



Emergency Use Authorization Toolkit

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ASTHO LEGAL PREPAREDNESS SERIES EMERGENCY USE AUTHORIZATION TOOLKIT

Overview of ASTHO Emergency Use Authorization Toolkit

The *Emergency Use Authorization (EUA) Toolkit* addresses key concepts and issues regarding the federal law allowing special uses for drugs, biologics, and devices during specified emergencies. The EUA Toolkit also addresses programs and issues related to the storage, dispensing, and use of medical countermeasures. The toolkit's component documents are designed to be used in education, training, and planning activities to prepare for emergencies, as well as to serve as a quick reference resource during an emergency response to an event. The *EUA Toolkit* is one of six toolkits in ASTHO's Legal Preparedness Series. Please see the Introduction document for additional background on the project and the other toolkits.

Intended Audiences

These documents are specifically designed to address the different needs of discrete audiences within a state health agency:

- State health officers, agency directors, or other senior governmental officials may find the executive overviews and fact sheets of particular interest.
- Preparedness directors and other programmatic staff will find the fact sheets, issue briefs, state analysis guides, and resource materials useful in understanding and gaining more in-depth knowledge about particular concepts and legal issues.
- Legal counsel will find the fact sheets about particular federal laws and regulations, issue briefs, state analysis guides, and citations within the resource materials a good basis from which to conduct additional research and analyze their particular state's authorities on these issues.
- The current issue updates are a good resource for all audiences to learn the latest developments on issues related to the toolkit topic.

Emergency Use Authorization Toolkit Contents

All documents are listed alphabetically within each document category

Executive Overviews

One-page snapshots of key concepts and issues

- [Key Emergency Use Authorization and Medical Countermeasures Laws and Programs](#)

Fact Sheets

Short documents addressing fundamental issues or legal authorities

- [Emergency Use Authorization: §564 of the Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#)
- [Comparing Emergency Use Authorization to Investigational New Drug & Investigational Device Exemption Protocols](#)
- [Federal Shelf Life Extension Program \(SLEP\)](#)
- [Project BioShield Act](#)
- [Public Readiness and Emergency Preparedness Act \(PREP Act\)](#)
- [Strategic National Stockpile \(SNS\)](#)

Issue Briefs

In-depth information and analyses of fundamental issues

- No issue briefs in the toolkit currently

State Analysis Guides

Aids to assist states in identifying and analyzing their own statutes, regulations, and policies

- [State Pharmaceutical and Dispensing Authorities](#) (Word document will download)

Current Issues and Updates

Periodic updates on new and evolving issues

- [Current Issues and Updates—Winter 2012—Pandemic and All-Hazards Preparedness Act Reauthorization](#)
- [Current Issues and Updates—Fall 2011—FDA Doxycycline Mass Dispensing EUA](#)
- [Current Issues and Updates—Summer 2011—Evolving Policy Issues](#)

Resource Materials

Bibliographies and links to key agencies, organizations, laws, and other documents

- [Emergency Use Authorization Supplemental Materials Document](#)

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