



## LOUISIANA BOARD OF WHOLESAL DRUG DISTRIBUTORS

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# In-State Licensee Newsletter

# September 2006

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## Welcome

The Board would like to welcome Mr. Eric Vidrine. Mr. Vidrine was appointed to the Board by the Governor in May 2006. Mr. Vidrine's term on the Board will expire in May 2011. We again welcome Mr. Vidrine and look forward to working with him.

### **2006 LICENSE RENEWAL AND NEW RENEWAL PROCEDURES**

Current Louisiana wholesale legend drug and/or device distributor licenses will expire on DECEMBER 31, 2006. License renewal forms for the 2007-year will be mailed to all licensees the first week of October.

In accordance with new rule amendments implemented in LAC 46:XCI.301 effective March 20, 2006, licenses must be timely and properly renewed by submitting a completed, signed renewal application form along with any required documentation and the \$200 license renewal fee to the Board office **on or before** the license expiration date of December 31, 2006. ***There will no longer be any grace period for completing license renewals.***

Those licenses not timely and properly renewed by December 31, 2006 (including renewals on hold at the Board office for incompleteness and those received postmarked after December 31, 2006) will be expired as of January 1, 2007 and will have to be reinstated. Reinstatement (renewal) application for those expired licenses must be made by submitting a reinstatement fee of \$200 along with the completed, signed renewal application form, any required documentation, and the \$200 license renewal fee (total fees for reinstatement of expired licenses = \$400). 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. A copy of the revised rules can be found on the Board's website at [www.lsbwdd.org](http://www.lsbwdd.org).

Please note that the format of the renewal application form has been modified. Information currently on file for the license will be pre-printed on the form. Please review the form format and the license information presented carefully making sure all information required is provided and is correct.

### **Summary of Rule Amendments Effective March 20, 2006**

- New definitions have been added.
- Licensure requirement of those companies that wholesale/distribute legend devices have been added.
- Application and renewal requirements and qualifications have been updated.
- License renewal procedures have been changed.
- License compliance requirements have been modified.
- New disciplinary procedures have been added.

## NEW LICENSING REQUIREMENTS

With the implementation of rule amendments in Louisiana Administrative Codes 46:XCI.101-801 effective March 20, 2006, 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](http://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](mailto:lsbwdd@bellsouth.net). THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

## ABOUT THE BOARD

The Louisiana Board of Wholesale Drug Distributors is made up of seven members with various knowledge and experience in wholesale drug distribution who are appointed by the Governor. Currently serving on the Board are:

- Robert Broadus, Board Chairman**, term expiration May 2011 - Recommended by PhRMA (Pharmaceutical Research and Manufacturers of America)
- William Crates, Board Vice-Chairman**, term expiration January 2007 - Recommended by LAWDD (Louisiana Association of Wholesale Drug Distributors)
- Randall Brooks, Board Secretary-Treasurer**, term expiration January 2007 - Recommended by LAWDD (Louisiana Association of Wholesale Drug Distributors)
- Hershall Paul, Board Member**, term expiration January 2008 - Recommended by LAWDD (Louisiana Association of Wholesale Drug Distributors)
- Andy Milligan, Board Member**, term expiration April 2010 - Recommended by LAWDD (Louisiana Association of Wholesale Drug Distributors)
- Wayne Gremillion, Board Member**, term expiration August 2010 - Recommended by PhRMA (Pharmaceutical Research and Manufacturers of America)
- Eric Vidrine, Board Member**, term expiration May 2011 - Recommended by LAWDD (Louisiana Association of Wholesale Drug Distributors).

## CHANGES AT TWO AFFILIATE STATE AGENCIES

Effective August 15, 2006 and in accordance with legislative changes made during the 2006 regular session of the state legislature, the CONTROLLED DANGEROUS SUBSTANCE program has been transferred from the Department of Health and Hospitals, Management and Finance, Health Standards to the **Louisiana Board of Pharmacy**. You should contact the Louisiana Board of Pharmacy at 5615 Corporate Boulevard, 8<sup>th</sup> Floor, Baton Rouge, Louisiana 70808, 225-925-6496, [www.labp.com](http://www.labp.com) for information regarding controlled dangerous substance licensure for locations where controlled dangerous substances are maintained and utilized (held and/or distributed from).

The Department of Health and Hospital, Office of Public Health, Food and Drug Program which is responsible for registering and regulating drug and device distribution locations by monitoring product safety, quality, and labeling has moved from its Bluebonnet Boulevard location to **628 North 4<sup>th</sup> Street, 1<sup>st</sup> Floor, PO Box 4489, Baton Rouge, LA 70821; new phone number is 225-342-7517, fax 225-342-7672.**

## **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.

## **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.

## **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.

## **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](http://www.lsbwdd.org).

## **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.

## **DISCIPLINARY ACTIONS**

There have been no disciplinary cases resolved since the last newsletter.

## **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](mailto:lsbwdd@bellsouth.net) and schedule a time for Mr. John Liggiro, 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.

## **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.

## **BOARD WEBSITE**

The BOARD'S WEBSITE AT [www.lsbwdd.org](http://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.