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]
2. Security for Legend Drugs or Devices [LAC 46:XCI.313.A]
   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]
   c. Segregation (quarantine) of Outdated, Damaged, Deteriorated, Misbranded or Adulterated Legend Drugs or Devices [LAC 46:XCI.313.A.4 and 309.A.1.c]
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]
   b. Distribution of Oldest Approved Stock First [LAC 46:XCI.313.A.1]
   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]
7. Handling of Recalls and Withdrawals of Legend Drugs or Devices \([\text{LAC 46:XCI.313.A.2}]\)
   a. FDA or other federal, state, or local law enforcement or government agency initiated action \([\text{LAC 46:XCI.313.A.2.a}]\)
   b. Voluntary action for removal of defective drugs or devices made by the manufacturer \([\text{LAC 46:XCI.313.A.2.b}]\)
   c. Replacement of existing merchandise with improved product or new design packaging \([\text{LAC 46:XCI.313.A.2.c}]\)
8. Handling of Crisis due to Strikes, Fire, Floods, or Other Natural Disaster or State of Emergency \([\text{LAC 46:XCI.313.A.3}]\)
   a. Preparation
   b. Protection
   c. Security
   d. Operations during
9. Returns or Destruction of Legend Drugs or Devices \([\text{LAC 46:XCI.309.5.a-d}]\)
10. Recordkeeping \([\text{LAC 46:XCI.311}]\)
    a. Verification of suppliers \([\text{LAC 46:XCI.311.F}]\)
    b. Establishing and maintenance of inventories and transaction records