LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

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In-State Licensee Newsletter JANUARY 2014

NEW OR CHANGED ITEMS ARE MARKED WITH A BROKEN LINE BOX.

2014 LICENSE RENEWAL – Update

The annual renewal period for renewal of Louisiana licenses for wholesale distribution of legend drugs or devices in/into Louisiana concluded on December 31, 2013. Licenses that were NOT renewed may NOT lawfully operate as a wholesale drug or device distributor in Louisiana until the expired license has been reinstated. YOU SHOULD UTILIZE THE BOARD WEBSITE AT www.Lsbwdd.org TO VERIFY YOUR SUPPLIERS CURRENTLY HOLD A VALID LOUISIANA LICENSE or a list of entities whose Louisiana licenses as a wholesale drug or device distributor in Louisiana expired on December 31, 2013 is available from the Board office upon request.

Pursuant to Board regulation LAC 46:XCI.311.F, licensed wholesalers located in Louisiana shall not purchase or receive drugs or devices from other than wholesale drug distributors licensed by the Board to ship or sell in or into Louisiana. Licensees discovered purchasing or receiving legend drugs or devices from unlicensed suppliers (including those former licensees whose Louisiana licenses are expired) could receive disciplinary action including assessment of fines.

RULE AMENDMENTS

Final Rule for amendments to Louisiana Administrative Codes in 46:XCI.301, 305, and 311 was published in the *Louisiana Register* in October 2013. The amendments are in regards to: Licensing Requirements, Qualifications, and Recordkeeping. The amendments should be available on the Board's website or to receive a copy of the Final Rule, please contact the Board office in writing at 12091 Bricksome Avenue, Suite B, Baton Rouge LA 70816, via fax at 225-295-8568, or via email at Lsbwdd@Lsbwdd.org.

The rule amendments relate specifically to:

Section 301 – The addition of item "L", a license will be revoked after 180 days from the date of issuance if a lack of legitimate business activity is found during inspection and after a disciplinary hearing is conducted.

Section 305 – The additional of new item "B", the Board will now require criminal history records information for the designated responsible party and any owners *(natural persons owning greater than ten percent interest in the applicant)* for all new license applicants physically located in Louisiana; criminal history records information will only be required of current licenses when there is a change of the designated responsible party or a transfer of ownership interest of more than ten percent to another owner.

Section 305 – amendment of item "D" (previously item "C") – Designated responsible party must be at least twenty-one years of age, have at least two years of full-time employment history with either a pharmacy or wholesale distributor in the capacity related to dispensing, distribution, and recordkeeping of drugs or devices, employed by the applicant or licensee in full-time position, actively involved in and aware of daily operation of the distributor, physically present at the facility during regular business hours, may serve as the designated responsible party for only one location at a time, and not have any felony convictions relating to wholesale or retail legend drug/device distribution or controlled substances (criminal history records information).

Section 311 – Addition of new item "B", the requirement for establishment and maintenance of financial records as they relate to drug, device, or medical gas sales, distribution, inventories, receipts or deliveries and monthly bank statements and deposit receipts for all bank accounts containing funds with which drugs or devices have been purchased and/or sold for a minimum of three years from date each record is created.

NEW LICENSES ISSUED DURING CALENDAR YEAR

In accordance with Louisiana Administrative Code Title 46, Part XCI, Sections:
301.B – **All new licenses issued by the Board shall expired on December 31 of the calendar year issued.**
301.C – A license shall be renewed annually by timely submitting an application and the license renewal fee.
301.D – Each application for renewal of the license must be made between October 1 and December 31 of each year on a form provided by the Board
301.E – Licenses renewed annually between October 1 and December 31 shall expire on December 31 of the following calendar year.

Please note that NEW licenses issued during the renewal period of October 1 through December 31 each year will expire on December 31 of the calendar year issued and would be required to be renewed within the renewal period for the next calendar year.

UNLICENSED SUPPLIERS

All wholesale drug distributors physically located and conducting operations in Louisiana should verify that each shipping location of every legend drug or legend device supplier they purchase from is licensed by this Board to distribute legend drugs/ devices into Louisiana.

In accordance with LAC 46:XCI.311.F, wholesale drug or device distributors located in Louisiana shall not purchase or receive drugs or devices from other than wholesale drug distributors licensed by the Board to ship or sell in or into Louisiana and they shall notify the Board of any wholesaler not licensed by this Board shipping in or into Louisiana or selling or offering to sell in or into Louisiana.

Louisiana licenses are valid only for the facility or physical location for which it is issued to (LAC 46:XCI.303.C).

The Board requires a separate license for EACH facility or physical location owned or operated by the same business entity that sells and/or distributes legend drugs or devices in/into Louisiana (LAC 46:XCI.301.A.1).

An entity must license all locations from which legend drugs or devices are sold and/or shipped (LAC 46:XCI.301.A.2).

ARE ALL OF YOUR LOCATIONS LICENSED

Separate licenses are required for each facility or physical location directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all entities.

If your business has more than one location that either sells and/or distributes legend drugs or devices, make sure each location is licensed for wholesale distribution of legend drug or device.

