



LOUISIANA BOARD OF WHOLESAL DRUG DISTRIBUTORS

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Baton Rouge, LA 70816

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In-State Licensee Newsletter

January 2007

2007 LICENSE RENEWAL

The 2007 license renewal period has concluded. Those licenses renewed are now current through December 31, 2007. There is no longer any grace period for completing renewal of the license. Those licenses not timely and properly renewed by December 31, 2006 are now expired as of January 1, 2007. Licensees with expired licenses were sent an expiration/cease & desist notice. Those companies who did not renew the license should immediately stop selling and/or shipping legend drugs and/or devices in and/or into Louisiana. If a Louisiana licensee is found to be selling/distributing with an expired license *OR* purchasing and receiving from a company with an expired Louisiana license, you will be in violation of Louisiana statutes and Board promulgated rules and could be subject to disciplinary action and fines.

Expired licenses may be reinstated by submitting the completed, signed renewal/reinstatement application form along with payment of the reinstatement fee of \$200 in addition to the \$200 license renewal fee (\$400 total fees). During the period a license is expired prior to reinstatement, the licensee may not lawfully operate as a wholesale distributor of legend drugs and/or devices in Louisiana.

NEW LICENSING REQUIREMENTS

The Louisiana Board of Wholesale Drug Distributors now requires companies that wholesale distribute legend (prescription) devices to be licensed to sell and/or distribute these legend devices in or into Louisiana to other than the consumer/patient (i.e. - to other wholesale distributors and administering/dispensing parties such as, but not limited to, hospitals, pharmacies, physician offices, home health/rehab facilities, emergency medical services, etc). A legend device or drug is a device or drug that is

intended for use by humans which can be dispensed by prescription or order of a licensed practitioner and whose labeling contains the legend (or variance of) "Caution: Federal law prohibits dispensing without a prescription" or "Caution: Federal law restricts except the sale by or on order of a physician or appropriate licensed practitioner" or "Rx Only". It is your responsibility to verify that your legend drug and/or device suppliers/vendors are properly licensed by the Board to sell and/or distribute in or into Louisiana.

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.

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.

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.

AGENCIES GOVERNING 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 are 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.

EMERGENCY PREPAREDNESS

In the event our state again finds itself in a state of emergency due to another disaster such that was experienced in late 2005 with Hurricanes Katrina and Rita where most land phones in the affected area as well as some cell phone services were hampered by the destruction, the utilization of a "satellite" phone may be helpful in keeping things running. Board office staff have found a web base satellite phone company - GlobalStar - that allows for the ordering and activation of a satellite phone via an "800" telephone number - 877-728-7466. The satellite phone is shipped next day FedEx delivery to you with rental and usage rates that can be charged by the day, week, or month.

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 while the inspector is present will be considered as violations found and reported to the Board's compliance officer.

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 or device 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 or devices 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 so the company can be contacted and provided with licensing information.

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 (Drug) 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 allow 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.

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.

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.

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.

DISCIPLINARY ACTIONS

Docket No. 2006001 –Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to the display of license, misuse of product, improper temperature monitoring, quarantined product, failure to have current customers’ licenses on file, failure to maintain or follow established policy and procedures, establishment and maintenance of perpetual inventory records, and relocation of product to unlicensed facility. The licensee accepted a consent order and was assessed a fine of \$5,000.

Docket No. 2006002 – Licensee was found in violation of Louisiana Revised Statues and Board promulgated rules with regards to failure to keep current licenses for all customers that are sold or shipped product. The licensee accepted a consent order and was assessed a fine of \$1,000.

Docket No. 2006003 – Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to failure to keep current licenses for all customers that are sold or shipped product. The licensee accepted a consent order and was assessed a fine of \$1,000.

Docket No. 2006006 – Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to failure to keep current licenses for all customers that are sold or shipped product. The licensee accepted a consent order and was assessed a fine of \$1,000.

Docket No. 2006007 – Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to failure to maintain current licenses for all customers that are sold or shipped product and failure to maintain appropriate product storage temperatures and failure to maintain temperature logs. The licensee accepted a consent order and was assessed a fine of \$8,300.

Docket No. 2006008 – Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to failure to keep current licenses for all customers that are sold or shipped product. The licensee accepted a consent order and was assessed a fine of \$1,000.

Docket No. 2006009 – Licensee was found in violation of Louisiana Revised Statutes and Board promulgated rules with regards to failure to maintain current licenses for all customers that are sold or shipped product, failure to maintain perpetual inventories, and failure to maintain policy and procedures at the facility for management’s familiarity. The licensee accepted a consent order and was assessed a fine of \$4,000.

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 rules, verify license information of wholesale drug and/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.

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

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