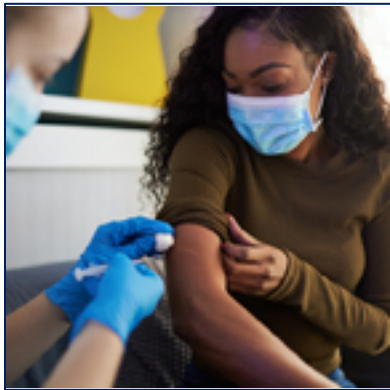


U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness & Response

Public Health Emergency Medical Countermeasure Enterprise

Strategy and Implementation Plan

2022



Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan

Introduction

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) was established by the Department of Health and Human Services (HHS) in 2006, and codified by Congress in 2019, to advance the country's medical countermeasure (MCM) preparedness against chemical, biological, radiological, nuclear, and emerging infectious disease threats.

The PHEMCE is a collaboration of federal partners that have expertise in the different MCM functions that are necessary to ensure countermeasure availability and use to protect people during public health emergencies. The PHEMCE exists to bridge the gaps in the country's MCM portfolio that might otherwise occur between these federal programs. PHEMCE members¹ include the Director of the Centers for Disease Control and Prevention (CDC), Director of the National Institutes of Health (NIH), Commissioner of the U.S. Food and Drug Administration (FDA), Secretary of Defense, Secretary of Homeland Security, Secretary of Agriculture, Secretary of Veterans Affairs (VA), and the Director of National Intelligence. Members work together to advise the Assistant Secretary for Preparedness and Response (Assistant Secretary)², who then makes recommendations to the Secretary of HHS on MCMs—including vaccines, treatments, devices, and personal protective equipment—that may be used to protect the American people during an emergency or other disaster.

Specifically, the Public Health Service (PHS) Act dictates the PHEMCE shall make recommendations to the Secretary of HHS regarding MCM research and development (R&D), procurement, stockpiling, distribution, and utilization; identify national health security needs; develop strategies for logistics, deployment, distribution, dispensing of countermeasures, particularly as it relates to the Strategic National Stockpile (SNS). With limited funding, the U.S. Government (USG) will always need to prioritize and strategize to ensure MCM needs are met with the limited resources available.

Medical countermeasures³ include **both** pharmaceutical interventions (*e.g.*, vaccines, antimicrobials, antidotes, and antitoxins) **and** non-pharmaceutical interventions (*e.g.*, medical devices—including diagnostics—ventilators, personal protective equipment, and patient decontamination), as well as other

¹ For purposes of this document and other PHEMCE documents, members will refer to the statutorily named organizations, and partners to the larger group those members interact with, *e.g.*, industry and SLTT response organizations whose input is outlined in 42 U.S.C. § 300hh–10 - Coordination of preparedness for and response to all-hazards public health emergencies, “(d)(2)(H) incorporate input from Federal, State, local, and tribal stakeholders.” Enterprise is an overarching term that comprises both members and partners.

² In 2022, HHS Secretary Becerra announced that the ASPR organization would move from a Staff Division to an Operating Division (OpDiv) and approved the organization's name change to the Administration for Strategic Preparedness and Response (ASPR). The individual title leading that organization remains the Assistant Secretary for Preparedness and Response. More about the [announcement](https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html) can be found here on the HHS website, <https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html>

³ They include (but are not limited to) qualified countermeasures as defined in section 319F–1(a)(2) of the PHS Act (42 U.S.C. § 247d–6a(a)(2)); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 U.S.C. § 247d–6d(i)(7)), and security countermeasures as defined in section 319F–2(c)(1)(B) of the PHS Act (42 U.S.C. § 247d–6b(c)(1)(B)).

needed medical products that may be used to prevent, mitigate, or treat the adverse health effects of an intentional, accidental, or naturally occurring public health emergency.

