LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS
12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816
Phone: 225-295-8567 Fax: 225-295-8568 Website: www.drugboard.La.gov email: admin@drugboard.La.gov

In-State Licensee Newsletter SEPTEMBER 2023

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

LICENSE RENEWAL
YEAR 2024

Current Louisiana licenses for legend drug or legend device distribution will expire ***DECEMBER 31, 2023***.

In accordance with Board regulations, a license shall be renewed annually by timely submitting a renewal application and the license renewal fee between October 1 and December 31 of each year.

Please note that Louisiana licenses with changes of ownership or changes of location CANNOT be renewed; Louisiana licenses are NOT transferable with regards to changes in ownership or location; application for new licensure under the new ownership or for the new facility location must be submitted.

Information regarding license renewal for the upcoming calendar year, 2024, will be mailed to all active licensees for the first week of October 2023. The online renewal submission portal with electronic fee payment will be available for year 2024 renewals starting October 1, 2023. To submit the renewal online, go to the Board's website at www.drugboard.La.gov; select the "Online Renewal" option in the list at the left side of the webpage; enter the Louisiana license number of the license to be renewed and the unique PIN assigned to the license number which is provided in the annual license renewal information mailing received. Licenses must be renewed online from October 1 through midnight December 31, 2023 to avoid the late fee. If you would prefer to complete a hard-copy, paper form for submission with fee payment by company/cashier/certified check or money order, you may email your request for a paper renewal form to the Board office at admin@drugboard.La.gov; a paper renewal application form in pdf will be provided by return email.

Louisiana licensee information currently on record is provided on the renewal format. All license information should be reviewed and verified, and corrected or provided, when applicable; each license information item must be checked off in the "✓" column as each line of information is verified or corrected- IF THIS STEP IS NOT PERFORMED THE ONLINE FORMAT WILL NOT BE ACCEPTED FOR ONLINE SUBMISSION AND THE PAPER FORM COULD BE RETURNED TO LICENSEE AS INCOMPLETE.

Renewals are processed individually for each license. Payment of renewal fee for multiple license renewals being submitted hard-copy 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 hard-copy renewal form being submitted to avoid having an incomplete renewal and delaying the renewal process.

If a license is not renewed on or before the current expiration date of December 31, 2023, the licensee must submit application for reinstatement and renewal of the expired license by submitting the renewal or a reinstatement application form, payment of the appropriate license renewal fee, and the license reinstatement (late) fee. Any license renewals that are submitted INCOMPLETE during the renewal period (October 1 through December 31) will be placed on HOLD at the Board office and must be completed prior to December 31; if not completed by December 31, the licensee must pay the additional $300 reinstatement (late) fee to complete the renewal.

A person may not lawfully operate as a distributor of legend drugs or legend devices in Louisiana until the expired license has been reinstated.

PERSONAL INFORMATION

Please do not provide personal information – such as home addresses and telephone numbers, social security numbers, or driver's license numbers – of any individuals such as facility or regulatory contacts, individual owners and designated responsible party (except where required for criminal history records (background) checks on forms provided by the Board), and officers and directors (listings). The Board's files are publicly accessible.

WHAT YOU SHOULD KNOW ABOUT THE DSCSA

Who must comply with the federal *Drug Supply Chain Security Act* (DSCSA)? Manufacturers, Repackagers, Wholesale Distributors, Third-party Logistics Providers, and Dispensers of legend drugs must all comply with upcoming federal DSCSA regulation guidelines.

