

**OBJECTIVE 6: PROMOTE AN EFFECTIVE COUNTERMEASURES
ENTERPRISE**

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4 Medical countermeasures (MCMs) include pharmaceutical, diagnostic, and non-
5 pharmaceutical items or products that aim to prevent or mitigate the adverse health
6 effects resulting from exposure to biological agents, chemicals, or a radiological/ nuclear
7 event.¹ Pharmaceutical MCMs may be initiated either before or after exposure for the
8 purposes of active immunoprophylaxis (e.g., vaccines), passive immunoprophylaxis (i.e.,
9 immunoglobulins and antitoxins), and chemoprophylaxis (i.e., post-exposure antibiotic or
10 antiviral prophylaxis) or therapy. Diagnostic MCMs are used to identify persons exposed
11 to or symptomatic from a particular agent. Non-pharmaceutical countermeasures include
12 personal protective equipment such as respiratory protective devices, protective suits and
13 gloves, ventilators, and procedures such as the isolation and decontamination of exposed
14 individuals.²

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16 The Nation has committed significant resources to developing and stockpiling MCMs.
17 The central framework for MCM planning and implementation in the federal government
18 is the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a
19 coordinated interagency effort responsible for defining and prioritizing requirements for
20 MCMs, supporting research and development of MCMs, and establishing deployment
21 and use strategies for MCMs through the Centers for Disease Control and Prevention
22 (CDC) Strategic National Stockpile (SNS).³ The SNS is a national repository with large
23 quantities of medicine, medical products, and medical supplies, which are designed to
24 supplement state and local supplies during a large-scale health incident. The Biomedical
25 Advanced Research and Development Authority (BARDA), within the Office of the
26 Assistant Secretary for Preparedness and Response (ASPR), provides an integrated,
27 systematic approach to the development and acquisition of MCMs.⁴ Other government
28 organizations, including the Department of Defense (DoD), are also involved in the
29 development and stockpiling of MCMs.

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31 Medical countermeasures may be needed to address a wide spectrum of natural and
32 deliberate threats to health security, including emerging and re-emerging diseases, drug-
33 resistant pathogens, deliberately bio-engineered germs, pandemics, and acts of
34 bioterrorism. A robust national health security framework is required to govern the
35 development, maintenance, and oversight of MCMs. From detection to decision to
36 distribution to dispensing, the efficient and timely administration of MCMs spans the
37 national health security spectrum, and affirms the Nation's resilience – community by
38 community.

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¹ "Mitigating illness and preventing death are the principal goals of our medical countermeasure efforts,"
Homeland Security Presidential Directive-18, January 31, 2007

² Testimony of Robin Robinson, Ph.D. to the Committee on Appropriations Subcommittee on Defense,
United States House of Representatives, April 24, 2008. Available at:
<http://www.hhs.gov/asl/testify/2008/04/t20080424a.html>

³ See <https://www.medicalcountermeasures.gov/BARDA/PHEMCE/phemce.aspx>

⁴ See <https://www.medicalcountermeasures.gov/BARDA/BARDA.aspx>.

BIP Objective 6

40 This chapter focuses on two components of an effective countermeasures enterprise:
41 support for the discovery and production of MCMs, and support for an efficient multi-
42 spectrum MCM distribution and dispensing strategy.

43
44 The first component was the focus of *The Public Health Emergency Medical*
45 *Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range*
46 *National Needs*.⁵ In this report, HHS highlights the need for a strategy that incorporates
47 the ability both to counter identified threats and to quickly produce MCMs for unknown
48 threats.

49
50 The second component addressed in this chapter focuses on the need for innovative
51 solutions to increase capabilities to distribute and dispense MCMs. The Office of the
52 ASPR has recently initiated efforts to explore alternative dispensing strategies by seeking
53 professional and public inputs.⁶ These will help inform federal policy, programs, and
54 plans.

55
56 The following list represents the desired four-year outcomes that, together, will promote
57 an effective countermeasures enterprise. In the following sections these outcomes are
58 described in more detail, and activities to help achieve each outcome are described
59 below. These activities can be undertaken over the next two years using existing
60 resources.

