



Ensuring Timely Access to Existing and Newly Developed AMR Therapeutics

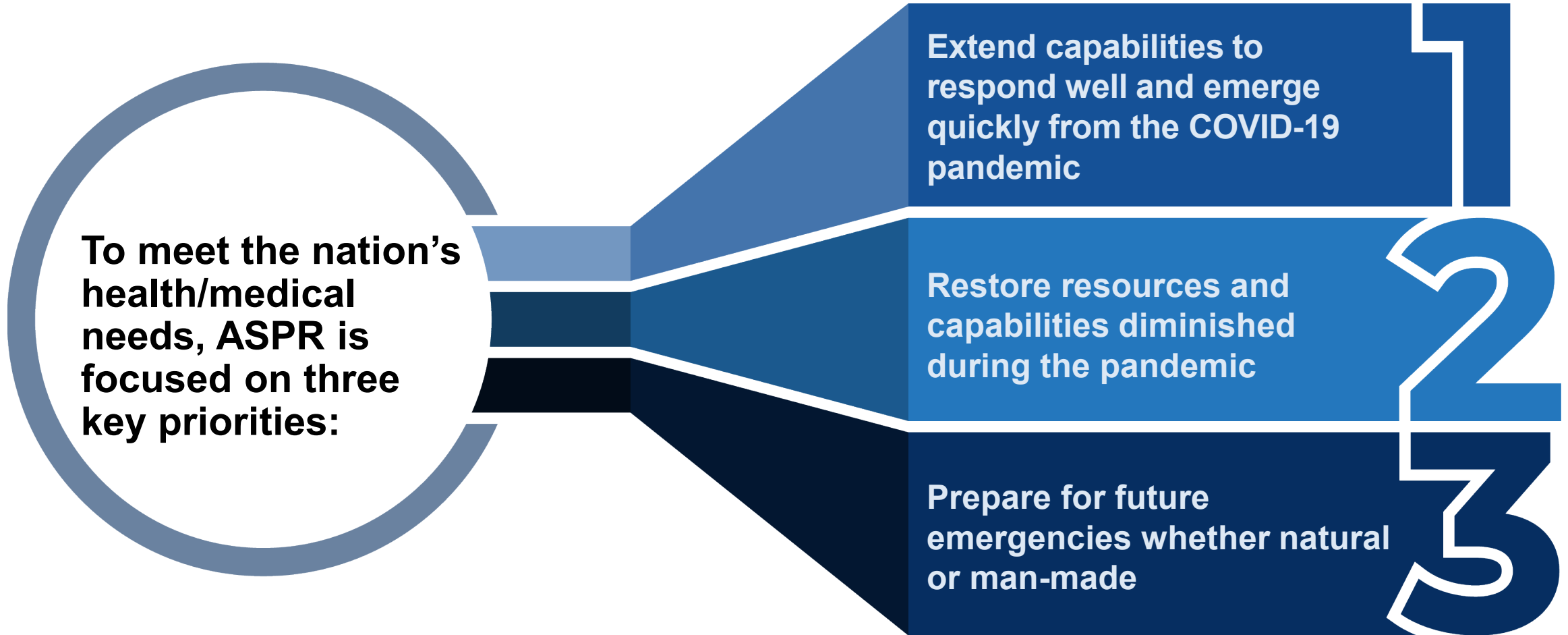
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PACCARB Meeting, Tysons Corner, Virginia

