National Academies of Sciences, Engineering, and Medicine

REVIEW OF THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE

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FOR PUBLIC USE

OPENING REMARKS & CHARGE TO THE COMMITTEE

Chris Hassell, PhD
Deputy Assistant Secretary for Preparedness and Response
Senior Science Advisor

Why this review?

- COVID-19 sets new precedents for medical countermeasure (MCM) preparedness
- Government must optimize business practices to
  - To meet MCM national security mission in context of current pharma economy
  - Drive necessary changes in current public health and biological preparedness industrial bases
  - Maintain analytical methodologies consistent with current standards of practice
- Public scrutiny of MCM preparedness activities further motivates need for independent review of PHEMCE
- Establish efficient processes to engage critical stakeholders/partners

Charge to the Subcommittee

- Review the effectiveness of existing PHEMCE activities and areas for improvement by
  - Review charters, memoranda of understanding, process documents, and public documents
  - Engage with PHEMCE personnel to understand historic practices
- Recommend on best business practices to
  - Incorporate industrial base, supply chain, and inventory strategies for MCM preparedness
  - Ensure defensible recommendations and enterprise-wide reviews, and
  - Harmonize programs and budgets
  - Integrate external partners into PHEMCE decision framework
    - State, Local, Tribal, Territorial
    - Private sector, manufacturers, pharma
    - OMB, Congress, etc.

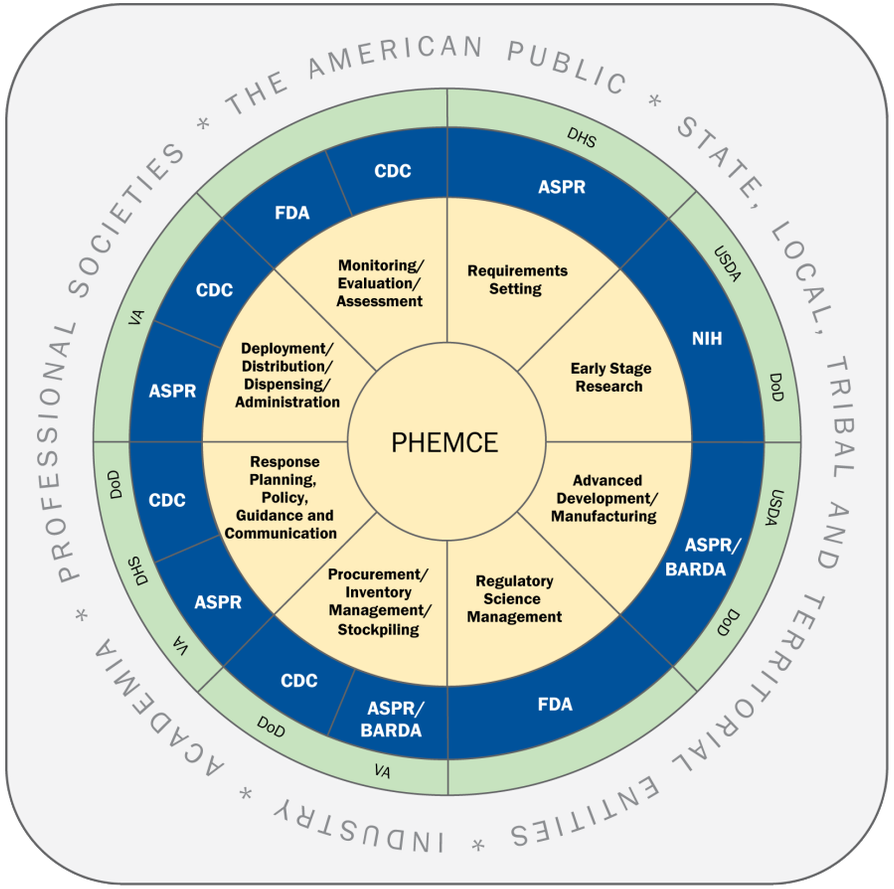
BRIEF HISTORY AND CONTEXT

Chad Hrdina, MS, CG-WMD, EMT
Director, Division of Requirements

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)

Organization - HHS-led, mandated multi-agency body

Intent – Advise on and coordinate federal **development and preparedness of medicines and medical supplies** to protect the **American public** during public health emergencies **of all kinds** [*such as a deliberate anthrax attack, severe earthquake, or a pandemic*].



