

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

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In-State Licensee Newsletter

MAY 2008

STATUTE AND RULE AMENDMENTS

The Board has promulgated amendments to rules in Louisiana Administrative Codes 46.XCI effective May 20, 2008. These amendments include changes to: General Provisions with the defining of applicant/responsible party and off-site storage facilities, the redefining of medical gas, and the clarification of the definitions of drug or device; Licensing, Renewal and Reinstatement Requirements by clarifying existing license and license reinstatement requirements, providing for off-site storage, and restrictions for distribution from dwellings of residential zoning; Storage and Handling which excludes the use of spring loaded and mercury driven temperature monitoring devices; and Recordingkeeping by clarifying the requirement for customer license lists held at the distribution facility. The Final Rule was published in the *Louisiana Register, Volume 34, No.05, May 20, 2008*.

The legislature has proposed amendments to the governing laws relative to the wholesale distribution of legend drugs and/or devices in the Revised Statutes, Title 37, Chapter 54, Sections 3461 through 3482 by HB 877. Legislative changes include providing for a short title, definitions, setting Board member terms, powers and duties of the Board, qualifications and requirements for licensure, inspections, out-of-state applicants, license denial/revocation/suspension, enforcement and injunction proceedings, product quarantine, criminal history records, penalties, fees, unauthorized sales, and other related matters.

REINSTATEMENT OF LICENSES

Expired licenses and any licensee that voluntarily surrenders the license but then wishes to "re-" license in order to again sell and/or distribute legend drugs and/or devices into the state may apply to reinstate the license by submitting a completed, signed application form along with payment of the license reinstatement

fee of \$200 in addition to the \$200 license fee (\$400 total fees). During the period a license is expired/invalid prior to reinstatement, the licensee may not lawfully operate as a wholesale distributor of legend drugs and/or devices in Louisiana and could be subject to the assessment of disciplinary fines.

UNLICENSED SUPPLIERS

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

Louisiana. Acquiring product from an unlicensed supplier/ vendor is a violation of Louisiana statutes and Board promulgated rules and will result in disciplinary action, which could include assessment of fines and other sanctions, being taken against the licensee.

CHANGE OF LICENSED FACILITY INFORMATION

Changes in any information regarding your licensed facility must be submitted to the Board in writing or by application, if applicable. 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 by applying for new licensure. Licenses are issued to

facilities locations by owner and are not-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.

INSPECTIONS

BOARD INSPECTOR(S) MAY 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 while the inspector is present will be considered as violations found and reported to the Board's compliance officer.

VIOLATIONS FREQUENTLY FOUND DURING FACILITY INSPECTIONS

Recent inspections conducted at licensed facility within Louisiana have found an increasing number of non-compliant/violations of state statutes and Board promulgated rules, including but not limited to, the following:

- LAC 46:XCI.311.A – Establishing and maintaining perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs or devices.
- LAC 46:XCI.311.C – Copies of current licenses for customers who are authorized by law or regulation to procure and possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices; and
- LAC 46:XCI.413 – Establishing, maintaining, and adhering to written (working) policies and procedures.

Violations of these as well as any of the statutes and rules governing the wholesale distribution of legend drugs or devices in/into Louisiana could result in disciplinary action being taken against the licensee which could result in assessment of monetary penalties of up to \$1,000 per violation offense.

PERPETUAL INVENTORY

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

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

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

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.

AUTHORIZED RECIPIENTS

In accordance with Louisiana Revised Statute 37:3480, sales and distribution of drugs or devices must be made to an authorized recipient – i.e., an individual, corporation, or entity that is authorized by law or regulation to procure or possess such drugs or devices. In addition, any location to which legend drugs or devices are sent must also be authorized to procure or possess such drugs or devices. In accordance with Board promulgated regulation, LAC 46.XCI.311.D and to ensure that the customers you sell/distribute to are authorized to procure or possess legend drugs or devices, you are required to maintain copies of licenses for all customers that are shipped or sold legend drugs or devices.

There are different types of licenses or permits that the Board will accept as verification of an authorized recipient of legend drugs or devices. These are as follows:

D.E.A License

Louisiana Controlled Dangerous 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 – OTC & Prescription Drugs

Food & Drug Permit 462 – OTC, Prescription Drugs and Controlled Substances

Food & Drug Permit 463 – Prescription Drugs

Food & Drug Permit 464 – Prescription & Controlled Substances

Food & Drug Permit 465 – Controlled Substances

Food & Drug Permit 467 – Prescription Generic Drugs

Food & Drug Permit 468 – OTC Generic & Prescription Generic Drugs

Food & Drug Permit 480 – Medical Devices

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

Emergency Medical Technician (EMT) Certification

First Responder Certification

Louisiana Dept. of Health & Hospitals

Food & Drug Permit 473 – Medical Gases

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. For those customers that do not have one of the above accepted license/ permits/ certificates, the Board would accept a letter from a licensed practitioner, along with a copy of the practitioners current medical license, stating he/she has been designated as the Medical Director/Supervisor for the customer and is allowing the customer to acquire legend drugs and/or devices under his legal authority as proof of authorized recipient verification for the customer.