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ASPR Key Priorities



The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



Flexible, nimble authorities

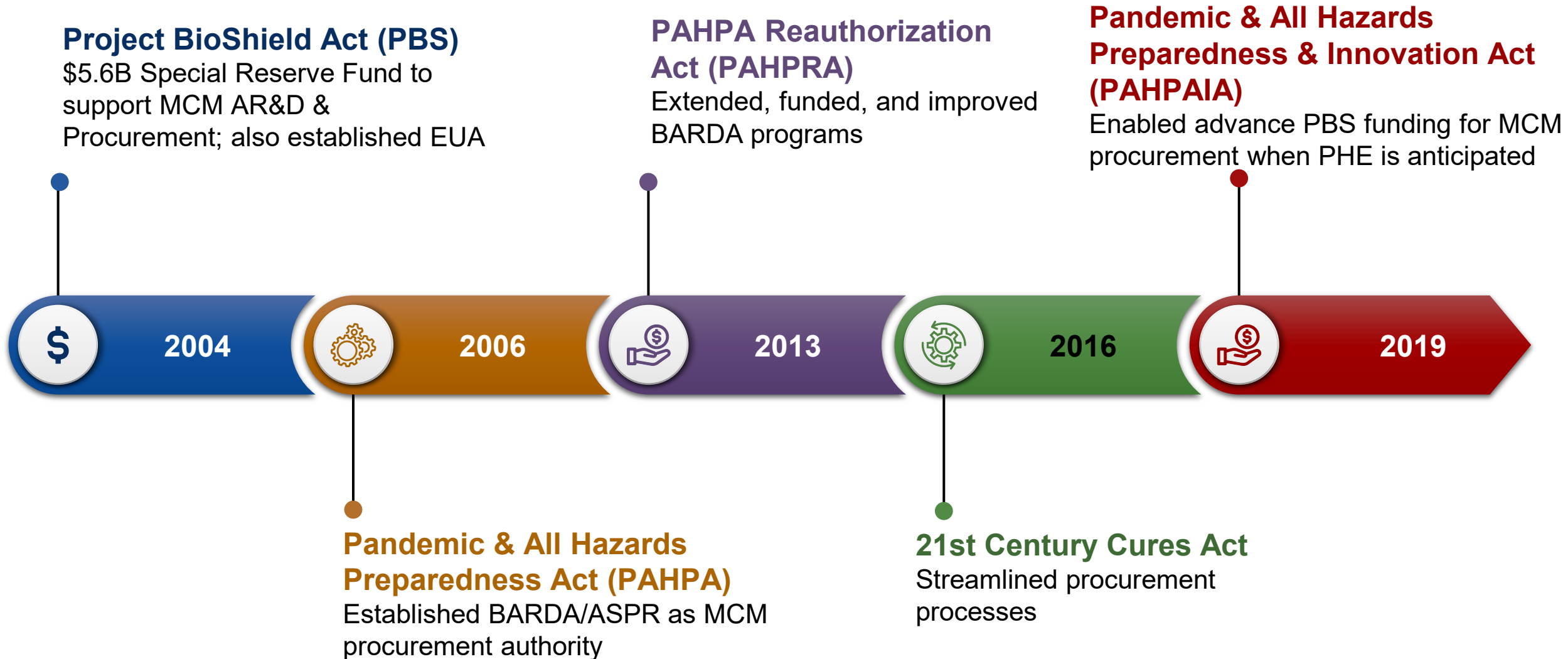
Multi-year funding

Cutting edge expertise

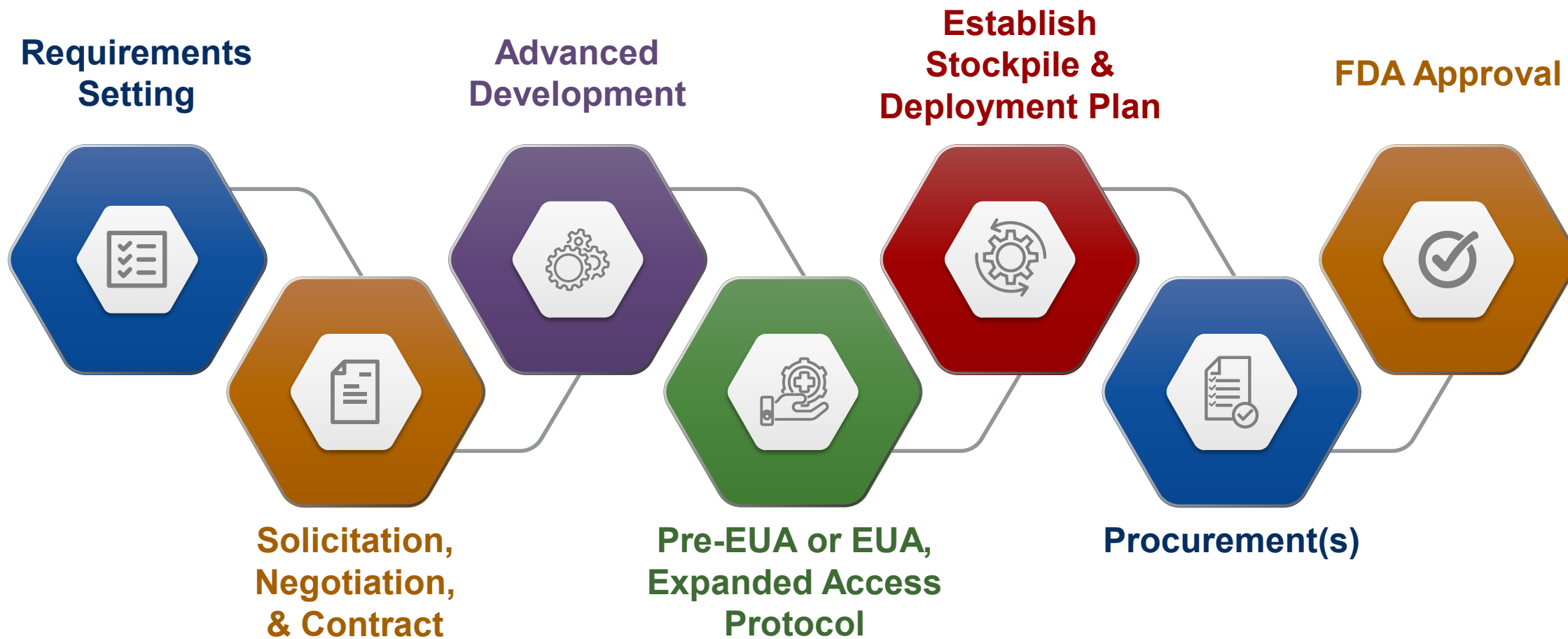
Facilitate partnerships

Promote innovation

Project BioShield (PBS) History



PBS: Preparedness to Respond



PBS Considerations



» PBS supports advanced development and procurement of MCMs for Chemical, Biological, Radiological, and Nuclear (CBRN) threats with a Material Threat Determination (MTD)



» Procurement quantities are linked to requirements



