

2024 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP)

September 2024



Letter from the Assistant Secretary for Preparedness and Response

Dear Colleague,

I am pleased to present the *2024 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP)* as required by section 2811(d) of the Public Health Service (PHS) Act (42 U.S. Code § 300hh–10).

Since its re-establishment in February 2022, the PHEMCE has made significant progress towards meeting the goals outlined in the *2022 SIP*, identifying gaps in the medical countermeasure portfolio and making strategic recommendations to close those gaps. This *2024 SIP* builds on those goals and lays out a more ambitious strategy for strengthening the public health system's ability to respond to naturally occurring, accidental, and deliberate threats that could severely impact health, safety, and well-being across the Nation.

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Administrator and Assistant Secretary for Preparedness and Response

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Executive Summary

The *2024 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP)* describes the PHEMCE's goals and objectives to improve the nation's medical countermeasure (MCM) preparedness against chemical, biological, radiological, and nuclear (CBRN) threats, including pandemic influenza and other emerging infectious diseases (EIDs). These goals were created in close collaboration with PHEMCE member agencies across the federal government. Aimed at establishing an ambitious agenda, these *PHEMCE SIP* goals include:

- ◆ *Ensuring the U.S. government (USG) has defined the right MCM capabilities to respond to public health emergencies and disasters* by reviewing the threat landscape, prioritizing those threats that represent the highest risks, and harmonizing USG capabilities.
- ◆ *Driving unified action toward developing and sustaining priority MCMs aligned with key USG strategies* by improving information sharing, reducing duplication of efforts, and identifying critical gaps and priorities to support MCM capabilities, particularly in an era of budget austerity.
- ◆ *Optimizing collaborations with partners* ensuring state, local, tribal, and territorial (SLTT), industry, and other stakeholders are ready to respond during public health emergencies and disasters.
- ◆ *Strengthening last-mile MCM efforts* to enable a more coordinated and equitable MCM response to future public health emergencies and disasters by ensuring incorporation of last-mile capabilities into appropriate USG response plans, with a focus on at-risk individuals and historically underserved communities.

Looking forward, the PHEMCE aims to strengthen the national ability to respond to naturally occurring, accidental, and deliberate threats that could severely impact health, safety, and well-being of the entire U.S. population. Successful implementation of the PHEMCE goals and objectives will also help build a foundation for future work.

2024 PHEMCE SIP GOALS			
Goal 1	Goal 2	Goal 3	Goal 4
Ensuring the U.S. government (USG) has defined the right MCM capabilities to respond to public health emergencies and disasters	Driving unified action toward developing and sustaining priority MCMs aligned with key USG strategies	Optimizing collaborations with partners	Strengthening last-mile MCM efforts

Introduction

Section 2811(d) of the Public Health Service (PHS) Act (42 U.S. Code § 300hh–10) directs the Administration for Strategic Preparedness and Response (ASPR) to develop a “coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats.” This plan is developed in consultation with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and is submitted to Congress biennially.

The PHEMCE was established by the U.S. Department of Health and Human Services (HHS) in 2006 and codified by Congress in 2019 to advance the country’s MCM preparedness against CBRN and emerging infectious disease threats. MCMs include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, antitoxins, or other therapies such as those that may target the host) and non-pharmaceutical interventions (e.g., medical devices — including diagnostics, life support products, personal protective equipment, decontamination systems, and clinical decision-making support tools), as well as other needed medical products that may be used to detect or assess, prevent, mitigate, or treat the adverse health effects of a public health emergency caused by a naturally occurring, accidental, or deliberate threat.

VISION	MISSION
<i>A coordinated medical countermeasure (MCM) enterprise that enables the nation to prepare for and respond to national health security threats.</i>	<i>To guide the USG MCM portfolio and enhance the nation’s capabilities to prepare for and respond to national health security threats.</i>

PHEMCE Structure and Function

The PHEMCE is an interagency partnership of federal MCM experts who collaborate across sectors to protect the U.S. population from public health emergencies that require the availability and timely provision of effective MCMs. The PHEMCE exists to support a cohesive federal process for MCM development, acquisition, distribution, and dispensing, bridging gaps in the country’s MCM portfolio. The PHEMCE does not direct or oversee plans, programs, and resources of other Departments or Agencies for medical countermeasures but rather develops recommendations that agencies may implement based on funding availability. Federal agency strategic priorities — including the work of the PHEMCE — should align with national strategies, such as the *National Security Strategy*, *National Biodefense Strategy*, and *National Health Security Strategy*.

