

**OUTLINE**  
**MINIMUM CONTENT FOR**  
**POLICY & PROCEDURES REQUIREMENT**

Per LAC 46:XCI.313, wholesale drug or device distributors shall establish, maintain, and adhere to written policies and procedures for the distribution of legend drug or device product.

A *policy* is a general overview/summary of what is to be accomplished; and the *procedure* is the step-by-step direction for accomplishing the stated policy.

Your company's *Policy and Procedure* should contain procedures for the following, but not limited to, policy items (this is a minimum list of policy and procedure requirements as specified in the rules promulgated in LAC 46:XCI.101-801):

1. Receipt of Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Inspection of Incoming shipments [LAC 46:XCI.309.A.4.a]
2. Security for Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Security systems [LAC 46:XCI.309.A.2.b-e]
  - b. Facility access and authorized personnel [LAC 46:XCI.309.A.2.a]
3. Storage of Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Temperature Monitoring and Recording [LAC 46:XCI.309.A.3.a-c]
  - b. Pest Control [LAC 46:XCI.309.A.1.e]
  - c. Segregation (quarantine) of Outdated, Damaged, Deteriorated, Misbranded or Adulterated Legend Drugs or Devices [LAC 46:XCI.313.A.4 and 309.A.1.c]
  - d. Facility/warehouse sanitation [LAC 46:XCI.309.A.1.b]
4. Inventory of Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Records of all product transactions [LAC 46:XCI.311]
  - b. Recording and Correcting Errors and Inaccuracies in Inventories [LAC 46:XCI.313.A]
5. Distribution of Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Validation of Authorized Customers [LAC 46:XCI.313.A.5]
    - i. Maintenance of Current Customer License Copies [LAC 46:XCI.311.D]
  - b. Distribution of Oldest Approved Stock First [LAC 46:XCI.313.A.1]
  - c. Inspection of Outgoing Shipments [LAC 46:XCI.309.A.4.b]
  - d. Review (Identifying, Recording, and Reporting) of Excessive or Suspicious Purchases [LAC 46:XCI.313.A.5]
6. Identifying, Recording, and Reporting Losses, Thefts, Contraband, Misbranded, or Counterfeit Legend Drugs or Devices [LAC 46:XCI.313.A]
  - a. Notification of Board [LAC 46:XCI.313.A.6 and 7]

7. Handling of Recalls and Withdrawals of Legend Drugs or Devices [LAC 46:XCI.313.A.2]
  - a. FDA or other federal, state, or local law enforcement or government agency initiated action [LAC 46:XCI.313.A.2.a]
  - b. Voluntary action for removal of defective drugs or devices made by the manufacturer [LAC 46:XCI.313.A.2.b]
  - c. Replacement of existing merchandise with improved product or new design packaging [LAC 46:XCI.313.A.2.c]
8. Handling of Crisis due to Strikes, Fire, Floods, or Other Natural Disaster or State of Emergency [LAC 46:XCI.313.A.3]
  - a. Preparation
  - b. Protection
  - c. Security
  - d. Operations during
9. Returns or Destruction of Legend Drugs or Devices [LAC 46:XCI.309.5.a-d]
10. Recordkeeping [LAC 46:XCI.311]
  - a. Verification of suppliers [LAC 46:XCI.311.F]
  - b. Establishing and maintenance of inventories and transaction records
11. Personnel Qualifications/Training and Responsibility [LAC 46:XCI.307]