January 2020

Louisiana Board of Pharmacy News

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Board Elects Officers for Calendar Year 2020 (20-01-622)

During the November 13, 2019 meeting, the Louisiana Board of Pharmacy members conducted their annual election of officers, with the following results:

- President – Carl W. Aron, from Monroe, LA, in District 5
- First Vice President – Marty R. McKay, from Woodworth, LA, in District 8
- Second Vice President – Jacqueline L. Hall, from New Orleans, LA, in District 2
- Third Vice President – Richard A. Soileau, from New Iberia, LA, in District 3
- Secretary – Richard M. Indovina, Jr, from River Ridge, LA, in District 1

Board Meeting Dates for Calendar Year 2020 (20-01-623)

The Board has announced the first meeting of the year will be held on February 5 at Xavier College of Pharmacy in New Orleans. In addition, the Board announced the following tentative dates for the rest of the calendar year: May 26-28, August 11-13, and November 17-19; these three meetings are planned to be held at the Board office in Baton Rouge, LA.

New Board Member (20-01-624)

Governor John Bel Edwards has appointed a new pharmacist member to the Board. **Dr Sajal K. Roy**, from Madisonville, LA, owns and operates Fast Access Specialty Therapeutics in Kenner, LA. He was appointed to represent Board District 1-A for a six-year term that will expire on June 30, 2025. He replaced Ms Diane Milano from Metairie, LA, who completed six years of service to the Board. The Board welcomes Dr Roy to the Board, and thanks Ms Milano for her service.

Board Member Nomination Election (20-01-625)

Appointments of members to the Board are made in accordance with Louisiana Revised Statute 37:1175, which provides that whenever a vacancy occurs among the members representing one of the eight pharmacy districts, the pharmacists who are bona fide residents of the district in which the vacancy occurs shall nominate from among their number a representative to the Board. Whenever that vacancy shall occur by reason of an expiring term, the nomination shall be made by mail at least 60 days in advance of the expiration date of the term.

The Board's secretary is responsible for mailing a ballot by United States Postal Service First Class Mail to each pharmacist holding an active license and residing in the district in which the vacancy will occur, at the last known address as indicated in the Board's records. The pharmacist may participate in the nomination election by recording the name of his or her pharmacist nominee on the ballot, completing the signature slip, and mailing both items to the Board office in the manner indicated on the ballot. The nominee may be any pharmacist holding an active license and residing in the district; there are no term limits for members of the Board. The ballot or another enclosed communication will state the date, time, and place for counting ballots. At a gathering open to the public, the secretary and one or more persons designated by him will open and count the ballots. The secretary will then certify to the governor the names of the three nominees in each district receiving the highest number of votes. For each district in which the vacancy will occur, the governor may appoint one of those three nominees to the Board.

The terms of five current Board members will expire on June 30, 2020. The deadline for any address changes

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National Pharmacy Compliance News

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NABPF
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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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relative to this nomination election is March 6, 2020. The ballots with the necessary information will be mailed to the pharmacists in the respective pharmacy districts on or about March 16, 2020. The deadline for the return of the ballots to the Board office will be April 17, 2020. The ballots will be opened and counted at the Board office on April 21, 2020; the information about the exact time will be included with the ballot.

Board member terms that will expire on June 30, 2020, and their district information are as follows:

- Jacqueline L. Hall: New Orleans (District 1, composed of the parishes of Orleans, Plaquemines, and St Bernard).
- Richard A. "Andy" Soileau: New Iberia (District 3, composed of the parishes of Ascension, Assumption, Iberia, Iberville, Lafourche, St Charles, St James, St John the Baptist, St Martin, St Mary, Terrebonne, and West Baton Rouge).
- Carl W. Aron: Monroe (District 5, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll, and Winn).
- Ronald E. Moore: Baton Rouge (District 6, composed of the parishes of East Baton Rouge, East Feliciana, Livingston, St Helena, Tangipahoa, Washington, and West Feliciana).
- Marty R. McKay: Woodworth (District 8, composed of the parishes of Allen, Avoyelles, Beauregard, Catahoula, Concordia, Evangeline, Grant, LaSalle, Pointe Coupee, Rapides, St Landry, and Vernon).

Should any pharmacist need a list of pharmacists in his or her own district for purposes related to this nomination election, the Board office will supply one complimentary list upon receipt of a written request by the pharmacist. The expiration date of the new appointees' terms will be June 30, 2026.