Figure 1. Medical Countermeasure Preparedness Partners



Co-chaired by the Assistant Secretary for Preparedness and Response (the ASPR) and the Director of the White House Office of Pandemic Preparedness and Response Policy (OPPR),¹ PHEMCE membership includes the Director of the Centers for Disease Control and Prevention (CDC), Director of the National Institutes of Health, Commissioner of the U.S. Food and Drug Administration, Secretary of Defense, Secretary of Homeland Security, Secretary of Agriculture, Secretary of Veterans Affairs, and the Director of National Intelligence. PHEMCE representatives also include the Director of the Center for the Biomedical Advanced Research and Development Authority (BARDA), the Director of the Center for the Strategic National Stockpile (SNS), the Director of the National Institute of Allergy and Infectious Diseases (NIAID) and the Director of the Office of Readiness and Response. A principal official for each agency coordinates within their respective

organizations to contribute technical expertise to PHEMCE's mission space. As the principal advisor to the HHS Secretary on federal public health and medical preparedness and response, the ASPR evaluates and synthesizes recommendations from the PHEMCE and presents them to the HHS Secretary. While ASPR leads each function outlined in the PHS Act, the PHEMCE ensures coordinated action across USG agencies. It does so by identifying what is needed to protect the U.S. population, developing strategies, and making recommendations to address any gaps, vulnerabilities, and challenges. PHEMCE's harmonization of these efforts results in a well-coordinated portfolio of MCMs available when needed to respond to and mitigate the impacts of public health emergencies.

Subject matter experts and technical teams from across the member agencies bring together information regarding threats; early research and development (R&D); advanced R&D (including enabling technologies); monitoring and surveillance; manufacturing and supply chains; regulatory science; procurement and stockpiling; and the deployment, distribution, dispensing, administration, and utilization of MCMs. The PHEMCE does not recreate each of these functions but rather builds on the existing infrastructure for these activities to inform recommendations for the HHS Secretary. The statute also directs PHEMCE to solicit and consider input from SLTT public health departments and

PHEMCE Functions



Identify Needs to Protect the Nation. PHEMCE will identify national health security needs, gaps in MCM preparedness and response, and challenges to addressing these needs.



Develop Strategies to Address Gaps. PHEMCE will optimize the USG's MCM portfolio by contemplating logistics, deployment, distribution, dispensing, and utilization.



Make Recommendations to the HHS Secretary. PHEMCE will provide the ASPR with the necessary input to make recommendations to the Secretary and inform preparedness and response efforts.

¹ PHS Act (42 U.S.C. § 300-10a) - Public Health Emergency Medical Countermeasures Enterprise.

officials. CDC's ongoing epidemiologic, laboratory, clinical consultation, and state and local support work with SLTT and clinical partners address not just routine, day-to-day outbreak and event responses but also informs ongoing planning and need for scaling as part of broader preparedness activities. ASPR accomplishes this through routine engagement from ASPR regional offices, formalized webinars, and targeted partnerships. Engagement with partners at all levels of emergency response improves understanding of capability needs, which serves to optimize USG investments in a more meaningful MCM portfolio. Additionally, when appropriate, the PHEMCE works with HHS and USG partners to consider international aspects of its mission to support global health security and international coordination to ensure national health security.

The PHEMCE produces three primary outputs: the Strategy and Implementation Plan (SIP), the Medical Countermeasure Preparedness Review (MCMPR), and the Multiyear Budget (MYB). The SIP and MYB are publicly available. The MCMPR is available for Congress, but due to sensitivities around quantities of stockpiled products, is distributed at FOUO classification and thus not available.

The Strategy and Implementation Plan (SIP) is developed in collaboration with PHEMCE leadership and describes PHEMCE's functions, accomplishments, and four main goals with objectives and key milestones that will mark progress during the next two years of implementation. The goals and objectives aim to encapsulate PHEMCE's overarching purpose and collaborative presence to convene an interagency body focused on public health emergency preparedness.

The Medical Countermeasure Preparedness Review (MCMPR) leverages partner agencies' technical expertise to inform an annual threat-based review of the Strategic National Stockpile (SNS) contents and other stockpiles. Technical experts evaluate existing Requirements, MCMs currently stockpiled or managed by the USG, and gaps in procurement and stockpiling for each high-priority threat. Based on this assessment, they formulate and propose changes and/or corrective actions to enhance the USG's preparedness posture.