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Four-Year Outcomes for Promoting an Effective Medical Countermeasures Enterprise

- Support for the discovery and production of medical countermeasures
 - Expand and enhance strategic collaboration with manufacturers of medical countermeasures
 - Enhance manufacturing surge capacity and use of flexible manufacturing, platform technologies, and an expanded product pipeline to more rapidly produce novel vaccines and medical countermeasures
 - Develop more rapid screening methods for field and point of care to decrease the time needed to diagnose disease, ensure appropriate use of limited available treatments, and reduce costs and infrastructure needs.
 - Develop MCMs intended for dispensing and administration to children in a mass casualty emergency, as well as protocols for using MCMs that do not have a pediatric indication
 - Support innovation in developing medical countermeasures delivery systems that are simple for non-medical personnel to administer, those that offer greater shelf-life, and / or reduce cold-chain requirements

⁵ HHS, *The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs*, August 2010. Available online at http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/korch_presentation.pdf (accessed 3/1/2011).

⁶ The HHS Office of the ASPR has entered into contracts with the Institute of Medicine and Litaker Group LLC to assess the viability of pre-positioning medical countermeasures for civilian non-responder populations.

- Support for an efficient, multi-spectrum medical countermeasures distribution and dispensing strategy to minimize mass casualties and/or fatalities
 - Develop adequately stocked and positioned repositories of medical countermeasures and ancillary supplies
 - Develop well-informed policy that addresses the full spectrum of dispensing strategies including pre-positioning options that enhance access to medical countermeasures
 - Develop a diverse paid and volunteer workforce that is prepared to rapidly, effectively, and appropriately dispense medical countermeasures during a large-scale incident
 - Provide education, communication and information-sharing, and transparency to help all citizens understand and participate in community governed medical countermeasures dispensing and administration strategies

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6.1 Support for the Discovery and Production of Medical Countermeasures

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Expand and Enhance Strategic Collaboration with Manufacturers of Medical Countermeasures

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A sustainable MCM enterprise requires the flexible capacity to increase the number and types of MCMs that will be made available pending or following a catastrophic health incident. Over the next two years the activities described below are intended to expand and enhance strategic collaboration with manufacturers of MCMs.

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6.1.1 HHS will work with academic and other research communities, government partners such as the DoD, and the private sector to catalyze the development of new MCMs across the spectrum of development from pre-clinical, testing, evaluation, and advanced development to manufacturing services.

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- Emphasis will be placed on priorities set by the PHEMCE. Specific focus will be given to technologies or approaches that can demonstrate increased efficacy, reduce costs, or accelerate administration times. MCM dispensing systems that utilize existing supply chains (such as vendor managed inventory of MCMs) may also offer efficiencies.

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- Examples of increased efficacy include products for cyanide and nerve agents as well as innovative work aimed at countering radiological and nuclear threats (biodosimetry, bioassay, antineutropenic agents, thermal and radiation burn treatments, decorporation agents, antithrombocytopenic agents) and biological threats (novel antibody-based therapies to treat specific diseases as well as antimicrobials and host-directed therapeutics with novel mechanisms of actions that could be used for a range of infectious diseases).

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- Examples of reduced cost include efforts to harmonize multi-year budget plans across the relevant agencies addressing MCM development

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- 92 ○ Examples of reduced administration time include strategies to ensure that
93 end-user requirements inform MCM product development. Other
94 examples include rapid diagnostic screening methods or access to Personal
95 Protective Equipment (PPE) for responders

96 **6.1.2 Relevant Departments and Agencies will coordinate the determination of**
97 **MCM requirements based on risk assessment.**
98

99 Develop Conditions that Enhance Manufacturing Surge Capacity and Use of Flexible
100 Manufacturing, Platform Technologies, and an Expanded Product Pipeline to More
101 Rapidly Produce Novel Vaccines and Medical Countermeasures

102 *The Public Health Emergency Medical Countermeasures Enterprise Review* emphasizes
103 the need for a strategy that incorporates the ability both to counter identified threats and
104 to quickly produce MCMs for unknown threats. This strategy is articulated through the
105 following vision:

106
107 Our Nation must have the nimble, flexible capacity to produce medical
108 countermeasures rapidly in the face of any attack or threat, known or unknown,
109 including a novel, previously unrecognized, naturally occurring emerging
110 infectious disease.