» During a public health emergency caused by a threat without an MTD or an available product, procurement can be funded with either a Congressional supplement or once a new MTD is made



» Once a product is in VMI or held by the US government (USG), the HHS Secretary or the ASPR can authorize release based on need



» PREP provides companies with liability coverage when a product is used according to its label in the U.S.

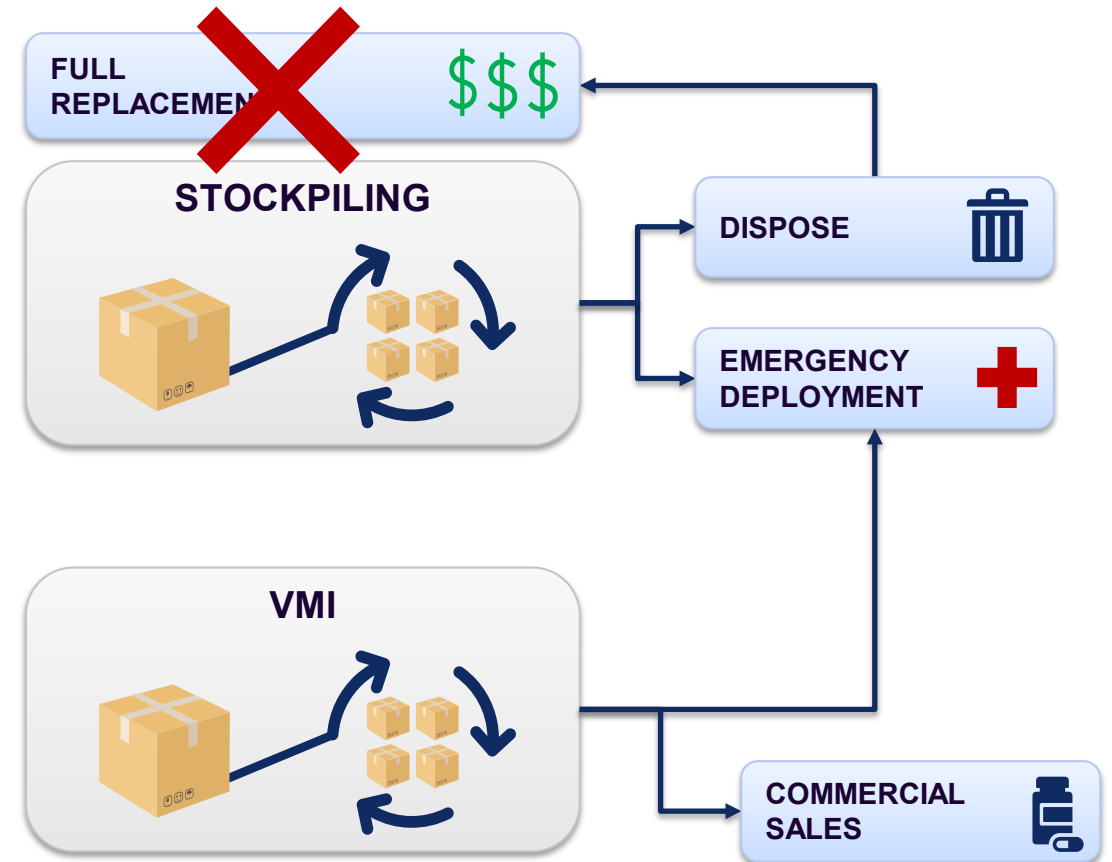
Stockpiling and Vendor Managed Inventory

Traditional Stockpiling

- Full MCM supply held by USG
- Used for emergency deployment only
- Require cycles of expiry/replacement
- USG responsible for deployment

Vendor Managed Inventory (VMI)

