July 2019

Louisiana Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

3388 Brentwood Drive • Baton Rouge, LA 70809-1700 • *www.pharmacy.la.gov*

Special Notice to PICs (19-07-608)

The Louisiana Board of Pharmacy has noticed a recent increase in the frequency with which pharmacists-in-charge (PICs) are abandoning their PIC positions in pharmacies without giving the required prior notice. While staff pharmacists only need to notify the Board within 10 days after their separation from a pharmacy, PICs shall give at least 10 days prior written notice to the owner of the permit **and** to the Board regarding their intent to relinquish the PIC position. The prior notice of a PIC intending to relinquish their PIC position must be sent to the Board via email, fax, or mail. Once the PIC has completed the requirements for a PIC change at a pharmacy, Board *Form No. 61: Notice of Change of Pharmacist-in-Charge (PIC)* must be completed, and a copy must be sent to the Board via email, fax, or mail.

If you need a refresher on the obligations of a PIC, the Board encourages you to visit the Pharmacy Resource Center on the Board's website at *www.pharmacy.la.gov.* The Board has directed staff to identify PICs who abandon their positions and fail to provide the required notice, and then refer them for disciplinary proceedings.

USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings (19-07-609)

The United States Pharmacopeial Convention (USP) published a new general chapter of standards relative to the handling of hazardous drugs in health care settings on June 1, 2019; those standards will become effective on December 1, 2019. During its May 29, 2019 meeting, the Board received a preliminary report from its Regulation Revision Committee relative to a proposal still under development to amend the Board's rules relative to the handling of hazardous drugs in pharmacies. The Board voted to delay its enforcement of the standards in USP General Chapter <800> until January 1, 2021, to provide time for the completion of the rulemaking activity.

Disciplinary Actions (19-07-610)

During its May 29-30, 2019 meeting and administrative hearing, the Board took action in the following matters:

Bocage Pharmacy Centre, Inc, dba Bocage Pharmacy Centre (Baton Rouge, LA) (CDS.039257): The Board granted its request for reinstatement of the previously suspended controlled substance (CS) license and restored the license to active and unrestricted status.

Michael Wayne Lindsey (PST.015624): The Board granted his request to reinstate the previously suspended license, contingent upon the satisfaction of certain requirements, converted the duration of the suspensive period from an indefinite term to a term of 15 years, and stayed the execution of the suspension, then placed the license on probation for 15 years, effective May 29, 2019, and subject to certain terms enumerated within the consent agreement.

Steve Khai Vu (PST.015586): The Board granted his request to reinstate the previously suspended license, contingent upon the satisfaction of certain requirements, converted the duration of the suspensive period from an indefinite term to a term of five years, and stayed the execution of the suspension, then placed the license on probation for five years, effective May 29, 2019, subject to certain terms enumerated within the consent agreement.

Todd Michael Durham (PST.016962): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective May 29, 2019.

David Collins Evans (PST.014181): The Board granted his request to reinstate the previously suspended license, contingent upon the satisfaction of certain requirements, converted the duration of the suspensive period from an indefinite term to a term of 15 years, and stayed the execution of the suspension, then placed

continued on page 4

National Pharmacy Compliance News

July 2019

NABPF
National Association of Boards of Pharmacy Foundation

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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

continued from page 1

the license on probation for 15 years, effective May 29, 2019, subject to certain terms enumerated within the consent agreement.

Destiny Araine Woolfolk (CPT.010453): For her repeated failures to disclose criminal history information on her renewal applications for her certificate despite specific questioning for such information, the Board suspended the certificate for one year and stayed the execution of the suspension, then placed the certificate on probation for one year, effective May 29, 2019, subject to certain terms enumerated within the consent agreement.

Walgreen Co, Inc, dba Walgreen Pharmacy No. 110-02995 (Baton Rouge) (PHY.002868): For permitting a person with an expired pharmacy technician candidate registration to continue to practice for approximately three weeks until discovered during a pharmacy inspection, the Board assessed a fine of $10,000 plus administrative and investigative costs.

Noah's Pharmacy, LLC, dba Noah's Pharmacy (Brusly, LA) (PHY.006145): (Case No. 2018-364) For its failure to maintain a perpetual inventory of CS, in violation of the terms of its February 2018 Probation Board Order, the Board suspended the permit for five years and stayed the execution of the suspension, then placed the permit on probation for five years, effective May 29, 2019, subject to certain terms enumerated within the consent agreement; and further, assessed administrative and investigative costs. **(Case No. 2019-24)** For its repeated failure to correct multiple erroneous reports to the state prescription monitoring program (PMP) when requested by the PMP staff, and for its failure to report 43 days of eligible prescription transactions to the PMP, the Board assessed a fine of $5,000 plus administrative and investigative costs.

