarify, document, and communicate the public health agency role in fatality management, based on jurisdictional risks, incident needs, and partner and stakeholder authorities. The public health agency role may include supporting:
 - o Recovery and preservation of remains,
 - Identification of the deceased.
 - o Determination of cause and manner of death, including whether disaster-related
 - o Release of remains to an authorized individual,
 - o Provision of mental/behavioral health assistance, and
 - o Plans to include culturally appropriate messaging around handling of remains.
- Coordinate with HCCs and other community partners, including law enforcement, emergency management, and medical examiners or coroners to ensure proper tracking, transportation, handling, and storage of human remains and ensure access to mental and behavioral health services for responders and families impacted by an incident.

- Have procedures in place to identify and support public health agency lead and/or support
 activities for fatality incident management, including continuity of operations, based on
 incident data and recommendations.
- Have procedures in place to share information with fatality management partners, including fusion centers or comparable centers and agencies, emergency operations centers, and epidemiologist(s), to provide and receive relevant surveillance information that may impact the response.

Coordinate Medical and Other Volunteers to Support Public Health and Medical Surge Coordinate with HPP, emergency management, and other partners and stakeholders to identify, recruit, register, train, and engage volunteers to support the jurisdiction's response to public health emergencies. Volunteers should be included in training, drills, and exercises throughout the five-year performance period to demonstrate skills and competencies.

Conduct the following activities to address volunteer planning considerations.

- Estimate the anticipated number of public health volunteers and health professional roles based on identified situations and resource needs.
- Identify and address volunteer liability, licensure, workers' compensation, scope of practice, and third-party reimbursement issues that may deter volunteer use.
- Identify processes to assist with volunteer coordination, including protocols to handle walk-up volunteers and others who cannot participate due to state regulations.

 Jurisdictions that do not use spontaneous or other volunteers due to state regulations must describe in their plans how they plan to handle those types of volunteers during an incident.
- Implement plans that comply with ESAR-VHP requirements regarding effective management and interjurisdictional movement of volunteer health personnel during emergencies.
- Leverage existing government and non-governmental volunteer registration programs, such as ESAR-VHP and Medical Reserve Corps (MRC).
- Develop a mechanism for rapid credential verification processes to facilitate emergency response.

To the greatest extent possible, all plans should be scalable to adapt to changing requirements based on the incident size, scope, and complexity. The number, type, and sources of resources must be able to expand or retract rapidly. In terms of staffing a large response, PHEP recipients should consider inclusion of the following nontraditional strategies in their plans:

- Using the National Guard as a potential resource for response operations.
- Explore whether federal workers assigned to state or regional office may be eligible to serve temporary details to staff state and local response operations in their jurisdiction.

See Capability 5: Fatality Management, Capability 7: Mass Care, Capability 10: Medical Surge, and Capability 15: Volunteer Management in <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health</u> for more information.

Domain 6: Strengthen Biosurveillance

Biosurveillance is the ability to conduct rapid and accurate laboratory tests to identify biological, chemical, radiological, and nuclear agents; and the ability to identify, discover, locate, and monitor - through active and passive surveillance - threats, disease agents, incidents, outbreaks, and adverse events, and provide relevant information in a timely manner to stakeholders and the public.

Associated Capabilities

- Capability 12: Public Health Laboratory Testing
- Capability 13: Public Health Surveillance and Epidemiological Investigation

Submit State Health Official Letter

To ensure strong partnerships across public health partners, PHEP recipients must provide a letter signed by the jurisdiction's state health official on official agency letterhead confirming that the PHEP director, the epidemiology lead, and the public health laboratory director or designated representatives have provided input into plans, strategies, and investment priorities for epidemiology, surveillance, and laboratory work plans. At the time of application, PHEP recipients must demonstrate their epidemiological and laboratory partnerships through the submission of signed letters. PHEP recipients that are unable to obtain effective input from these stakeholders must submit separate attachments with their funding applications describing the reasons why input was not obtained and describe the steps taken to obtain input. Recipients must name this file "State Health Official Letter" and upload it as a PDF under "Other Attachment Forms" at www.grants.gov. An optional letter template is available in the 2019-2024 PHEP Supplemental Guidance and Resources.

Conduct Epidemiological Surveillance and Investigation

Continue to develop, maintain, support, and strengthen surveillance and detection systems and epidemiological processes.

PHEP recipients must continue to create, maintain, support, and strengthen routine surveillance and detection systems and epidemiological processes. In addition, PHEP recipients must be able to surge these systems and processes in response to incidents of public health significance.

Collaborate to enhance essential surveillance systems.

In conjunction with epidemiological and other public health partners, PHEP recipients should support biosurveillance capabilities with modern technological tools and make them more versatile in meeting the demands for timely, population-specific, and geographically specific surveillance information. CDC encourages PHEP recipients work with their public health partners to:

- Enhance the public health information system workforce: Prioritize implementation of targeted cross-cutting workforce training and development opportunities to maintain functionality and increase capacity of public health information systems.
- Advance electronic information exchange: Focus efforts on improving information sharing and coordinate information technology goals, investments, and work plans with input from state laboratory directors, state epidemiologists, information technology or informatics directors, or specifically designated individuals empowered by these

authorities by:

- Participating in CDC's National Notifiable Diseases Surveillance System (NNDSS) Modernization Initiative to increase NNDSS case reports submitted electronically to CDC using HL7 messaging
- Advancing electronic laboratory reporting (ELR) to improve overall surveillance, timeliness, and accuracy of case reporting, confirmation to state and local public health, and subsequent information sharing with CDC
- Participating in the National Syndromic Surveillance Program (NSSP) to increase the proportion of emergency department visits monitored by jurisdictions
- o Implementing electronic test order and results reporting (ETOR) to accept electronic test orders and to return findings electronically
- Implementing electronic case reporting (eCR) consistent with national standards to accept and process electronically transmitted reportable disease information from electronic health records.

Have access to personnel trained to manage and monitor routine jurisdictional surveillance and epidemiological investigation systems and support surge requirements in response to threats. This includes supporting populations at risk of adverse health outcomes as a result of the incident.

Have procedures in place to establish partnerships, conduct investigations, and share information with other governmental agencies, partners, and organizations.

This includes supporting populations at risk of adverse health outcomes as a result of the incident.

Evaluate effectiveness of public health surveillance and epidemiological investigation processes and systems.

PHEP recipients should evaluate surveillance and epidemiological investigation outcomes to identify deficiencies encountered during responses to public health threats and incidents and recommend opportunities for improvement.

Conduct border health surveillance activities.

Jurisdictions located on the United States-Mexico border or the United States-Canada border must conduct activities that enhance border health, particularly regarding disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally occurring or due to bioterrorism. This focus on cross- border preparedness reinforces the U.S. public health whole community approach, which is essential for local-to-global threat risk management and response to actual events regardless of source or origin.

Implement processes for using poison control center data for public health surveillance. Such data can be particularly helpful in 1) providing situational awareness during a known public health threat, 2) identifying an emerging public health threat, 3) identifying unmet public health communication needs following a public health threat, or 4) providing surveillance for specific exposures or illnesses of concern to the health department. For more information, please refer to the 2019-2024 PHEP Supplemental Guidance and Resources: Considerations for Poison Control Center Data Usage.

Coordinate with epidemiological and vital records partners to implement electronic death registration (EDR) systems.

PHEP recipients must coordinate with epidemiological partners to implement processes for active

and passive mortality surveillance and EDR use. Depending upon the jurisdiction's prior experience with utilizing EDR systems during a response, several steps can be taken to further the implementation and use of EDR systems.

- PHEP recipients that have not yet begun developing EDR preparedness capability should prioritize development of scalable plans designed to initially implement an EDR system, such as developing reporting and technological capability; assessing potential legal information sharing barriers and restrictions; and other actions that will help establish initial functionality. This could also include implementing pilot projects. An option for EDR development planning can include working with the jurisdictional vital records office (VRO) and the CDC National Center for Health Statistics (NCHS) to design, plan, and implement the next generation EDR system in the state. States electing this option should work directly with NCHS in the development of its scalable plans.
- PHEP recipients that have an existing operational EDR system should work with the appropriate public health partners to prioritize goals and objectives that advance the utility and geographic coverage of current vital records systems to improve vital records data timeliness, quality, and access. Such activities include incorporating updated technologies; implementing updated information systems with VRO vital registration; and establishing partnerships that increase physician, medical examiner, or coroner, and funeral home participation.

See the 2019-2024 PHEP Supplemental Guidance and Resources: Considerations for Electronic Death Registration Systems for more information.

Recommendation: Participate in disaster epidemiology training initiatives as determined by jurisdictional priorities.

Following are recommended activities and tools.

- Community Assessment for Public Health Emergency Response (CASPER);
- Disaster death certification and death scene investigation resources, including:
 - o CDC's Reference Guide for Certification of Deaths in the Event of a Natural, ;Human-induced, or Chemical/Radiological Disasters and
 - o CDC's Death Scene Investigation Toolkit and Training;
- Rapid Response Registry (RRR)
- Emergency Responder Health Monitoring and Surveillance System (ERHMS); and
- Assessment of Chemical Exposures (ACE).

Conduct Laboratory Testing

It is important to maintain the capabilities of public health laboratories to safely prepare for and respond to all threats, including EIDs and natural disasters. CDC strongly encourages PHEP support of public health laboratory and clinical laboratory connectivity in collaboration with other partners for more timely detection of threats.

The following Laboratory Response Network-Biological (LRN-B) and Laboratory Response Network-Chemical (LRN-C) requirements do not apply to USAPI and USVI recipients; LRN-C requirements do not apply to Chicago.

LRN-B Requirements

PHEP recipients must work with public health laboratory staff to ensure adherence to the following LRN-B requirements and to maintain the tools and resources necessary for LRN-B participation.

Meet LRN-B proficiency testing (PT) requirements – **PHEP Benchmark**.

Demonstrate that LRN-B laboratories can pass validated proficiency testing (PT), which includes the ability to receive, test, and report on one or more suspected biological agents or assays during each budget period. PHEP recipients must also ensure that state public health LRN-B laboratories have or have access to the necessary resources to successfully pass proficiency testing. The minimum performance requirement is that the LRN-B laboratory cannot fail more than one PT challenge in a budget period (July 1 through June 30). This benchmark applies to the 50 states, Los Angeles County, New York City, and Washington, D.C.

See the Evaluation and Performance Measurement section for more information on PHEP benchmarks.

Meet or sustain standard reference laboratory requirements.

Work with public health laboratory staff to plan activities to meet standard reference level laboratory requirements in their work plans and budgets. Minimum requirements for standard reference level LRN-B laboratories describe the tools and resources necessary for LRN-B standards, including staffing and equipment requirements; attending national meetings; maintaining partnerships; meeting CDC benchmark requirements; coverage for High Priority Areas (HPAs); maintaining proficiency; maintaining communications with sentinel laboratories; and providing support for the detection of EIDs. Standard reference laboratories, which include most state public health laboratories, must be able to meet the requirements in the standard reference laboratory checklist. The checklist requires the performance of multiple-agent screening on high-risk environmental samples as well as other capabilities.

Meet or sustain advanced reference laboratory requirements.

PHEP recipients must work with public health laboratory staff to plan activities to meet and sustain LRN-B program requirements for advanced reference laboratories. Advanced reference laboratories are required to meet standard laboratory requirements, maintain registration in the Federal Select Agent Program, and provide support for LRN program activities. These include, but are not limited to, assay development, multicenter validation studies, performance of technically advanced assays, and, if requested, supporting the LRN-B program with evaluation of new technologies, proficiency testing remediation, and high throughput surge capacity.