PHEMCE coordination will include the full range of partners, processes, and products outlined above. This strategy captures our vision and goals for the newly relaunched PHEMCE moving forward.

Structure

The Assistant Secretary serves as the principal advisor on federal public health and medical preparedness and response⁴ to the Secretary of HHS. As part of this role, the Assistant Secretary leads and coordinates the PHEMCE, ultimately using the PHEMCE's assessments to inform MCM decision making.

While the Administration for Strategic Preparedness and Response (ASPR) is the head of each of the functions⁵ outlined in the PHS Act, the PHEMCE's design ensures coordinated input from USG agencies. If the PHEMCE is successful, the federal government will have a coordinated portfolio of MCMs available in federal stockpiles such as the SNS, available for deployment to State, Local, Tribal, and Territorial (SLTT) governments.

As stated above, the PHEMCE is chaired by the Assistant Secretary and made up of the Director of CDC, Director of NIH, Commissioner of the FDA, Secretary of Defense, Secretary of Homeland Security, Secretary of Agriculture, Secretary of VA, and the Director of National Intelligence. Each of these principals coordinates within their own organizations to bring technical expertise to the PHEMCE related to their mission space. From there, the Assistant Secretary evaluates, synthesizes, and presents MCM recommendations to the Secretary of HHS.

Existing technical teams, both formalized and non-formalized, will provide technical expertise. The Assistant Secretary relies on these technical teams, comprised of subject matter experts from across the PHEMCE, to bring together information regarding threats, early R&D, advanced R&D, monitoring and surveillance, manufacturing and supply chains, regulatory science, procurement and stockpiling, and the deployment, distribution, dispensing, and administration of MCMs. The PHEMCE does not recreate each

⁴ 42 U.S.C. § 300hh–10 - Coordination of preparedness for and response to all-hazards public health emergencies, “(1) Leadership—Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.”

⁵ 42 U.S.C. § 300hh–10a - Public Health Emergency Medical Countermeasures Enterprise, (c) Functions. (1) In general The functions of the PHEMCE shall include the following:

(A) Utilize a process to make recommendations to the Secretary regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization with respect to countermeasures, as defined in section 247d–6b(c) of this title, including prioritization based on the health security needs of the United States. Such recommendations shall be informed by, when available and practicable, the National Health Security Strategy pursuant to section 300hh–1 of this title, the Strategic National Stockpile needs pursuant to section 247d–6b of this title, and assessments of current national security threats, including chemical, biological, radiological, and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures and challenges to addressing such needs (including any regulatory challenges), and support alignment of countermeasure procurement with recommendations to address such needs under subparagraph (A).

(C) Assist the Secretary in developing strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 247d–6b(a) of this title.

(D) Provide consultation for the development of the strategy and implementation plan under section 300hh–10(d) of this title.

of these functions; rather, the PHEMCE builds on the existing infrastructure for these activities and informs the recommendations for the Secretary of HHS.

Statute⁶ also directs the PHEMCE to solicit and consider input from SLTT public health departments and officials. ASPR accomplishes this by engaging SLTT public health departments and officials via routine engagement from ASPR regional offices, formalized webinars, and targeted partnerships. By considering end-users, PHEMCE members can ensure that they are optimizing the USG's investments in an MCM portfolio.

Mission

To inform the United States Government medical countermeasures portfolio—in the Strategic National Stockpile and other federal stockpiles—by drawing on information and expertise across the PHEMCE.

Vision

A PHEMCE that meets regularly to inform MCM decision making throughout the U.S. Department of Health and Human Services and the federal landscape. In addition to informing long term, strategic decision-making, the PHEMCE will be nimble and responsive to immediate issues that impact the current stockpile and/or demand for certain MCMs.

PHEMCE Functions

The key PHEMCE functions are outlined in the PHS Act⁷ and illustrated below in Figure 1.