A critical component of the MCMPR is to inform Congress when annual appropriations for procurement and stockpiling do not allow for replacement of all expiring product and procurement of new products to fulfill existing Requirements. Additionally, when funds are insufficient for the SNS to maintain current capabilities and absorb additional products, ASPR, in consultation with PHEMCE member agencies, must weigh considerable tradeoffs. Inability to replenish MCM stocks or add new and innovative products that are safer and more effective may ultimately translate to increasing levels of risk across the threat portfolios and reduce ASPR's ability to respond in the event of a public health emergency or disaster.

The Multiyear Budget (MYB) forecasts the funding required to conduct basic research, advanced R&D, regulatory review, procurement, stockpiling, and replenishment of the USG's civilian MCM products. The MYB is a professional judgement budget, meaning it is formulated irrespective of the competing priorities considered in the annual budget formulation process. This report is focused on HHS's MCM needs but may incorporate other Departments and Agencies in future iterations.

Recent Accomplishments

Leveraging federal and non-federal partners, the PHEMCE made progress toward the three previously established goals in the 2022 *SIP*. The accomplishments below, achieved throughout 2022 and 2023, informed vital decisions that strengthened the MCM enterprise:

1. Identified needs to protect Americans against current and emerging threats.

2022 was a critical year for continuing to reconstitute the PHEMCE infrastructure and ensuring the PHEMCE meets the statutory requirements set forth by the PHS Act. In 2022, the PHEMCE aligned on MCM goals and funding availability. The PHEMCE established critical processes, such as business rules and mechanisms for information sharing, integral to PHEMCE's ability to make recommendations. Next, the PHEMCE reviewed all existing Requirements and made recommendations to retire, update, or validate existing models and the Requirements on which they are based. In parallel, PHEMCE responded to emerging MCM-related issues in Ukraine as well as the mpox outbreak.

In 2023, the PHEMCE conducted threat horizon scans to assess emerging threats and associated risks to determine whether Requirements need to be updated. Importantly, because these activities drive many technical discussions across interagency partners, they included subject matter experts and decision-makers to ensure the enterprise is aligned on the PHEMCE's highest priorities. While the threat landscape analysis did not significantly shift the portfolio, the PHEMCE members recognized the importance of emerging pandemic threats to national security. Because these emerging pandemic threats pose risk to national security, the PHEMCE will take steps to recognize, assess, and prioritize them in addition to CBRN threats already in the PHEMCE mission. The PHEMCE also reviewed and made recommendations for four updated Requirements, which incorporate lessons learned from the COVID-19 and mpox responses, update the scenarios that drive Requirements setting, and update capabilities based on recent learnings to ensure the USG is prepared for the next public health emergency.

Additionally, the PHEMCE:

- Expanded its membership to include the newly established White House OPR as a PHEMCE co-chair to provide policy perspectives and ensure alignment between PHEMCE efforts and overall USG strategies and priorities for pandemic preparedness and biodefense.
- Initiated portfolio assessments to identify gaps in MCM preparedness, including for EIDs. While PHEMCE agencies have already been investing in EIDs, in 2024 and beyond PHEMCE will build on these efforts to conduct detailed appraisals of needs to address these threats across the MCM space.

2. Developed strategies to address identified gaps and assess opportunities for continuous improvement.

In 2023, the PHEMCE took important steps to align and extend collaboration with SLTTs, the private sector, non-governmental organizations, the broader MCM community, and international partners. Outreach included engaging via public meetings, hosting webinars, and connecting with partners in topic-focused conversations. These efforts increased transparency into PHEMCE operations, collected lessons learned, and identified opportunities to improve collaboration. PHEMCE met with partners around the following topics:

- Increasing awareness around important emerging technologies, such as platform approaches and development pathways for threat agnostic products that should be on PHEMCE's horizon.
- Understanding challenges SLTT partners face in the wake of the COVID-19 pandemic response and opportunities to transform as we prepare for future emergencies.
- Sharing best practices with international partners on Requirements setting, prioritization, and stockpiling processes.

In parallel with these outreach efforts, the PHEMCE conducted thorough assessments of the MCM budget landscape and reviewed the contents of the SNS, incorporating feedback from industry, SLTT, and other partners.