CDC's LRN program office recognizes the following 14 public health laboratories as advanced reference laboratories:

- Arizona State Public Health Laboratory
- California State Public Health Laboratory
- Colorado State Public Health Laboratory
- Jacksonville, Florida, State Public Health Laboratory
- Los Angeles County Public Health Laboratory
- Maryland State Public Health Laboratory
- Massachusetts State Public Health Laboratory
- Michigan State Public Health Laboratory
- Minnesota State Public Health Laboratory

- New York State Public Health Laboratory
- North Carolina State Public Health Laboratory
- Texas State Public Health Laboratory
- Virginia State Public Health Laboratory
- Washington State Public Health Laboratory

Successfully complete 24/7 emergency contact drill.

All PHEP-funded state public health LRN-B laboratories must complete an annual 24/7 emergency contact drill in 45 minutes or less. PHEP recipients must demonstrate the time required to complete notification between CDC, the on-call laboratorian, and the on-call epidemiologist; or the time required to complete notification between CDC, the on-call epidemiologist, and the on-call laboratorian, depending on drill direction.

Attend national meetings.

Work with public health laboratory staff to ensure at least one representative, such as the laboratory director, the PHEP director, or their appropriate designee, attends the LRN-B national meeting held approximately every 18 months.

Ensure national coverage.

If an HPA is contained in the jurisdiction, the PHEP-funded laboratory must ensure ability to receive and test samples as well as report results within 24 hours for that HPA. If a jurisdiction has a high-population area that is not included on the HPA list, it is a best practice for the jurisdictional LRN-B laboratory to have the ability to expeditiously transport, test, and report threat samples for that area within 24 hours. The HPA list is included in *the 2019-2024 PHEP Supplemental Guidance and Resources: Laboratory Response Network-Biological (LRN-B)*.

Maintain partnerships.

PHEP recipients are required to work with LRN-B laboratory staff to ensure there are established partnerships and processes for addressing joint investigations of intentional public health threats or incidents between the appropriate Federal Bureau of Investigation field office, law enforcement, and state public health departments including local public health departments where relevant.

Maintain communication with sentinel laboratories.

Work with public health laboratory staff to provide support for the detection of EIDs. Each PHEP-funded laboratory must maintain a list of sentinel laboratories with current contact information. CDC strongly recommends that PHEP-funded laboratories engage sentinel laboratories utilizing contact drills. In addition, PHEP-funded laboratories should provide training or guidance on access to training for packaging and shipping of infectious substances.

LRN-B funding can be used for personnel, supplies, equipment (including service and maintenance contracts), travel, and contracts. Because PHEP recipients receive substantial financial assistance from other programs, PHEP recipients should ensure that requested budget line items are funded by the appropriate program. The following are examples of items that are not typically funded by the PHEP cooperative agreement.

- Instruments, reagents, and supplies for testing seasonal influenza;
- Instruments, reagents, and supplies for testing rabies;
- Instruments, reagents, and supplies for routine food testing (surveillance);

- Instruments, reagents, and supplies for testing vaccine-preventable diseases such as measles or mumps;
- Instruments, reagents, and supplies for routine testing of vector-borne illnesses (both clinical and vector surveillance);
- Routine drug screening of laboratory staff; and
- Influenza vaccines for the general public.

Maintain staffing and equipment requirements.

Work with LRN-B laboratory staff to ensure the following LRN-B standard laboratory checklist requirements are met.

- A designated bioterrorism (BT) coordinator must serve as the point of contact (POC) for the CDC LRN-B program office to ensure that:
 - o Applicable LRN-B procedures and policies in use by the laboratory are current and being followed appropriately, and
 - o Laboratory personnel are trained and competent to perform LRN-B assays.
- A designated biological safety officer/official(s) (BSO) is available to provide:
 - o Technical support and guidance regarding internal laboratory activities and
 - o Technical assistance to strengthen biosafety in sentinel clinical laboratories.

See the 2019-2024 PHEP Supplemental Guidance and Resources: Laboratory Response Network-Biological (LRN-B) for more information.

LRN-C Requirements

CDC has identified nine core methods and four additional methods for detecting and measuring a diverse range of chemical threat agents in clinical samples. Participating LRN-C laboratories are designated as either Level 1, Level 2, or Level 3. PHEP recipients must work with public health laboratory staff to ensure adherence to the following LRN-C requirements and maintain the tools and resources necessary for LRN-C participation.

Meet LRN-C basic membership requirements.

Work with laboratory staff to ensure all Level 3 LRN-C laboratories maintain specimen packing and shipping capabilities in accordance with CDC guidelines for clinical samples.

Work with laboratory staff to ensure all Level 2 laboratories can demonstrate satisfactory testing capabilities for at least four LRN-C core methods. Level 2 laboratories leverage their core chemical threat capabilities to ensure response readiness to human exposures to local public health threats such as toxic metals, plant and marine toxins, toxic industrial chemicals, and synthetic drugs.

Level 1 laboratories serve as CDC's first line of laboratory surge capacity. Thus, Level 1 laboratories must maintain enhanced sample throughput and testing capabilities for all LRN-C core methods as well as any additional LRN-C high threat chemical methods.

See the 2019-2024 PHEP Supplemental Guidance and Resources: Laboratory Response Network-Chemical (LRN-C) for more information.

Meet LRN-C exercising and proficiency testing requirements – **PHEP Benchmarks**. Ensure that at least one jurisdictional LRN-C laboratory passes the LRN-C specimen packaging and shipping (SPaS) exercise. This annual exercise evaluates the ability of a laboratory to collect

relevant samples for clinical chemical analysis and ship those samples in compliance with International Air Transport Association regulations. PHEP recipients must ensure at least one LRN-C laboratory passes CDC's SPaS exercise with a score of 90% or higher. If a laboratory fails the exercise on its first attempt but passes on the second attempt, then the PHEP recipient will meet the benchmark. This benchmark applies to the 50 states and the directly funded localities of Los Angeles County, New York City, and Washington, D.C.

Ensure that LRN-C laboratories pass 90% of the proficiency testing in core and additional analysis methods. This requirement applies to the 10 PHEP recipients with Level 1 laboratories: California, Florida, Massachusetts, Michigan, Minnesota, New Mexico, New York, South Carolina, Virginia, and Wisconsin. Although this benchmark does not apply to PHEP recipients with Level 2 laboratories, those recipients must report on LRN-C proficiency testing performance measures as specified in PHEP performance measure and specifications guidance. Successful demonstration of this capability is defined by the LRN-C proficiency testing policy.

See the Evaluation and Performance Measurement section for more information on PHEP benchmarks.

Improve secured data messaging and LIMS capabilities.

All Level 1 laboratories should include work plan activities in support of improving laboratory information management system (LIMS) capabilities.

Participate in chemical threat program response reporting.

All LRN-C laboratories must notify CDC's LRN-C program office of any chemical threat program activities such as laboratory emergency response, biomonitoring or biosurveillance testing, exercises with local preparedness partners, or training and outreach.

Successfully complete 24/7 emergency contact drill.

All LRN-C laboratories must complete the annual 24/7 emergency contact drill in 45 minutes or less. PHEP recipients must demonstrate the time required to complete notification from CDC to the on-call laboratorian, to the on-call epidemiologist, and back to CDC; or the time required to complete notification from CDC, to the on-call epidemiologist, to the on-call laboratorian, back to CDC, depending on drill direction.

Participate in LRN-C Level 2 laboratory equipment replacement.

In Fiscal Year (FY) 2017, CDC began a four-year cycle of funding to replace chemical laboratory equipment that was reaching the end of its viability. During that period, LRN-C Level 1 and Level 2 laboratories were required to replace the inductively coupled plasma mass spectrometry (ICP-MS) equipment by 2018 and nerve agent metabolites (NAM) equipment by 2020 to maintain their LRN-C membership requirements. With two years completed, the remaining Level 2 laboratories must work to complete the NAM equipment replacement. Approximately half will be funded in FY 2019 and the remainder in FY 2020. For more information, see the funding tables in the Other Information section.

PHEP recipients funded in each year must describe their equipment replacement activities in their appropriate Budget Period 1 or Budget Period 2 public health laboratory testing work plans and budgets. PHEP recipients should work in partnership with their laboratory directors and chemical threat program coordinators to ensure the effective replacement of equipment. Further, they should work with CDC staff as necessary when obtaining quotes and making procurement decisions. For more information on LRN-C laboratory equipment specifications, please contact

the LRN program office at LRN-C_QA_Program@cdc.gov. For more information on LRN-C planning, please see the 2019-2024 PHEP Supplemental Guidance and Resources: Laboratory Response Network-Chemical (LRN-C).

See Capability 12: Public Health Laboratory Testing and Capability 13: Public Health Surveillance and Epidemiological Investigation in <u>Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health for more information.</u>

Maintain and Exercise Laboratory COOP Plans

PHEP recipients must maintain a current laboratory COOP plan to ensure the ability to conduct ongoing testing for routine and emerging public health threats. COOP plans should include at a minimum:

- Procedures for regular maintenance of redundant testing supplies,
- Processes to designate alternate testing facilities for short-term duration in case of localized infrastructure failure,
- Agreements with other agencies to take over critical testing, as appropriate,
- Procedures to address personnel shortages,
- Procedures to address equipment failures, and
- Procedures to address operational loss of laboratory facilities.

Recipients must exercise their laboratory COOP plans at least once every five years. Recipients can choose to exercise either their LRN-B or LRN-C COOP plans during a real incident, a TTX, an FE, or an FSE. CDC strongly encourages recipients to coordinate with HPP to complete this requirement, either separately or as part of a broader exercise.

Administrative Requirements and Assurances

For the 2019-2024 performance period, PHEP recipients must address and comply with the following administrative and federal requirements. CDC will publish prior to the start of each budget period a summary of PHEP reporting requirements and their associated deadlines.

Comply with reporting requirements.

Submit documents and deliverables according to program instructions and timelines. Failure to adhere to these requirements may adversely affect future funding. See the Evaluation and Performance Measurement section for more information on potential funding implications.

The following concessions may be available:

- If required documentation cannot be provided by the due date, the PHEP recipient is required to contact the Office of Grant Services (OGS) no less than seven business days prior to the submission date to request an extension. This request must be submitted via email to the grants management officer and the CDC project office), include a reason for the requested extension, and include a proposed submission date.
- Only with prior approval from OGS and the CDC project officer can PHEP recipients submit deliverables outside of the designated reporting system(s).
- Corrective action plans or financial penalties may be instituted for PHEP recipients that miss submission deadlines.

• Corrective action plans or financial penalties may be instituted for PHEP recipients that do not meet legislative benchmarks.

Obtain local health department (LHD) concurrence.

At the time of application, PHEP recipients, as applicable, should provide the following.

• Local Health Department Concurrence Letter

Each decentralized state must provide a written, signed letter to ensure evidence that at least a majority, if not all, of local health departments within the jurisdiction approves or concurs with the approaches and priorities described in the application. This letter should be signed by the local health departments or representative entities within the jurisdiction. PHEP recipients that are unable to gain 100% concurrence, despite good-faith efforts to do so, should submit a document with their applications describing the reasons for lack of concurrence and the steps taken to address them. Recipients should name this file "Local Health Department Concurrence Letter" and upload it as a PDF under "Other Attachment Forms" to www.grants.gov.

• Description of Local Health Department Engagement Process

The collaboration section of the recipient's project narrative must contain a description of the process(s) for engagement with local health departments within the jurisdiction. This should include a description of local health department priorities or strategies for achieving operational readiness and describe how local, PHEP-funded activities will contribute to achieving statewide public health preparedness goals. The project narrative should be a part of the official grant submission in Grants.gov.

• Description of Work Plan Activities

o Domain work plans must include local activities that demonstrate integrated efforts at the state and local levels.

• Description of Subrecipient Monitoring and Accountability Methods

 PHEP recipients must upload a copy of their subrecipient monitoring plan, or a similar document, that outlines the jurisdiction's process(s) for managing subrecipient funds, subrecipient reporting, subrecipient progress, technical assistance, and guidance.