Gaylyn Elizabeth Bellaire (PST.014692): For her failure as the PIC of Noah's Pharmacy in Brusly to maintain a perpetual inventory of CS as required by the pharmacy's February 2018 Probation Board Order, the Board restricted her license by prohibiting her from serving as a PIC of any pharmacy until May 29, 2020; and further, assessed a fine of $500 plus administrative costs.

Kimberly Juanita Murphy (PST.016122): For her failure as the owner of Noah's Pharmacy in Brusly to comply with the terms of the pharmacy's February 2018 Probation Board Order, the Board suspended the license for five years, and stayed the execution of the suspension, then placed the license on probation for five years, effective May 29, 2019, subject to certain terms enumerated within the consent agreement; and further, assessed a fine of $7,500 plus administrative costs.

Lato Drug Co, Inc, dba Post Haste Pharmacy (Hollywood, FL) (PHY.006650): For its failure to report all eligible dispensing transactions to the state PMP, and for its failure to operate the pharmacy with a Louisiana-licensed PIC for approximately six months, the Board assessed a fine of $15,000 plus administrative and investigative costs.

Winn Dixie Stores, Inc, dba Pathstone Health Services (Jacksonville, FL) (PHY.007203): For its failure to operate the pharmacy with a Louisiana-licensed PIC for approximately 11 months and for its failure to timely pay its Medical Assistance Trust Fund payments to the state health department, the Board assessed a fine of $12,500 plus administrative and investigative costs.

Leslie Dominique Threatts (CPT.014040): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective March 21, 2019.

Pharmcore, Inc, dba Hallandale Pharmacy (Fort Lauderdale, FL) (PHY.007866): For its dispensing of approximately 65 prescriptions into Louisiana without a Louisiana pharmacy permit, the Board assessed a fine of $10,000 plus administrative costs.

Robert Brent Clevenger (PST.021999): In recognition of the probationary period imposed on his Alabama pharmacist license by the Alabama State Board of Pharmacy for professional conduct that constitutes a basis for action against his Louisiana pharmacist license, the Board suspended his Louisiana license for four years, nine months, and 20 days, and stayed the execution of the suspension, then placed the license on probation for four years, nine months, and 20 days, effective May 29, 2019, subject to certain terms, noting the probationary period is scheduled to proceed concurrently with the probationary period imposed by the Alabama State Board of Pharmacy.

Nguyet Anh Thi Nguyen (CPT.006154): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective April 22, 2019.

Pharmaceutical Specialties, Inc, dba Hoye's Pharmacy (Tampa, FL) (PHY.007496): For its dispensing of approximately two prescriptions into Louisiana with an expired Louisiana nonresident pharmacy permit, the Board assessed a fine of $5,000 plus administrative costs.

continued on page 5

continued from page 4

Whitney Nicole Cantrelle (PST.021219): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective April 29, 2019.

Tiffani Lauren Burnaman (CPT.010443) – *Formal Administrative Hearing:* For her failure to disclose her October 2017 arrest on her June 2018 application for the renewal of her certificate, and for her failure to provide information about that arrest in response to the Board's specific request for that information, the Board suspended her certificate for an indefinite period of time, effective May 30, 2019; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the certificate upon the satisfaction of certain requirements identified within the hearing order.

Jonnesha D'Shae London (PTC.024692) – *Formal Administrative Hearing:* For her misrepresentation of the status of her registration during an inspection of the pharmacy where she was discovered practicing with an expired registration, the Board suspended her registration for an indefinite period of time, effective May 30, 2019; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application upon the satisfaction of certain requirements identified within the hearing order.

During the same meeting, the Board issued letters of reprimand to three pharmacists, two pharmacy technicians, and one pharmacy, as well as a letter of warning to one pharmacist.

The Board approved applications for reinstatement of lapsed credentials from two pharmacy technicians, contingent upon the satisfaction of certain requirements identified within the consent agreement.

Calendar Notes (19-07-611)

The Board office will be closed on July 4 in observance of Independence Day and on September 2 for Labor Day.

Special Note (19-07-612)

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. The Board encourages you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference. Electronic copies dating back to 2000 are posted on the Board's website.

Louisiana Lagniappe (19-07-613)

"Every artist was first an amateur." – Ralph Waldo Emerson

The *Louisiana Board of Pharmacy News* is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Malcolm J. Broussard, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager