



# Emergency Use Authorization Toolkit

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## ASTHO LEGAL PREPAREDNESS SERIES EMERGENCY USE AUTHORIZATION TOOLKIT

### Supplemental Materials

The Supplemental Materials compilation lists key documents and additional resources about the issues raised in the Emergency Use Authorization Toolkit. The documents listed are for reference purposes only and are not a complete listing of resources available on the issue. Individual users are responsible for researching the current text of laws, statutes, regulations, and other materials. The document lists bibliographical information and, where available, online links to the resources. All links are current as of January 31, 2012. Please report broken links to ASTHO at [communications@astho.org](mailto:communications@astho.org).

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#### General Resources and Compilations

##### Governmental

HHS Office of the Assistant Secretary for Preparedness and Response. "Legal Authority and Related Guidance" webpage. Available at <http://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx>.

HHS Office of the Assistant Secretary for Preparedness and Response. "Legal Authority of the Secretary" webpage. Available at <http://www.phe.gov/preparedness/support/secauthority/Pages/default.aspx>.

Lister SA. Congressional Research Service. *The Public Health and Medical Response to Disasters: Federal Authority and Funding* (RL33579). August 1, 2008. Available at [http://digital.library.unt.edu/ark:/67531/metacrs9495/m1/1/high\\_res\\_d/RL33579\\_2006Jul28.pdf](http://digital.library.unt.edu/ark:/67531/metacrs9495/m1/1/high_res_d/RL33579_2006Jul28.pdf).

Swendiman KS and Jones NL. Congressional Research Service. *The 2009 Influenza Pandemic: Selected Legal Issues* (R40560). June 15, 2009. Available at [http://digital.library.unt.edu/ark:/67531/metadc26152/m1/1/high\\_res\\_d/R40560\\_2009Jun15.pdf](http://digital.library.unt.edu/ark:/67531/metadc26152/m1/1/high_res_d/R40560_2009Jun15.pdf).

#### Other Sources

American Health Lawyers Association. Emergency Preparedness Toolkit. May 4, 2010. Available at <http://www.healthlawyers.org/Members/PracticeGroups/THAMC/EmergencyPreparednessToolkit/Pages/default.aspx>.

### At-Risk Individuals and Communities

#### Offices/Programs/Activities

HHS Office of the Assistant Secretary for Preparedness and Response. “At-Risk Individuals, Behavioral Health, and Human Services Coordination” webpage. Available at <http://www.phe.gov/Preparedness/planning/abc/Pages/default.aspx>.

#### Other Resources

Association of State and Territorial Health Officials. “At-Risk Populations Project” webpage. Available at <http://www.astho.org/Programs/Infectious-Disease/At-Risk-Populations/>.

### Biomedical Advanced Research and Development Authority (BARDA)

See also “[Countermeasures Injury Compensation Program](#)”

#### Offices/Programs/Activities

HHS Office of the Assistant Secretary for Preparedness and Response. “Biomedical Advanced Research and Development Authority (BARDA)” webpage. Available at <http://www.phe.gov/about/barda/Pages/default.aspx>.

HHS MedicalCountermeasures.gov webpage available at <https://www.medicalcountermeasures.gov/default.aspx>.

#### Other Resources

Gottron F. Congressional Research Service. *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress* (R41033). March 3, 2011. Available at [http://assets.opencrs.com/rpts/R41033\\_20110303.pdf](http://assets.opencrs.com/rpts/R41033_20110303.pdf).

### Cities Readiness Initiative (CRI)

#### Offices/Programs/Activities

Centers for Disease Control and Prevention. “Cities Readiness Initiative” webpage. Available at <http://www.cdc.gov/phpr/stockpile/cri/>.

### Countermeasures Injury Compensation Program (CICP)

#### Offices/Programs/Activities

Health Resources and Services Administration. “Countermeasures Injury Compensation Program” webpage. Available at <http://www.hrsa.gov/cicp/>.

#### Rules and Regulations

##### CICP Administrative Rules

A correction to the Interim Final Rule was published on October 21, 2010. Available at [http://www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/cicp\\_final\\_rule\\_correction.pdf](http://www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/cicp_final_rule_correction.pdf).

The CICIP Administrative Implementation Interim Final Rule was published in the Federal Register on October 15, 2010. Available at [http://www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/cicp\\_admin\\_final\\_rule.pdf](http://www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/cicp_admin_final_rule.pdf).

## Defense Medical Materiel Program Office (DMMPO)

See “*Shelf Life Extension Program*”

## Emergency Use Authorization (EUA)

### Public Law, Statute, and Regulations

Federal Food, Drug, and Cosmetic Act §564, as amended. Codified at 21 U.S.C. §564.

### Guidance Documents

U.S. Food and Drug Administration. Emergency Use Authorization of Medical Products Guidance. July 2007. Available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>.

### Offices/Programs/Activities

U.S. Food and Drug Administration. “Emergency Use Authorization” webpage. Available at <http://www.fda.gov/emergencypreparedness/counterterrorism/ucm182568.htm>. Webpage includes all current and archived EUAs.

U.S. Food and Drug Administration. “Emergency Use Authorizations Questions and Answers” webpage. Available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153297.htm>.

U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. “Emergency Use Authorization” online course. Available at <http://www.bt.cdc.gov/training/eua/index.html>.

Beers D. U.S. Food and Drug Administration. “FDA Regulation of Medical Products.” Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

Sadove E. Food and Drug Administration. “Emergency Use of FDA Regulated Medical Products.” Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

Yu Y. Centers for Disease Control and Prevention. “EUA: CDC’s Roles and Responsibilities.” Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

Sherman S. Dept. of Health and Human Services. “Public Health Emergency Authorities: Determinations and Declarations.” Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

*Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model*. Workshop Summary. Institute of Medicine (US). Forum on Medical and Public Health Preparedness for Catastrophic Events. Washington, DC. National Academies Press. 2010. Available at <http://www.ncbi.nlm.nih.gov/books/NBK53126/pdf/TOC.pdf>.

## Federal Food, Drug, and Cosmetic Act (FD&C Act)

### Public Law, Statute, and Regulations

Federal Food, Drug, and Cosmetic Act, as amended. Codified at 21 U.S.C. 301 et seq. Available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>.

## Federal Tort Claims Act (FTCA)

### Public Law, Statute, and Regulations

Federal Tort Claims Act, as amended. Codified at 28 U.S.C. §§1346(b), 2671-2680. Available at <http://origin.www.gpo.gov/fdsys/pkg/USCODE-2009-title28/pdf/USCODE-2009-title28-partIV-chap85-sec1346.pdf>.

## Food and Drug Administration (FDA)

### Offices/Programs/Activities

Food and Drug Administration. Emergency Preparedness and Response website. Available at <http://www.fda.gov/EmergencyPreparedness/default.htm>.

## HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)

### Offices/Programs/Activities

HHS Office of the Assistant Secretary for Preparedness and Response website. Available at <http://www.phe.gov/preparedness/support/secauthority/Pages/default.aspx>.

## Pandemic and All-Hazards Preparedness Act (PAHPA)

### Public Law, Statute, and Regulations

Pandemic and All-Hazards Preparedness Act of 2006. Pub. L. No. 109-417 (120 STAT. 2831). Available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>.

Codified, in part, in the Public Health Service Act, 42 U.S.C. 201 et seq. Available at <http://www.gpo.gov/fdsys/pkg/USCODE-2009-title42/pdf/USCODE-2009-title42-chap6A.pdf>.

### Summaries of Law, Statute, and Regulations

Department of Health and Human Services. "Pandemic and All Hazards Preparedness Act" webpage. Available at <http://www.phe.gov/Preparedness/legal/pahpa/Pages/default.aspx>.

Lister SA and Gottron F. Congressional Research Service. *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law* (RL33589). March 12, 2007. Available at <http://www.fas.org/programs/bio/resource/documents/CRS%20-%20PAHPA%203-07.pdf>.

### Offices/Programs/Activities

HHS Assistant Secretary for Preparedness and Response website. Available at <http://www.phe.gov/preparedness/pages/default.aspx>.

