



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 lsbwdd@bellsouth.net www.lsbwdd.org

04/2010

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 - Handling of outdated, damaged, deteriorated, misbranded or adulterated drug, device, and/or medical gas product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]
- Has off-site storage facility(s) [46:XCI.301.J]
- 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
 - Ventilation
 - Temperature
 - Sanitation
 - Humidity
 - Space
 - Equipment
 - 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
 - Storage
 - Inventory and distribution
 - Correction of inventory errors and inaccuracy
 - Inspection of all incoming & outgoing shipments [45:XCI.309.A.4]
 - Product rotation
 - Recalls and withdrawals
 - Out-dated product segregation
 - Product returns or destruction [45:XCI.309.A.5]
 - Reporting of loss and theft
 - Security and crisis handling
 - Validation of customer licenses [46:XCI.311.D]
 - Notification of theft & diversions; findings of contraband, counterfeit or misbranded drugs
 - Verification of suppliers [46:XCI.311.F]
 - Review of excessive or suspicious purchases
 - 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
 - Has current DEA registration