Three Policy and Procedures to Prepare Now for (DSCSA) Compliance:

1. Include policy and procedure for confirming business is only conducted with *Authorized Trading Partners* of the pharmaceutical drug supply chain. Authorized trading partners must be confirmed as having valid registration with the appropriate federal and state agencies. Wholesale distributors and third-party logistics providers must also comply with yearly licensure reporting requirements with the FDA.
2. Update policy and procedures for verifying products received. The term 'verification' or verify means determining whether the product identifier affixed to or imprinted upon, a package or homogenous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager as applicable. Verification of the product identifier may occur by human-readable or machine-readable methods.
3. Include policy and procedures for quarantining *Suspect Product* until such product is cleared or dispositioned; promptly investigate in coordination with trading partners to determine if the product is illegitimate. This includes validating any applicable transaction history and transaction information in the possession of the manufacturer and verifying the product at the package level, including the standardized numerical identifier. Include the policies and procedures for if a product is determined to be *Illegitimate*. Documents steps of Quarantining product, dispositioning illegitimate product from the drug supply chain, take appropriate steps to notify and assist trading partners, and retain a sample of the product for further examination and laboratory analysis that may be requested.

FDA has issued a discretionary enforcement period for DSCSA track and trace requirements until November 2025. While track and trace capabilities will be limited it is required that distributors and dispensers of legend drugs have updated policy and procedures regarding increased supply chain security to be compliant with DSCSA.

Per the federal Food and Drug Administration (FDA), "The 2020 Compliance Policies relate to provisions in the Federal Food, Drug, and Cosmetic Act (FD&CA), as added by the Drug Supply Chain Security Act (DSCSA), requiring wholesale distributors to verify the product identifier prior to further distributing saleable returned product and requiring dispensers to verify the product identifier for suspect or illegitimate product in the dispenser's possession or control."

If you are interested in further discussion of the federal DSCSA and its requirements, contact the Board office at 225-295-8567 or by email to admin@drugboard.La.gov.

CRIMINAL HISTORY RECORDS CHECK REQUIREMENT

Criminal history records (background) checks are required for the designated responsible party (DRP) and any individual owners possessing greater than 10% owner interest in the applicant company for all new license applicants physically located in Louisiana; and for those licensees physically located in Louisiana previously issued a Louisiana license if they appoint a new designed responsible party or add a new individual owner who will possess greater that 10% owner interest in the licensee without changing the current majority ownership (which would require application for new licensure).

LICENSE SUB-TYPES

Per Board statutes and regulations, there are three (3) sub-types for the Drug and Device Distributor license issued by the Board; the sub-types are as follows:

STANDARD DISTRIBUTOR

Any person (entity) that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, distribution by manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

WHOLESALE DISTRIBUTOR

Any person (entity) that sales or facilitates the delivery of drug product to persons other than the consumer or patient excluding, but not limited to, manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; Radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

THIRD-PARTY LOGISTICS PROVIDER DISTRIBUTOR

Any person (entity) that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

Based on federal regulations, a manufacturer, manufacturer's co-license partner, third-party logistic provider, and re-packager are not a "wholesale distributor". A "wholesale distributor" is a distributor who sells and/or physically distributes prescription drug product. An entity distributing any legend product other than prescription drugs – such as only medical devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components, radioactive drugs or biologicals, imaging drugs, homeopathic drugs, or compounded drugs – is not a "wholesale distributor" license sub-type; the entity is a "standard distributor" license sub-type. If an entity distributes prescription drugs and another type of legend product, both the "standard" and "wholesale" distributor license sub-type would apply.

DESIGNATED RESPONSIBLE PARTY QUALIFICATIONS

Designated Responsible Parties (DRPs) are required to:

- be at least 21 years of age;
- have at least two years full-time employment history with either a legend drug/device or medical gas distributor or pharmacy in a capacity related to distribution or dispensing, and recordkeeping of legend drugs or devices;
- is physically present at the applicant/licensee facility daily during regular business hours; and
- be employed by the applicant/licensee in a full-time position which is actively involved in or aware of the daily distribution operations of the applicant/licensee distribution location (or the 3PLP distribution operation if a 3PLP is utilized for facilitation of delivery of the licensee's drugs or devices).