Key

- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

Acronyms

PHEMCE: Public Health Emergency Medical Countermeasure Enterprise
DHS: Department of Homeland Security
DoD: Department of Defense
USDA: U.S. Department of Agriculture
VA: Department of Veterans' Affairs
HHS: Department of Health and Human Services

ASPR: Assistant Secretary for Preparedness and Response
BARDA: Biomedical Advanced Research & Development Authority
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
NIH: National Institutes of Health

PHEMCE-related Authorities

2004

BioShield Act

42 USC 247d-6b

- Gives Secretary authority for development of security (medical) countermeasures
- Establishes the **Project BioShield Special Reserve Fund** to pay for advanced research and development of novel MCMs
- Requires the **SNS Annual Review**

2006

Pandemic and All-hazards Preparedness Act

42 USC 300hh-10

- PAHPA
- Establishes ASPR authorities
- Gives ASPR the **Biomedical and Advanced Research and Development Authority**
- Assigns ASPR responsibility for MCM development under **Project BioShield**
- Assigns ASPR oversight of **Strategic National Stockpile**

2012

Pandemic and All-hazards Preparedness Reauthorization Act

42 USC 300hh-10

- PAHPRA
- Assigns **PHEMCE Strategy and Implementation Plan** to ASPR
- Assigns **MCM Multi-year Budget** to ASPR

2019

Pandemic and All-hazards Preparedness and Advancing Innovation Act

42 USC 300hh-10a

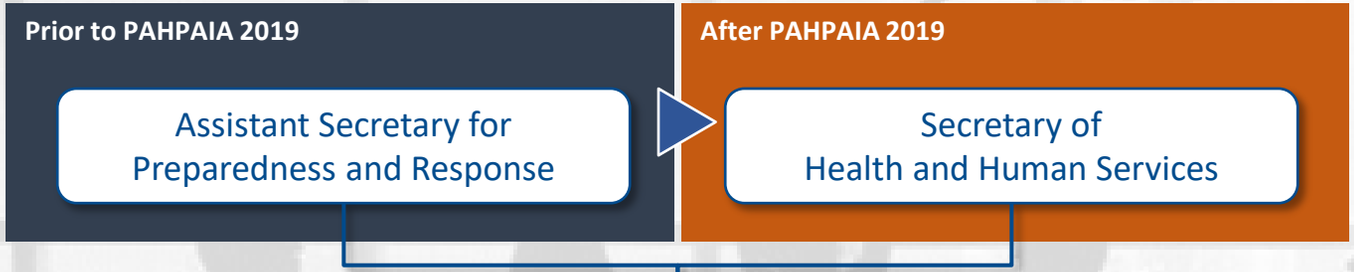
- PAHPAIA
- Establishes PHEMCE statutorily
- Names **interagency members**
- Assigns **roles and responsibilities**
- Establishes PHEMCE as an **advisory body**
- Shifts PHEMCE from advising ASPR to **advising Secretary**
- Assigns **ASPR as chair** of PHEMCE

PHEMCE Members*

- ASPR – “Chair”
- FDA commissioner
- CDC director
- NIH director
- Secretary of Agriculture
- Secretary of Defense
- Secretary of Veterans Affairs
- Director of National Intelligence
- Secretary of Homeland Security

*42 USC 300hh-10a, Additional representatives can be determined by HHS Secretary, which may include BARDA director, SNS director, NIAID director, and CDC CPR director

Past PHEMCE Organizational Structure



Agency heads/ assistant and under secretaries / equivalent	Enterprise Senior Council / Enterprise Governance Board	• Provided political leadership deliberation on deliverables • Guided strategic and policy direction
Deputy assistant secretaries program directors	Enterprise Executive Committee / Senior Federal Officials	• Provided program and budgetary level review of IPT deliverables • Advised MCM program prioritization for SNS and BARDA, etc.
Staff-level, Subject matter experts, program, etc.	Integrated Portfolio Teams / Portfolio Advisory Teams	• Typically organized by threat or function • Generated requirements, plans, acquisition recommendations, etc.

PHEMCE Brief History

PAHPA establishes ASPR, authorities

Established to guide MCM Requirements and make R&D and procurement recommendations to ASPR

2010 PHEMCE Review published

PAHPRA codifies annual PHEMCE Strategy and Implementation Plan

PAHPAIA codifies PHEMCE as advisory body to Secretary HHS and reestablishes PHEMCE SIP biennially from March 15, 2020

*PRROC established to approve Requirements

2006 | | | **2009** | **2010** | | **2012** | | | | | **2017** | | **2019** | **2020** | **2021**

PHEMCE 1.0 | PHEMCE 2.0 | PHEMCE 3.0

Managed by Requirements Division

PHEMCE role as a "consensus-based gatekeeper" solidifies

- Mission expands over time to assess end-to-end activities: industrial base, deployment/distribution, end-use planning, regulatory, populations, etc.
- Depth of analysis and standardization of methodologies improves to ensure well-informed, defensible decisions