CHANGE OF LICENSED FACILITY INFORMATION

Changes in any information with regards to such items as contact persons for the facility or physical location, the owners of the licensee including the percentage of interest owned (without a change in ownership), the person designated as the responsible party, the directors and officers, or the regulatory contact person must be submitted to the Board in writing and should be submitted within 60 days after such changes become effective. A *Request for Change of License Information* form is available on the Board's website for use. *DURING THE RENEWAL PERIOD, SUCH INFORMATION MAY BE CHANGED ON THE PRE-PRINTED RENEWAL FORM AND SUBMITTED WITH THE RENEWAL BY LEGIBLY PROVIDING THE NEW INFORMATION WHERE INDICATED.*

Any licensee changing their physical location is required to submit an application (location change) for new licensure of the new location at least 30 days prior to such change of location. A new location physically located in Louisiana requires inspection before a new license will be issued.

If your facility has a change in ownership, you should notify this Board by applying for a new license under the new ownership as soon as the change becomes effective. Louisiana licenses are issued to facility locations by owner and are not-transferable.

LOCATION CHANGES AND/OR CHANGES IN OWNERSHIP MAY NOT BE REPORTED ON THE ANNUAL RENEWAL FORM; APPLICATION FOR NEW LICENSURE MUST BE SUBMITTED. NEW LICENSES ISSUED DURING THE RENEWAL PERIOD WILL BE VALID FOR THE CALENDAR YEAR (expiring 12/31/2013) AND WILL BE REQUIRED TO BE RENEWED FOR THE UPCOMING CALENDAR YEAR.

In accordance with La. R.S. 37:3478.A, no person shall participate or engage in the wholesale drug distribution business without a license; therefore a new location must be licensed before the move and business is conducted from the new location. Failure to adhere to current laws and regulations could result in disciplinary action being taken against the licensee.

AUTHORIZED RECIPIENTS

In accordance with La. R.S. 37:3480, sales or distribution of legend drugs or devices shall be made only to an authorized recipient – i.e., a person such as a natural or juridical person including an individual, corporation or other legal business entity - who 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. Verification of customer licenses or registration printed from state licensing websites is acceptable to have on file in compliance with Board regulation requirements.

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 for Physicians
Dentist License
Veterinarian License
Therapeutic Pharmaceutical Agent Certificate, Board
Of Optometry for Optometrists
Pharmacy License (Do not use Drug Kit Permit)
Durable Medical Equipment Permit, Board of Pharmacy (for legend devices only)
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 for only radioactive drugs. All other drug sales require a license or permit as previously listed above.

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

Some violations of state statues and Board rules frequently found during inspection of licensed facilities within Louisiana including, but not limited to, the following:

- LAC 46:XCI.303.C (and La. R.S. 37:3474.2(A)) – A license is valid only for the facility or location for which it is issued (selling or shipping drugs or devices from a facility not licensed). (*Moving and conducing business before acquiring a new license for the new location.)*
- 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.
- LAC 46:XCI.311.F – Purchasing or receiving legend drugs or devices from a supplier not licensed as a wholesale drug distributor to ship or sell in/into Louisiana.

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 and legend devices (if applicable).

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 entities authorized by law or regulation to procure and possess legend drugs or devices.

DAY GATES

It has been found during inspections, on occasion, that warehouse doors at a licensee's facility are left open and there may be no licensee personnel within line of site of the open access. This can create an opportunity for product to be stolen. Recommendation is made by the Board to all licensees finding themselves with such a situation that setting up a "Day Gate" or a manned location to limit access into the warehouse for security of product.

ADDITIONAL REQUIREMENTS FOR MEDICAL GAS DISTRIBUTORS ALSO DISTRIBUTING LEGEND DEVICES

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.

DISCIPLINARY ACTIONS

There have been no disciplinary actions or enforcement actions concluded 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. A copy of the statutes and rules may be obtained by contacting the Board office at 12091 Bricksome Avenue, Suite B, 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.

FEES and SERVICE CHARGES

In accordance with La. R.S. 37:3479 and LAC 46:XCI.801, the board may collect the following fees.

1. Initial License Fee - $400
2. License Renewal Fee - $300
3. Initial Inspection Fee - $100
4. Duplicate License Fee - $10
5. License Reinstatement Fee for licenses suspended, revoked, or expired - $300
6. License Verification Fee - $15

Requests for duplicate license certificate should be made in writing to the Board office and must include payment of the $10 fee. Requests for license verifications must include payment of the $15 fee per each verification requested.

Name change requests, not associated with a change in ownership, must be made by approved request form available on the Board's website and submitted along with a $25 processing charge. Requests for electronic Excel spreadsheet listing of Louisiana licensees must be made by written request, including an email address for receipt of the electronic list, along with a $15 processing charge.

NOTICE TO WHOLESALER/PHARMACIES

Pharmacies that are licensed with the Louisiana Board of Wholesale Distributor for wholesale drug distribution and who are selling/ distributing controlled substances should contact the Louisiana Board of Pharmacy to determine if a separate controlled dangerous substance license as issued by the Board of Pharmacy is required as a distributor.

LOUISIANA BOARD OF PHARMACY, Controlled Dangerous Substance Program
225-925-6496 (Option 4), www.labp.com

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, jobbers, third party logistic providers, retail pharmacy warehouses, brokers, agents, and pharmacies - 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; LBOP also manages the state CONTROLLED DANGEROUS SUBSTANCE PROGRAM which licenses locations where controlled substances are held and/or distributed and permits and regulates DURABLE MEDICAL EQUIPMENT (DME) providers.

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 (instructions available on site), 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, complete and print a name change request (not associated with a change in ownership), and view licensing information - such as general license information, inspection and policy & procedure guidelines for in-state licensees/ applicants, making a request for license verification, and the fee schedule.

There are 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.

NOTE: The Board's email address has changed to Lsbwdd@Lsbwdd.org .

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* can 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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