Decisions From November 2019 Board Meeting (20-01-626)

During its meeting, the Board took action on several items of business, including:

- Approval of a proposed budget for Fiscal Year 2020-2021
- Approval of several regulatory proposals for promulgation, the progress of which may be monitored on the Board's website at *www.pharmacy.la.gov* by selecting Public Library, then selecting Rulemaking Activity:
  - ◊ Proposal 2019-C – Automated Medication Systems
  - ◊ Proposal 2019-F – Prescription Monitoring Program
  - ◊ Proposal 2019-H – Pharmacist License Display
  - ◊ Proposal 2019-J – Hepatitis Drugs of Concern
  - ◊ Proposal 454-2019-01 – Rest Breaks
  - ◊ Proposal 454-2019-03 – Medication Administration
  - ◊ Proposal 454-2019-17 and 18 – Square Footage and Storage Space
  - ◊ Proposal 454-2019-22 – Pharmacist-In-Charge (PIC) Change Notice
  - ◊ Proposal 454-2019-26 – Retention of Scanned Prescriptions
  - ◊ Proposal 454-2019-28 – Drug Enforcement Administration Registration on Permit Applications
  - ◊ Proposal 454-2019-37 and 38 – Electronic Capture of Faxed Prescriptions
  - ◊ Proposal 454-2019-40 – Prescription Receipt and Verification
  - ◊ Proposal 454-2019-41 and 43 – Refills and Expiration Date of Schedule V Prescriptions
  - ◊ Proposal 454-2019-42 – Emergency Refill Authorizations
- Approval of an enforcement policy document relative to the addition of flavoring agents to prescription medications. The policy document is posted on the Board's website at *www.pharmacy.la.gov* by selecting Public Library, then selecting Declaratory Statements, Advisory Opinions, & Policy Statements.
- Took under advisement two requests for interpretation of pharmacy law relative to scope of practice – one relative to orders for laboratory testing and another for administration of penicillin skin testing.

The members also received a presentation on contemporary pharmacy education from Dr Michael Cockerham, associate dean at University of Louisiana Monroe College of Pharmacy, and Dr Kristi Rapp, associate dean at Xavier College of Pharmacy.

Disciplinary Actions (20-01-627)

During its November 13-14, 2019 meeting and administrative hearing, the Board took action in the following matters:

Quality Medical Care & Services, LLC, dba Quality Medical Care & Services (Ville Platte, LA) (DME.000259): For its fraudulent billing practices relative to a continuous positive airway pressure device, and for its failure to comply with durable medical equipment professional practice standards, the Board issued a letter of reprimand, and further, assessed a fine of $10,000 plus administrative and investigative costs.

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Fred's Stores of Tennessee, Inc, dba Fred's Pharmacy No. 1666 (Franklinton, LA) (PHY.005034): For its failure to designate a PIC from September 22, 2017, to April 29, 2019, and for its failure to conduct the required controlled substance (CS) inventory during that time, the Board revoked the permit, and further, assessed administrative costs. The pharmacy closed permanently on August 22, 2019.

Lauren Ruffino Etienne (PST.019969): Board granted her request for modification of previous orders, then removed Article 2-e from her November 2018 Probation Board Order, which had prevented her from accepting an appointment as the PIC of a pharmacy; and further, reiterated all other terms shall remain in effect.

Kacie Dore Keith (PST.020248): Board granted her request for modification of previous orders, then terminated the probationary period originally scheduled to conclude on August 10, 2021, and restored the license to active and unrestricted status.

Jeffery Charles Pierre (PST.020332): Board granted his request for modification of previous orders, then terminated the probationary period originally scheduled to conclude on November 14, 2023, and restored the license to active and unrestricted status.

John Sherwood Bannister (PST.015778): Board granted his request for modification of previous orders, then terminated the probationary period originally scheduled to conclude on May 4, 2021, and restored the license to active and unrestricted status.

Lauren Moore Caldwell (PST.020057): Board granted her request for modification of previous orders, then conditioned the removal of all probationary terms upon the receipt of evidence of four hours of Accreditation Council for Pharmacy Education (ACPE)-accredited and pharmacist-specific continuing pharmacy education (CPE) on pharmacy ethics; and further, the CPE records submitted in satisfaction of this requirement shall not be valid for license renewal purposes. Board staff noted receipt of required CPE records the following day and implemented the provisions of the conditional order. The probationary period originally scheduled to conclude on November 14, 2020, was terminated by the Board on November 15, 2019, and the license was restored to active and unrestricted status.

Terry James Veillon, Jr (PST.018988): Board granted his request for modification of previous orders, then removed Article 2-e from his August 2018 Probation Board Order, which had prevented him from accepting an appointment as the PIC of a pharmacy; and further, reiterated all other terms shall remain in effect.

Shelette Marie Wade (PST.014865): Board granted her request for modification of previous orders, terminated the probationary period originally scheduled to conclude on August 20, 2021, and restored the license to active and unrestricted status.