The Board has developed a worksheet to assist you with determining if an individual you wish to appoint as DRP meets the required qualifications. The worksheet is available on the Board's website; the worksheet is not required to be submitted to the Board with the application, renewal, or change of information request. A DRP may serve in the capacity as DRP for only one licensed location at a time, except where more than one licensee is co-located in the same facility location.

LICENSE CERTIFICATES

License certificates for newly issued and renewed licenses are emailed from the Board's license management system to the regulatory contact person on record for the license at the time the new license is issued, or a completed renewal is released. This is your OFFICIAL license certificate. The emailed certificate should be printed and displayed as required.

If you would like a hard-printed certificate mailed from the Board office, please make written request to the Board office at the time the new license is issued, or license renewal is released complete.

With regards to new licenses issued, request for a duplicate license certificate may be made in writing if the initial certificate email sent from the Board office is not received. Per administrative policy, the duplicate license certificate fee of $10 is waived for duplicate license requests received within 60 days after issuance of the new license; after 60 days since license issuance, a request for duplicate license certificate must include payment of the $10 duplicate license certificate fee.

Regarding renewed licenses, request for a duplicate renewed license certificate may be made in writing if the initial certificate email sent from the Board is not received. Per administrative policy, requests for a duplicate renewed license certificate are not accepted prior to December 21 of the annual renewal period; the duplicate license certificate fee is waived for requests received after December 20 of the annual renewal period and through the last day of February of the follow calendar year; as of March 1, a request for duplicate renewed license certificate must include payment of the $10 duplicate license certificate fee.

NEW LICENSES ISSUED DURING CALENDAR YEAR

In accordance with Louisiana Administrative Code Title 46, Part XXXIV, Sections:
301.C – **All new licenses issued by the Board shall expired on December 31 of the calendar year issued.**
301.D – A license shall be renewed annually by timely submitting an application and the license renewal fee.
301.E – 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.F – 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.

REPORTING DISCIPLINARY ACTION FROM OTHER STATES

The disciplinary action questions on the Louisiana distributor license application form and annual renewal form must be answered for the facility location being applied for or renewed. Louisiana distributor licenses are facility location specific. Thereby, final disposition documents for disciplinary action taken in other states must pertain to the applicant/ licensee facility location that is being applied for or renewed only.

During renewals, if a *yes* is checked for disciplinary action in another state for the licensee facility on the renewal form and the information has already been provided to the Board via the initial application, or any previous year renewals, or provided during the year between renewals, another copy of the documents should NOT be submitted to the Board as a copy is already on file. The option available on the renewal form in the disciplinary action section denoting that the information has already been submitted should be checked-off. If the disciplinary action in another state occurred during the year since the last renewal or initial license issuance, a copy of the final disposition of the action documents from the other state and pertaining to the applicant/licensee location only must be provided to the Board.

Again, disciplinary action notification and documents must pertain to the applying/licensed facility location only. Disciplinary action information for other facility locations owned by the applicant/licensee company should not be provided except if the other locations are licensed or applying and only with the application or renewal for that specific location licensure.

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 annual renewal period, changes of such information as noted above may be made legibly on the pre-printed renewal form or online renewal form submission.

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. New locations may not possess at or distribute from the premise until a Louisiana distributor license has been issued for the location.

If your facility has a change in ownership, you should notify this Board by applying for a new license under the new ownership within 60 days after the owner change becomes effective. Louisiana licenses are issued to facility locations by owner and are non-transferable.

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

Location changes and/or change in ownership may NOT be reported on the annual license renewal form; application for new licensure must be submitted. New licenses issued during the renewal period will be valid for the calendar year issued and will be required to be renewed for the upcoming calendar year.

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 distribution of legend drug or device.