### HHS Status Reports on PAHPA Implementation

HHS Assistant Secretary for Preparedness and Response. Pandemic and All-Hazards Preparedness Act Public Law 109-417 Progress Report. November 2007. Available at <http://healthyamericans.org/reports/bioterror07/PAHPAProgressReport.pdf>.

HHS Assistant Secretary for Preparedness and Response. *Progress Report on the Implementation of Provisions Addressing At-Risk Individuals*. August 2008. Available at <http://www.phe.gov/Preparedness/legal/pahpa/Documents/pahpa-at-risk-report0901.pdf>.

HHS Assistant Secretary for Preparedness and Response. *Telehealth Report to Congress*. January 2009. Available at <http://www.phe.gov/Preparedness/legal/pahpa/Documents/telehealthrtc-091207.pdf>.

## Pandemic Strategies and Plans

**Key Documents**

Homeland Security Council. *The National Strategy for Pandemic Influenza*. November 2005. Available at <http://www.flu.gov/professional/federal/pandemic-influenza.pdf>.

Homeland Security Council. *National Strategy for Pandemic Influenza: Implementation Plan*. May 2006. Available at <http://www.flu.gov/professional/federal/pandemic-influenza-implementation.pdf>.

HHS. *HHS Pandemic Influenza Plan*. November 2005. Available at <http://www.flu.gov/planning-preparedness/federal/hhspandemicinfluenzaplan.pdf>.

Department of Homeland Security. *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*. September 2006. Available at <http://www.flu.gov/professional/pdf/cikrpandemicinfluenzaguide.pdf>.

CDC. *National Biosurveillance Strategy for Human Health (NBSHH)*. July 2012. Available at [https://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Biosurveillance\\_July\\_2012.pdf](https://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf).

**Offices/Programs/Activities**

Flu.gov. Available at <http://www.flu.gov>.

**Project BioShield Act of 2004****Public Law, Statute, and Regulations**

Project BioShield Act of 2004. Pub. L. No. 108-276.

**Offices/Programs/Activities**

Department of Health and Human Services. “Medical Countermeasures” webpage available at <http://www.phe.gov/preparedness/mcm/pages/default.aspx> and “Medical Countermeasures.gov” website at <http://www.medicalcountermeasures.gov>.

Department of Health and Human Services, Office of the Assistant Secretary of Preparedness and Response. “Public Health Emergency” webpage. Available at <http://www.phe.gov/Preparedness/pages/default.aspx>.

**Other Resources**

Gottron F. Congressional Research Service. *Project BioShield: Purposes and Authorities* (RS21507). July 6, 2009. Available at <http://www.hsdl.org/?view&did=15074>.

U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. “Emergency Use Authorization” online course. Available at <http://www.bt.cdc.gov/training/eua/index.html>.

U.S. Government Accountability Office. *Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities* (GAO-09-820). July 21, 2009. Available at <http://www.gao.gov/new.items/d09820.pdf>.

U.S. Government Accountability Office. *Project BioShield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats* (GAO-09-878R). July 24, 2009. Available at <http://www.gao.gov/new.items/d09878r.pdf>.

**Public Health Service Act, Section 319—Authorities Related to Public Health Emergencies****Public Law, Statute, and Regulations**

PHS Act Sec. 319. Codified at 42 U.S.C. § 247d. Available at <http://www.gpo.gov/fdsys/pkg/USCODE-2009-title42/html/USCODE-2009-title42-chap6A-subchapII.htm>.

## Public Readiness and Emergency Preparedness Act (PREP Act)

See also *“Countermeasures Injury Compensation Program”*

### Public Law, Statute, and Regulations

Public Readiness and Emergency Preparedness Act of 2005. Pub. L. No. 109-417 (120 STAT. 2831). Available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>.

Codified in the Public Health Service Act at 42 U.S.C. §§ 247d-6d, 247d-6e. Available at <http://www.gpo.gov/fdsys/pkg/USCODE-2009-title42/html/USCODE-2009-title42-chap6A-subchapII.htm>.