Submit independent audit reports every two years to the Federal Audit Clearinghouse within 30 days of receipt of the reports.

Document maintenance of funding and matching funds at the time of application.

Have fiscal and programmatic systems in place to document accountability and improvement at the state and local levels.

Submit quarterly reconciliation of the PHEP program's financial records in the Payment Management System (PMS).

PHEP recipients must ensure accurate accounting and timely expenditures of funds. Copies of these reports are due in PMS on the following dates.

- October 30, 2019 (for quarter ending September 30, 2019)
- January 30, 2020 (for quarter ending December 31, 2019)
- April 30, 2020 (for quarter ending March 31, 2020)

• September 30, 2020 (for quarter ending June 30, 2020)

A copy of this report should be uploaded into GrantSolutions in the respective grant file and emailed to the CDC project officer.

Maintain all program documentation for purposes of data verification and validation. Develop internal electronic systems that allow jurisdictions to share documentation with PHEP project officers and specialists, including evidence of progress completing corrective actions for weaknesses identified during exercises and drills. In Budget Period 1, CDC will emphasize verification and validation of requirements to identify strengths and potential gaps, better review and evaluate progress, and provide technical assistance.

Engage in technical assistance planning.

Actively work with CDC project officers, MCM specialists, and subject matter experts to identify, manage, and update technical assistance (TA) needs and progress. Technical assistance conference calls and written action plan updates are completed in alternating quarters of the budget period. Following are the deadlines for TA action plan submissions and verbal updates.

Quarter 1 – Submit updated written report to CDC – September 30, 2019

Quarter 2 – Participate in conference call update – December 30, 2019

Quarter 3 – Submit updated written report to CDC – March 31, 2020

Quarter 4 – Participate in conference call update – June 30, 2020

CDC will no longer collect TA plans in PERFORMS. Instead, recipients must submit technical assistance action plans in CDC's Online Technical Resource and Assistance Center (On-TRAC).

Participate in program monitoring activities.

PHEP recipients are expected to participate in CDC's monitoring activities, including, but not limited to the following:

- Monthly calls with their PHEP project officer(s) to provide updates on current work plan activities and unobligated program funding amounts.
- Quarterly calls with their MCM specialist(s) to provide updates on current MCM activities and addressing action plan gaps.
- Quarterly TA planning calls with CDC project officers, MCM specialists, and subject matter experts to identify, manage, and update TA action plans and address action plan progress.
- Site visits and other real-time, in-person monitoring meetings will take place throughout the performance period. PHEP recipients are encouraged to invite CDC staff to attend or observe events such as scheduled exercises, regional meetings, jurisdictional conferences, senior advisory committee meetings, and coalition meetings supported by PHEP funding to gain insight on strengths and challenges in preparedness planning.
- Provide situational awareness data during emergency response operations and other times as requested.

USAPI and USVI recipients have additional expectations for this activity. Please refer to 2019-2024 PHEP Program Supplemental Guidelines, Modified Requirements for U.S.-Affiliated

Pacific Islands (USAPI) and U.S. Virgin Islands (USVI) Recipients for additional details.

Describe progress on capabilities.

In addition to reporting progress through the previously mentioned monitoring methods, PHEP recipients must submit written progress reports and program and financial data. This includes, but is not limited to:

- Annual progress reporting (in PERFORMS);
- Demonstrating progress in achieving benchmarks and performance measure standards (in PERFORMS);
- Outcomes of annual preparedness exercises including strengths, weaknesses, and associated corrective actions (in the ORR); and
- Final performance report (in Grants Management Module).

Submit Capabilities Planning Guide (CPG) data.

This annual self-assessment must be completed prior to applying for the subsequent budget period funding. The data from the CPG report should help to inform strategic priorities.

Participate in essential meetings and trainings.

Annual budgets should include detailed travel information for appropriate staff to attend the following essential meetings:

- Annual Public Health Preparedness Summit sponsored by the National Association of County and City Health Officials (NACCHO);
- Directors of Public Health Preparedness Annual Meeting sponsored by the Association of State and Territorial Health Officials (ASTHO);
- Training for MCM coordinators sponsored by ASPR and CDC and other MCM regional workshops
- LRN-B National Meeting (held every 18 months); and
- Other mandatory training sessions that may be conducted via webinar or other remote meeting venues.

Comply with SAFECOM requirements.

Jurisdictions that use federal preparedness grant funds to support emergency communications activities must comply with current SAFECOM guidance for emergency communications grants. SAFECOM guidance is available at www.safecomprogram.gov.

Submit exercise documentation.

To effectively implement the quality improvement cycle, PHEP recipients and subrecipients should ensure submission of the following drill and exercise documentation as specified.

Requirement	Submission Cycle	Submission Location	States	Directly Funded Localities	Higher Risk Jurisdictions	Otl CR Jui
Drill: facility setup	Once a year, no later than June 30	ORR	Intentionally blank	X	X	X

Drill: staff notification and assembly drill	Once a year, no later than June 30	ORR	Intentionally blank	X	X	X
Drill: site activation	Once a year, no later than June 30	ORR	Intentionally blank	X	X	X
Drill: dispensing throughput Only used if throughput not calculated during dispensing FSE	Once every 5 years	ORR		X	X	X
Test: IMATS/IDE	Once a year, no later than June 30	ORR	X	X	Intentionally blank	Inte
Annual PHEP exercise: must include at-risk population partners	Once a year, no later than June 30	ORR	X	X	Intentionally blank	Inte
Joint exercise with HPP and emergency management: either an FE, an FSE, or a real incident	Once every 5 years	ORR	X	X	Intentionally blank	Inte
Drill: EOC staff notification and assembly drill (formerly performance measure 3.1)	Once a year, no later than June 30			X	Intentionally blank	Inte
		Now collected in the ORR	X			
TTX: anthrax	Once every 5 years	ORR	X	X	X	X

TTX: pandemic influenza	Once every 5 years	ORR	X	X	X	X
TTX: administrative preparedness	Once every 5 years	ORR	X	Intentionally blank	Intentionally blank	Inte
TTX: COOP	Once every 5 years	TBD	X	X	Intentionally blank	Inte
TTX: Lab COOP	Once every 5 years	ORR	X	X	Intentionally blank	Into
FE: pandemic influenza - critical workforce	Once every 5 years	ORR	X	X	X	X
FSE: pandemic influenza	Once every 5 years	ORR	X States without higher risk jurisdictions**	Intentionally blank	Intentionally blank	Inte
FSE: anthrax distribution	Once every 5 years	ORR	X States with higher risk jurisdictions**	X	Intentionally blank	Into
FSE: anthrax dispensing	Once every 5 years	ORR	Submit only if MCM plan includes state-run PODs	X	X	Inte
All EOC activations having a public health component (including health EOC, DOC, etc.)	activation	ORR	X	X	Intentionally blank	Inte
AAR/IP	Submit with each incident, FE, and FSE	ORR	X	X	X	X
Training and exercise planning workshop (TEPW) form	Once a year, no later than June 30	ORR	X	X	Intentionally blank	Inte

Training and exercise	Once a year,	ORR	X	X	X	X
planning form with	no later than					
supporting multiyear training	June 30					
and exercise plan						

^{*}USAPI/USVI recipients must complete one of the three drill options (facility setup, staff notification and assembly, or site activation) annually. The same drill option must not be submitted in consecutive years.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

PHEP recipients must provide evidence of proposed or existing key collaborations. Memoranda of agreement (MOA), memoranda of understanding (MOU), letters of commitment, or service agreements may be used to formally document the scope of work, intensity, and duration of collaborations with partners. Each document should thoroughly describe the proposed collaboration and specific activities, which parties are responsible for what, and the intended outcomes and benefits for the overall proposed program.

The Strategies and Activities section of this NOFO outlines the anticipated collaborations for the implementation of this cooperative agreement. Funding cannot be used for activities already covered by other federal grants or cooperative agreements. PHEP recipients are encouraged to collaborate with their jurisdictional laboratory, surveillance, and epidemiology leads, maternal-child health programs, immunization programs, environmental health programs, occupational health programs, legal counsel, health care providers, blood safety organizations, and emergency management partners to ensure PHEP activities and funding are complementary and not duplicative.

Federal agencies participating in the Emergency Preparedness Grant Coordination process are working to identify current preparedness activities and areas for collaboration across federal grants with public health and health care preparedness components. The participating federal agencies include:

- Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR)
- Department of Homeland Security (DHS) Federal Emergency Management Agency (FEMA)
- HHS Centers for Disease Control and Prevention (CDC)
- HHS Health Resources and Services Administration (HRSA)
- Department of Transportation (DOT) National Highway Traffic Safety Administration (NHTSA)

Federal agencies are actively coordinating guidance and technical assistance and encourage all preparedness funding recipients to actively coordinate preparedness activities for their

^{**}States that have **both** higher risk CRI planning jurisdictions for intentional anthrax release and CRI planning jurisdictions that do not meet the higher risk criteria can demonstrate operational readiness through a distribution FSE for anthrax **or** pandemic influenza.

jurisdictions. More information on the Emergency Preparedness Grant Coordination process can be found at http://www.phe.gov/Preparedness/planning/hpp/Pages/emergency-prep-grant.aspx.

b. With organizations not funded by CDC:

Consistent with the whole-community approach to preparedness, PHEP recipients should actively work with and engage community leaders outside of public health. Community engagement creates greater awareness of the public health's role in emergency preparedness activities, and promotes community resilience.

PHEP recipients are expected to establish, build, and sustain strategic and meaningful collaborative partnerships. Toward the implementation of the plans, training, exercising, and technical assistance, applicants should also consider working relationships with other federal agencies and key partners such as educational entities; other state and local public health departments; community health care centers; community- and faith-based organizations; stakeholders; law enforcement; national organizations, such as poison control centers; and other entities interested in promoting improved public health emergency preparedness outcomes. Formal MOUs may be established as needed to help formalize partnerships.

PHEP recipients are required to provide the following letters demonstrating collaboration with their applications.

- State Health Official Letter
- Local Health Department Concurrence Letter

2. Target Populations

This NOFO covers, in broad terms, the entire U.S. population and the public health systems within the United States and its territories and freely associated states. Specifically, funds are intended to support the needs of any community impacted by a public health emergency or disaster and to ensure that public health systems are ready and capable of keeping their communities safe and mitigating the impacts of any public health emergency.

Additionally, there is a special emphasis on ensuring the health needs of tribal populations, at-risk populations, and those with access and functional needs to ensure that plans and processes are in place pre-event and during an event to address the unique needs of this population.

a. Health Disparities

Recipients must show evidence that they are integrating the access and functional needs of at-risk and vulnerable population(s) as indicated in their planning. Recipients must describe the structure or processes in place to integrate the access and functional needs of at-risk individuals, including but not limited to children, pregnant women, minorities and other diverse populations with a disproportionate burden of disease and disability, older adults, people with disabilities, persons from underserved populations, and people with limited English proficiency and non-English speaking populations.

Strategies to integrate the access and functional needs of at-risk individuals involve inclusion in public health, health care, and behavioral health response strategies; furthermore, these strategies must be identified and addressed in operational work plans. Recipients and subrecipients are

encouraged to identify community partners with established relationships with diverse at-risk populations, such as social services organizations, and to use demographic tools such as the Social Vulnerability Index and the U.S. Census/American Community Survey to better anticipate the potential access and functional needs of at-risk community members before, during, and after an emergency.

iv. Funding Strategy

The distribution of PHEP funds is calculated using a formula established under section 319C-1(h) of the PHS Act, as amended. States and U.S. territories and freely associated states receive the greater of a minimum amount prescribed by the formula or a base amount, as determined by the HHS Secretary, supplemented by a population-based formula, and possible additional funding based on findings about significant unmet needs and high degree of risk. Eligible political subdivisions receive an amount determined by the HHS Secretary and possible additional funding based on findings that the political subdivision has a substantial number of residents, a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk.

