



LOUISIANA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

New Rules (23-07-744)

The Louisiana Board of Pharmacy completed the rulemaking process for two regulatory projects with publication of the rule changes in the April 20, 2023 edition of the *Louisiana Register*, with immediate effective dates. The Board distributed three separate email notices regarding the progress of these regulatory projects, in addition to maintaining the information on the “Regulatory Projects” page of the Board’s website.

Regulatory Project 2022-06 – Nonresident Pharmacies amended the rules for nonresident pharmacies to replace the term “out-of-state” with “nonresident,” create parity between nonresident and resident pharmacy requirements, clarify intent, and modify the responsibility on the pharmacist-in-charge (PIC) in the matter of policy and procedures. The rule was also amended to remove the requirement for nonresident pharmacies to designate a resident agent and registered office in Louisiana.

Regulatory Project 2022-09 – Partial Fills of CDS Prescriptions amended Sections 2735 and 2747 of rules relative to prescriptions for controlled dangerous substances (CDS). The change in Section 2735 places a requirement on pharmacies dispensing prescriptions for CDS to use a dispensing information system capable of accurately recording partial fills and refills of such prescriptions. The change in Section 2747 places a requirement on a pharmacist to dispense a partial fill of a prescription for a CDS when requested by the patient or prescriber, subject to the pharmacist’s obligation relative to corresponding responsibility.

National Pharmacy Compliance News

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Ongoing Regulatory Projects (23-07-745)

The Board continues to make progress on the following regulatory projects:

- **Regulatory Project 2023-01 – Prescriptions**
- **Regulatory Project 2023-02 – Temporary Closure of Pharmacy**
- **Regulatory Project 2023-03 – Pharmacy Benefit Managers**
- **Regulatory Project 2023-04 – Healthcare Workplace Violence Prevention**
- **Regulatory Project 2023-05 – Pharmacy Change of Ownership**
- **Regulatory Project 2023-06 – Staffing Ratios**
- **Regulatory Project 2023-07 – Marijuana Pharmacy**
- **Regulatory Project 2023-08 – DATA-Waiver Registration Elimination**

The Board’s regulatory activity, which includes detailed information regarding each proposal and project, can be monitored on the Board’s “Rulemaking Activity” section of its website.

Spotlight on Compliance (23-07-746)

Board regulations (Louisiana Administrative Code 46:LIII.Chapter 25, Subchapter C) require compounding to be accomplished in compliance with the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations, and all relevant chapters of the United States Pharmacopeia (USP) and the National Formulary. This includes Section 503A of the FD&C Act, USP Chapter <795> (for compounded nonsterile products), and USP Chapter <797> (for compounded sterile products).

Section 503A of the FD&C Act specifies that to qualify for the exemptions of that section, compounding must be performed by either a licensed pharmacist in a state-licensed pharmacy or a federal facility, or a licensed physician for individual patients. In addition, bulk drug substances must meet certain criteria in order to be eligible for compounding under the exemptions of Section 503A:

- (1) Comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the [USP] chapter on pharmacy compounding;
- (2) If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
- (3) If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d).

Additionally, bulk drug substances must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with Food and Drug Administration under Section 510 of the FD&C Act.

Revised versions of USP Chapters <795> and <797> were published on November 1, 2022, and will become official on November 1, 2023. Current versions remain in effect until that date. During its November 2022 meeting, the Board voted to delay enforcement of the revised USP Chapters <795> and <797> until November 1, 2024.

Pharmacies and pharmacists who elect to compound drug products are encouraged to review and be familiar with all relevant laws and regulations. Compounders and compounding pharmacies have the responsibility to ensure that the products with which they compound meet the requirements of FD&C Act Section 503A. Those compounders must also comply with the standards set in USP Chapter <795>, USP Chapter <797>, or both, depending on the compounding process.

Disciplinary and Other Licensure Actions (23-07-747)

During its May 24, 2023 meeting, the Board took action in the following matters:

Southern University, dba SU Student Health Services Pharmacy (Baton Rouge, LA) (PHY.004675): For its accountability for controlled substance (CS) audit shortages, the Board assessed a fine of \$1,000 plus administrative and investigative costs.

Claudia Marie Robin (PST.014188): For her accountability for CS audit shortages as PIC of SU Student Health Services Pharmacy, the Board issued a letter of warning; and further, placed a condition upon acceptance of a PIC position and assessed administrative costs.

Michael Kevin Tomb (PST.013993): For his actions as PIC, related to the loss of 5,492 hydrocodone/acetaminophen 10/325 mg tablets and 400 oxycodone/acetaminophen 10/325 mg tablets from McDonald's Pharmacy, the Board suspended his license for two years beginning on May 24, 2023, and terminating on May 24, 2025, suspended the suspension, and placed his license on probation for the period of suspension, subject to conditions; and further, assessed a fine of \$10,000 plus administrative and investigative costs.

Pharmaceutical Specialties, LLC, dba Pharmaceutical Specialties (Baton Rouge) (PHY.008107): For its failure to comply with federal standards for compounding, the Board suspended the credential for one year beginning on May 24, 2023, and terminating on May 24, 2024, suspended the suspension, and placed the credential on probation for the period of suspension, subject to conditions; and further, assessed administrative and investigative costs.