### Offices/Programs/Activities

Department of Health and Human Services. “Public Readiness and Emergency Preparedness Act” webpage. Available at <http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

Department of Health and Human Services. “Public Readiness and Emergency Preparedness Act Questions and Answers” webpage. Available at <http://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>.

### Public Readiness and Emergency Preparedness Act (PREP) Act Declarations

Current and expired PREP Act Declarations. Available at <http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

## Shelf Life Extension Program (SLEP)

### Offices/Programs/Activities

Shelf Life Extension Program website. Available at [https://slep.dmsbfda.army.mil/portal/page/portal/SLEP\\_PAGE\\_GRP/SLEP\\_HOME](https://slep.dmsbfda.army.mil/portal/page/portal/SLEP_PAGE_GRP/SLEP_HOME).

Defense Medical Materiel Program Office website available at <http://www.dmsb.mil/aboutUs.asp> and DMMPO SLEP webpage at <http://www.dmsb.mil/slep.asp>. [Note: Sites may contain security warnings.]

Defense Medical Materiel Program Office. “Extending the Shelf Life of Critical Chemical, Biological, Nuclear, and Radiological (CBRN) Medical Materiel Using the FDA/DOD Shelf Life Extension Program.” January 24, 2006. Available at [https://slep.dmsbfda.army.mil/slep/slep\\_info\\_paper\\_JAN\\_2006.doc](https://slep.dmsbfda.army.mil/slep/slep_info_paper_JAN_2006.doc). [Note: Site may contain security warnings.]

Food and Drug Administration. “Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations” website. Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm>.

Food and Drug Administration. CGMP in Manufacturing, Processing, Packing, or Holding of Drugs. 21 CFR Part 210. Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=210>.

Food and Drug Administration. CGMP for Finished Pharmaceuticals. 21 CFR Part 211. Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=211>.

### Other Resources

Borio L. Food and Drug Administration. July 25, 2011 Letter to William G. Burel, CDC et al regarding answers to questions raised during December 2010 *Federal, State, and Local Public Health Preparedness* meeting in Baltimore, MD. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm234336.htm>.

Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic. Institute of Medicine. *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*. National Academies Press. 2008.

Courtney B et al. “Maximizing State and Local Medical Countermeasure Stockpile Investments Through the Shelf Life Extension Program.” *Biosecurity and Bioterrorism*. Vol. 7 No. 1. 2009.

Homeland Security Council. *National Strategy for Pandemic Influenza: Implementation Plan* (May 2006) (see *Pandemic Plans* section above).

Leissa B. U.S. Food and Drug Administration. “Shelf Life Extension Program” presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

Lyon RC et al. Stability profiles of drug products extended beyond labeled expiration dates. *J Pharm Sci* 2006;95(7):1549-1560.

Tegeris J. Dept. of Health and Human Services. "Cost Comparison: Shelf Life Extension Program (SLEP) vs. Repurchase for State Stockpiles." Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm>.

United States Pharmacopeial Convention (USP) website. Available at <http://www.usp.org/aboutUSP/>.

## Strategic National Stockpile (SNS)

### Public Law, Statute, and Regulations

The Strategic National Stockpile is authorized by Public Health Service Act §319F-2; 42 U.S.C. § 247d-6b.

### Offices/Programs/Activities

CDC. "Strategic National Stockpile" website. Available at <http://www.cdc.gov/phpr/stockpile/stockpile.htm>.

### Other Resources

Institute of Medicine (US). Forum on Medical and Public Health Preparedness for Catastrophic Events. *Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model*. Workshop Summary. Washington, DC. National Academies Press. 2010. Available at [www.ncbi.nlm.nih.gov/books/NBK53126/pdf/TOC.pdf](http://www.ncbi.nlm.nih.gov/books/NBK53126/pdf/TOC.pdf).

## Vaccine Injury Compensation Program (VICP)

### Offices/Programs/Activities

Health Resources and Services Administration. "National Vaccine Injury Compensation Program (VICP)" webpage. Available at <http://www.hrsa.gov/vaccinecompensation/default.htm>.

Note: This document was compiled from August–December 2011 and reflects the laws and programs current then. It reflects only portions of the laws relevant to public health emergencies and is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.

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