- MCMs with commercial markets
- Full MCM supply usually held by Vendor
- Product rotation prior to expiry
 - “first in, first out” - used when USG product does not exceed commercial use
 - Prevents product expiration on the shelf
- Strategic National Stockpile (SNS) directs emergency deployment by Vendor
 - SNS retrieval or Vendor shipment



Product Release Process

Outbreak is detected



State requests MCM from USG



MCM is packaged for distribution



Patients are treated



Public health emergency could be declared but is not required



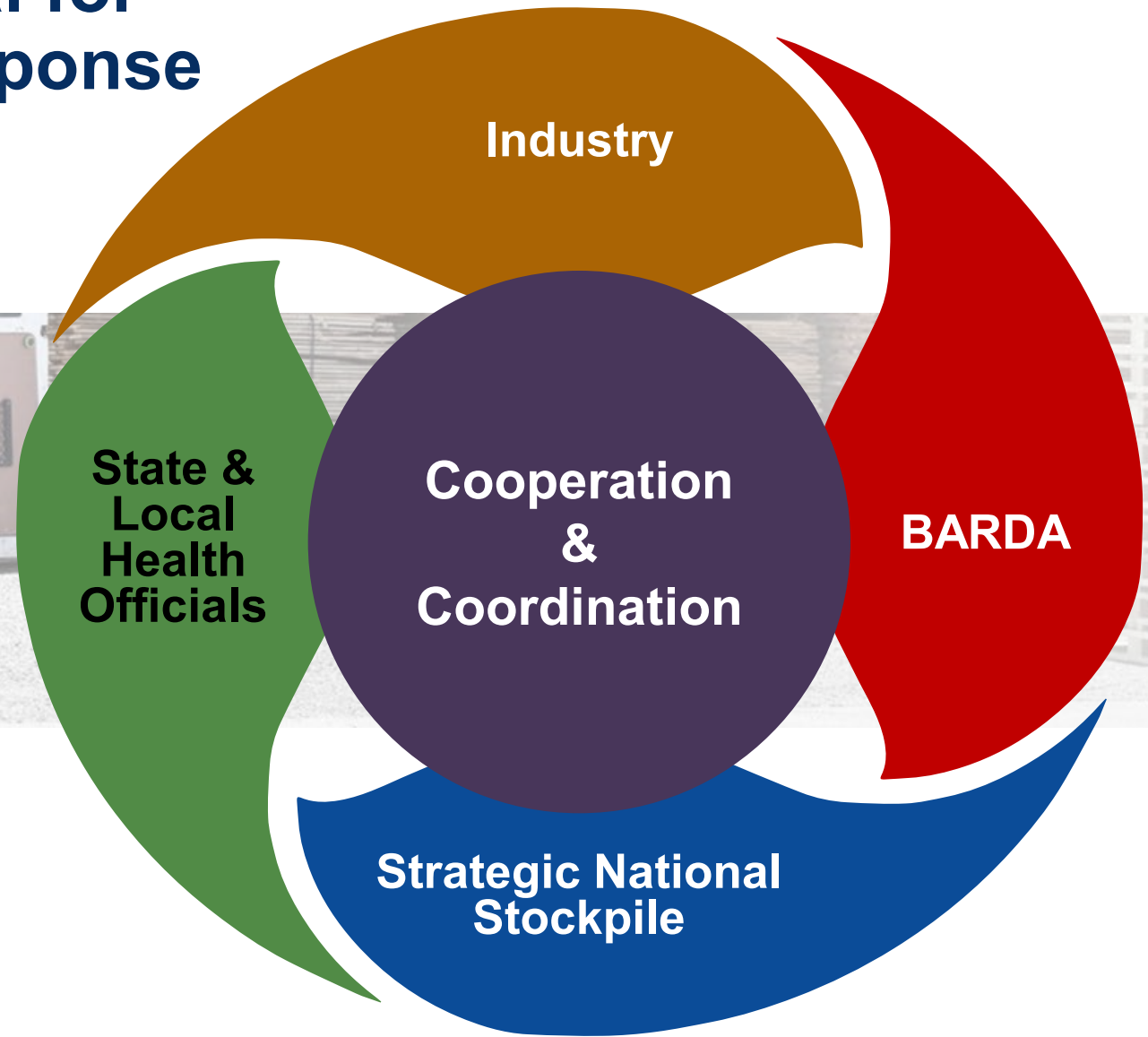
HHS Secretary or ASPR decides to release assets



Delivery to incident site(s)



Partnership is Critical for Preparedness and Response





medicalcountermeasures.gov
Portal to BARDA: Register to request a TechWatch meeting!



[sam.gov/](https://sam.gov)
Official announcements and info for all government contract solicitations



aspr.hhs.gov/MCM/
Program description, information, news, announcements



drive.hhs.gov
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