January 2019

Louisiana Board of Pharmacy News

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Board Elects Officers for Calendar Year 2019 (19-01-590)

During their November 14, 2018 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 2019 (19-01-591)

The Board has announced the first meeting of the year will be held on February 18-19 at the University of Louisiana at Monroe. In addition, the Board announced the following tentative dates for the rest of the calendar year: May 28-30, August 13-15, and November 12-14. All meetings are planned to be held at the Board office in Baton Rouge, LA.

Are You an Immunizer? Know the Site and Get it Right (19-01-592)

As mass flu vaccination campaigns are occurring, now is a great opportunity to ensure staff who provide vaccines know how to do them correctly. The Immunization Services Division of Centers for Disease Control and Prevention (CDC) has developed tools to educate and remind providers about proper flu vaccine administration techniques to help avoid shoulder injuries and other adverse events. The materials include comprehensive vaccine administration information, a short video on the correct technique for intramuscular injection, an infographic on administering a flu vaccine to an adult, and a link to CDC's Vaccine Administration e-Learn, which provides continuing education units.

Board Member Nomination Election (19-01-593)

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 a pharmacist from that district 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 ballot or another enclosed communication will state the date, time, and place for counting the ballots. At a gathering open to the public, the Board's 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 receiving the highest number of votes. The governor may appoint one of those nominees to the Board.

The term of one current member of the Board – Ms Diane G. Milano, representing District 1 – will expire on June 30, 2019. The deadline for any address changes relative to this nomination election for District 1 is March 8, 2019. The ballots with the necessary information will be mailed to the pharmacists in District 1, which is composed of the parishes of Jefferson and St Tammany, on or about March 18, 2019. The deadline for the return of the ballots to the Board office is April 19, 2019. The ballots will be opened and counted at the Board office on April 23, 2019; information about the exact time will be included with the ballot.

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 appointee's term will be June 30, 2025.

Reporting Changes of Mailing Address and Pharmacy Employment (19-01-594)

During its November 14, 2018 meeting, the Board took note of the apparently widespread noncompliance with the law and rule that requires pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates to report changes in their mailing address and pharmacy employment, in writing, no later than 10 days following such changes. The Board instructed staff to develop a proposal describing the sanctions that will be

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National Pharmacy Compliance News

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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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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applied when staff discovers noncompliance with the rules. As a gentle reminder, the Board's *Form No. 90 ~ Notification of Change in Mailing Address or Employment* is designed to help you comply with this requirement. The form is available in the Forms & Applications section of the Board's website at *www.pharmacy.la.gov.*

Advisory Opinions and Guidance Documents (19-01-595)

During its November 14, 2018 meeting, the Board issued advisory opinions and guidance documents on multiple topics, including the following:

- Joint Accreditation for Interprofessional Continuing Education – this opinion recognizes continuing education (CE) activities with the Joint Accreditation credit mark as valid to substantiate compliance with CE requirements for pharmacists and technicians.
- Recordkeeping Requirements for Written Prescription Forms Received in Pharmacies by Facsimile or Electronic Images – this opinion clarifies the Board's intent for such forms that they may be stored electronically and are not required to be printed and maintained in hard copy form merely for record keeping purposes.
- Compounding of Drugs by Nurses – this opinion addresses the emergent preparation of medication for immediate use, where waiting for a pharmacist to compound such medication might not be in the patient's best interest.
- Guidance Information re Cannabidiol (CBD) Oil – this guidance document was issued in response to the many requests for the legal status of CBD oil products and the retail sale of such products.

All of these advisory opinions and guidance documents can be found on the Board's website by following the Public Library link on the horizontal menu bar and selecting Declaratory Statements, Advisory Opinions & Policy Statements.

Disciplinary Actions (19-01-596)

During its November 14-15, 2018 meeting and administrative hearing, the Board took action on the following matters:

Tonisha Re'nette Sanders (CPT.011400): For her participation in a pre-trial diversion program subsequent to her arrest and sentencing for unlawful possession of a controlled substance (CS) listed in Schedule I, the Board suspended her certificate and stayed the execution of the suspension, then placed the certificate on probation for one year effective November 14, 2018, subject to certain terms enumerated within the consent agreement; and further, assessed a fine of $250 plus administrative costs.

Thrift Clinic Pharmacy on Union, LLC, dba Thrift Clinic Pharmacy on Union (Opelousas, LA) (PHY.006398): For the failure to obtain a new pharmacy permit and state CS license when the ownership of the pharmacy changed by more than 50% in December 2015, and for the continued operation of the pharmacy with an invalid pharmacy permit and invalid state CS license until May 2018, the Board assessed a fine of $7,500 plus administrative and investigative costs.

Germ's Thrift Clinic Pharmacy, LLC, dba Germ's Thrift Clinic Pharmacy (Opelousas) (PHY.007705): For the failure to obtain a new pharmacy permit and state CS license when the pharmacy was purchased from the previous owner in December 2015, and for the continued operation of the pharmacy with an invalid pharmacy permit and invalid state CS license until May 2018, the Board assessed a fine of $7,500 plus administrative and investigative costs.

Matthew John Guarisco (PST.014303): The Board granted his request for release from a previously executed agreement to refrain from practice, suspended the license for five years and stayed the execution of the suspension, then placed the license on probation for five years effective November 14, 2018, subject to certain terms enumerated within the consent agreement.