Using PHEP Funds for Response

PHEP cooperative agreement funding is intended primarily to support preparedness activities that help ensure state and local public health departments are prepared to prevent, detect, respond to, mitigate, and recover from a variety of public health threats. PHEP funds may, on a limited, case-by-case basis, be used to support response activities to the extent they are used for their primary purposes: to strengthen public health preparedness and enhance the capabilities of state, local, and tribal governments to respond to public health threats. Some PHEP planning activities may have immediate benefit when conducted or performed simultaneously with an actual public health emergency. It is acceptable to spend PHEP funds on PHEP planning activities that benefit the response effort as long as the activities demonstrably support progress toward achieving CDC's 15 public health preparedness and response capabilities and demonstrate related operational readiness.

PHEP recipients must receive approval from CDC to use PHEP funds during response for new activities not previously approved as part of their annual funding applications or subsequent budget change requests. The approval process may include a budget redirection or a change in the scope of activities. Prior approval by the CDC grants management officer (GMO) is required for a change in scope under any award, regardless of whether or not there is an associated budget revision. Any change in scope must also be consistent with the PHEP cooperative agreement's underlying statutory authority, Section 319C-1 of the PHS Act, applicable cost principles, the notice of funding opportunity, and PHEP recipient applications, including the jurisdictional all-hazards plans.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC will implement monitoring and accountability measures to track PHEP recipient progress in achieving desired programmatic outcomes and financial performance levels. Monitoring and reporting activities also help to identify jurisdictions that may need additional guidance and

assistance.

Using the ORR data collection and other online program management systems, CDC will continue to review performance systematically. In addition, CDC will monitor PHEP recipient performance through site visits, conference calls, and technical evaluation of various PHEP recipient reports. CDC's strategy for monitoring and technical assistance requires regular PHEP recipient contact, including monthly conference calls, email correspondence, engagement with updating technical assistance action plans quarterly, and site visits throughout the performance period. Monitoring activities require routine and ongoing communication between project officers, MCM specialists, and PHEP recipients. Consistent with applicable grants regulations and policies, CDC expects the following to be part of routine monitoring communications:

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

CDC may modify PHEP funding or implement other grants management measures to reflect PHEP recipient performance in the following areas.

Fiscal Performance

CDC routinely monitors historical use of funding as demonstrated through fiscal management reports. Beginning this performance period, CDC will review PHEP recipient spending rates over a three-year rolling basis and will provide targeted technical assistance to improve fiscal performance and consider adjusting base funding as needed for those at risk of lapsing funds.

Administrative Performance

CDC will continue to monitor compliance with PHEP reporting requirements and other grants management deliverables to ensure timely submission of critical program data.

CDC may restrict funds for noncompliance and may modify base funding for continued noncompliance.

Programmatic Performance

CDC will continue to assess PHEP recipient progress made across the six domains and their related strategies, activities, and outcomes as described in the Strategies and Activities section of this announcement. CDC measures PHEP programmatic performance using a variety of methods, including collection of process measures, performance measures, and the ORR process. PHEP recipients that do not meet specific programmatic outcomes may be subject to funding restrictions.

Evidence-based Benchmarks

CDC has specified a subset of measures and select program requirements as benchmarks as mandated by Section 319C-1(g) of the PHS Act. To substantially meet a benchmark, PHEP recipients must provide complete and accurate information describing how the benchmark was met.

Accountability Provisions

PHEP recipients that fail to "substantially meet" the benchmarks required by this NOFO are

subject to withholding of a statutorily mandated percentage of the award if the PHEP recipient fails substantially to meet established benchmarks for the immediately preceding fiscal year or fails to submit a satisfactory pandemic influenza plan.

HHS is required to treat each failure to substantially meet all the benchmarks and each failure to submit a satisfactory pandemic influenza plan as a separate withholding action. For example, a PHEP recipient that fails to substantially to meet benchmarks AND that fails to submit a satisfactory pandemic influenza plan could have 10% withheld for each failure for a total of 20% for the first year this happens. If this situation remained unchanged, HHS would then be required to assess 15% for each failure for a total of 30% for the second year this happens. The percentages continue to increase with each successive annual failure or failures. Alternatively, if one of the two failures is corrected in the second year but one remained, HHS is required to withhold 15% of the second year funding.

PHEP Budget Period 1 Benchmarks Subject to Withholding

PHEP Demonstrate submit: MCM operational

readiness

PHEP recipients must demonstrate readiness to receive, stage, store, distribute, and Benchmark dispense material during a public health emergency. This benchmark applies to all 62 PHEP recipients. In Budget Period 1, PHEP recipients must complete and

- MCM operational readiness review data;
- Reports demonstrating significant annual progress in mitigating MCM gaps identified through the MCM ORR process, including gaps in pandemic influenza preparedness; and
- Review 50% of their local CRI planning jurisdictions and provide ORR data for each review, with the remaining CRI jurisdictions reviewed during the following budget period. Such updates are required to track progress on addressing identified gaps.

On or before the end of Budget Period 3, June 30, 2022, 100% of PHEP recipients must achieve an overall status level of "established" for MCM operational readiness.

PHEP Benchmark 2: proficiency in public health laboratory testing for biological agents

PHEP recipients must demonstrate that biological laboratories in the Laboratory Response Network (LRN-B) can pass validated proficiency testing which includes the ability to receive, test, and report on one or more suspected biological agents. Demonstrate This benchmark applies to the 50 states and the directly funded localities of Los Angeles County, New York City, and Washington, D.C.

> PHEP-funded LRN-B laboratories cannot fail more than one validated proficiency test challenge during the budget period. Successful demonstration of this capability is defined by the LRN-B proficiency testing policy. CDC will use these elements to determine if the PHEP recipient met this benchmark:

- Number of validated LRN-B proficiency tests successfully passed by the PHEP-funded laboratory during any attempt, including remediation, if applicable
- Number of validated LRN-B proficiency tests participated in by the PHEP-

funded laboratory, including remediation, if applicable

CDC's LRN-B program office requires state public health laboratories to participate in all available proficiency testing challenges specific to each laboratory's testing capability; if a laboratory has testing capability for a specific agent and a proficiency testing challenge for that agent is being offered, the PHEP-funded laboratory must participate in that proficiency testing challenge. PHEP-funded laboratories that are offline for extended periods, undergoing renovation, or have other special circumstances are not expected to have their proficiency testing challenges completed by partner or backup labs (such as municipal labs or labs in neighboring states). Instead, those laboratories are expected to report to the LRN-B program office what they would do in real situations had the proficiency testing challenge been associated with a true emergency event. In such a circumstance, this will not adversely affect the PHEP recipient in terms of determining whether this benchmark has been met.

PHEP
Benchmark
3:
Demonstrate
proficiency
in public
health
laboratory
specimen
packaging,
and shipping
exercises for
chemical
agents

PHEP recipients must ensure that at least one LRN chemical (LRN-C) laboratory in their jurisdictions passes the LRN-C specimen packaging, and shipping (SPaS) exercise. This benchmark applies to the 50 states and the directly funded localities Demonstrate of Los Angeles County, New York City, and Washington, D.C.

This annual exercise evaluates the ability of a laboratory to collect relevant samples for clinical chemical analysis and ship those samples in compliance with International Air Transport Association regulations. PHEP recipients must ensure at least one LRN-C laboratory passes CDC's SPaS exercise. If a laboratory fails the exercise on its first attempt but passes on the second attempt, then the PHEP recipient will meet the benchmark. If a PHEP recipient has multiple laboratories, at least one laboratory must participate and pass. To pass, a laboratory must score at least 90% on a SPaS exercise.

PHEP Benchmark 4:

Demonstrate proficiency in public health laboratory testing for chemical agents

PHEP recipients must demonstrate that LRN chemical (LRN-C) laboratories can pass proficiency testing. This benchmark applies to the 10 states with Level 1 laboratories: California, Florida, Massachusetts, Michigan, Minnesota, New Mexico, New York, South Carolina, Virginia, and Wisconsin.

- PHEP recipients must ensure that LRN-C laboratories pass 90% of the proficiency testing in core and additional analysis methods to meet the CDC benchmark requirement. Although this benchmark does not apply to PHEP recipients with Level 2 laboratories, PHEP recipients with Level 2 laboratories must report on LRN-C proficiency testing performance measures as specified in PHEP performance measure and specifications guidance. Successful demonstration of this capability is defined by the LRN-C proficiency testing policy. CDC will use these elements to determine if PHEP recipients met this benchmark:
 - Number of LRN-C proficiency tests successfully passed by the PHEP-funded laboratory, during any attempt, including remediation,

if applicable. o Number of LRN-C proficiency tests participated in by the PHEPfunded laboratory, including remediation, if applicable. The LRN-C conducts proficiency testing for all Level 1 and Level 2 chemical laboratories to support meeting the regulatory requirements for the reporting of patient results as part of an emergency response program. Each high complexity test is proficiency tested three times per budget period and each laboratory is evaluated on the ability to report accurate and timely results through secure electronic reporting mechanisms. Submit All 62 PHEP recipients must have updated plans describing activities they will conduct with respect to pandemic influenza as required by Section 319C-1 of the updated pandemic PHS Act. PHEP recipients must meet this annual requirement through their participation in CDC's ORR process, which evaluates pandemic influenza and influenza Plans mass vaccination elements. In addition, PHEP recipients must address pandemic influenza planning gaps as part of their MCM action plans.

Criteria to Determine Potential Withholding of PHEP Fiscal Year 2020 Funds

Benchmark Measure	Yes	No	Possible % Withholding
Did the PHEP recipient (all PHEP recipients) demonstrate capability to receive, stage, store, distribute, and dispense material during a public health emergency?			10%
Did the applicable PHEP recipient demonstrate proficiency in public health laboratory testing for biological agents?			
Did the applicable PHEP recipient demonstrate proficiency in public health laboratory specimen packaging, and shipping exercises for chemical agents?			
Did the applicable PHEP recipient demonstrate proficiency in public health laboratory testing for chemical agents?			
Did the PHEP recipient (all PHEP recipients) meet the 2019 pandemic influenza plan requirement?			10%
Total Potential Withholding Percentage			20%

Scoring Criteria

The first four benchmarks are weighted the same, so failure to substantially meet any one of the four benchmarks will count as one failure and result in withholding of 10% of the fiscal year 2020 PHEP award. Failure to meet the pandemic influenza preparedness planning requirement may result in withholding of 10% of the fiscal year 2020 PHEP award.

Evaluation and Performance Measurement

CDC's evaluation and performance measurement strategy will assess recipient progress made across the six domains, and the recipient's related strategies, activities, and outcomes. CDC will deploy several methods for assessing PHEP recipient performance throughout this five-year performance period, including, but not limited to:

- CPG reports;
- ORRs;
- Additional process measures;
- Outcome measures; and
- Progress reports.

CPG Reports. This annual self-assessment reports three process measures for each capability function:

- Function importance;
- Function status; and
- Function challenges and barriers.

ORRs. CDC expects PHEP recipients to achieve the goal of "established" operational readiness across all capabilities by the end of the performance period. PHEP recipients are still required to meet the goal of "established" operational readiness for MCM capabilities on or before June 30, 2022. CDC determines operational readiness through the ORR process, when PHEP recipients provide information and data on their program, which CDC evaluates to determine whether jurisdictions have met operational readiness objectives.