Managed by BARDA then immediate office

- Mission culled to R&D and procurement budgets harmonization between HHS/DOD
  - Management transferred
- Gatekeeper power terminated- PHEMCE made more advisory
- Requirements expanded to capabilities and moved out of PHEMCE

Managed by Requirements Division

- Management transferred
- PHEMCE re-envisioned as advisory "PHEMCE 3.0"

*Preparedness and Response Requirement Oversight Council

PHEMCE Past and Present Processes

Past processes

Deliverables

- PHEMCE Strategy and Implementation Plan
- Threat portfolio assessments and Preparedness assessments
- SNS Annual Review
- Multi-year Budget
- Scenario Based Analyses and
- Product Specific Requirements
- Acquisition and MCM program recommendations

Currently established process

Capability-based Requirements

Integrated Portfolio Teams / Portfolio Advisory Teams

Enterprise Executive Committee / Senior Federal Officials

Enterprise Senior Council / Enterprise Governance Board

Assistant Secretary for Preparedness and Response

Threat-based analysis, MCM-based assessment, initial development

Goals and objectives setting Program and budget -based review

Strategic guidance, leadership review and approval/concurrence

Approval, promulgation

Consulting: development and technical validation

Consulting: program level validation

Preparedness and Response Requirements Oversight Council (PRROC)

Requirements Approval by PRROC

Shared Documents

- Foundational Documents
  - Charters
  - Memoranda of understanding
  - PHEMCE Review (publicly available)
  - PHEMCE Strategy and Implementation Plan (SIP; publicly available)
  - Government Accountability Office (GAO) recommendations (publicly available)

- Process Documents
  - PHEMCE strategic planning process
  - SNS Annual Review processes
  - Threat and preparedness assessment methodologies
  - MCM requirement development process

RE-ENVISIONED PHEMCE AND SCOPE OF REVIEW

Lara Lamprecht, DrPH
Chief, PHEMCE Branch

Current PHEMCE Status

- Re-establishing membership and organization
- Minimal operations pending ASPR decisions on
  - Organization
  - Decision support framework
  - Some administrative functions
- Conducting some program reviews and providing some recommendations to ASPR as needed

PHEMCE Advisory and Coordination Roles in Support of Secretary

Strategic and Policy Direction

- Identify and prioritize
  - Threats
  - MCM and operational gaps
  - MCM capability requirements/needs
- Consult on
  - Strategic goals
  - MCM-related authorities
  - Operational planning
  - Intended use
  - Cost efficient and cost-effective strategic investments

- PHEMCE Strategy and Implementation Plan (SIP)

Budget Alignment/Harmonization

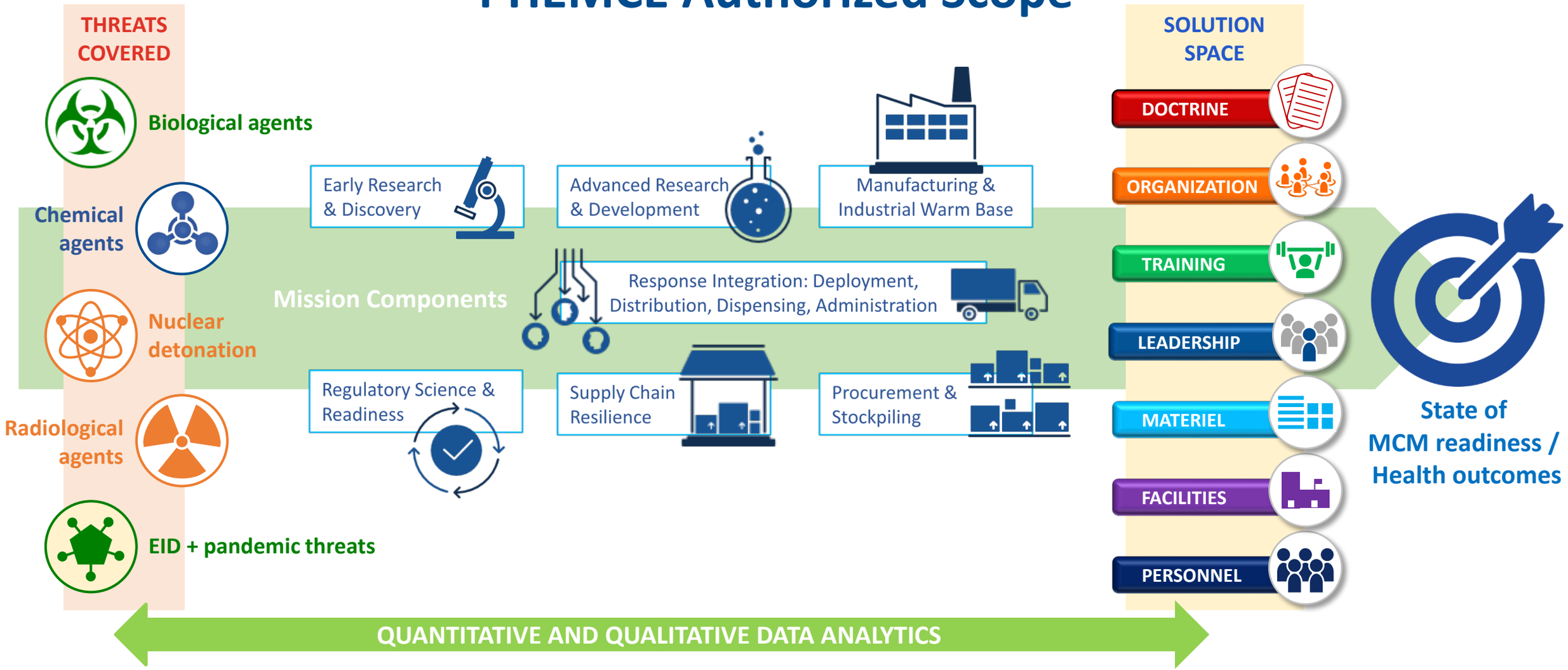
- Align interagency budgets to PHEMCE SIP / priorities
- Harmonize spending across programs (prevent budget gaps)
- Align MCM multi-year budget to SIP
- Coordinate interagency budget forecasting / planning
  - Maximize use of funds
  - Account for lifecycle costs

