



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C

Baton Rouge, LA 70816

Phone: 225-295-8567

Fax: 225-295-8568

Website: www.lsbwdd.org

email: lsbwdd@bellsouth.net

In-State Licensee Newsletter

September 2004

RULE AMENDMENTS

Final rule amendments as published in the Louisiana Register on and made effective as of July 20, 2004

Title 46

PROFESSIONAL AND OCCUPATION STANDARDS

Part XCI. Wholesale Drug Distributors

Chapter 3. Wholesale Distributors

§303. Required Information

A. - D. ...

E. Wholesale drug distributors with a place of business physically located in Louisiana must notify the Board within three business days of the incident of any theft or diversion of legend or prescription drug product.

F. Wholesale drug distributors with a place of business physically located in Louisiana must notify the Board within 24 hours of discovery of any counterfeit or misbranded legend or prescription drug product in their possession.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992); amended LR 29:1479 (August 2003); LR 30:1481 (July 2004).

Chapter 5. Powers and Functions of the Board

§509. Inspection Contracts

A. The Board may contract with any person or agency it deems qualified to conduct any inspections required by state or federal law.

B. The Board shall retain exclusive jurisdiction to adjudicate all complaints, allegations or misconduct, or noncompliance by any licensee and to impose appropriate sanctions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992); amended LR 30:1481 (July 2004).

IGNORANCE OF THE LAW IS NO EXCUSE

State statutes and Board promulgated regulations can be viewed on the Board's website at www.lsbwdd.org and copies of the statutes and rules can be obtained by contacting the Board's administrative office at 12046 Justice Avenue, Suite C, Baton Rouge, LA 70816, (225) 295-8567, fax (225) 295-8568, email lsbwdd@bellsouth.net. A current statute and regulation booklet is being prepared and will be mailed to all in-state licensees with the next renewal. THE BOARD ENCOURAGES YOU TO KEEP THIS BOOKLET HANDY FOR YOUR FUTURE REFERENCE.

PERPETUAL INVENTORY

As per Board promulgated regulation, specifically LAC 46:XCI.311.A which reads:

“Wholesale drug distributors shall establish and maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. the source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped;
2. the identity and quantity of the drugs received and distributed or disposed of; and
3. the dates of receipt and distribution.”

Therefore, your company will be found in violation of this regulation and could be assessed a fine if during an inspection it is found that no perpetual inventory of product is being kept or is not readily available and current.

Medical gas distributors should note that you are not required to maintain a perpetual inventory on oxygen, but you are required to maintain perpetual inventories on all other medical gases.

You can see full versions on the state statutes and board promulgated regulations governing wholesale drug distributors on the Board’s website at www.lsbwdd.org.

INSPECTIONS

BOARD INSPECTOR(S) DO NOT ANNOUNCE OR SCHEDULE INSPECTIONS IN ADVANCE. Your facility will be inspected during your normal business hours. During that time, there must be someone available that can produce records and assist the Board inspector with the inspection. If the owner/manager is not at the facility when the inspector arrives for the inspection, there must be someone designated to act in his or her place to allow an inspection as authorized in R.S. 37:3470 to take place. It is your responsibility to be in compliance when the inspector arrives. Non-compliance issues that are corrected during the inspection will still be considered as violations found.

ARE ALL OF YOUR LOCATIONS LICENSED

Both sales locations and distribution locations of prescription drugs require wholesale licensing. Each location must be licensed on its own. If you

have multiple locations that either sell or distribute legend/prescription drug product, be sure they are all licensed.

CHANGE OF LICENSED FACILITY INFORMATION

Changes in any information regarding your licensed facility must be submitted to the Board. If you are planning to move your facility to a new location or if you facility has a change in ownership, you must notify this Board. Licenses are issued to facilities locations by owner and are non-transferable. A new location requires inspection and issuance of a new license. All license information changes must be submitted to the Board within 60 days of such change as per LAC 46:XCI.303.C.

⇒⇒⇒⇒⇒ LICENSE RENEWAL TIME WILL SOON BE HERE ⇐⇐⇐⇐⇐⇐

Current licenses will expire on December 31, 2004. License renewal packets consisting of a pre-printed renewal form will be mailed out to all licensees the last week in October. Please make sure all information regarding your license is current. If you do not receive a renewal packet by the first part of November, please contact the Board office. Complete renewal information and fee payment is due in the Board office postmarked by January 31, 2005. If the renewal is postmarked after January 31, 2005, a \$50 *per month* late renewal penalty is assessed and must be paid to complete the renewal process. As of April 1, 2005, all non-renewed licenses will be cancelled and will become null and void at which time a \$200 reinstatement fee must be paid in addition to the delinquent renewal license fee and all late penalty fees in order to re-activate the license. So, get your renewal in as early as possible upon receipt to avoid any late penalty fees.