3. **Provided recommendations to the HHS Secretary based on the best available evidence combined with situational awareness and field deployment realities.**

The first two goals of the *2022 PHEMCE SIP* highlighted how PHEMCE conducts day-to-day business, leveraging the best available evidence to coordinate, share information, and make recommendations that balance the evidence against real-world limitations. These recommendations are shared with the HHS Secretary through various venues, including:

- As part of the *PHEMCE MYB*, the PHEMCE outlined the near- and long-term priorities for MCM R&D, procurement, stockpiling, and replenishment. The *MYB* outlines funding priorities for HHS agencies to ensure the end-to-end MCM development cycle is efficient, innovative, and adaptive to emerging threats while accounting for budget limitations.
- As part of a comprehensive SNS portfolio review, PHEMCE led the threat-based review of the SNS contents, taking stock of the portfolio of products, identifying gaps, and making recommendations. Such recommendations, captured in the *MCMPR*, account for updating the threat landscape and Requirements as needed, capturing advances in R&D and advanced product development, and feedback from relevant stakeholders.

2024 PHEMCE Goals

GOAL 1: Ensure the U.S. government has defined the right MCM capabilities to respond to future public health emergencies and disasters.

Up-to-date risk assessments of the current and evolving threat landscape are critical for preparedness and response planning, and decision-making. These assessments help identify the most critical CBRN, pandemic influenza, and other EID threats to national security and inform USG's MCM development and procurement. They also provide decision-makers with information needed to prioritize threats, support the capabilities needed to deploy and use MCMs effectively, and integrate available solutions into MCM preparedness and response.

ASPR collaborates with the U.S. Department of Homeland Security (DHS) to leverage risk assessments, as well as existing material threat determinations (MTDs), to establish Requirements that (a) assess capabilities, (b) identify gaps, (c) outline solutions, and (d) justify the timely allocation of resources. Such Requirements inform tradeoffs that balance existing resources and constraints and inform MCM

procurement and sustainment decisions for both CBRN and emerging threats. To guide PHEMCE's evaluation and prioritization of MCMs, PHEMCE members will:

Objective 1.1 Conduct a comprehensive threat landscape review and update scenarios and modeling to inform Requirements.

Key Milestones:

1.1.1 Continue annual threat briefing for PHEMCE member agencies.

1.1.2 Conduct annual risk analysis that integrates updated intelligence and surveillance information on emerging and re-emerging threats.

1.1.3 Leverage interagency expertise to review and update scenarios and models used to inform Requirements development for 25 percent of the threats each year.

Objective 1.2 Update Requirements for MCM-related activities, including stockpiling, to reflect current and emerging threats and operational plans.

Key Milestones:

1.2.1 Leverage the current risk analysis to ensure that high priority threats are aligned with DHS's list of MTDs, such that as new threats emerge, new MTDs are added, as needed, and rescinded if certain threats wane. These determinations incorporate latest threat information and guide the MCM portfolio.

1.2.2 Use current scenarios and models to finalize requirements for developing and acquiring MCMs and the capabilities required to use and monitor them.

1.2.3 Ensure all populations, particularly vulnerable, at-risk, and historically underserved are considered in updated scenarios and models.

1.2.4 Integrate updated Requirements and MTDs into the *MCMPR* report.

Objective 1.3 Increase the visibility of current USG capabilities through the development of a comprehensive MCM database for federal partners (ensuring appropriate protections for information contained in the database), which outlines the status of products and technologies from the development pipeline through stockpiling.

Key Milestones:

1.3.1 Ensure PHEMCE members have access to the latest information on products in the MCM pipeline, including how these address updated MTDs and Requirements.

1.3.2 Establish and maintain a comprehensive database of available MCMs across all priority CBRN and emerging infectious disease threats. Database should capture the regulatory approval status for high-risk populations, including pregnant women and children.

GOAL 2: Drive unified action toward developing and sustaining priority MCMs aligned with key USG strategies.

PHEMCE member agencies do not have access to the funds needed to fully support and sustain a robust MCM pipeline and capabilities that ensures full preparedness — from early research to delivery, utilization, and safety monitoring — necessary to meet the established Requirements for a holistic MCM enterprise. At the same time, the PHEMCE is addressing an increasing number of threats, including emerging infectious diseases, some of which do not have established MTDs. This growing gap in projected need versus available funding identified by the *PHEMCE MYB* makes it challenging for PHEMCE agencies to ensure our nation is best prepared to respond to future public health emergencies or disasters. A well-harmonized set of priorities across interagency partners is critical to ensuring all key stakeholders work together and maximize available resources. Guided by national strategies, including the *National Health Security Strategy* and *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (NBS)*, the PHEMCE pursues unified priorities balanced against existing resources. For example, the *NBS*'s implementation plan calls for seven Joint Capabilities Plans (JCPs), many of which are specific to MCMs and relevant to the PHEMCE's scope. Where possible, the PHEMCE's approach is to prioritize broadly acting or threat-agnostic countermeasures, aligning to the goals of the JCPs, to ensure MCMs can be adapted and readily scaled to address novel emerging threats. To this end, the PHEMCE members will:

Objective 2.1 Conduct routine USG MCM portfolio reviews to ensure coordinated action (and avoid duplication) across partners, departments, and agencies.