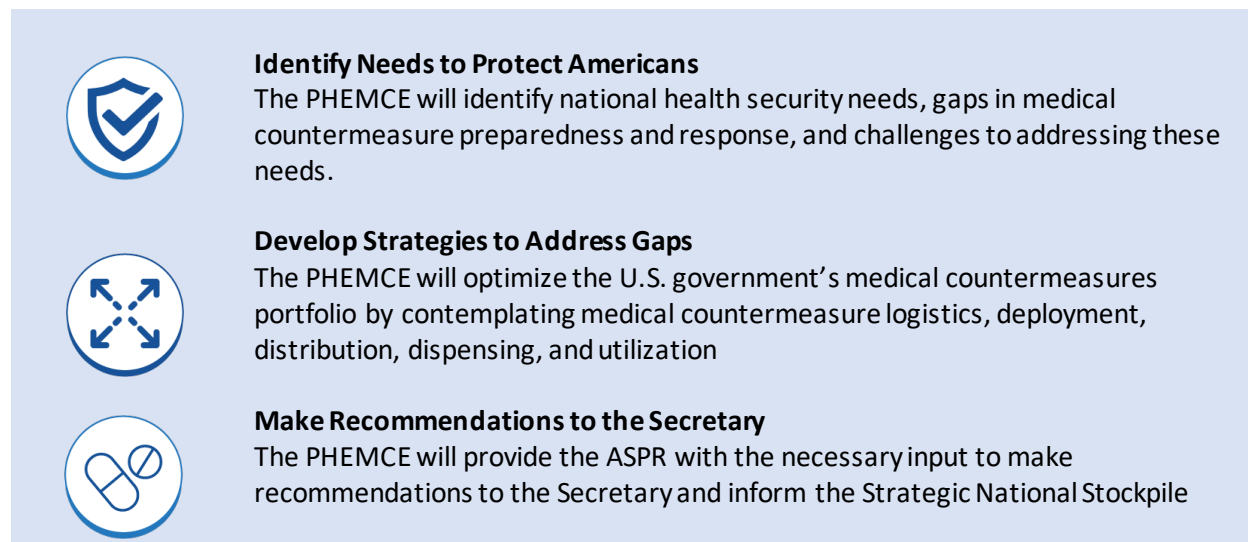


Figure 1: PHEMCE Goals

⁶ 42 U.S.C. § 300hh–10 - Coordination of preparedness for and response to all-hazards public health emergencies, “(d)(2)(H) incorporate input from Federal, State, local, and tribal stakeholders.” Enterprise is an overarching term that comprises both members and partners.

⁷ 42 U.S.C. § 300hh–10a - Public Health Emergency Medical Countermeasures Enterprise, (c) [Functions](#).
<https://www.law.cornell.edu/uscode/text/42/300hh-10a>, accessed 12/28/2021.

The PHEMCE officially reconvened on February 24, 2022 and has since hosted four follow-on meetings. The first meeting was a review of the critical role the PHEMCE will play in helping the USG align MCM goals against available funding. The second meeting was a review and evaluation of several time-sensitive MCM requests from Ukraine. The third meeting was a review of the process for the Department of Homeland Security to make a material threat determination and how such a determination might impact MCM priorities and strategy. The fourth reviewed ASPR's smallpox requirement and what, if any, changes the 2022 monkeypox outbreak necessitated to federal requirements and holdings. Each of these meetings supported the current goals of the PHEMCE, which seek to ensure the PHEMCE meets its statutory requirements as per section 2881 of the PHS Act.

PHEMCE Goals

The below PHEMCE goals are designed to reinforce the functions, utilizing information to solve for critical needs, addressing gaps, and ensuring the right portfolio of MCMs.