111
112 *The Medical Countermeasure Enterprise Review* recommends new infrastructure
113 initiatives that address more robust regulatory science, enhancements to the
114 manufacturing process, and the establishment of an independent strategic investment firm
115 to support innovation in MCMs.

116
117 The activities described below are intended to enhance manufacturing surge capacity and
118 the use of flexible manufacturing, platform technologies, and an expanded product
119 pipeline to more rapidly produce novel vaccines and MCMs over the next two years.

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121 **6.1.3 HHS and DoD will work with manufacturers of MCMs to expand production**
122 **capability and surge capacity through nimble, multiuse technology**
123 **platforms/facilities.**

124 **6.1.4 FDA will work with the rest of HHS, academic and other research**
125 **communities, government partners such as DoD, and the private sector to**
126 **develop clear regulatory pathways along which manufacturers may develop**
127 **their products from bench-top to approval**

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⁷ HHS, *The Public Health Emergency Medical Countermeasures Enterprise Review*, p. 6

131 Support Innovation for more Durable and Easy-to-Administer Medical Countermeasures

132 A wide range of strategies is needed to optimize access to MCMs during or following an
133 incident. Development of MCMs that can be administered by non-medical personnel,
134 have a long shelf life, and/or reduce the need for refrigeration are enhanced steps towards
135 more efficient and sustainable MCM dispensing practices. The activity described below
136 is intended, over the next two years, to support innovation in developing MCM delivery
137 systems of this sort.

138 **6.1.5 HHS and DoD will work with manufacturers of MCMs and their medical and**
139 **public health collaborators to promote the development of MCMs that are**
140 **simple to administer or use (e.g. oral vs. IV, patch vs. oral) and/or have an**
141 **extended shelf-life.**

142
143 **6.2 Support for an Efficient, Multi-Spectrum Medical Countermeasures**
144 **Distribution and Dispensing Strategy to Avert Mass Casualties and/or**
145 **Fatalities**
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147 Develop an Adequately Stocked and Positioned Repositories of Medical
148 Countermeasures and Ancillary Supplies
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150 A wide-ranging national approach for dispensing MCMs will harness and integrate the
151 capabilities and commitment of all sectors and agencies, governmental and non-
152 governmental, to reduce morbidity and mortality in the communities they serve. Timely
153 and effective access to MCMs requires more than familiarity with the type and location
154 of incident-appropriate pharmaceuticals. It also requires knowledge of the geographic
155 distribution of both indigenous and transitory (e.g., daily workforce) populations and
156 their transportation and mobility systems; an easily assembled workforce (paid and
157 volunteer) that is trained and prepared to dispense MCMs; multimedia channels of
158 culturally and linguistically sensitive risk communication and notification systems to
159 direct exposed persons efficiently to medical care and therapeutics; and a repertoire of
160 strategies to optimize access to life-saving drugs for both ambulatory and non-ambulatory
161 persons as well as other at-risk individuals. Public health efforts should utilize existing
162 public emergency services when available.

163
164 The activities described below are intended, over the next two years, to help develop
165 adequately stocked and positioned repositories of MCMs and ancillary supplies.
166

167 **6.2.1 HHS will ensure that state and private sector entities continue to collaborate**
168 **regarding MCM stockpiles and put in place systems that facilitate sharing and**
169 **augment equitable and efficient MCM use.**

- 170 ○ Establish strategy and partnerships regarding governmental and private-
171 sector caches to share and augment local MCMs dispensing capacity and
172 capabilities

173 **6.2.2 CDC SNS will continue to work with federal, state and local governmental**
174 **agencies and private partners to align strategies and ensure adequately stocked**
175 **and forward-positioned repositories of MCMs.**

- 176 ○ The SNS should continue to work through the PHEMCE to ensure that
177 Concepts of Operations (ConOps) are considered and validated prior to
178 product acquisition
- 179 ○ The SNS should continue to pursue efficiencies through consideration of
180 comprehensive lifecycle costs and the merits of all potential storage
181 modalities prior to acquisition. This should include the potential for
182 commercial product rotation, the potential of cost deferral with the Shelf
183 Life Extension Program (SLEP⁸), as well as any operational limitations
184 which might preclude particular storage options prior to MCM acquisition

