



## State Analysis Guide

## State Pharmaceutical Laws and Dispensing Authorities

This *State Analysis Guide* is intended to assist state health agency staff and legal counsel in locating and analyzing their state's laws, rules, policies, and implementation plans governing the storage, distribution, dispensing, and administration of pharmaceuticals and other regulated medical products in the context of emergency preparedness and response activities. Although the Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes the minimum regulation of medical products (e.g., drugs, devices, biologics), state laws may add more stringent requirements and generally govern the licensing of persons who distribute, compound, dispense, and administer medical products.

Space is provided on the document to insert references or summaries of appropriate state and/or local authorities. Because each state's law is unique, this guide may not identify all issues that arise in the course of analyzing a state's law. **In all instances the language and requirements of specific state/local laws, regulations, ordinances, rules, policies, guidances, case law, and other sources of legal authority overrule this general analysis guide. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice.**

| Issues for Analysis                                                                                                                                                                                     |                                                                                                                                                                                         | State/Local Information |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <b>Storage of Medical Products</b>                                                                                                                                                                      |                                                                                                                                                                                         |                         |
| Identify state legal authorities governing the storage of medical products (e.g., drugs, devices, biologics).                                                                                           |                                                                                                                                                                                         |                         |
|                                                                                                                                                                                                         | How is the term "storage" defined?                                                                                                                                                      |                         |
| Identify if and how the legal requirements for storage differ depending on the type of medical product.                                                                                                 |                                                                                                                                                                                         |                         |
| Identify if and how the legal authorities apply to caches and stockpiles of medical products.                                                                                                           |                                                                                                                                                                                         |                         |
|                                                                                                                                                                                                         | Are the legal requirements any different for government caches and stockpiles or private caches and stockpiles?                                                                         |                         |
|                                                                                                                                                                                                         | Are there different requirements if the government caches and stockpiles are stored/managed in a government-owned or -controlled facility? In a privately owned or controlled facility? |                         |
| Are there any state immunities or other liability protections available to those storing medical products? If so, identify the protected parties, protected actions, and any limits on the protections. |                                                                                                                                                                                         |                         |
| Identify if and how the legal requirements change when there is an emergency declaration.                                                                                                               |                                                                                                                                                                                         |                         |

| Issues for Analysis                                                                                                                                                                                                                                                           |                                                                              | State/Local Information |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------------------|
| Identify if any state legal authorities governing storage of medical products conflict with any federal legal requirements.                                                                                                                                                   |                                                                              |                         |
|                                                                                                                                                                                                                                                                               |                                                                              |                         |
| <b>Labeling and Packaging of Medical Products</b>                                                                                                                                                                                                                             |                                                                              |                         |
| Identify state legal authorities governing the labeling/relabeling or packaging/repackaging of medical products.                                                                                                                                                              |                                                                              |                         |
|                                                                                                                                                                                                                                                                               | How are the terms "labeling/relabeling" and "packaging/repackaging" defined? |                         |
| Identify if and how the state legal authorities differ for governments and other actors (e.g., private organizations).                                                                                                                                                        |                                                                              |                         |
| Are there any state immunities or other liability protections available to those labeling or packaging medical products? If so, identify the protected parties, protected actions, and any limits on the protections.                                                         |                                                                              |                         |
| Identify if and how the legal requirements change when there is an emergency declaration.                                                                                                                                                                                     |                                                                              |                         |
| Identify if any state legal authorities governing the labeling/relabeling or packaging/repackaging of medical products conflict with any federal legal requirements.                                                                                                          |                                                                              |                         |
|                                                                                                                                                                                                                                                                               |                                                                              |                         |
| <b>Distribution of Medical Products</b>                                                                                                                                                                                                                                       |                                                                              |                         |
| Identify state legal authorities governing the distribution of medical products.                                                                                                                                                                                              |                                                                              |                         |
|                                                                                                                                                                                                                                                                               | How is the term "distribution" defined?                                      |                         |
| Identify if state legal authorities specify or limit the types of persons or professions that can undertake distribution activities (e.g., breaking down pallet shipments of medical products, packing shipments for dispensing, transporting shipments to dispensing sites). |                                                                              |                         |
| Identify if and how the legal authorities apply to the distribution of medical products from government caches or stockpiles.                                                                                                                                                 |                                                                              |                         |