Michael Marist Bourg (PST.016141): For his actions as the owner and PIC of Pharmaceutical Specialties in Baton Rouge, by failing to comply with federal standards for compounding, the Board assessed a fine of \$10,000 plus administrative costs.

Green Tree Pharmacies, LLC, dba West Saint James Pharmacy (Vacherie, LA) (PHY.006783): For allowing a pharmacy technician with a lapsed credential to assist in the practice of pharmacy, the Board assessed a fine of \$2,500 plus administrative and investigative costs.

Brian Joseph Delatte (PST.011097): For allowing a pharmacy technician with a lapsed credential to assist in the practice of pharmacy while serving as the PIC of West Saint James Pharmacy in Vacherie, the Board issued a letter of warning; and further, assessed a fine of \$1,000 plus administrative costs.

Paige Anne Bourgeois (CPT.014265): For assisting in the practice of pharmacy with a lapsed credential at West Saint James Pharmacy in Vacherie, the Board issued a letter of reprimand; and further, assessed a fine of \$500 plus administrative costs.

Neumann's Pharmacy, LLC, dba Neumann's Pharmacy (Tallulah, LA) (PHY.006815): For its accountability for CS audit shortages and prescription monitoring program reporting irregularities, the Board assessed a fine of \$1,000 plus administrative and investigative costs.

James Homan (PST.024764): For his failure to disclose a California State Board of Pharmacy disciplinary action issued April 2, 2021, on his reciprocity application to the Louisiana Board of Pharmacy, the Board issued a letter of reprimand; and further, assessed a fine of \$1,000 plus administrative cost.

Stacy Duwon Landrum Hull Nolan (CPT.004903): For the theft of eight oxycodone tablets from a patient's prescription, the Board revoked her credential; and further, prohibited her from applying or reapplying to practice or assist in the practice of pharmacy.

Brian Allen Miller (PST.022042): In lieu of immediate administrative action on a pending matter, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time commencing on April 17, 2023.

Blair Freshe Swafford Guillory (PNT.049122): In lieu of immediate administrative action on a pending matter, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the registration for an indefinite period of time commencing on April 27, 2023.

John Sherwood Bannister (PST.015778): In lieu of immediate administrative action on a pending matter, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time commencing on April 24, 2023.

Courtney Elizabeth-Marie McNeal (PST.022118): Board granted her request for reinstatement of the previously suspended license, converted the duration of the suspensive period to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective May 24, 2023, subject to certain terms enumerated within the voluntary consent agreement.

Brittney Irene Champagne (PNT.049244): Board granted her request for reinstatement of the previously suspended registration, converted the duration of the suspensive period for the registration

and any other subsequent credential issued by the Board to a term of five years and stayed the execution of the suspension, then placed the credential on probation for five years, effective May 24, 2023, subject to certain terms enumerated within the voluntary consent agreement.

Lisa Kay Moreau (PST.014955): Board granted request for the removal of all terms and conditions imposed by previous order, then restored the license to active and unrestricted status.

Sekari Washington Davis (CPT.005962): Board granted her request for reinstatement of the lapsed pharmacy technician certificate, conditioned upon her satisfaction of the following requirements prior to May 24, 2025: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit subject to certain terms; and (2) acquisition of at least 10 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited technician-specific continuing pharmacy education (CPE) subject to certain terms.

Samantha Ann Allen Smith (CPT.010783): Board granted her request for reinstatement of the lapsed pharmacy technician certificate, conditioned upon her satisfaction of the following requirements prior to May 24, 2025: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit subject to certain terms; and (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE.

Sabrina Nicole Pitre Borskey (CPT.004208): Board granted her request for reinstatement of the lapsed pharmacy technician certificate, conditioned upon her satisfaction of the following requirements prior to May 24, 2025: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit subject to certain terms; (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE; and (3) successful completion of a Board-approved pharmacy technician examination (Pharmacy Technician Certification Exam administered by Pharmacy Technician Certification Board or, in the alternative, Exam for the Certification of Pharmacy Technicians administered by National Healthcareer Association).

Tanisha Casandra Macklin (CPT.010777): Board granted her request for reinstatement of the lapsed pharmacy technician certificate, conditioned upon her satisfaction of the following requirements prior to May 24, 2025: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit subject to certain terms; and (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE.

Catherine Rachel Voorhies (CPT.005206): Board granted her request for reinstatement of the lapsed pharmacy technician certificate, conditioned upon her satisfaction of the following requirements prior to May 24, 2025: (1) acquisition of at least 250 hours of updated practical experience under the authority of a special work permit subject to certain terms; and (2) acquisition of at least 10 hours of ACPE-accredited technician-specific CPE.

Calendar Notes (23-07-748)

Upcoming Holidays: The Board office will be closed on July 4 in observance of Independence Day and on September 4 for Labor Day.

Upcoming Board Meeting: The next regular quarterly meeting of the Board and some of its committees is tentatively scheduled for August 15 and August 16, 2023. Upcoming events can be found on the home page of the Board's website.

Special Note (23-07-749)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. Electronic copies dating back to 1998 are posted on the Board's website.

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