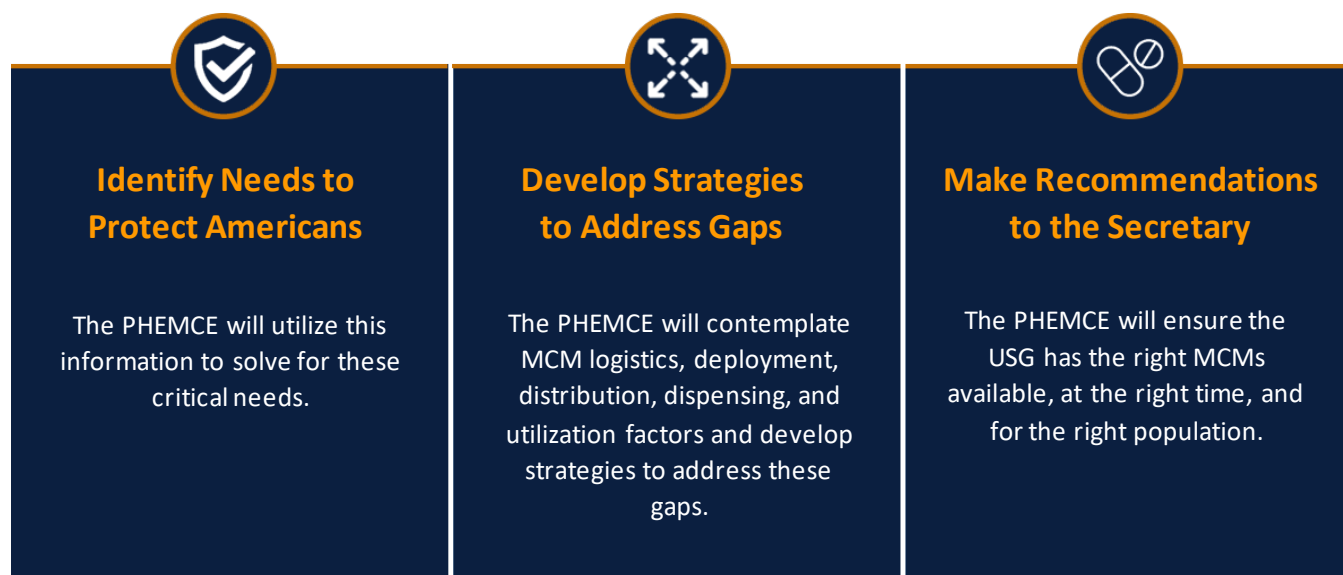


Figure 2: PHEMCE Goals

Goal 1: Identify needs to protect Americans against current and emerging threats

The PHEMCE will utilize threat information to address critical needs by developing threat assessments that are shared among PHEMCE members and partners.

- **Objective 1.1:** Conduct regular threat horizon scans to better prepare for Chemical, Biological, Radiological, and Nuclear threats (CBRN) and emerging infectious disease (EID) threats, as well as novel and emerging public health threats, and integrate the full range of solutions (including non-pharmaceutical interventions) into MCM preparedness and response plans.
- **Objective 1.2:** Integrate threat characterization and risk analysis information into MCM portfolio considerations including an assessment of tradeoffs and future development pathways.
- **Objective 1.3:** Develop portfolio optimization strategies that include an evaluation of development challenges and opportunities as well as end user needs.

- **Objective 1.4:** Implement all the above into a capabilities-based requirements process and utilization framework.

Goal 2: Develop strategies and coordinate with PHEMCE members and partners to address identified gaps and assess opportunities for continuous improvement

The PHEMCE will contemplate MCM logistics, deployment, distribution, dispensing, and utilization factors and develop strategies to address identified gaps.

- **Objective 2.1:** Engage with established advisory committees, senior leader councils, SLTT authorities, and non-governmental organizations (domestic and international) to identify the challenges within the MCM enterprise.
- **Objective 2.2:** Establish a plan for rapid identification of MCM gaps that prioritizes and coordinates expediting advanced R&D to close those gaps during emerging pandemics, and rapidly assess safety and efficacy of novel MCMs.
- **Objective 2.3:** Outline short-, medium-, and long-term R&D priorities for the end-to-end MCM development cycle and adjust based on strategic environment and threat assessment.
- **Objective 2.4:** Establish feedback mechanisms with PHEMCE partners to ensure two-way communication on addressing gaps and shortfalls.

