



## LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12091 Bricksome Avenue, Suite B    Baton Rouge, LA 70816  
(225) 295-8567    Fax (225) 295-8568    lsbwdd@bellsouth.net    www.lsbwdd.org

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### INSPECTION GUIDELINES

The following areas will be reviewed when performing the inspection of the wholesaler:

#### 1. Responsibility for Operation

- Check for posting of license
- Names of officers
- Ownership information
- Administration – Who is responsible for operations?

#### 2. Policies and Procedures

- Review written policies and procedures - these should cover the following (minimums):
  - Receipt of product
  - Inventory and distribution
  - Inspection of incoming and outgoing shipments of legend drug, device, and/or medical gas products
  - Identification, recording, and correction of inventory variances and adjustments for legend drug, device, and/or medical gas products
  - Assure the legend drug, device, and/or medical gas product is shipped only to authorized recipients (e.g., pharmacies, hospitals, physicians, dentists, veterinarians, other wholesale distributors)
    - ❖ Check for valid licensure
  - Product stock rotation
  - Excess or unusual purchases of legend drug, device, and/or medical gas product
  - Security
    - ❖ Security system
  - Storage
  - Temperature monitoring and logs (when required)
  - Facility sanitation and pest control
  - Handling of recalls and withdrawals of legend drug, device, and/or medical gas products
  - Handling of outdated, damaged, deteriorated, misbranded or adulterated drug, device, and/or medical gas product
    - ❖ Product segregation
  - Handling of returned legend drug, device, and/or medical gas product
    - ❖ Product destruction
  - Reporting losses, theft, contraband, misbranded, or counterfeit product
  - Crisis handling
  - Recordkeeping
  - Personnel qualification/training and responsibility

#### 3. Suspicious and Excessive Purchases and Sales (Sales personnel should provide input)

- What criteria is used?
- To whom do they report?

#### 4. Record Keeping

- Records readily available
- Inventories and transactions current
- Sales and receipts records
- Temperature monitoring logs current (not required of licenses who distribute medical gas product only)
- Customer licenses
  - Customer list - must include customer name, address, authorizing license, permit, certificate number and expiration date
  - Copies of valid authorizing license, permit, certificate for each customer must be on file
  - Cross-check records - select some records for verification of customer license

- Suppliers/vendors are verified as current, valid LBWDD licensees
- Check on excess returned legend drug, device, and/or medical gas product
- Maintenance of records for a minimum of three years.

#### 5. **Recalls**

- Where are recalled legend drugs, devices, and/or medical gases stored?
- Are they in a signed and separated (quarantined) location?

#### 6. **Returned Goods**

- How are returned products from the customer handled?
- Where are returned items stored?
- How are outdated products checked?
- How is it determined which returned items may be resold?

#### 7. **Facilities**

- Is the facility suitable for wholesale/distribution operations
  - Suitable size and construction
  - Clean and orderly
  - Free of infestation from insects, rodents, birds, etc.

#### 8. **Storage Area**

- Adequate lighting
- Ventilation
- Product stored at appropriate temperature and humidity conditions in accordance with USP or labeled requirements
- Sanitary
- Spacious
- Properly equipped
- Secure
- Has a designated and marked quarantine area
- Product stored away from poisons or harmful substances such as cleaning solutions, vermin repellent, and chemicals.

#### 9. **Security**

- Working monitored alarm system; or for licensees who distribute medical gas product only, product is stored under lock and key in Board approved facility and/or working monitored alarm system on open dock area
- Working security system against theft or diversion
  - How does security system operate?
  - Are legend drugs, devices, and/or medical gases stored in secure area? Is the shipping /receiving area secure?
  - Who has access to legend drugs, devices, and/or medical gases?
  - Is access to legend drugs, devices, and/or medical gases restricted?
  - Who has access to facility after operating hours?
  - Has there ever been any lost or stolen legend drug, device, and/or medical gas product at the facility.

# ARE YOU READY FOR INSPECTION?

## TEST INSPECTION - CHECKLIST

- Current LBWDD license displayed [46:XCI.301.E] (not for initial (new) applications)
- Has off-site storage facility(s) [46:XCI.301.J]  Not Applicable
- Facility is of suitable size and construction [46:XCI.309.A.1.a]
- Facility is clean and orderly [46:XCI.309.1.d]
- Facility is free from infestation by insects, rodents, birds, etc. [46:XCI.309.1.e]
- Storage area provides adequate: [46:XCI.309.1.b]
  - Lighting
  - Humidity
  - Ventilation
  - Space
  - Temperature
  - Equipment
  - Sanitation
  - Security
- Storage area has a designated and clearly marked quarantine area [46:XCI.309.1.c]
- Storage facility has working monitored alarm system OR (medical gas only) is a Board-approved facility kept under lock and key [46:XCI.309.2.b/c]
- Medical gases stored on open dock area has a working monitored alarm system [46:XCI.309.2.d]
- Facility is equipped with working security system suitable for protection against theft or diversion of product and tampering with computer or electronic records [46:XCI.309.2.e]
- Drug or Device products are stored at appropriate temperature [46:XCI.309.3]
- Inventory records readily available for inspection [46:XCI.311.B/C]
- Perpetual inventories and records of all transactions for all drugs, devices, and/or medical gases are current [46:XCI.311.A]
- Temperature monitoring logs are maintained and current (excluding medical gases only) [46:XCI.309.A.3.b]
- Copies of customer licenses verifying authority to purchase drug products on file and current [46:XCI.311.D]
- Has verified all suppliers are licensed by LBWDD [46:XCI.311.F]
- Has established and maintains policies and procedures covering: [46:XCI.313]
  - Receipt of drug, devices, and/or medical gases
  - Product returns or destruction [45:XCI.309.A.5]
  - Storage
  - Reporting of loss and theft
  - Inventory and distribution
  - Security and crisis handling
  - Correction of inventory errors and inaccuracy
  - Validation of customer licenses [46:XCI.311.D]
  - Inspection of all incoming & outgoing shipments [45:XCI.309.A.4]
  - Notification of theft & diversions; findings of contraband, counterfeit or misbranded drugs
  - Product rotation
  - Verification of suppliers [46:XCI.311.F]
  - Recalls and withdrawals
  - Review of excessive or suspicious purchases
  - Out-dated product segregation
  - Monitoring & recording of storage temperatures [46:XCI.309.A.3]
- Has current list of responsible persons – owners, officers, directors, and responsible party [46:XCI.315]
  - List of employees with access to product
  - List of employees with access to building after hours
- Facilities handling controlled substances = [46:XCI.317.2]
  - Has current CDS registration  Not Applicable
  - Has current DEA registration  Not Applicable