| Issues for Analysis                                                                                                                                                                                                                                                                                     | State/Local Information |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Are there any state immunities or other liability protections available to those distributing medical products? If so, identify the protected parties, protected actions, and any limits on the protections.                                                                                            |                         |
| Identify if and how the legal requirements change when there is an emergency declaration.                                                                                                                                                                                                               |                         |
| <b>Identify if any state legal authorities governing the distribution of medical products conflict with any federal legal requirements.</b>                                                                                                                                                             |                         |
|                                                                                                                                                                                                                                                                                                         |                         |
| <b>Compounding and Dispensing of Medical Products</b>                                                                                                                                                                                                                                                   |                         |
| Identify state legal authorities governing the compounding and dispensing of medical products.                                                                                                                                                                                                          |                         |
| How are the terms “compounding” and “dispensing” defined?                                                                                                                                                                                                                                               |                         |
| Identify the types of persons/professions permitted to compound or dispense medical products and the types of medical products each is allowed to compound or dispense.                                                                                                                                 |                         |
| Identify if state legal authorities specify or limit the types of persons or professions that can undertake compounding or dispensing activities (e.g., cannot compound but can dispense, can only dispense certain types of medical products).                                                         |                         |
| Are there any state immunities or other liability protections available to those compounding or dispensing medical products? If so, identify the protected parties, protected actions, and any limits on the protections.                                                                               |                         |
| Do the persons/professions authorized to compound/dispense medical products, the types of medical products they are authorized to compound/dispense, or the conditions under which they are authorized to compound/dispense change when there is an emergency declaration? If so, identify the changes. |                         |
| <b>Identify if any state legal authorities governing the compounding or dispensing of medical products conflict with any federal legal requirements.</b>                                                                                                                                                |                         |
|                                                                                                                                                                                                                                                                                                         |                         |

| Issues for Analysis                                                                                                                                                                                                                                                                  | State/Local Information |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <b>Administration of Medical Products</b>                                                                                                                                                                                                                                            |                         |
| Identify state legal authorities governing the administration of medical products.                                                                                                                                                                                                   |                         |
| <div></div> How is the term “administration” defined?                                                                                                                                                                                                                                |                         |
| Identify the types of persons/professions permitted to administer medical products and the types of medical products each is allowed to administer.                                                                                                                                  |                         |
| Identify if state legal authorities specify or limit the types of persons or professions that can administer medical products (e.g., only administer to adults, only give pills, but not vaccinate).                                                                                 |                         |
| Identify if and how the state legal authorities apply to administering medical products from government caches/stockpiles.                                                                                                                                                           |                         |
| Identify if and how state legal authorities apply to administration of medical products at government-controlled open points of dispensing (PODs?) Government-controlled closed PODs? Privately controlled PODs?                                                                     |                         |
| Do the persons/professions authorized to administer medical products, the types of medical products they are authorized to administer, or the conditions in which they can administer them change when there is an emergency declaration? If so, identify the changes.               |                         |
| Are there any state immunities or other liability protections available to those administering medical products? If so, identify the protected parties, protected actions, and any limits on the protections.                                                                        |                         |
| Are there any state legal authorities governing informed consent requirements? If so, what are they?                                                                                                                                                                                 |                         |
| Are there any state legal authorities requiring that certain information or literature be given to patients/recipients before or after the administration of a medical product? If so, is the required content specified?                                                            |                         |
| Are there any state legal authorities requiring the reporting of adverse events from the administration of a medical product to state or federal agencies? If so, identify the information to be reported, the person required to make the report, and the agency(ies) to report to. |                         |

| Issues for Analysis                                                                                                                    | State/Local Information |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Identify if any state legal authorities governing the administration of medical products conflict with any federal legal requirements. |                         |
|                                                                                                                                        |                         |

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.