LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS
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In-State Licensee Newsletter MARCH 2018

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

2018 LICENSE RENEWAL – Update

The annual period for renewal of Louisiana licenses for distribution of legend drugs or legend devices in/into Louisiana for year 2018 concluded on December 31, 2017.

Licenses that were NOT renewed may NOT lawfully operate as a drug or device distributor in Louisiana until the expired license has been reinstated.

YOU SHOULD UTILIZE THE BOARD WEBSITE AT www.Lsbwdd.org, *Licensee Search*, TO VERIFY YOUR SUPPLIERS CURRENTLY HOLD A VALID LOUISIANA LICENSE. Pursuant to Board regulation LAC 46:XXXIV.311.G.1 and 2, licensed distributors located in Louisiana shall not purchase or receive drugs or devices from other than drug and device distributors licensed by the Board to distribute 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.

LICENSE CERTIFICATES

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

If you would like a hard-printed certificate mailed directly 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 email sent from the Board is not received. Per office policy, the duplicate license certificate fee is waived for 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 email sent from the Board is not received. Per office policy, requests for a duplicate renewed 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; after the last day of February, a request for duplicate renewed license certificate must include payment of the $10 duplicate license certificate fee.

REGULATORY REQUIREMENT - LICENSE SUB-TYPES

Per Board statutes and regulations, there are now license sub-types for the drug and device distributor license 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.

The appropriate license sub-type(s) (all that apply) should be chosen when completing an application and the license renewal forms. With the license sub-types, the schedule of fees collected by the Board has changed. Please see the next newsletter item with regards to the new fees.

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.

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.

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 public accessible.

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 not-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.

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.

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, 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.

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 <u>one</u> licensed location at a time, except where more than one licensee is co-located in the same facility location.

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.

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 recorded 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.

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.

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).

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 VIOLATIONS 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:XXXIV.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 (participating or engaging in distribution without a license). (*Moving and conducting distribution before acquiring a new license for the new location.)*
- LAC 46:XXXIV.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:XXXIV.311.E – 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:XXXIV.313 – Establishing, maintaining, and adhering to written (working) policies and procedures.
- LAC 46:XXXIV.311.G – 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.

Violations of these as well as any of the statutes and rules governing the 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.

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 is within line of site can create an opportunity for product to be stolen.

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).

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 posses 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/distribute 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.

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 Registration (Pharmacy Board)
Louisiana Drug and Device 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

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
Advanced Cardiovascular Life Support Experienced Provider (ACLSEP) Certification
(American Heart Association)

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, hospice care facilities, and hospitals, a 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 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 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 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.

DISCIPLINARY ACTIONS

Docket No. 2017001, AGC DISTRIBUTORS LLC, Slidell LA, Louisiana license number 8271- The licensee admitted it violated La. R.S. 37:3474.1(A)(8), and LAC 46:XXXIV (formerly XCI) 311.A.2 whereby it failed to maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs or device in by the identity and quantity of the drugs or devices received and distributed or disposed of was not kept; and 311.E. whereby it failed to maintain copies of current licenses for customers that are shipped or sold drugs or devices. The licensee accepted a consent agreement and paid a fine of $2,500 and administrative costs of $250.

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 admin@Lsbwdd.org. THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

AGENCIES OVERSEEING 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, medical devices, and medical gases within Louisiana.

The Louisiana Board of Pharmacy is the state regulatory agency for the practice of pharmacy and also manages the state CONTROLLED DANGEROUS SUBSTANCE PROGRAM which licenses locations where controlled substances are held and/or distributed.

The UNITED STATES DRUG ENFORCEMENT AGENCY (DEA), Office of Diversion Control is the federal agency for registration and enforcement of the provisions of the Controlled Substance Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.

The UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) is the federal agency that registers, regulates, and enforces drug and device pre-marketing approval, manufacturing standards, and safety and effectiveness.

Contract information for these state agencies as well as local state offices of these federal agencies can be obtained from the Board office or on the Board's website under *Links*.

BOARD WEBSITE

The BOARD'S WEBSITE, **www.Lsbwdd.org**, has many active functions and helpful links. You can complete and print an application form (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.

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.

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