- Strategic National Stockpile (SNS) Annual Review
- MCM multi-year budget

Program Coordination

- Sponsor interagency data analytics, threat and public health consequence assessment, etc.
- Coordinate and advise on
  - MCM research and development and acquisition programs
  - Requirement development
  - Operational planning
  - Stockpiling, Industrial base solutions, supply chain and commercial inventory
  - Deployment, distribution, dispensing, utilization
  - Regulatory issues
- Engagement with stakeholders: White House, OMB, Congress, SLTT, private sector

PHEMCE Authorized Scope



Importance of PHEMCE Review

- High visibility and expectations
  - Priority of the Executive and Legislative Branches (thus, American people)
  - PHEMCE advice must be actionable every time

- Good government
  - Cost-efficient and cost-effective use of taxpayers' money for MCMs
  - Institutionalize lessons from current incident (COVID)
  - Effective and efficient business operations
  - Proactive and strategic posture

- Health outcomes
  - Lifesaving provision and use of medicines and medical supplies
  - Potentially impact current pandemic or its effects

High-level and Complementary Engagement

Recommendations

GAO
U.S. GOVERNMENT ACCOUNTABILITY OFFICE

- Establish and document process plans
- Implement records management
- Engage Congress and SLTT stakeholders

Report

The National Academies of SCIENCES ENGINEERING MEDICINE

October 2021

- Review effectiveness of activities
- Recommendations: business practices, industrial base strategies, stakeholders

White House Expectations

- Focus on domestic industrial base and supply chain solutions
- Pandemic MCM considerations for SNS

Legislative Interest

- Funding support for medical countermeasure sustainability
- Ensure PHEMCE is authorized to do its mission

Scope of the Review (Level of Analysis)

- Is…
  - Organizational design
  - Administrative policies
  - Organization of activities and outputs within a planning, programming, budget and execution (PPBE) model
  - Business processes
  - Ability to be prepared
  - Ability to support response quickly
- Is NOT…
  - PHEMCE member programs
  - ASPR organizational structure
  - Medical countermeasure prioritization
  - Medical countermeasure capability gaps
  - Threat or risk assessment
  - Current response activities

Initial Topics of Interest for Your Consideration

- To ensure thorough end-to-end MCM lifecycle consideration
  - How to best matrix professional and technical experts in analytic workgroups
  - How to meaningfully integrate non-Federal professional and technical experts
- What evidence-based organizational models and processes would better support both long-term policy planning and urgent policy decision needs
- How we might better influence/impact/understand the industry economy to support government MCM preparedness mission
- How to better integrate economic analyses in planning, policy analysis and evaluation processes to inform business decisions
- How to further improve budget alignment with strategy; and budget harmonization among agencies and departments
- How to effectively consider health equity in each step of the MCM process

Questions?