Goal 3: Provide recommendations to the HHS Secretary and communicate MCM needs to all stakeholders based on the best available evidence combined with situational awareness and field deployment realities

The PHEMCE will ensure the USG has the right MCMs available, at the right time, and for the right population.

- **Objective 3.1:** Outline recommendations and progress made in a comprehensive portfolio that meets declared MCM priorities, including MCMs that address at-risk population and pediatric needs, to project SNS stockpiling and replenishment.
- **Objective 3.2:** Evaluate progress of all development activities: R&D, procurement, stockpiling, deployment, distribution, and utilization; using an evaluation system based on performance management best practices--including progress made in meeting timelines, allocations, benchmarks, and milestones.
- **Objective 3.3:** Communicate MCM prioritization needs with stakeholders including the public, the private sector, legislators, and the HHS Secretary.
- **Objective 3.4:** Regularly assess and communicate priorities in a transparent and deliberative fashion.

Conclusion

This PHEMCE Strategy provides the strategic goals and objectives by which the PHEMCE will modernize its efforts to establish and maintain an improved state of MCM preparedness. It establishes a clear mandate on how to enhance the MCM Enterprise, including through domestic manufacturing, and

ensure the USG has the adaptive and responsive capabilities needed to mitigate all types of public health emergencies.

The goals and objectives outlined above require extensive coordination among federal, SLTT, and private-sector partners. This strategy serves as a basis for a long-term implementation plan to promote readiness in the MCM Enterprise by aligning efforts across the USG; become an Enterprise that is constantly innovating; and enhance the use of partnerships as a strategic business practice. The PHEMCE members, and its support staff, are responsible for developing and implementing this long-term MCM enterprise plan. This PHEMCE Strategy highlights goals and objectives and serves as a transparent monitoring and evaluation platform to illustrate how the PHEMCE operates and how it can improve.

Public health and MCM preparedness are essential components of national security. Without a strong domestic MCM Enterprise, all Americans remain vulnerable to an expanding list of naturally occurring, accidental, and intentional threats. Extensive collaboration and coordination at the federal level, with SLTT partners, and with private sector stakeholders mitigates public health threat consequences. The PHEMCE mission is to lead MCM preparedness.

Appendices

Appendix A: Implementation Timelines

Table 1: PHEMCE SIP Implementation Timelines

GOALS	OBJECTIVES	TIMELINES
Goal 1: Identify needsto protect Americans against current and emerging threats	Objective 1.1: Conduct regular threat horizon scans to better prepare for CBRN and EID threats, as well as novel and emerging and public health threats, and integrate the full range of solutions (including Non-Pharmaceutical Interventions) into MCM preparedness and response plans	Within 273 days of SIP approval
	Objective 1.2: Integrate threat characterization and risk analysis information into MCM portfolio considerations including an assessment of tradeoffs and future development pathways	Within 273 days of SIP approval
	Objective 1.3: Develop portfolio optimization strategies that include an evaluation of development challenges and opportunities as well as end user needs	Within 365 days of SIP approval
	Objective 1.4: Implement all of the above into a capabilities-based requirements process and utilization framework	Within 365 days of SIP approval
Goal 2: Develop strategies to address identified gaps and assess opportunities for continuous improvement	Objective 2.1: Engage with established advisory committees, senior leader councils, SLTT authorities, and non-governmental organizations (domestic and international) to identify the challenges within the MCM enterprise	Within 180 days of SIP approval
	Objective 2.2: Establish a plan for rapid identification of MCM gaps that prioritizes and coordinates expedited advanced R&D to close those gaps during emerging pandemics, and rapidly assess safety and efficacy of novel MCMs	Within 365 days of SIP approval
	Objective 2.3: Outline short-, medium-, and long-term R&D priorities for the end-to-end MCM development cycle and adjust based on strategic environment and threat assessment	Within 365 days of SIP approval
	Objective 2.4: Establish Feedback mechanisms with PHEMCE partners to ensure two-way communication on addressing gaps and shortfalls	Within 120 days of SIP approval
Goal 3: Provide recommendations to the Secretary based on the best available evidence combined with situational awareness and field deployment realities	Objective 3.1: Outline recommendations and progress made in a comprehensive portfolio that meets declared MCM priorities, including MCMs that address at-risk population and pediatric needs, to project SNS stockpiling and replenishment	Within 550 days of SIP approval
	Objective 3.2: Evaluate progress of all development activities: R&D, procurement, stockpiling, deployment, distribution, and utilization; using an evaluation system based on performance management best practices—including progress made in meeting timelines, allocations, benchmarks, and milestones	Within 550 days of SIP approval
	Objective 3.3: Communicate MCM prioritization needs with stakeholders including the public, the private sector, legislators, and the HHS Secretary	Within 60 days of completing Objective 3.1
	Objective 3.4: Regularly assess and communicate priorities in a transparent and deliberative fashion	Ongoing