For those customers that do not have one of the above accepted licenses/ permits/ certificates for the acquisition and possession of medical gases, the Board would accept a letter from a licensed EMT, First Responder, or medical practitioner stating that he/she is employed by and is responsible for acquiring medical gases for the customer, along with a copy of the EMT, First Responder, or medical practitioner's valid, current license.

For laboratory facilities which perform human specimen examination or procedures that do not have a licensed medical practitioner affiliated with the facility, a Clinical Laboratory Improvement Amendments (CLIA) certificate may be accepted for the purchase of legend devices only (no legend drugs permitted).

For ocean vessels that may be fixed, transient, or engaged in international trade, if there is a medical director employed, a copy of the medical director's medical license along with a copy of the employment contract or statement of employment may be accepted. If there is no medical director employed, the master or first officer of the vessel may procure and possess legend drugs or devices on behalf of the vessel as long as they provide and you maintain on file: (1) a copy of the vessel's requisition/purchase order for the drugs and/or devices; and (2) a copy of the delivery ticket/receipt signed by the master or first officer and stamped with the vessel's official seal. All documentation must include the vessels name, official number, and country of registry.

Nuclear or Positron Emission Tomography (PET) pharmacies engaged in wholesale distribution of legend drugs may accept the RAM (Radioactive Material) license from their customers.

DISPOSAL OF EXPIRED OR QUARANTINED DRUGS OR DEVICES

Do not forget that disposals of legend drugs or devices must be fully documented for a complete inventory record. In addition, legend drugs or devices should only be transferred to authorized recipients.

ARE ALL OF YOUR LOCATIONS LICENSED

Both sales locations and the distribution locations (if different) for your company are required to be licensed as wholesale drug distributors. Each location must be licensed on its own. If you have multiple locations that either sell or distribute legend drug or device product, be sure they are all licensed

AGENCIES WHO OVERSEE WHOLESALE DRUG DISTRIBUTION IN LOUISIANA

There are several state and federal government agencies that work together for the regulation of the wholesale distribution of legend (prescription) drugs and devices in and within the state of Louisiana. First, there is this Board, the LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS, which is charged by the state legislature to license and regulate wholesale distributors of legend drugs and devices - including but not limited to manufacturers, repackers' own-label distributors, private label distributors, jobbers, brokers, warehouses including manufacturers', distributors', chain drug and wholesale drug warehouses, independent wholesale drug traders, retail pharmacies that conduct wholesale distribution, and freight forwarders - that sell and distribute in/within Louisiana to entities other than the consumer/patient. There is also the FOOD AND DRUG PROGRAM of the Louisiana Department of Health and Hospitals, Office of Public Health, Center for Environmental Health/Sanitarian Services which is responsible for registering and regulating manufacture and storage distribution locations for drugs, medical devices, and medical gases and ensuring the sanitation of these facilities. The Louisiana Board of Pharmacy is the state regulatory agency for the practice of pharmacy and also manages the state CONTROLLED DANGEROUS SUBSTANCE PROGRAM which licenses locations where controlled substances are held and/or distributed from. There is the UNITED STATES DRUG ENFORCEMENT AGENCY (DEA), Office of Diversion Control which is the federal agency for registration and enforcement of the provisions of the Controlled Substance Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances. The UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) is the federal agency that registers, regulates, and enforces drug and device pre-marketing approval, manufacturing standards, and safety and effectiveness. Contract information for these state agencies as well as local state offices of these federal agencies can be obtained from the Board office or on the Board's website under Links.

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 rules, verify license information of wholesale drug or device 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, and the Louisiana Board of Medical Examiners. 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. You can get information on applying for a license with the Louisiana Controlled Dangerous Substance Program through the Board of Pharmacy. There is also a link to the NDC directory.

DISCIPLINARY ACTIONS

There were no cases processed since the last Licensee newsletter.

IGNORANCE OF THE LAW IS NO EXCUSE

State statutes and Board promulgated rules 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. THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

Check to make sure your suppliers/vendors have current Louisiana licenses.

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