Jason Conrad Dove (PST.015811): Board granted his request for modification of previous orders, terminated the probationary period originally scheduled to conclude on August 6, 2029, and restored the license to active and unrestricted status.

Ramona Lois Cormier (CPT.005761): Board granted her request for reinstatement of the certificate, which expired on June 30, 2011, contingent upon her satisfaction of the following requirements prior to November 13, 2021: (1) acquire 250 hours of updated and supervised practical experience under the authority of a special work permit; and (2) acquire 14 hours of ACPE-accredited technician-specific CPE.

Shana Venable Smith (CPT.003222): Board granted her request for reinstatement of the certificate, which expired on June 30, 2003, contingent upon her satisfaction of the following requirements prior to November 13, 2021: (1) successfully complete a Board-approved pharmacy technician certification examination; (2) acquire 250 hours of updated and supervised practical experience under the authority of a special work permit; and (3) acquire 10 hours of ACPE-accredited technician-specific CPE.

Amber Mone Loup (PST.018248): In lieu of immediate administrative action on her August 2019 arrest for unlawful possession of CS, the Board accepted the voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective August 16, 2019.

Amy Rebecca Johnson (Douglass; Voorhees) (PST.021377): In lieu of immediate administrative action on her Louisiana license pursuant to action taken by the Texas State Board of Pharmacy on her Texas license for conduct, which also constitutes a basis for action against her Louisiana license, the Board accepted the voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective August 22, 2019.

Paige Marie Childers (CPT.013387): In lieu of administrative action pursuant to her November 2018 arrest for the diversion of hydrocodone and oxycodone by prescription forgery, the Board accepted the voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective September 9, 2019.

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April Latrice Vaughn (CPT.008865): For her diversion of CS from her employer pharmacy, the Board revoked the certificate, effective September 18, 2019, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Positudes, Inc, dba The Alliance Pharmacy (Westbury, NY) (PHY.006206): For its failure to disclose the January 2016 disciplinary action taken by the Hawaii State Board of Pharmacy on its November 2016 application for the renewal of its Louisiana permit despite specific questioning for such information, the Board assessed a fine of $5,000 plus administrative costs.

Keenan Mitchell Wheeler (CPT.010403): For his diversion of CS from his employer pharmacy, the Board revoked the certificate, effective October 18, 2019, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

George Lamar Munn, Jr (PST.009445): In lieu of immediate administrative action, the Board accepted the voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective October 22, 2019.

Chandler Evan Bennett Riley (PTC.027746): In lieu of immediate administrative action for his diversion of CS from his employer pharmacy, the Board accepted the voluntary surrender of the credential, resulting in the suspension of the registration for an indefinite period of time, effective November 13, 2019.

Renee Marie Mims (CPT.007313) – *Formal Hearing:* For her diversion of promethazine with codeine and tramadol by prescription forgery from her employer pharmacy, the Board revoked the certificate, effective November 14, 2019; and further, assessed a fine of $5,000 plus administrative, hearing, and investigative costs; and further, conditioned the acceptance of any application for the reinstatement of the certificate or for any other credential issued by the Board upon the satisfaction of the following terms: (1) shall have paid all assessments levied herein; (2) shall have no pending legal or disciplinary matters against her in any jurisdiction; and (3) shall have received a favorable recommendation for her return to the practice of pharmacy without posing a threat to the public's health, safety, or welfare pursuant to a medical evaluation from an addiction medicine specialist approved by the Board at her own expense.

Harold Scott Otwell (PST.015945) – *Formal Hearing:* For the revocation of his Arkansas pharmacist license by the Arkansas State Board of Pharmacy for conduct that also constitutes a basis for action against his Louisiana license, the Board revoked his Louisiana pharmacist license, effective November 14, 2019; and further, assessed a fine of $5,000 plus administrative, hearing, and investigative costs; and further, conditioned the acceptance of any future application for the reinstatement of the license or for any other credential issued by the Board upon the satisfaction of the following terms: (1) shall have paid all assessments levied herein; and (2) shall have all pharmacist licenses held in all other jurisdictions reinstated and without restrictions.

During the same meeting, the Board issued letters of reprimand to two pharmacies, one pharmacist, and seven pharmacy technicians.

Calendar Notes (20-01-628)

The Board office will be closed on January 20 for Martin Luther King, Jr Day, February 25 for Mardi Gras Day, and April 10 for Good Friday.

Special Note (20-01-629)

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.

Louisiana Lagniappe (20-01-630)

"Progress is impossible without change, and those who cannot change their minds cannot change anything." – George Bernard Shaw

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