Key Milestones:

2.1.1 Leverage the MCM database (see Objective 1.3) to conduct a comprehensive PHEMCE-wide portfolio review and identify critical gaps and inefficiencies.

2.1.2 Establish a regular review cadence to ensure the portfolio stays up-to-date and aligned with key priorities.

2.1.3 Promote information sharing with key international partners to improve the global preparedness posture.

Objective 2.2 Identify the most critical capability gaps and priorities across MCM development, including platform technologies and threat-agnostic approaches.

Key Milestones:

2.2.1 Identify opportunities for collaboration among priority areas for research and development, from discovery through approval and sustainment. Given limited funds, these priorities will be weighed against existing priorities to minimize risk.

2.2.2 Identify opportunities for development activities to leverage flexible technologies that can adapt more easily to novel, unknown threats.

2.2.3 Identify in advance regulatory mechanisms to support medical product use in identified populations at risk.

2.3.4 Coordinate across interagency partners and maximize resources for the development and use of emerging technologies.

Objective 2.3 Leverage USG plans to develop critical MCM capabilities.

Key Milestones:

2.3.1 Leverage development of Requirements, stakeholder engagements, lessons learned initiatives, table-top exercises, and/or other mechanisms or policy initiatives to update or refine USG plans and policies, including the JCPs.

2.3.2 Identify opportunities to coordinate planning exercises to ensure appropriateness of proposed plans and policies.

2.3.3 Identify innovative approaches to develop MCM capabilities.

2.3.4 Ensure PHEMCE partners share MCM-related strategic plans, playbooks, or other relevant guiding documents to support communication and cross-collaboration.

2.3.5 Incorporate development of new initiatives into *PHEMCE's MYB* to track and forecast budget needs.

GOAL 3: Optimize and strengthen collaborations with stakeholders.

An effective MCM enterprise is contingent on close coordination and collaboration among all partners.

As required in statute, PHEMCE member agencies routinely engage with non-federal partners. With SLTT public health departments and officials, these occur via routine engagement from ASPR regional offices, formalized webinars, and targeted partnerships and from CDC emergency management, epidemiology, laboratory, clinical and state and local staff who engage with epidemiologic, laboratory, healthcare and regulatory partners. With industry partners, PHEMCE engages via market research, new and existing partnerships, and targeted solicitations. These mechanisms, among others, were actively utilized during recent response efforts and are continuously assessed for improvement opportunities. The PHEMCE will also continue to improve coordination and collaboration between federal and non-federal partners and:

Objective 3.1 Enhance collaboration between federal and non-federal (e.g., industry and nonprofit, SLTT, pharmacies, and healthcare systems) partners to improve engagement for effective MCM decision-making and use.

Key Milestones:

3.1.1 Finalize a PHEMCE stakeholder engagement strategy for engaging non-federal partners, leveraging existing available channels, and developing new mechanisms to fill gaps.

3.1.2 Ensure quarterly engagement with industry partners through appropriate channels.

3.1.3 Ensure regular engagement among federal partners through appropriate channels.

3.1.4 Conduct targeted outreach on specific topics identified and prioritized by PHEMCE members and stakeholders.

3.1.5 Leverage existing cooperative agreements that can support partnership building and collaboration.

Objective 3.2 Identify and develop resources or tools to support collaboration with relevant partners. Tools should improve how MCMs are developed, manufactured, sustained, distributed, used, or monitored for safety and effectiveness.

Key Milestones:

3.2.1 Identify existing tools used across interagency partners for MCM training, deployment, data collection (such as safety and real-world effectiveness monitoring), and guidance development.

3.2.2 Develop a new resource or tool for coordinated partner engagement.

3.2.3 Integrate external feedback into development of resources or tools.

GOAL 4: Strengthen last-mile MCM access efforts to enable a more coordinated and equitable MCM response to a future public health emergency or disasters.