CDC plans to expand the ORR to encompass measurement for all public health preparedness capabilities beginning in Budget Period 2. PHEP recipients are expected to achieve or make substantial progress toward achieving a status level of "established" by the end of the performance period. The ORR process will collect data on domain activities and outcomes:

- Domain activities
 - Risk-based planning
 - o Core staff planning, vacancies, and training
 - Whole community planning
 - o First responder planning, staffing, and training
 - o Volunteer planning, staffing, and training
- Domain outputs
 - Risk assessments
 - All-hazards and risk-based plans
 - Risk communication systems / materials
 - Incident management systems
 - Workforce development/training plans
 - Information management systems (e.g., electronic death registration systems, health information exchange systems/protocols)
 - Storage and distribution centers
 - Inventory management systems

- Trained MCM staff
- Available PPE
- Interoperable data storage systems
- Electronic volunteer registry systems
- (Post incident) assessments of public health, medical and mental/behavioral health infrastructure
- Laboratory response networks
- Electronic disease surveillance systems
- Integrated laboratory and epidemiology systems
- AARs/IPs
- MYTEPs

Additional Process Measures. PHEP recipients will report on the following specific process measures on key program requirements and deliverables:

- Number of times a year that a jurisdiction activated (partial or full activation) the public health emergency operations center (EOC) or state EOC (when public health is involved);
- Percent of funds that are allocated to local and tribal health departments;
- Number of days from the start of the budget period to execution of subrecipient contracts to local/tribal public health if applicable (not during an emergency);
- Number of days from the start of the budget period to execution of subrecipient contracts to local/tribal public health during a public health incident where there is CDC emergency supplemental funding (if applicable);
- Development and submission of a jurisdictional fiscal and administrative plan that ensures emergency funding moves quickly through the state (or local) fiscal systems and that emergency hiring capabilities can be activated to effectively respond to a public health incident:
- Percent of funds that are left unspent by the end of the two-year budget spend-down period; and
- Successful completion and submission of pandemic influenza requirements.

Outcome Measures

In addition to the ORR measurement objectives, process performance measures, and CPG reports, PHEP recipients must submit outcome performance measures throughout the five-year performance period. These are measures related to the short-term outcomes depicted in the logic model and described in the narrative approach. Some of the measures are PHEP benchmarks subject to funding penalties. CDC will aggregate selected outcome measures reported by PHEP recipients into a program measure that presents a national picture of preparedness to include (but not limited to):

Timely Implementation of Intervention and Control Measures.

- **Program Measure**: Percent of PHEP recipients that receive reports for E. coli STEC (shiga toxin-producing E. coli) within seven days.
- **Program Measure:** Percent of PHEP recipients that initiate control measures for E. coli within three days of initial case identification.

Continuity of Emergency Operations throughout the Surge of an Emergency or Incident.

- **Program Measure**: Percent of PHEP recipients that exercise COOP plans for EOCs and laboratories.
- **Program Measure**: Percent of PHEP recipients that have exercised or implemented MCM plans.

Timely Communication of Situational Awareness and Risk Information by Partners.

- **Program Measure**: Percent of PHEP recipients collaborating with stakeholders to disseminate information during an incident or exercise.
- **Program Measure**: Percent of PHEP recipients meeting target time (45 minutes) for emergency contact drill (laboratorians and epidemiologists).

<u>Timely Procurement and Expedited Staffing (Hiring or Reassignment) to Support Medical Countermeasure Distribution and Dispensing.</u>

• **Program Measure**: Percent of PHEP recipients that exercise plans to expedite administrative preparedness.

Timely Coordination and Support of Response Activities with Health Care and Other Partners.

• **Program Measure**: Percent of PHEP recipients that have procedures in place to manage volunteers supporting an emergency or incident.

Earliest Possible Identification and Investigation of an Incident.

- **Program Measure**: Percent of PHEP-funded laboratories that successfully pass proficiency testing.
- **Program Measure**: Percent of PHEP-funded LRN-C Levels 1, 2, and 3 laboratories that can successfully package and ship test specimens.

Progress Reports. In addition to the ORR, process, and outcome measures, CDC requires timely submission of all progress and financial reports. These reports will be technically reviewed by CDC staff.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance

measurement planning processes.

- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

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

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

At the time of application, applicants must include in their project narrative a brief description of how they plan to fulfill the requirements described in the Evaluation and Performance Measurement and Project Description sections of this NOFO. They also must briefly outline the scope of work, planned activities, and intended outcomes of work performed via subrecipients.

Recipients are required to submit, within the first six months of award, a brief evaluation and performance measurement plan, including a Data Measurement Plan (DMP), as described in the Reporting section of this NOFO. CDC does not require recipients to follow a specific evaluation template; however, a template will be available upon request. CDC recommends that recipients develop a five-year evaluation plan that will evaluate interim progress including subrecipient and local monitoring annually.

CDC will review and approve recipient monitoring and evaluation plans to ensure that they are appropriate for the activities to be undertaken as part of this funding opportunity. If a recipient does not desire to use the CDC-provided template, then the Evaluation and Performance Measurement Plan should include the following details.

Performance Measurement

- Performance measures and targets.
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards

achieving NOFO goals, such as reaching target populations or achieving expected outcomes.

- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted, such as process or outcome evaluations.
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publicly available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO, such as the effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit.
- Dissemination channels and audiences.

c. Organizational Capacity of Recipients to Implement the Approach

PHEP recipients must address their ability to implement the requirements and expectations set forth in the Project Description section. PHEP recipients should have public health organizational capacity to implement the National Response Framework, which is built on scalable, flexible, and adaptable concepts and coordinating structures identified in NIMS. The flexibility of such structures helps ensure that communities across the country can organize response efforts to address a variety of risks based on their unique needs, capabilities, demographics, governing structures, and nontraditional partners. The National Response Framework is not based on a one-size-fits-all organizational construct, but instead it acknowledges the concept of tiered response which emphasizes that response to incidents should be handled at the lowest jurisdictional level capable of handling the mission.

Additionally, PHEP recipients must provide copies of the organizational chart(s) for their PHEP programs. Recipients must name this file "PHEP Organizational Chart" and upload it as a PDF files at www.grants.gov at the time of application submission.

d. Work Plan

PHEP recipients must prepare a high-level work plan that describes the proposed strategies and activities at the state and local levels. The work plan integrates and delineates specifically how the recipient plans to achieve the performance period outcomes through the implementation of capability-based strategies and activities.

In addition, PHEP recipients must submit a detailed Budget Period 1 work plan that describes their planned activities for addressing the strategies and activities described in the CDC Project Description. Recipients must name the file "Domain Work Plan" and upload it as a separate PDF file at www.grants.gov in "Other Attachment Forms."

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients,

site visits, and recipient 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 recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient 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 deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients 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.

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 recipients.

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring. Project Officers, specialists, and subject matter experts will review applications to ensure activities are in scope and do not duplicate those funded by other grants and cooperative agreements. CDC will use application submission information to identify strengths and weaknesses and to establish priorities for site visits and technical assistance. To assist PHEP recipients in achieving the purpose of this award, CDC will conduct the following activities.

- Provide ongoing guidance, programmatic support, training, and technical assistance related to public health emergency preparedness;
- Provide ongoing guidance, programmatic support, training, and technical assistance related to activities outlined in this funding opportunity. Technical assistance resources include PHEP supplemental guidance and resources, funding application instructions, quarterly spend plan templates, and other resources as needed;
- Facilitate communication among recipients to advance the sharing of expertise on preparedness and response activities;
- Facilitate technical assistance through CDC's online technical assistance portal;
- Facilitate regional technical assistance meetings for medical countermeasure planning and

administration.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

CDC's substantial involvement in this program appears in the CDC Program

Support to Recipients Section.

2. Award Mechanism: U09

3. Fiscal Year: 2019

4. Approximate Total Fiscal Year Funding: \$620,250,000 **5. Approximate Period of Performance Funding:** \$3,061,250,000

This amount is subject to the availability of funds.

Estimated Total Funding: \$620,250,000

6. Approximate Period of Performance Length: 5 year(s)

7. Expected Number of Awards: 62

8. Approximate Average Award: \$10,000,000 Per Budget Period

9. Award Ceiling: \$10,000,000 Per Budget Period

This amount is subject to the availability of funds.

Throughout the 2019-2024 performance period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient in meeting PHEP benchmarks and programmatic requirements (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 (performance 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 performance period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

10. Award Floor: \$350,000 Per Budget Period

Set by formula established under section 319C-1(h) of the PHS Act.

11. Estimated Award Date:07/01/201912. Budget Period Length:12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the 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 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 period of performance comprises the

initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is available through this NOFO.

Direct assistance (DA) is available through this NOFO. Consistent with the cited authority for this announcement, DA may be available in the form of equipment, supplies and materials, and/or federal personnel. If DA is provided as a part of the PHEP recipient's award, CDC will reduce the financial assistance award amount provided directly to the recipient as a part of the award. The amount by which the award is reduced will be used to provide DA; the funding shall be deemed part of the award and as having been paid to the recipient.

Recipients planning to request DA in lieu of financial assistance must complete and submit the DA request form annually per CDC deadlines. Note that DA may be requested for personnel, such as public health advisors, Career Epidemiology Field Officers, informatics specialists, or other technical consultants, provided the work is within scope of the cooperative agreements and is financially justified.

DA also may be requested for any Statistical Analysis Software (SAS) licenses desired for future budget periods.

Recipients should consider cost sharing options with partner programs to substantiate PHEP-funded support of all shared resources.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments

Additional Eligibility Category:

Government Organizations:

agents (includes the District of Columbia)
Local governments or their bona fide agents
Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern

Marianna Islands, American Samoa,

State governments or their bona fide

Guam, the Federated States of

Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

2. Additional Information on Eligibility

Government Organizations:

- States: 50
- Local governments or their bona fide agents: (4) Chicago, Los Angeles County, New York City, and Washington, D.C.
- Territorial governments or their bona fide agents and freely associated states: (8) American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Puerto Rico, Republic of the Marshall Islands, Republic of Palau, and U.S. Virgin Islands

Eligible recipients for this funding opportunity announcement are limited to those currently funded under CDC-RFA-TP17-1701.

3. Justification for Less than Maximum Competition

Section 319C-1, which authorizes the PHEP cooperative agreement program, limits eligibility for the formula awards to states or a consortium of states that prepare and submit a sufficient application compliant with the statutory and administrative requirements described in this document. The term "state" includes the several states, American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, U.S. Virgin Islands, and the Freely Associated States of Palau, Republic of the Marshall Islands, and Federated States of Micronesia. Because the formula awards are statutorily prescribed, no limited justification is necessary.

In addition to the formula awards, the statute authorizes CDC to make awards to up to three political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. CDC has determined that Chicago, Los Angeles County, and New York City meet the requirements of this provision.

The statute also authorizes CDC to make awards to "eligible entities" that have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by the formula award, and face a particularly high degree of risk of such a threat. CDC has determined that the Cities Readiness Initiative local planning jurisdictions and the Level 1 Laboratory Response Network chemical laboratories meet the requirements of these provisions. And, by statute, Washington, D.C., is deemed to meet the requirements for one of these awards.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

Yes

CDC may not award a cooperative agreement to a state or consortium of states under these programs unless the recipient agrees that, with respect to the amount of the cooperative

agreements awarded by CDC, the state will make available nonfederal contributions in the amount of 10% (\$1 for each \$10 of federal funds provided in the cooperative agreement) of the award, whether provided through financial or direct assistance. Match may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the federal government or services assisted or subsidized to any significant extent by the federal government may not be included in determining the amount of such nonfederal contributions.

Documentation of match, including methods and sources, must be included in recipient budgets each budget period, include calculations for both financial assistance and direct assistance, follow procedures for generally accepted accounting practices, and meet audit requirements.

Exceptions to Matching Funds Requirement

- The match requirement does not apply to the political subdivisions of New York City, Los Angeles County, or Chicago.
- Pursuant to department grants policy implementing 48 U.S.C. 1469a(d), any required matching (including in-kind contributions) of less than \$200,000 is waived with respect to cooperative agreements to the governments of American Samoa, Guam, the U.S. Virgin Islands, or the Northern Mariana Islands (other than those consolidated under other provisions of 48 U.S.C. 1469)."