185 **6.2.3 CDC SNS will continue to work with each state to develop plans to receive and**
186 **distribute SNS medical products and medical supplies to local communities as**
187 **quickly as possible, and to explore diverse distribution and dispensing strategies**
188 **to best meet the needs of their populations.**

189 Develop a Well-Informed Policy that Addresses the Full Spectrum of Antibiotic Pre-
190 positioning Strategies from Home, Community, and Other Population-Proximate Sites to
191 Eliminate Disparities in Access to Medical Countermeasures

192
193 A national strategy should examine approaches for pre-positioning medical stockpiles
194 that are redundant, accessible, and appropriately refreshed. This strategy must also
195 include the timely destruction of products that can no longer be used as well as FDA
196 authorized shelf-life extension in certain circumstances. The SNS has goals targeting the
197 federal capability for receiving and distributing large quantities of MCMs. However,
198 diverse strategies should be identified and improved upon to achieve the national goals
199 underpinning the NHSS. Potential gaps in public health systems' capacity, durability and
200 response time for dispensing MCMs require the use of well-informed strategies to ensure
201 that MCMs are optimally accessible through the use of such strategies as pre-positioning
202 in homes, workplaces, and community-accessible pharmacies, among other options.⁹

⁸ The Shelf Life Extension Program (SLEP) is administered jointly by FDA and DOD. The SNS also participates in the program. DOD and SNS both maintain large stockpiles of medications and vaccines in order to ensure that both military and civilian populations have access to needed antidotes, and treatments in the event of a medical emergency. In order to save federal dollars, FDA and DOD developed this system to extend the shelf life of these drugs and vaccines beyond the manufacturer's expiration date. All testings for extensions are done at FDA test facilities. U.S. Army Medical Materiel Agency, "Extending the Shelf Life of Critical 'War Reserves' Medical Materiel Using the FDA/DOD Shelf Life Extension Program." U.S. Department of Defense. <http://www.usamma.army.mil/documents/SLEPInfoPaper-Mar2005.pdf> (accessed March 7, 2010).

⁹ These dispensing strategies may require an Emergency Use Authorization (EUA) prior to the dispensing and administration of certain medical countermeasures. An EUA is a legal means that enables the FDA under Section 564 (b) of the Federal Food, Drug and Cosmetic Act to approve of new drugs or new indications for previously approved drugs during a declared emergency. On April 27, 2009, for example, the FDA issued an EUA to make available diagnostic tools (rRT-PCR Swine Flu Panel) to identify and

203

204 The following activity will be undertaken during the next two years to help address the
205 full spectrum of pre-positioning strategies.

206

207 **6.2.4 HHS will analyze the efficacy and feasibility of pre-positioning personal or**
208 **home stockpiles of oral antibiotics for certain groups of responders and**
209 **subgroups of the public.¹⁰**

210

211 Develop a Diverse Paid and Volunteer Workforce that Is Prepared to Rapidly,
212 Effectively, and Appropriately Dispense Medical Countermeasures During a Large-Scale
213 Incident

213

214 Increasing the number and availability of different MCMs needed to address various
215 threats, and their availability, will place significant demands on the workforce designated
216 to help dispense and administer these products. This workforce will require knowledge
217 and continual refreshing of information regarding the use and administration of MCMs
218 among a diverse and expanding national population. Additionally, this workforce should
219 have access to exercises to practice what they will communicate and how they will
220 perform during a public health emergency. This workforce should also have the tools and
221 knowledge to protect themselves during an incident (e.g., by receiving an early flu
222 vaccine) before they put themselves in harm's way to protect their families and their
223 communities.

224

225 Over the next two years, the following activities will be undertaken by HHS, in
226 coordination with local, state, territorial, and tribal public health agencies and with
227 interagency partners and other relevant organizations, to help develop a workforce to
228 support the dispensing of MCMs.

