



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C

Baton Rouge, LA 70816

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In-State Licensee Newsletter

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PRESCRIPTION FILLING

Filling a doctor's prescription for an individual (patient/consumer) is not within the legal scope of authorized actions that a licensed wholesale drug distributor can perform. A wholesale drug distributor (distribution) is defined in La. R.S. 37:3462 as meaning *any person who sells legend drugs to other than consumer or the patient ...; distribution of legend drugs to other than the consumer or patient ...*. Therefore, filling a doctor's prescription for an individual who is not a wholesale authorized recipient is a violation of the statutes and regulations of the Louisiana Board of Wholesale Drug Distributors.

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.

REGULATORY COMPLIANCE TRAINING

If your company has a change in management at the facility licensed by the Louisiana Board of Wholesale Drug Distributors, you may contact the Board's administrative office at (225)295-8567 or by email at lsbwdd@bellsouth.net and schedule a time for Mr. John Liggio, Executive Director/Inspector, to come to your facility and speak with the new management team regarding regulatory compliance issues relative to the Louisiana wholesale drug distributor license.

BOARD NOMINATIONS

At its meeting held on November 17, 2004, the LOUISIANA ASSOCIATION OF WHOLESALE DRUG DISTRIBUTORS, PO Box 51367, Shreveport, LA 71135, took nominations for seats currently vacant on the Louisiana Board of Wholesale Drug Distributors. The ASSOCIATION sent in the following three names to the Governor's Office for consideration for appointment to fill three of the four vacant seats:

Mr. John LeMaster
McKesson Drug Company
Mr. Hershal Paul
Morris & Dickson Company
Mr. Andy Milligan
Medox, Inc.

We are currently awaiting Governor Blanco's appointments.

Farwell To A Good Friend

It is with sadness in our hearts that we must say good-bye to a very good friend. Mr. Fredric King, Board Member serving as Secretary/Treasurer for the Board, passed away in December 2004. Mr. King was a founding force in the creation of this Board and has help safeguard the public by serving on this Board since 1988. Mr. King will be truly missed by all.

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.

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 your 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.

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.

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.

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

Controlled Drug Substance License

Medical Examiner's License

Dental License

Veterinarian License

Pharmacy License (Do not use Drug Kit Permit)

Louisiana Wholesale Drug Distributors License

Louisiana Dept. of Health & Hospitals Permit:

Food & Drug Permit 461

Food & Drug Permit 462

Food & Drug Permit 463

Food & Drug Permit 464

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.

DISCIPLINARY ACTIONS - 2004

Disciplinary Docket No. 200405 - 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.

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 a copy 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 statute and regulation booklet was prepared and mailed to all in-state licensees with the renewed license certificate. THE BOARD ENCOURAGES YOU TO KEEP THIS BOOKLET HANDY FOR YOUR FUTURE REFERENCE.

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.

Please pass this newsletter around so that all of your employees can have the benefit of learning more about regulation of the industry.