



## 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

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### In-State Licensee Newsletter

MAY 2009

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#### **PROPOSED RULE AMENDMENTS**

The Board has begun promulgation of amendments to its rules. The Notice of Intent for amendments to Louisiana Administrative Codes 46.XCI.103, 105, 301, 303, 305, 315, 317, 319, 321, 501, 507, 509, 711, and 801 was published in the *Louisiana Register* on April 20, 2009. These amendments include changes to: General Provisions- Definitions and Exemptions; Licensing, Renewal and Reinstatement Requirements; Required Information and Qualifications; Powers & Functions of the Board; Disciplinary Action; and Fees. The Board will accept comments regarding the proposed rule amendments in writing via mail through close of business on May 19, 2009. If you would like to receive a copy of the Notice of Intent, please contact the Board office by making written request via mail, fax, or email.

#### **UNLICENSED SUPPLIERS**

Pursuant to Board regulation LAC 46:XCI.311.F, licensed wholesalers located in Louisiana should verify that their suppliers of drugs or devices are licensed by this Board to sell or ship in or into Louisiana prior to purchasing or receiving product from the supplier. Licensed wholesale distributors in Louisiana are responsible for notifying the Board of any unlicensed wholesalers found.

If evidence is found that a licensee acquired product from an unlicensed supplier/ vendor, disciplinary action may be taken against the licensee and could include assessment of fines and other sanctions.

#### **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 a new license for the new facility location.

Licenses are issued to facility locations by owner and are not-transferable. A new location requires inspection and a new license. All license information changes must be submitted to the Board within 60 days of such change per LAC 46:XCI.303.C.

#### **ARE ALL OF YOUR LOCATIONS LICENSED**

Each location that sells or distributes (if different) legend drug or devices is required to be licensed as wholesale drug distributor. If your business has more than one location that either sells or distributes legend drugs or devices, make sure each location is licensed for wholesale legend drug or device distribution.

#### **DISPOSAL OF EXPIRED OR QUARANTINED DRUGS OR DEVICES**

Remember that all disposals of legend drugs or devices must be fully documented for a complete inventory record. Legend drugs or devices should only be transferred to authorized recipients.

## **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 the inspection authorized in La. R.S. 37:3470 to take place. It is your responsibility to be in compliance when the inspector arrives. Even non-compliance issues corrected while the inspector is present will be considered violations and reported to the Board's compliance officer.

## **VIOLATIONS FREQUENTLY NOTED DURING FACILITY INSPECTIONS**

Recent inspections conducted at licensed facility within Louisiana have found an increasing number of violations of state statutes and Board 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.D - 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.313 - 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 may result in disciplinary action against the licensee, with the assessment of fines of up to \$1,000 per violation.

## **PERPETUAL INVENTORY**

Board regulation LAC 46:XCI.311.A provides:

"A. 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 principal 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 are not required to maintain a perpetual inventory on oxygen, but are required to maintain perpetual inventories on all other medical gases.

## **!! NOTICE !!**

WHOLESALE DRUG DISTRIBUTOR LICENSEES DISTRIBUTING MEDICAL GASES (ONLY) who also distribute legend devices must adhere to Board promulgated rules with regards to security and inventory. Pursuant to LAC 46:XCI.309.A.2, a facility used for wholesale device distribution must be secure from unauthorized entry: access from outside the premises shall be kept to a minimum and be well-controlled; the outside perimeter of the premises shall be well-lighted; and entry into areas where devices are held shall be limited to authorized personnel. The facility shall be equipped with a monitored alarm system to detect entry after hours and shall be equipped with a security system that will provide suitable protection against theft or diversion. Pursuant to LAC 46:XCI.311.A, device distributors must establish and maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of devices.

## **AUTHORIZED RECIPIENTS**

In accordance with La. R.S. 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. 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 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, wholesale drug distributors are required to maintain copies of licenses for all customers that are shipped or sold legend drugs or devices.