229

230 **6.2.5 HHS and DHS will identify and enumerate the multiple classes of personnel**
231 **designated within the broad classification of "responder" whose actions may be**
232 **critical to preserving infrastructure and continuity as well as protecting the**
233 **health and safety of others during or after an incident.**

234

235 **6.2.6 HHS will ensure that a diverse paid and volunteer workforce is trained and**
236 **routinely exercised in the knowledge and skills required to rapidly dispense**
appropriate MCMs to their communities.

237

238 **• For those circumstances in which a trained workforce is not available,**
239 **identify a competent chain- of- command for MCM dispensing by untrained**
volunteers

respond to the 2009 swine flu outbreak under certain circumstances. It is believed that during an emergency this process will not hinder the timely dispensing of MCMs to certain populations.

¹⁰ Executive Order 13527 was signed by President Obama 31 December 2009 to identify approaches for "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." This EO particularly addresses federal Mission Essential Personnel (MEPs), other state and local emergency response capability, and enhancing the U.S. Postal Model for dispensing medical countermeasures.

240 **6.2.7 HHS will develop policies and strategies to ensure that this workforce is**
241 **provided the appropriate MCMs to protect their health and safety. These**
242 **strategies may include, as appropriate, pre-incident vaccination, access to**
243 **worksite medical countermeasure caches, or personal antibiotic stockpiles.**

244 **6.2.8 CDC will ensure that local, state, territorial, and tribal public health officials**
245 **and designated hospital authorities have sufficient knowledge of the contents**
246 **and dispensing policies associated with the materiel from the SNS.**

247 Provide Education, Communication and Information-Sharing, and
248 Transparency Regarding MCMs

249
250 A national MCM strategy is one in which all parties – from those who manufacture
251 vaccines, antibiotics and other medical products to those who will be the recipients of
252 these potentially life-saving products – have a coordinated understanding of their use.
253 The properties, risks, and benefits of MCMs must be understood so that they will be
254 accepted by the medical and public health communities and by the public for whom they
255 are intended. The products developed for the national pharmaceutical repository must be
256 safe, efficacious, and, ideally, easy to administer during or after an incident. Ineffective
257 products could erode public confidence and possibly negate the intent of the program. If
258 MCMs are dispensed in advance to certain groups, the reasons for providing the MCMs,
259 including the medical justification, must be clear to avoid diminished trust in
260 government. The public must also know in advance that that the decision to dispense
261 MCMs is guided by data concerning the publics predicted exposure to an agent or
262 pathogen and the safety of a particular medical countermeasure.

263
264 Education and knowledge-building must take place well before a catastrophic incident.
265 Lines of communication must be built, bridges between the public health and medical
266 communities must be buttressed, and outreach to communities through social networking
267 and other channels must be established.

268
269 The following activities will be undertaken during the next two years to support
270 education, communication and information-sharing, and transparency.

271
272 **6.2.9 HHS will work to enhance the familiarity of public health departments with**
273 **the populations for whom they are responsible, such as promoting**
274 **understanding of the populations' socioeconomic status, housing, language**
275 **needs, daily patterns of activity, movement and transportation patterns, and**
276 **access patterns to emergency care.**

277 **6.2.10 HHS will support education, information sharing, and transparency across**
278 **government, the private sector, and the public to promote understanding,**
279 **acceptance, and participation in MCM dispensing and administration strategies.**

280 **6.2.11 HHS will encourage public health officials to continue to work within their**
281 **communities to discuss and inform mass MCM dispensing strategies, and to**
282 **provide justification for selected approaches, given such factors as population**
283 **demographics and vulnerabilities, exposure to agents, availability of MCMs, and**

284 **other information which will educate the public and increase transparency of**
285 **government.**

286 **6.2.12 HHS will encourage local, state, territorial, and tribal public health officials**
287 **to engage in regular communication with government, business, and other**
288 **community sectors to develop and test plans for MCM dispensing.**

289 ○ Existing funding for exercises or other trainings should be re-shaped to
290 incorporate MCM dispensing

291 **6.2.13 HHS will encourage local, state, territorial, and tribal public health officials**
292 **to establish regular contact with their media partners, including television and**
293 **print media, to determine their willingness to support messages to the public**
294 **regarding MCMs.**

295 ○ Establish the role of designated Public Information Official or other
296 credible spokespersons

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