MEDICAL GAS DISTRIBUTORS ALSO DISTRIBUTING LEGEND DEVICES

DISTRIBUTOR LICENSEES DISTRIBUTING MEDICAL GASES who also distribute legend devices must adhere to Board promulgated rules with regards to security and inventory. Pursuant to LAC 46:XXXIV.309.A.2, a facility used for 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:XXXIV.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 or physical 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 legend drugs or devices. Any location to which legend drugs or devices are delivered must also be authorized to procure or possess such drugs or devices. In accordance with Board regulation LAC 46.XXXIV.311.E, and to ensure that the customers you sell/ship to are authorized to procure or possess legend drugs or devices, drug and device 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.

Acceptable verification of an authorized recipient of legend drugs or legend devices include the following types of licenses, certificates, registrations, or permits:

Drug Enforcement Agency (DEA) Registration
LA Controlled Dangerous Substance Registration (Pharmacy Board)
LA Board of Medical Examiners- Physician License
LA Board of Dentistry- Dentist License
LA Board of Veterinary Medicine- Veterinarian License
LA Board of Optometry Examiners- Optometrists License
LA Board of Pharmacy- Pharmacy Permit (Not Drug Kit Permit)
Durable Medical Equipment Registration (Pharmacy Board)
LA Legend Drug and Device Distributors License
LA Dept. of Health, Food & Drug Permits for:
OTC & Prescription Drugs
OTC, Prescription Drugs and Controlled Substances
Prescription Drugs
Prescription & Controlled Substances
Controlled Substances
Prescription Generic Drugs
OTC Generic & Prescription Generic Drugs

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

Emergency Medical Technician (EMT) Certification
First Responder Certification
LA Dept. of Health, Food & Drug Permit for Medical Gases
Advanced Cardiovascular Life Support (ACLS) Certification

A *nursing facility* or *nursing home* registration issued by the LA Dept. of Health may be accepted as authorization for the procurement of medical oxygen only for emergency use by a nursing facility or nursing home.

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 customers not having one of the above accepted licenses/ permits/ certificates/ registrations, the Board will accept a letter from a licensed practitioner 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, along with a copy of the practitioner's current medical license.

For customers not having one of the above accepted licenses/ permits/ certificates/ registrations for the acquisition and possession of medical gases including medical oxygen, 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/medical oxygen 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 is 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 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.

Physical therapists licensed by the LA Physical Therapy Board may procure and possess (store) legend devices and topical legend drugs which are employed in the delivery of physical therapy per LAC 46:LIV.315 of the Physical Therapy Board's regulations.

Midwives licensed by the LA State Board of Medical Examiners may procure and have possession of small quantities of medication as listed in LAC 46:XLV.5325 of the Medical Examiners Board's regulations.

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, the facility's appointed designated responsible party (DRP) must be available to produce records and assist the Board inspector with the inspection. If the DRP is not at the facility due to authorized leave 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.

PERPETUAL INVENTORY

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

> "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).

DAY GATES

The Board recommends to all licensees who leave warehouse doors open during regular business hours to set up a "Day Gate" or a manned location to limit access into the warehouse for security of product. Open warehouse doors located where no licensee personnel are within line of site can create an opportunity for product to be stolen.

TEMPERATURE MONITORING DEVICES

Spring-loaded or mercury driven temperature monitoring devices are not allowed for use in monitoring and recording legend drug and device product storage temperatures. Only appropriate electromechanical or electronic temperature recording equipment, devices, and logs shall be utilized for monitoring and recording proper storage of product in accordance with LAC 46:XXXIV.309.A.3.b. Contact the Board's administrative office if you would like descriptions of electromechanical and electronic temperature recording equipment.

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.

SOME THINGS TO REMEMBER

- Louisiana legend drug/device distributor licenses are valid only for the facility or location for which it is issued - LAC 46:XXXIV.303.C.
- Establishing and maintaining perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs or devices - LAC 46:XXXIV.311.A.
- 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 - LAC 46:XXXIV.311.E.
- Establishing, maintaining, and adhering to written (working) policies and procedures - LAC 46:XXXIV.313.
- Purchasing or receiving legend drugs or devices from a supplier not licensed as a distributor of legend drugs or legend devices to ship or sell in/into Louisiana - LAC 46:XXXIV.311.G.