The Board will accept as verification of an authorized recipient of legend drugs or devices the following types of licenses, certificates, or permits:

<b>D.E.A License</b>	<b>Food &amp; Drug Permit 462 – OTC, Prescription Drugs and Controlled Substances</b>
<b>Louisiana Controlled Dangerous Substance License</b>	<b>Food &amp; Drug Permit 463 – Prescription Drugs</b>
<b>Medical Examiner’s License</b>	<b>Food &amp; Drug Permit 464 – Prescription &amp; Controlled Substances</b>
<b>Dental License</b>	<b>Food &amp; Drug Permit 465 – Controlled Substances</b>
<b>Veterinarian License</b>	<b>Food &amp; Drug Permit 467 – Prescription Generic Drugs</b>
<b>Pharmacy License (Do not use Drug Kit Permit)</b>	<b>Food &amp; Drug Permit 468 – OTC Generic &amp; Prescription Generic Drugs</b>
<b>Louisiana Wholesale Drug Distributors License</b>	<b>Food &amp; Drug Permit 480 – Medical Devices</b>
<b>Louisiana Dept. of Health &amp; Hospitals Permit:</b>	
<b>Food &amp; Drug Permit 461 – OTC &amp; Prescription Drugs</b>	

The types of licenses, permits, and certifications that can be used as verification of an authorized recipient of medical gases include those listed above and the following:

**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. A Medical Gas Installer license or Medical Gas/Vacuum Systems Verifier license as issued by the State Plumbing Board of Louisiana does not authorize the holder to procure and possess legend (Rx) medical gases including medical grade nitrogen.

For nursing homes and hospitals, a wholesale drug distributor *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 customers not having one of the above accepted license/ permits/ certificates, the Board will accept a letter from a licensed practitioner, along with a copy of the practitioner’s current medical license, stating designation as the Medical Director/ Supervisor for the customer and that the practitioner is allowing the customer to acquire legend drugs and/or devices under the practitioner’s legal authority.

For customers not having one of the above accepted licenses/ permits/ certificates for the acquisition and possession of medical gases, the Board will 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 ocean vessels that may be fixed, transient, or engaged in international trade with 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 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.

## **DISCIPLINARY ACTIONS**

**Docket No. 2008008** - The entity was found in violation of Louisiana Revised Statutes and Board promulgated rules, specifically La. R.S. 37:3474.2.A(1) and (3), participating or engaging in wholesale drug distribution by operating a facility without a license issued by the Board. The licensee accepted a consent agreement, applied for licensure and paid all applicable fees, and was assessed and paid a fine of \$1,000 and administrative costs of \$250.

**Docket No. 2008009** - The licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules, specifically LAC 46:XCI.311.A, failing to maintain perpetual inventory on site. The licensee accepted a consent agreement and was assessed and paid a fine of \$1,000 and administrative costs of \$250.

**Docket No. 2009010** - The entity was found in violation of Louisiana Revised Statutes and Board promulgated rules, specifically La. R.S. 37:3474.2.A(1) and (3), participating or engaging in wholesale drug distribution by operating a facility without a license issued by the Board. The licensee accepted a consent agreement, applied for licensure and paid all applicable fees, and was assessed and paid a fine of \$1,000 and administrative costs of \$250.

## **AGENCIES OVERSEEING 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.

This Board, the LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS, 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, manufacturers' and distributors' warehouses, 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.

The FOOD AND DRUG PROGRAM of the Louisiana Department of Health and Hospitals, Office of Public Health, Center for Environmental Health/Sanitarian Services is responsible for ensuring the sanitary manufacture and storage of drugs, medical devices, and medical gases within Louisiana.

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.

The UNITED STATES DRUG ENFORCEMENT AGENCY (DEA), Office of Diversion Control 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.

## **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](http://www.Lsbwdd.org). A copy of the statutes and rules may be obtained by contacting the Board office at 12046 Justice Avenue, Suite C, Baton Rouge, LA 70816, 225-295-8567, fax 225- 295-8568, email [lsbwdd@bellsouth.net](mailto:lsbwdd@bellsouth.net). THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

## BOARD WEBSITE

The BOARD'S WEBSITE, [www.Lsbwdd.org](http://www.Lsbwdd.org), has many active functions and helpful links. You can complete and print an application form, view previous newsletters, view a list of the current Board Members and staff, view and print the state statutes and Board rules, verify license information of wholesale drug or device distributors licensed by the Board, and make various inquiries, such as license verification, using the links to other agencies including the Louisiana Board of Pharmacy, Louisiana Board of Dentistry, and the Louisiana Board of Medical Examiners. License information printed from these sites can be kept on file

as customer license verification copies for wholesalers in Louisiana.

There is a link to the FDA website that can be used 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.

*Please share this newsletter so that your employees may benefit by learning more about regulation of the industry.*

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