Please refer to 45 CFR § 75.306 for more information.

5. Maintenance of Effort

Maintaining State Funds

In accordance with 42 U.S.C.A. § 247d-3a, an entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding two-year period. The definition of eligible state expenditures for public health security includes:

- Appropriations specifically designed to support public health emergency preparedness as expended by the entity receiving the award; and
- Funds not specifically appropriated for public health emergency preparedness activities but which support public health emergency preparedness activities, such as personnel assigned to public health emergency preparedness responsibilities or supplies or equipment purchased for public health emergency preparedness from general funds or other lines within the operating budget of the entity receiving the award.

PHEP recipients must stipulate the total dollar amount in their cooperative agreement funding applications. PHEP recipients must be able to account for the maintenance of funding separate from accounting for federal funds and separate from accounting for any matching funds requirements; this accounting is subject to ongoing monitoring, oversight, and audit. Maintaining state funding may not include any subrecipient matching funds requirement where applicable.

D. Application and Submission Information

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-recipients, those sub-recipients 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 a recipient. 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 can require 10 or more 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 at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

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

Step	System	Requirements	Duration	Follow Up
1	Data	1. Click on http://	1-2 Business	To confirm that
	Universal	fedgov.dnb.com/ webform	Days	you have been
	Number	2. Select Begin DUNS	_	issued a new
	System	search/request process		DUNS number
	(DUNS)	3. Select your country or		check online at
		territory and follow the		(http://
		instructions to obtain your		fedgov.dnb.com/
		DUNS 9-digit #		webform) or call

		4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number		1-866-705-5711
2	(SAM) formerly Central Contractor	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	to 2 weeks and must be renewed	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	can take 8 weeks to be fully registered and approved	Register early! Log into grants.gov and check AOR status until it shows you have been approved

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 notice of 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 OGS staff at 770-488-2700 or e-mail OGS ogstims@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 NOFO, it will not be processed. Office of Grants Services (OGS) 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 OGS.

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

Due Date for Letter of Intent: N/A

b. Application Deadline

Due Date for Applications: **05/03/2019**, 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.

May 3, 2019, 11:59 p.m. EDT (Daylight Savings Time begins March 10, 2019)

Date for Information Conference Call

Wednesday, March 6, 2019, 2:30 p.m. to 4 p.m. EST

Wednesday, March 13, 2019, 2:30 p.m. to 4 p.m. EDT

Thursday, March 14, 2019, 1:30 p.m. to 3 p.m. EDT

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa)))
/Homepage.aspx.

Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with 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.

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will

include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS. When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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

A letter of intent is not requested or required as part of the application for this funding opportunity.

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page 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

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. 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 period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

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 public health 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, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance 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 the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

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. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

• How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by

the Office of Management and Budget. For further information about CDC's requirements under PRA see http://www.hhs.gov/ocio/policy/collection/.

- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

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

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

(Included in the Project Narrative's 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 recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. 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 could include the cost of collecting, managing, sharing and preserving data. Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

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 NOFO 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 NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

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 Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

Recipients must submit an itemized budget narrative. When developing the budget narrative, recipients 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

Expanded Authority for Unobligated Funds

In accordance with 45 CFR § 75.308(d), recipients have expanded authority to carry forward unobligated balances to the successive budget period without receiving prior approval from CDC's Office of Grants Services. The following restrictions apply with this authority.

- 1. The expanded authority can only be used to carry over unobligated balances from one budget period to the next successive budget period. Any unobligated funds not expended in the successive budget period must be de-obligated and returned to the U.S. Treasury as required.
- 2. Extensions will not be allowed for the last 12 months of the budget/performance period.
- 3. The recipient must report the amount carried over on the Federal Financial Report for the period in which the funds remained unobligated.
- 4. This authority does not diminish or relinquish CDC administrative oversight of PHEP programs. CDC program offices will continue to provide oversight and guidance to the award recipients to ensure they are in compliance with statutes, regulations, and internal guidelines.
- 5. The roles and responsibilities of the CDC project officers will remain the same as indicated in the terms and conditions of the award.
- 6. The roles and responsibilities of the grants management specialists in CDC's Office of Grants Services will remain the same as indicated in the terms and conditions of the award.
- 7. All other terms and conditions remain in effect throughout the budget period unless otherwise changed in writing by the CDC grants management officer.

Note: Recipients are responsible for ensuring that all costs allocated and obligated are allowable, reasonable, and allocable and in line with the goals and objectives outlined in CDC-RFA-TP19-1901 and approved work plans.

Support for Accreditation Standards

PHEP recipients may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (http://www.phaboard.org) or Emergency Management Accreditation

Program (EMAP) (https://emap.org).

- Applicant entities to whom this provision applies include state, local, territorial governments (including Washington D.C., the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana 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).
- O 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 NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed
- EMAP is a voluntary standards, assessment, and accreditation process for disaster preparedness programs throughout the country. It fosters excellence and accountability in emergency management and homeland security programs, by establishing credible standards applied in a peer review accreditation process.

Applicants must name their budget file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a current 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 recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it as a separate PDF file at www.grants.gov with the other application documentation.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

• Records that identify adequately the source and application of funds for federally-funded

activities.

- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Intergovernmental Review

Executive Order 12372 does not apply to this program.

15. 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 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients 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.

16. Copyright Interests Provisions

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.

17. Funding Restrictions

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

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients 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 generally is not allowed, unless the CDC provides written approval to the recipient.
- 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 <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability

(https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

The following are restrictions that must be taken into consideration while developing the application budget. To address questions or concerns, please contact the respective CDC project officer and the CDC Office of Grant Services (OGS) grants management specialist (GMS) in advance of submission.

General Restrictions

• Recipients may supplement but not supplant existing state or federal funds for activities

described in the budget.

- Payment or reimbursement of backfilling costs for staff is not allowed.
- None of the funds awarded to these programs may be used to pay the salary of an individual at a rate in excess of Executive Level II or \$189,600 per year.
- Funds may not be used to purchase or support (feed) animals for labs, including mice.
- Funds may not be used to purchase a house or other living quarters for those under quarantine. Rental may be allowed with approval from the CDC OGS.
- Recipients may (with prior approval) use funds for overtime for individuals directly
 associated (listed in personnel costs) with the award with prior approval from CDC
 OGS.

Lobbying

Other than for normal and recognized executive-legislative relationships, PHEP funds may not 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 <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients (<u>http://www.cdc.gov/grants/documents/Anti-Lobbying Restrictions for CDC Grantees July 2012.pdf).</u>

Construction and Major Renovations

- Recipients may not use funds for construction or major renovations.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly justified in the budget.

Passenger Road Vehicles

- Funds cannot be used to purchase over-the road passenger vehicles.
- Funds cannot be used to purchase vehicles to be used as means of transportation for carrying people or goods, such as passenger cars or trucks and electrical or gas-driven motorized carts.
- Recipients can (with prior approval) use funds to lease vehicles to be used as means of transportation for carrying people or goods, e.g., passenger cars or trucks and electrical or gas- driven motorized carts during times of need.
- Additionally, PHEP grant funds can (with prior approval) be used to make transportation agreements with commercial carriers for movement of materials, supplies and equipment. There should be a written process for initiating transportation agreements (e.g., contracts, memoranda of understanding, formal written agreements, and/or other

letters of agreement). Transportation agreements should include, at a minimum:

- Type of vendor
- o Number and type of vehicles, including vehicle load capacity and configuration
- o Number and type of drivers, including certification of drivers
- o Number and type of support personnel
- Vendor's response time
- o Vendor's ability to maintain cold chain, if necessary to the incident
- This relationship may be demonstrated by a signed transportation agreement or documentation of transportation planning meeting with the designated vendor.
 All documentation should be available to the CDC project officer for review if requested.

Transportation of Medical Materiel

- Funds can (with prior approval) be used to procure leased or rental vehicles for movement of materials, supplies and equipment.
- Recipients can (with prior approval) use funds to purchase material-handling equipment (MHE) such as industrial or warehouse-use trucks to move materials, such as forklifts, lift trucks, turret trucks, etc. Vehicles must be of a type not licensed to travel on public roads.
- Recipients may purchase basic (non-motorized) trailers with prior approval from the CDC OGS.

Procurement of Food and Clothing

- Funds may not be used to purchase clothing such as jeans, cargo pants, polo shirts, jumpsuits, sweatshirts, or T-shirts. Purchase of vests to be worn during exercises or responses may be allowed.
- Generally, funds may not be used to purchase food.

Vaccines

- PHEP recipients can, with prior CDC approval, use funds to purchase caches of antibiotics for use by public health responders and their households to ensure the health and safety of the public health workforce during an emergency response, or an exercise to test response plans. Funds may not be used to supplant other funding intended to achieve this objective.
- PHEP recipients can, with prior CDC approval, use funds to purchase caches of vaccines for public health responders and their households to ensure the health and safety of the public health workforce.
- PHEP recipients can, with prior CDC approval, use funds to purchase caches of vaccines for select critical workforce groups to ensure their health and safety during an exercise testing response plans.
 - Recipients must document in their submitted exercise plans the use of vaccines for select critical workforce personnel before CDC will approve the vaccine purchase.
- Recipients may not use PHEP funds to supplant other funding intended to achieve these

objectives.

- Recipients of PHEP-funded vaccines (within the context of the exercise) may include:
 - Persons who meet the criteria in the CDC-Advisory Committee on Immunization Practices (CDC/ACIP) recommendations www.cdc.gov/vaccines/acip/index.html for who should receive vaccine; and
 - Persons who are not eligible to receive the vaccine through other entitlement programs such as Medicare, Medicaid, or the Vaccines for Children (VFC) program.
 - VFC-eligible children or Medicare beneficiaries may participate in the exercise; however, they should be vaccinated with vaccine purchased from the appropriate funding source.
- PHEP funds may not be used to purchase vaccines for seasonal influenza mass vaccination clinics or other routine vaccinations covered by ACIP schedules.
- PHEP funds may not be used to purchase influenza vaccines for the general public.

Recipients may not use funds for clinical care except as allowed by law. For the purposes of this NOFO, clinical care is defined as "directly managing the medical care and treatment of individual patients." PHEP-funded staff may administer MCMs such as antibiotics or vaccines as a public health intervention in the context of an emergency response or an exercise to test response plans. CDC does not consider this clinical care since it is not specific to one.

Laboratory Supplies

Instruments, reagents and supplies for the following are not generally purchased with PHEP funding:

- Instruments, reagents and supplies for testing seasonal influenza;
- Instruments, reagents and supplies for testing rabies;
- Instruments, reagents and supplies for routine food testing (surveillance);
- Instruments, reagents and supplies for testing vaccine preventable diseases (e.g. measles, mumps, etc.)
- Instruments, reagents and supplies for routine testing of vector-borne illnesses (both clinical and vector surveillance):
- Routine drug screening of laboratory staff; and
- Influenza vaccines (for the general public).

Because recipients receive substantial assistance from CDC through other programs, recipients should ensure these line items are funded under the appropriate program.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

19. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option. If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770- 488-2700 or by e-mail at ogstims@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 OGS 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 NOFO. 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 Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get Started%2FGet Started.htm

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@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@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 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 received via e-mail to the GMS/GMO listed below 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, OGS 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 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/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 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.

i. Approach Maximum Points:40

CDC ensures grant applications undergo a multilevel technical review to be considered for

funding. This review process involves the thorough and consistent examination of applications based on technical merit or other relevant aspects of the applications.

CDC's Office of Grants Services will conduct an initial review of applications for completeness. In addition, project officers from CDC's Division of State and Local Readiness (DSLR) and CDC subject matter experts will jointly review applications for responsiveness to the requirements contained in this NOFO and technical acceptability. CDC will provide recipients with technical review reports with their notices of awards.