MCM preparedness efforts are only successful if products are able to be used when they are needed by those who need them the most. This requires a concerted effort among key federal and non-federal partners on MCM dispensing, distribution, and administration, including safety and effectiveness monitoring, paying particular attention to challenges faced by vulnerable individuals and underserved communities disproportionately impacted by public health emergencies and disasters. Lessons learned from COVID-19 and mpox provide opportunities to improve last-mile MCM capabilities. The PHEMCE will incorporate recent lessons into USG preparedness efforts to ensure a more coordinated and equitable MCM response during future public health emergencies or disasters. To strengthen last-mile efforts, the PHEMCE members will:

Objective 4.1 Identify last-mile MCM dispensing, distribution, and administration lessons from COVID-19 and mpox, capitalizing on preserving capabilities built during responses and new capabilities that need to be established.

Key Milestones:

4.1.1 Review existing after-action and lessons-learned reports from recent response efforts as well as trainings and exercises. Examples include but are not limited to COVID-19 and mpox. Identify areas of improvement for MCM use that may be addressed by guidance development.

4.1.2 Leverage collaborative tools (Objective 3.2) to engage key federal and non-federal partners on MCM dispensing, distribution, and administration issues experienced during response efforts.

Objective 4.2 Ensure lessons are incorporated into appropriate HHS plans, including product development, acquisition, and stockpiling efforts.

Key Milestones:

4.2.1 Collaborate with interagency partners on developing response plans, as appropriate, to align last-mile roles and responsibilities and reduce duplication of efforts. Where possible, plans should include triggers for release of products.

4.2.2 Develop data-driven tools to address last-mile dispensing and administration and safety monitoring efforts.

4.2.3 Share collected distribution lessons learned with stakeholders, as appropriate.

4.2.4 Where relevant, incorporate last-mile lessons learned into product research and development efforts.

Objective 4.3 Consider MCM needs across ALL populations — focusing on vulnerable, at-risk, and historically underserved communities — to improve equitable deployment and access to MCMs.

Key Milestones:

4.3.1 Review research and development portfolios as well as stockpiled MCMs to identify data gaps, including clinical studies, to address the needs of vulnerable individuals and underserved communities.

4.3.2 Integrate existing efforts analyzing vulnerable and medically fragile populations into planning and response efforts.

4.3.3 Coordinate updates to guidance documents incorporating new information, including lessons learned from recent response efforts.

4.3.4 Identify mechanisms to collect and inform product access and use across underserved communities.

Conclusion

Public health, healthcare, and MCM preparedness are essential components of national health security. Without a strong domestic MCM enterprise, the nation remains vulnerable to an expanding list of naturally occurring, accidental, and deliberate threats. The above goals and objectives require extensive coordination among federal, SLTT, and public- and private-sector partners. This strategy and implementation plan are intended to promote readiness in the MCM enterprise by aligning efforts across the USG, assessing preparedness and response capabilities, supporting innovation, enhancing strategic partnerships, and strengthening last-mile distribution efforts.

The PHEMCE will continue to modernize its efforts to establish and maintain an improved state of MCM preparedness, track the execution of these priorities, and provide periodic updates through the PHEMCE governance structure and future iterations of the *PHEMCE SIP*.

Appendix: PHEMCE High-Priority Threats

The U.S. continues to face a range of serious threats to its health security from naturally occurring, accidental, and deliberate use of CBRN agents, as well as naturally occurring EIDs, including pandemic influenza.

PHEMCE High-Priority Threats

The PHEMCE will continue to address MCM needs to protect against high-priority threats. These may be determined by the Secretary of Homeland Security to pose a sufficient material threat to affect national security or determined by PHEMCE leadership to have the potential to threaten national health security. The PHEMCE high-priority threats are (in alphabetical order by threat area):

Biological Threats

- *Bacillus anthracis* (anthrax)* and multidrug resistant *B. anthracis* (MDR anthrax)*
- *Burkholderia mallei* (glanders)* and *Burkholderia pseudomallei* (melioidosis)*
- *Clostridium botulinum* toxin (botulism)*
- *Ebolavirus* (Ebola hemorrhagic fever)*
- Emerging infectious diseases
- *Francisella tularensis* (tularemia)*
- *Marburgvirus* (Marburg hemorrhagic fever)*
- Pandemic influenza virus
- *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 (potassium and sodium cyanide)*
- Hydrogen cyanide*
- Pharmaceutical based agents (including opioids)*
- Phosgene
- Vesicants*

Radiological and Nuclear* Threats

- Radiological and nuclear agents*

(*) Indicates an identified material threat under section 319F-2(c)(2)(A)(ii) of the Public Health Service Act.