Nancy Lynn Odom Fontenot (PST.014796): The Board granted her request for reinstatement of the previously suspended license, contingent upon the completion of at least 200 hours of supervised practice under the authority of a special work permit; and further, the Board converted the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension; and then placed the special work permit and subsequently reinstated license on probation for five years, effective on the date of issuance of the special work permit, subject to certain terms enumerated within the consent agreement.

Lauren Moore Caldwell (PST.020057): The Board granted her request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of two years, and stayed the execution of the suspension, then placed the license on probation for two years effective November 14, 2018, subject to certain terms enumerated within the consent agreement.

Jeffery Charles Pierre (PST.020332): The Board granted his request for reinstatement of the previously suspended license, 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 November 14, 2018, subject to certain terms enumerated within the consent agreement.

Lauren Ruffino Etienne (PST.019969): The Board granted her request for reinstatement of the previously suspended license, 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 November 14, 2018, subject to certain terms enumerated within the consent agreement.

Tiffany Cathleen Luse Upshaw (PST.018936): The Board granted her request for early termination of the probationary period originally scheduled to conclude in November 2019, removed all probationary terms, and then restored the license to active and unrestricted status.

Amanda Schubert Balli (PST.019454): The Board denied her request to terminate the probationary period. However, it did remove Article 2-e from her November 2017 Probation Order, which had prevented her from accepting an appointment as the pharmacist-in-charge (PIC) of a pharmacy; and further, all remaining probationary terms shall continue in effect.

Scott Nolan Gewin (PST.017104): The Board granted his request for modification of previous orders, then removed

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Article 2-e from his May 2014 Probation Order, which had prevented him from accepting an appointment as the PIC of a pharmacy. However, all remaining probationary terms shall continue in effect.

Thadrian Marquis Johnson (PST.013542): The Board granted her request for modification of previous orders, then removed Article 5-e from her February 2015 Probation Order, which had prevented her from accepting an appointment as the PIC of a pharmacy. However, all remaining probationary terms shall continue in effect.

Henry Ford Pharmacy Advantage Southfield, dba Henry Ford Pharmacy Southfield Advantage (Rochester Hills, MI) (PHY.007154): For continuing to dispense prescriptions into Louisiana after its Louisiana pharmacy permit expired on December 31, 2017, and for dispensing approximately 17 prescriptions into the state from January 2018 until the discovery thereof in August 2018, the Board assessed a fine of $5,000 plus administrative costs.

Steve Khai Vu (PST.015586): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time effective September 10, 2018.

Laurie Bonin Warf (CPT.002632): For her termination by her employer pharmacy (St Martin Pharmacy), for her alleged diversion of CS from that pharmacy, the Board revoked her certificate effective September 12, 2018; and further, permanently prohibited the acceptance of any application for the reinstatement of the certificate or for any other credential issued by the Board.

Danyel Deone D'Shay Wilson (CPT.011347): For her termination by her employer pharmacy (Walmart No. 10-7233), for her alleged diversion of CS from that pharmacy by means of a forged prescription, the Board revoked her certificate effective October 3, 2018; and further, permanently prohibited the acceptance of any application for the reinstatement of the certificate or for any other credential issued by the Board.

Nakia Richelle Lockett (CPT.012426): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time effective October 9, 2018.

Bailey Nicole Bel (CPT.011146): For her termination by her employer pharmacy (John's Pharmacy), for her alleged diversion of hydrocodone from that pharmacy, the Board revoked her certificate effective October 12, 2018; and further, permanently prohibited the acceptance of any application for the reinstatement of the certificate or for any other credential issued by the Board.

Bocage Pharmacy Centre, Inc, dba Bocage Pharmacy Centre (Baton Rouge) (CDS.039257-PHY): Pursuant to the surrender of its federal Drug Enforcement Administration registration, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the state CS license for an indefinite period of time effective October 30, 2018.

Latasha Monique King (CPT.008866) – *Formal Administrative Hearing:* The Board denied her request for reinstatement of the previously suspended certificate; and further, prohibited any future application for the reinstatement of the certificate until November 1, 2020; and further, assessed administrative costs as well as administrative hearing costs.

Bryanna Danae' Wilridge (PTC.025764) – *Formal Administrative Hearing:* For her admission to the theft of hydrocodone from her employer pharmacy (Walgreens Pharmacy No. 5747), the Board revoked her registration effective November 15, 2018; and further, assessed administrative, investigative, and hearing costs.

Kathryn Elizabeth Hutchings (PTC.026695) – *Formal Administrative Hearing:* For her admission to the theft of alprazolam, clonazepam, and oxycodone from her employer pharmacy (Walgreens Pharmacy No. 15571), the Board revoked her registration effective November 15, 2018; and further, assessed administrative, investigative, and hearing costs.

During the same meeting, the Board issued letters of reprimand and assessed fines to seven pharmacy technicians who failed to disclose prior criminal or disciplinary action despite specific questioning for such information on their applications for renewal of their certificates. The Board also issued a letter of reprimand and assessed a fine to one pharmacy permit for continuing to dispense prescriptions into the state with an expired pharmacy permit.

The Board approved a request from one pharmacist to return a voluntary inactive license to active status. Finally, it approved applications for reinstatement of lapsed credentials from two pharmacy technicians, contingent upon the satisfaction of certain requirements identified within their consent agreements.

Calendar Notes (19-01-597)

The Board office will be closed on January 21 in observance of Martin Luther King, Jr Day and March 5 for Mardi Gras Day.

Special Note (19-01-598)

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 (19-01-599)

"Opportunity is missed by most people because it is dressed in overalls and looks like work." – Thomas A. Edison

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