UNLICENSED SUPPLIERS

All drug or device 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:XXXIV.311.G, drug or device distributors located in Louisiana shall not purchase or receive drugs or devices from other than drug or device distributors licensed by this Board to distribute in or into Louisiana and they shall notify the Board of any distributors not licensed by this Board that may be distributing in or into Louisiana or offering to distribute in or into Louisiana.

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

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

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

FEES and SERVICE CHARGES

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

Initial License Fee: (based on number of license sub-types that apply)	License Renewal Fee: (based on number of license sub-types that apply)
One license sub-type- $400	One license sub-type- $300
Two license sub-types- $425	Two license sub-types- $325
Three license sub-types- $450	Three license sub-types- $350

Initial Inspection Fee (in-state locations only)- $100

License Reinstatement (late renewal) Fee- $300

Duplicate License (certificate) Fee- $10

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 $10 processing charge.

BOARD WEBSITE

The BOARD'S WEBSITE, **www.drugboard.La.gov**, has many active functions and helpful links. You can complete and print an application form for submission by USPS/carrier with fee payment by check or money order or you can complete and submit an application electronically with electronic fee payment by major credit card and e-check (application instructions also available on website), view previous licensee newsletters, view a list of the current Board Members and staff, view and print the state statutes and Board rules, verify license information of 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 distributors 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.

NOTICE TO PHARMACIES THAT ALSO DISTRIBUTE

Pharmacies that are licensed with the Louisiana Board of Drug and Device Distributors for drug and device distribution and who are selling/ distributing controlled substances should contact the Louisiana Board of Pharmacy to determine if a separate (from the CDS registration currently held for the pharmacy) 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, www.pharmacy.la.gov.

IGNORANCE OF THE LAW IS NO EXCUSE

State statutes and Board promulgated rules can be viewed on the Board's website at www.drugboard.La.gov. 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 admin@drugboard.La.gov. THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

DISCIPLINARY ACTIONS

There are no concluded disciplinary action cases to report at this time.

RULE AMENDMENTS

There are no regulatory amendments in promulgation process at this time.

STATUTORY AMENDMENTS

There are no statutory amendments in legislative process at this time.

SOME AGENCIES THAT OVERSEE DISTRIBUTION IN LOUISIANA

There are several state and federal government agencies that work together for the regulation of the distribution of legend (prescription) drugs and devices in and within the state of Louisiana.

This Board, the LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS is charged by the state legislature to license and regulate distributors of legend drugs and legend devices - including but not limited to distribution by manufacturers, repackagers, own-label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, brokers, agents, and wholesale distributors - that sale or facilitate delivery of legend drugs and legend devices in/into 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 and medical gases within Louisiana.

The Louisiana Board of Pharmacy is the state regulatory agency for the practice of pharmacy and the administration of the state CONTROLLED DANGEROUS SUBSTANCE PROGRAM which registers 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*.

The *Louisiana Board of Drug and Device Distributors* licensee newsletter is considered an official method of notification to drug and device 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.

This public document was published and distributed (via USPS) at a cost of $3.41 per copy. Copies totaling 200 of this public document was published and distributed (via USPS) in this first mailing at a cost of $681.77. The total cost of all mailings of this document, including any reprints, is $682.00 This document was published and distributed (via USPS) by the *Louisiana Board of Drug and Device Distributors, 12091 Bricksome Avenue, Suite B, Baton Rouge, Louisiana 70816* to provide licensing information to licensees. This material was printed in accordance with the standards for printing by state agencies established pursuant to R.S. 43:31.

LOUISIANA BOARD OF DRUG
AND DEVICE DISTRIBUTORS
12091 Bricksome Avenue
Baton Rouge, LA 70816