AUTHORIZED RECIPIENTS

In accordance with Louisiana Revised Statute 37:3480, all sales and distribution of prescription drugs must be made to an authorized recipient. In addition, any location to which prescription drugs are sent must be authorized to possess prescription drugs. In accordance with Board promulgated regulation, LAC 46.XCI.311.D, to ensure that the customers you sell/distribute to are authorized to purchase and possess legend drugs, copies of licenses for customers must be maintained for all customers that are shipped or sold legend drugs.

There are different types of licenses or permits that the Board will accept as verification of an authorized recipient of prescription/legend drugs (excluding medical gases - see below). These are as follows:

D.E.A License	Louisiana Dept. of Health & Hospitals
Controlled Drug Substance License	Permit:
Medical Examiner's License	Food & Drug Permit 461
Dental License	Food & Drug Permit 462
Veterinarian License	Food & Drug Permit 463
Pharmacy License (Do not use Drug Kit Permit)	Food & Drug Permit 464
Louisiana Wholesale Drug Distributors License	Food & Drug Permit 465
	Food & Drug Permit 467
	Food & Drug Permit 468

The types of licenses, permits, and certifications that can be used as verification of an authorized recipient of medical gases including medical grade oxygen are the one listed above as well as:

Emergency Medical Technician (EMT) Certification
First Responder Certification
Louisiana Dept. of Health & Hospitals
Food & Drug Permit 473

A Divers Alert Network (DAN) certificate or a certificate issued by the American Red Cross cannot be used and is not medical authorization for the holder to refill oxygen cylinders with medical grade oxygen in Louisiana. These two certificates are not acceptable.

For nursing homes and hospitals, you *cannot* use copies of the Louisiana Department of Health and Hospitals license to operate/occupational license (is generally, a 3-digit license number) that specifies a licensed capacity number on file.

If your customer does not have one of the above listed acceptable licenses, permits or certificates in their name, a letter on your customer's letterhead stating the name of the designated Medical Director or the designated, authorized individual for the customer along with a copy of the appropriate authorizing license or certificate for the designated individual must be on file.

UNLICENSED SUPPLIERS

As per Board promulgated regulation, specifically LAC 46:XCI.311.F, wholesalers located in Louisiana are responsible for verifying that their legend drug product suppliers are licensed by the Louisiana Board of Wholesale Drug Distributors to ship or sell product into Louisiana. Wholesalers are also responsible for notifying the Board of any unlicensed wholesalers.

The PREFERRED method of notification of a supplier of legend drugs that is not licensed by the Louisiana Board of Wholesale Drug Distributors to sell or ship product into Louisiana is for the receiving company to mail or fax a copy of the invoice from that unlicensed supplier to the LBWDD Board office.

DISPOSAL OF EXPIRED OR QUARANTINED Rx DRUGS

Do not forget that all dispositions of legend/prescription (Rx) drugs must be fully documented for a complete inventory record. In addition, legend/prescription (Rx) drugs should only be transferred to authorized recipients. "Reverse Distributors" with a physical location within Louisiana that receives legend/prescription (Rx) drugs or stores legend/prescription (Rx) drugs for destruction purposes must be licensed by this Board.

DISCIPLINARY ACTIONS - 2004

Disciplinary Docket No. 200403 - Voluntary Consent Agreement - Licensee was found to be in violation of LAC 46:XCI.311.D - copies of licenses for customers who are authorized by law or regulation to procure or possess federal legend drugs were not being maintained for all customers that were shipped or sold federal legend drugs (approximately 70% of license copies for current customers were expired). The licensee signed a consent agreement and was assessed a fine of \$1,000.

Disciplinary Docket No. 200404 - Voluntary Consent Agreement - Licensee was found to be in violation of LAC 46:XCI.311.A and E - perpetual inventory and records of all transactions for medical gases, with the exception of oxygen, were not maintained current and did not match the physical inventory performed at the time of the inspection. The licensee signed a consent agreement and was assessed a fine of \$1,000.

BOARD WEBSITE

The BOARD'S WEBSITE AT www.lsbwdd.org has many active functions and helpful links. You can print an application form, view previous newsletters to licensees, view a list of the current Board Members and staff, view and print the state statutes & Board regulations, verify license information of wholesale drug distributors licensed by the Board, and do various inquiries, such as verify and print licenses, using the links to other agencies such as the Louisiana Board of Pharmacy, Louisiana Board of Dentistry, Louisiana Board of Medical Examiners, and the Louisiana Controlled Dangerous Substance Program. The license information printed from these sites can be kept on file as customer license verification copies for wholesalers in Louisiana. You can even download a spreadsheet list of all Louisiana licensed wholesale drug distributors.

There is a link to the FDA website so you can use it to review recalls and safety alerts issued by the FDA. There is a link to get information on product registration from the DHH, Office of Public Health, Food and Drug Program. You can also get information on applying for a license with the Louisiana Controlled Dangerous Substance Program. There is also a link to the NDC directory.