Appendix B: PHEMCE High-Priority Threats

The PHEMCE continues to address MCM needs to protect against high-priority threats. In 2017-2018, the PHEMCE added one new category of chemical agents (pharmaceutical-based agents) to the list, and in 2019-2020, one new category of biological threat (severe acute respiratory syndrome-related coronavirus (SARS-CoV)) was added. The PHEMCE high-priority threats are (in alphabetical order by threat area):

Biological Threats

- Bacillus anthracis* (anthrax)* and multi-drug resistant *B. anthracis* (MDR anthrax)*
- Burkholderia mallei* (glanders)*
- Burkholderia pseudomallei* (melioidosis)*
- Clostridium botulinum* toxin (botulism)*
- Ebola virus (Ebola disease)*
- Emerging infectious diseases
- Francisella tularensis* (tularemia)*
- Marburg virus (Marburg virus disease)*
- Pandemic influenza
- Rickettsia prowazekii* (typhus)*
- Severe acute respiratory syndrome-related coronavirus (SARS-CoV) (including SARS-CoV-1 and -2)*
- Variola virus (smallpox)*
- Yersinia pestis* (plague)*

Chemical Threats

- Acetylcholinesterase inhibitor nerve agents*
- Chlorine
- Cyanide salts – hydrogen, potassium, and sodium cyanide*
- Pharmaceutical based agents (including opioids)*
- Phosgene
- Vesicants*

Radiological and Nuclear Threats

- Radiological and nuclear agents*

* Indicates an identified material threat under section 319-2(c)(2)(A)(ii) of the Public Health Service Act, that, among other things, may make an MCM developer eligible to be awarded a material threat MCM priority review voucher pursuant to meeting the statutory criteria of 21 U.S.C. § 360bbb-4a.

Appendix C: Key Legislative Authorities

The Public Health Service Act (42 U.S. Code), notably the below Sections:

- Sec. 2811-1. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE

Relevant Executive Orders

- [EO 13676](#): Combating Antibiotic-Resistant Bacteria
- [EO 13985](#): Advancing Racial Equity and Support for Underserved Communities through the Federal Government
- [EO 13988](#): Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation
- [EO 13994](#): Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats
- [EO 13995](#): Ensuring an Equitable Pandemic Response and Recovery
- [EO 13996](#): Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats
- [EO 13997](#): Improving and Expanding Access to Care and Treatments for COVID-19
- [EO 14001](#): A Sustainable Public Health Supply Chain
- [EO 14005](#): Ensuring the Future Is Made in All of America by All of America's Workers
- [EO 14017](#): America's Supply Chains
- [EO 14036](#): Promoting Competition in the American Economy