



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C

Baton Rouge, LA 70816

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In-State Licensee Newsletter

SEPTEMBER 2009

2010 LICENSE RENEWAL PERIOD

Current Louisiana wholesale legend drug or device distributor licenses will expire on **DECEMBER 31, 2009**. License renewal forms for the 2010-year will be sent out to all licensees the first weeks of October 2009. In accordance with Board rules, a license shall be renewed annually by timely submitting an application and the license renewal fee between October 1 and December 31.

Current file information will be provided on a pre-printed renewal form. All information should be reviewed, verified, and corrected, if applicable.

If a license is not renewed on or before the expiration date of December 31, 2009 (including any license renewals that had been submitted incomplete and would be on HOLD at the Board office), the licensee must make application for (renewal and) reinstatement of the expired license by submitting the renewal application, the license renewal fee of \$200, and the license reinstatement fee of \$200.

A person may not lawfully operate as a wholesale drug or device distributor in Louisiana until the expired license has been reinstated.

Renewals are processed individually for each license. Payment for multiple license renewals being submitted together may be made by one check or money order, but any additional documents submitted for the licenses should be copied and provided for each renewal being submitted.

PROPOSED RULE AMENDMENTS

The Board will begin promulgation of amendments to its rules. The Notices of Intent for amendment to Louisiana Administrative Codes in 46:XCI.105, 301 and 311, and new rule 901 (Chapter 9) should be published in the Louisiana Register by October 2009. These amendments include changes to: General Provisions- Exemptions; Licensing, Renewal and Reinstatement Requirements; Recordkeeping; and Enforcement Action Proceedings. To receive a copy of the published Notices, please contact the Board office in writing at 12046 Justice Avenue, Suite C, Baton Rouge LA 70816, via fax at 225-295-8568, or via email at Lsbwdd@bellsouth.net.

RULE AMENDMENTS

The Board has promulgated amendments to its rules. The Final Rule 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* and became effective on August 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.

FEE SCHEDULE

In accordance with Chapter 8 of the Louisiana Administrative Codes 46.XCI.801, the Board may collect the following fees:

Initial License Fee	\$ 200
License Renewal Fee	\$ 200
Initial Inspection Fee	\$ 100
Duplicate License Fee	\$ 10
License Reinstatement Fee	\$ 200
License Verification Fee	\$ 15

Effective August 20, 2009, new applications for licensure submitted for facilities physically located in Louisiana must include payment of the initial inspection fee of \$100 as well as the initial license fee of \$200. Requests for duplicate licenses (to replace lost or damaged/destroyed certificates previously issued) must include payment of a \$10 fee. Requests for license verifications now require payment of a \$15 fee.

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.

!! 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.

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.B.

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.

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.

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.

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. 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. THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

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:

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 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. Mechanical Contractors or plumbers are not authorized to procure or possess legend medical gases for testing of medical gas delivery system installations. The mechanical contractor or plumber must have a contracted medical director which allows the mechanical contractor or plumber to procure the legend medical gas through the auspice of the medical director's license. Otherwise, the legend medical gases must be procured by the location where the delivery system is being installed – such as but not limited to hospitals, medical clinics, surgery centers, dentists, physician offices, or other entities that hold a license authorizing the procurement and possession of legend medical gases.

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. 2009EA1002 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1003 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1005 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1014 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1017 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, agreed to cease and desist wholesale drug distribution in Louisiana until a license application is approved by the Board and a Louisiana license is issued, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1020 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1021 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1023 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1026 - Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale

drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1027 – Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, agreed to cease and desist wholesale drug distribution in Louisiana until a license application is approved by the Board and a Louisiana license is issued, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1028 – Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1030 – Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1032 – Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

Docket No. 2009EA1033 – Enforcement action was taken against the entity found to be in violation of La. R.S. 37:3474.2(A), the sale or shipment of a legend drug or device into Louisiana without being licensed as a wholesale drug distributor in Louisiana. The entity accepted a consent agreement, applied for and received a Louisiana license, and was assessed and paid a fine of \$1,000.

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.

BOARD WEBSITE

The BOARD'S WEBSITE, 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.

The *Louisiana Board of Wholesale Drug Distributors* licensee newsletter is considered an official method of notification to wholesale drug distributors licensed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them for future reference. Newsletters are available on the Board's website for viewing.

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

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