CDC project officers, MCM specialists, subject matter experts, and DSLR executives will evaluate complete, eligible applications in accordance with the criteria below.

Eligible applications must meet all requirements defined in this NOFO. Specifically, eligible applications will be evaluated against the following criteria. Not more than 30 days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

CDC will evaluate the extent to which the recipient:

- Presents outcomes that are consistent with the performance period outcomes described in the CDC Project Description and logic model.
- Describes an overall strategy and activities consistent with the CDC Project Description and logic model.
- Describes strategies and activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable).
- Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the performance period outcomes.
- 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 format proposed.
- Presents narrative descriptions for work plan activities, technical assistance needs, budget and five-year forecasts have a reasonable relationship, correlation, and continuity, where applicable, with data from past performance (e.g., public health capabilities self-assessment data, prior year performance measures, and prior year application narratives and planned activities).
- Proposes adequate planned activities to prioritize, build and sustain public health capabilities during the budget period.
- Proposes adequate planned activities which reflect progress to coordinate public health and health care preparedness program activities and leverage program funding streams.
- Describes the process used to engage local health departments to reach consensus/approval/concurrence for the strategic approach or direction of the preparedness program.
- Describes the process used to engage federally recognized American Indian/Alaska Native tribes for the implementation, strategic approach, or direction of the preparedness program.
- Adheres to HHS grant regulations and grants management policies.
- Presents a budget that is well aligned to the work plan wherein the line items associated

with the completion of the proposed strategies and activities are achievable, reasonable, and allowable.

• Sufficiently details budget line items to contain detailed justifications and cost calculations.

ii. Evaluation and Performance Measurement

Maximum Points:30

CDC will evaluate the extent to which the recipient:

- 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 recipient in their approach.
- Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities.
- Describes how performance measurement and evaluation findings will be reported, and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement.
- Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base.

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points:30

CDC will evaluate the extent to which the recipient:

• Addresses their ability to implement the requirements and expectations set forth in this funding opportunity.

Recipients will be notified of their awards, which will include the technical review report.

Budget

c. Phase III Review

The final review phase will be completed by the Office of Grants Services.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the

Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards:
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Recipients will receive an e-mail from GrantSolutions with a link to their Notices of Award (NOA) no later than July 1, 2019. Funding will take effect July 1, 2019.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The

NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity 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

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available

at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

The HHS Grants Policy Statement is available

at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

The following Administrative Requirements (AR) apply to this project:

AR-7: Executive Order 12372

AR-9: Paperwork Reduction Act http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html

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-24: Health Insurance Portability and Accountability Act AR-25: Release and Sharing of Data

AR-26: National Historic Preservation Act of 1966

AR-29: Compliance with EO13513, ?Federal Leadership on Reducing Text Messaging while Driving,? October 1, 2009

AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973 AR-33: Plain Writing Act of 2010

ARs applicable to awards related to conferences: AR-20: Conference Support

AR-27: Conference Disclaimer and Use of Logos

For more information on the CFR visit http://www.access.gpo.gov/nara/cfr/cfr-table-search .html

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit

Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

3. Reporting

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

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance 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 NOFO.

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 NOFO copying the CDC Project Officer.

Report	When?	Required?	
Performance Measurement Plan, including Data Management Plan (DMP)	No later than December 30, 2019.		
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes	
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes	
CDC may require more frequent circumstances.	financial reporting for PHEP rec	ipients based on individual	
Quarterly spend plan reports that include obligation rates	30 days after the end of the quarter	Yes	
Final Performance and Financial Report	90 days after end of project period	Yes	
Payment Management System (PMS) Reporting	Quarterly reports	Yes	

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publically available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed. This report must include the following:

• Performance Measures: Recipients must report on performance measures for each

budget period and update measures, if needed.

- Evaluation Results: Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- Work Plan: Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.

Successes

- Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
- Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- o Recipients must describe success stories.

• Challenges

- Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- o Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

• CDC Program Support to Recipients

 Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

• Administrative Reporting (No page limit)

- o 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.

In addition to the annual performance report, recipients must submit annual progress reports. The end-of-year progress reports are due no later than 90 days after the end of the budget period.

This report assesses the following:

- 1. **Work Plan Progress**: Recipients must update work plan each budget period to reflect any changes in performance period outcomes, activities, timeline, etc.
- 2. **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed. In addition, recipients must submit program benchmark and pandemic influenza planning data. Recipients that fail to "substantially meet" PHEP benchmarks and pandemic influenza planning information required by this NOFO are subject to withholding of a statutorily mandated percentage of the following year's award.
- 3. **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- 4. Challenges and Barriers
- 5. **EOC Activations:** Recipients must submit summary information regarding their

responses to real incidents involving partial or full activation of their EOCs, including virtual activations, if applicable.

6. Successes

The recipients must submit the Annual Performance Report via <u>www.Grantsolutions.gov</u> no later than 120 days prior to 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 recipients at the beginning of the award period.

See the *Recipient Evaluation and Measurement Strategy* section for more information on PHEP performance measure reporting.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period. 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, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

CDC may require more frequent financial reporting for PHEP recipients based on individual circumstances.

e. Final Performance and Financial Report (required)

This report is due 90 days after the end of the period of performance. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories Recipients 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.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

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 awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov. 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 applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000. For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www.fsrs.gov/documents/ffata legislation 110 252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;
- "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:
- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.
- 6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Sharon Sharpe, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd, NE
Mailstop H21-5
Atlanta, GA 30329-027

Telephone: (404) 639-0817

Email: lss1@cdc.gov

Grants Staff Contact

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

Shicann Phillips, Grants Management Specialist

Department of Health and Human Services Office of Grants Services 2920 Brandywine Rd Atlanta, GA 30341

Telephone: (770) 488-2809

Email: ibq7@cdc.gov

For assistance with **submission difficulties related to** <u>www.grants.gov</u>, 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 Office of Financial Resources Office of Grants Services 2920 Brandywine Road, MS E-14 Atlanta, GA 30341

Telephone: 770-488-2700 Email: ogstims@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
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Summary of NOFO Amendments

Amendments to this NOFO are found in the following sections.

Part II. Full Text

A. Funding Opportunity Description

- 2. CDC Project Description
- a. Approach
- iii. Strategies and Activities/Programmatic Requirements

Domain 1

Strengthen and Implement Plans through Training and Exercising

Coordinate training, exercise planning, and implementation. MYTEP submission changed to May 3, 2019.

Domain 2

Activate and Coordinate Public Health Emergency Operations

Maintain and exercise continuity of operations (COOP) plans. Added requirement for COOP planning for laboratories.

Domain 4

<u>Demonstrate MCM Operational Readiness – PHEP Benchmark: deleted submission of self-assessment data.</u>

Domain 6

Added requirement: Maintain and Exercise Laboratory COOP Plans

iii. Strategies and Activities/Administrative Requirements and Assurances

Engage in technical assistance planning. Added quarterly deadlines for written and verbal updates on technical assistance action plans.

Participate in program monitoring activities. Clarified frequency of technical assistance planning calls with CDC.

<u>Submit exercise documentation</u>. Added information on joint exercises, EOC staff notification and assembly drills; laboratory COOP plan exercises, and pandemic influenza functional exercises.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

PHEP Budget Period 1 Benchmarks Subject to Withholding: Clarified PHEP Benchmark 1: Demonstrate MCM operational readiness

Criteria to Determine Potential Withholding of PHEP Fiscal Year 2020 Funds: Corrected scoring criteria to indicate that failure to substantially meet any one of the first four benchmarks will count as one failure and result in withholding of

10% of the fiscal year 2020 award.

C. Eligibility Information

- 4. Cost Sharing or Matching: Clarified matching funds requirements and exceptions
- D. Application and Submission Information
 - 12. Budget Narrative: Added information on expanded authority for unobligated funds.
- F. Award Administration Information
 - 3. Reporting: Corrected requirements for spend plan reports to quarterly submissions.
 - b. Annual Performance Report (APR) (required): Clarified differences between the annual performance reports and the annual progress reports.

H. Other Information

Application Submission Requirements: Added to list of mandatory attachments: Risk questionnaire, OMB Control Number 0920-1132

Application Submission Requirements

Following is a list of attachments applicants **must** upload as PDF files as part of their applications at www.grants.gov. If other documents are attached, CDC will not review the applications.

- Table of Contents
- Project Abstract
- Project Narrative
- Domain Work Plan
- Budget Narrative
- Application for Federal Assistance (SF-424)
- Budget Information for Non-Construction Programs (SF-424A)
- Indirect Cost Rate Agreement or Cost Allocation Plan
- CDC Assurances and Certifications (PHS-5161)
- Senior Health Official (SHO) Letter
- Local Health Department Concurrence Letter (for applicable recipients)
- Subrecipient Monitoring Plan
- Organizational Chart
- Disclosure of Lobbying Activities (SF-LLL)
- Risk Questionnaire, OMB Control Number 0920-1132

Optional attachments:

- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent Status Documentation, if applicable

PHEP Funding Table

Recipient	FY 2019 Base Plus Population Funding	FY 2019 Cities Readiness Initiative Funding	FY 2019 Level 1 Chemical Laboratory Funding	FY 2019 Level 2 Chemical Laboratory Funding*	FY 2019 Total Funding Available
Alabama	\$8,388,823	\$292,798	\$0	\$372,600	\$9,054,221
Alaska	\$5,000,000	\$75,000	\$0	\$372,600	\$5,447,600
American Samoa	\$411,385	\$0	\$0	\$0	\$411,385
Arizona	\$10,906,659	\$1,167,265	\$0	\$372,600	\$12,446,524
Arkansas	\$6,322,708	\$199,522	\$0	\$372,600	\$6,894,830
California	\$35,406,043	\$5,314,718	\$1,175,583	\$0	\$41,896,344
Chicago	\$8,084,259	\$1,630,935	\$0	\$0	\$9,715,194
Colorado	\$9,279,295	\$716,242	\$0	\$372,600	\$10,368,137
Connecticut	\$6,938,823	\$531,100	\$0	\$372,600	\$7,842,523
Delaware	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Florida	\$26,482,266	\$2,914,646	\$932,317	\$0	\$30,329,229
Georgia	\$14,597,603	\$1,459,002	\$0	\$372,600	\$16,429,205
Guam	\$532,702	\$0	\$0	\$0	\$532,702
Hawaii	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Idaho	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Illinois	\$14,052,042	\$1,872,337	\$0	\$372,600	\$16,296,979
Indiana	\$10,377,720	\$777,404	\$0	\$372,600	\$11,527,724
Iowa	\$6,479,614	\$200,929	\$0	\$372,600	\$7,053,143
Kansas	\$6,209,901	\$390,706	\$0	\$0	\$6,600,607
Kentucky	\$7,926,363	\$367,409	\$0	\$0	\$8,293,772
Los Angeles County	\$16,539,654	\$3,323,413	\$0	\$372,600	\$20,235,667
Louisiana	\$8,137,573	\$534,721	\$0	\$0	\$8,672,294
Maine	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000

Marshall Islands	\$408,616	\$0	\$0	\$0	\$408,616
Maryland	\$9,662,029	\$1,364,512	\$0	\$0	\$11,026,541
Massachusetts	\$10,609,541	\$1,253,992	\$1,080,144	\$0	\$12,943,677
Michigan	\$14,020,384	\$1,101,640	\$1,063,587	\$0	\$16,185,611
Micronesia	\$467,114	\$0	\$0	\$0	\$467,114
Minnesota	\$9,186,262	\$885,440	\$1,092,880	\$0	\$11,164,582
Mississippi	\$6,292,616	\$235,157	\$0	\$0	\$6,527,773
Missouri	\$9,754,344	\$860,453	\$0	\$0	\$10,614,797
Montana	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
N. Mariana Islands	\$410,851	\$0	\$0	\$0	\$410,851
Nebraska	\$5,126,996	\$202,631	\$0	\$0	\$5,329,627
Nevada	\$6,345,383	\$540,616	\$0	\$372,600	\$7,258,599
New Hampshire	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
New Jersey	\$12,821,543	\$2,206,035	\$0	\$0	\$15,027,578
New Mexico	\$5,310,186	\$231,621	\$1,096,376	\$0	\$6,638,183
New York	\$15,038,638	\$1,779,383	\$1,726,734	\$0	\$18,544,755
New York City	\$14,790,218	\$4,000,647	\$0	\$0	\$18,790,865
North Carolina	\$14,447,824	\$535,704	\$0	\$372,600	\$15,356,128
North Dakota	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Ohio	\$15,887,478	\$1,469,164	\$0	\$0	\$17,356,642
Oklahoma	\$7,347,200	\$346,390	\$0	\$0	\$7,693,590
Oregon	\$7,620,214	\$489,593	\$0	\$0	\$8,109,807
Palau	\$374,215	\$0	\$0	\$0	\$374,215
Pennsylvania	\$17,119,639	\$1,662,637	\$0	\$0	\$18,782,276
Puerto Rico	\$6,522,620	\$0	\$0	\$0	\$6,522,620
Rhode Island	\$5,000,000	\$75,000	\$0	\$372,600	\$5,447,600
South Carolina	\$8,605,193	\$301,733	\$1,010,999	\$0	\$9,917,925
South Dakota	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000

TOTAL	\$551,183,005	\$51,145,995	\$11,586,800	\$6,334,200	\$620,250,000
Wyoming	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Wisconsin	\$9,409,393	\$478,919	\$1,445,235	\$0	\$11,333,547
West Virginia	\$5,000,000	\$183,848	\$0	\$0	\$5,183,848
Washington, D.C.	\$5,774,449	\$684,393	\$0	\$372,600	\$6,831,442
Washington	\$11,307,904	\$1,075,939	\$0	\$372,600	\$12,756,443
Virginia	\$12,390,652	\$1,503,750	\$962,945	\$0	\$14,857,347
Virgin Islands (U.S.)	\$465,667	\$0	\$0	\$0	\$465,667
Vermont	\$5,000,000	\$75,000	\$0	\$0	\$5,075,000
Utah	\$6,485,083	\$299,442	\$0	\$0	\$6,784,525
Texas	\$34,643,460	\$4,124,965	\$0	\$372,600	\$39,141,025
Tennessee	\$10,463,860	\$734,244	\$0	\$0	\$11,198,104

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 75 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 NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assitance Listings (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.

Assistance Listings (CFDA) Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

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.

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 period of performance (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 recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

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 NOFO evaluation plan is used to describe how the recipient 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. **Health Equity:** Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions. **Health Inequities:** Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

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: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-SPOC_01_2018_OFFM.pdf.

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 activitles; 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.

Period of performance –**formerly known as the project period** -: The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs. **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 NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

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.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

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 period of performance 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.

NOFO-specific Glossary and Acronyms

Access and Functional Needs: Refers to persons who may have additional needs before, during and after an incident in functional areas, including but not limited to maintaining health, independence, communication, transportation, support, services, self-determination, and medical care. Individuals in need of additional response assistance may include those who have disabilities; live in institutionalized settings; are older adults; are children; are from diverse cultures; have limited English proficiency or are non-English speaking; or are transportation disadvantaged (U.S. Federal Emergency Management Agency definition).

Administer: For the purposes of Domain 4, Capability 8: Medical Countermeasure Dispensing and Administration, this term refers to the act of a clinician or other trained provider giving a medical countermeasure to an individual according to protocols established for that incident, ensuring:

- The right individual,
- The right medical countermeasure,
- The right timing, including the correct age and interval, as well as before the product expiration time and date,
- The right dosage,
- The right route, including the correct needle gauge, length, and technique,
- The right site, and
- The right documentation.

Protocols for the administration of medical countermeasures may consist of routine standard of practice guidance, such as how to give an injection, or may deviate from standard practice if involving emergency use authorizations, investigational new drug protocols, or the federal Shelf Life Extension Program. Some medical countermeasures must be administered by a clinician or other trained personnel, such as vaccines administered by injection. This task is different from dispensing medical countermeasures when an individual can independently take a pill or use a device without further clinical supervision.

After-action Report/Improvement Plan: The main product of the evaluation and improvement planning process. The after-action report/improvement plan (AAR/IP) has two components: an AAR captures observations of an exercise and makes recommendations for post-exercise improvements; and an IP identifies specific corrective actions, assigns them to responsible parties, and establishes targets for their completion. AARs summarizes and analyzes performance in both exercises and real incidents or events. The reports for exercises also may evaluate achievement of the selected exercise objectives and demonstration of the overall capabilities being exercised.

CMIST Framework: The Communication; Maintaining Health; Independence; Services and Support; and Transportation (CMIST) framework defines cross-cutting categories of the access and functional needs of at-risk individuals. The framework addresses a broad set of common

access and functional needs that are not tied to specific diagnoses, status, or labels, such as pregnant women, children, or elderly. Ultimately, individuals with access and functional needs must be addressed in all federal, territorial, tribal, state, and local emergency and disaster plans.

Corrective Action Plan: Improvements and corrective actions that are implemented based on lessons learned from actual incidents or from training and exercises.

Critical Workforce Personnel: This term is generally defined as the staff (or volunteers) who are required to report to a designated location to ensure the operation of essential functions during a public health emergency or response. This includes but is not limited to all workers (or volunteers) with critical skills, experience, certification or licensure status whose absence would create severe bottlenecks in or the collapse of critical operations.

Critical Infrastructure Workforce: This broadly defined term refers to the individuals who work to support the systems, assets, facilities and networks that provide essential services and are necessary for the national health security, economic security, prosperity, and health and safety of the jurisdiction.

Emergency Support Function (ESF): Grouping of governmental and certain private sector capabilities into an organizational structure to provide support, resources, program implementation, and services that are most likely needed to save lives, protect property and the environment, restore essential services and critical infrastructure, and help victims and communities return to normal following domestic incidents. The 15 ESFs are annexes to the United States National Response Framework (NRF). While the primary ESF supported by public health agencies is ESF #8 Public Health and Medical Services, public health agencies also may support other ESFs in coordination with jurisdictional partners and stakeholders.

ESF-8 Public Health and Medical Services: Provides the mechanism for coordinated federal assistance to supplement state, tribal, and local public health, medical, and mental health resources in response to an emergency.

Essential Elements of Information (EEI): Discrete types of reportable public health or health care-related, incident-specific knowledge communicated or received concerning a particular fact or circumstance, preferably reported in a standardized manner or format, which assists in generating situational awareness for decision-making purposes. EEI are often coordinated and agreed upon before an incident, and communicated to local partners as part of information collection request templates and emergency response playbooks.

Essential Public Health Services: Public health activities that all communities should undertake. The Core Public Health Functions Steering Committee developed the framework for the Essential Services in 1994. The committee included representatives from U.S. Public Health Service agencies and other major public health organizations. The 10 Essential Public Health Services are

- 1. Monitor health status to identify and solve community health problems
- 2. Diagnose and investigate health problems and health hazards in the community
- 3. Inform, educate, and empower people about health issues
- 4. Mobilize community partnerships and action to identify and solve health problems
- 5. Develop policies and plans that support individual and community health efforts
- 6. Enforce laws and regulations that protect health and ensure safety

- 7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assure competent public and personal health care workforce
- 9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems

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 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 NOFO evaluation plan is used to describe how the recipient and CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Fiscal Preparedness: The process of ensuring that fiscal and administrative authorities and practices that govern funding, procurement, contracting, hiring, and legal capabilities necessary to mitigate, respond to, and recover from public health emergencies can be accelerated, modified, streamlined, and accountably managed at all levels of government.

Health Care Coalition (HCC): ASPR defines a health care coalition as a coordinating body that incentivizes diverse and often competitive health care organizations and other community partners with differing priorities and objectives to work together to prepare for, respond to, and recover from emergencies and other incidents that impact the public's health.

Homeland Security Exercise and Evaluation Program (HSEEP): A capabilities- and performance-based exercise program that provides a standardized policy, methodology, and language for designing, developing, conducting, and evaluating all exercises.

Incident: An occurrence, either human-caused or naturally occurring, that requires action to prevent or minimize loss of life or damage to property or natural resources. In the context of the capability standards, the term "incident" is used to describe any scenario, threat, disaster, or other public health emergency.

Jurisdictions: Planning areas, such as cities, counties, states, regions, territories, and freely associated states.

Laboratory Information Management System (LIMS): A software program that enables laboratories to fulfill data exchange needs for the Laboratory Response Network using their own systems.

Laboratory Response Network (LRN): A coordinated network of public health and other laboratories for which CDC provides standard assays and protocols for testing biological and chemical terrorism agents. The categories of laboratories include LRN-C focusing on chemical threats and LRN-B focusing on biological threats. Although referenced in the capabilities document, LRN-R for radiological threats has not been established. The LRN is charged with maintaining an integrated network of state and local public health, federal, military, and

international laboratories that can respond to bioterrorism, chemical terrorism, and other public health emergencies. The LRN also links state and local public health, veterinary, agriculture, military, and water- and food-testing laboratories

Mental/Behavioral Health: An overarching term to encompass behavioral, psychosocial, substance abuse, and psychological health.

Mission Ready Package (MRP): Describes specific response and recovery resource capabilities that are organized, developed, trained, and exercised prior to an emergency or disaster.

Outcome Measure: Also may be called impact measures, outcome measures assess direct and indirect program impact over time.

Partners and stakeholders: As referenced throughout the capabilities, partners and stakeholders refer to the diverse array of groups and individuals that public health agencies should engage to support the preparedness and response needs of the whole community. Many different kinds of communities, including communities of place, interest, belief, and circumstance can exist both geographically and virtually, such as online forums. A whole-community approach attempts to engage the full capacity of the private and nonprofit sectors, including businesses, coalitions, faith-based organizations, disability organizations, and the public, in conjunction with the participation of federal, state, local, tribal, and territorial governmental partners.

Preparedness Cycle: A continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action in an effort to ensure effective coordination during incident response. This cycle is one element of a broader National Preparedness System to prevent, respond to, and recover from natural disasters, acts of terrorism, and other disasters.

Process Measure: Focuses on the actual operation of a program to help identify progress as well as strengths and weaknesses. Process measures help define the structural and process components of the program and can be applied to document the delivery and improvement of the program.

Program Measure: For the purposes of PHEP program evaluation, program measures indicate the level of implementation and improvement of the PHEP program and the impact of the program overall across all PHEP jurisdictions. Program measures are compiled from the individual recipient performance measures to provide an overall measure of PHEP program impact.

Public Health First Responders: Defined in U.S. Homeland Security Presidential Directive (HSPD) 8, the term refers to public health staff or volunteers who, in the early stages of an incident, are responsible for the protection and preservation of life, property, evidence, and the environment; and provide immediate support services during prevention, response, and recovery operations. As the people on the front lines of public health, these responders play a vital role in preparing for, responding to, and recovering from public health emergencies.

Situational Awareness: Capturing, analyzing, and interpreting data to inform decision making in a continuous and timely cycle. National health security calls for both routine and incident-related situational awareness. Situational awareness requires not only coordinated information collection to create a common operating picture (COP), but also the ability to process, interpret,

and act upon this information. Action, in turn, involves making sense of available information to inform current decisions and making projections about likely future developments. Situational awareness helps identify resource gaps, with the goal of matching available resources and identifying additional resources to current needs. Ongoing situational awareness provides the foundation for successful detection and mitigation of emerging threats, better use of resources, and better outcomes for the population.