January 2018

Louisiana Board of Pharmacy News

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Board Elects Officers for 2018 (18-01-559)

During the November 15, 2017 Louisiana Board of Pharmacy meeting, Board members conducted their annual election of officers, with the following results:

- President – Carl W. Aron, from Monroe, LA, in District 5
- First Vice President – T. Morris Rabb, from Monroe, in District 5
- Second Vice President – Marty R. McKay, from Woodworth, LA, in District 8
- Third Vice President – Chris B. Melancon, from Carencro, LA, in District 7
- Secretary – Brian A. Bond, from Jena, LA, in District 8

Board Meeting Dates for Calendar Year 2018 (18-01-560)

The Board has announced the first meeting of the year will be held on February 21-22, as well as the following tentative dates for the rest of the calendar year: May 23-24, August 15-16, and November 14-15. All meetings are planned to be held at the Board office in Baton Rouge, LA.

Board Member Appointments (18-01-561)

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 their 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 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, 2018. The deadline for any address changes relative to this nomination election is March 9, 2018. The ballots with the necessary information will be mailed to the pharmacists in the respective pharmacy districts on or about March 20, 2018. The deadline for the return of the ballots to the Board office is April 20, 2018. The ballots will be opened and counted at the Board office on April 24, 2018; information about the exact time will be included with the ballot.

Board member terms that will expire on June 30, 2018, and their district information are as follows:

- **Blake P. Pitre:** Houma, LA (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).
- **Rhonny K. Valentine:** Mansfield, LA (District 4, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster).
- **T. Morris Rabb:** Monroe (District 5, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll, and Winn).
- **Chris B. Melancon:** Carencro (District 7, composed of the parishes of Acadia, Calcasieu, Cameron, Jefferson Davis, Lafayette, and Vermilion).
- **Brian A. Bond:** Jena (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 pharmacist member six-year terms was fixed by the Louisiana State Legislature in 2012; therefore, the expiration date of the new appointees' terms will be June 30, 2024.

Prescriptions for Opiate Medications (18-01-562)

As you should know, the 2017 Louisiana State Legislature adopted multiple laws concerning the prescribing and dispensing of prescriptions for opiate medications. The Board previously described these new laws in *Bulletin No. 17-01,* which was distributed on July 15, 2017, and also may be found on the Board's website in the Public Library section at *www.pharmacy.la.gov.*

The Board office continues to receive information from a variety of sources indicating some pharmacists have misinterpreted the new law relative to the quantity limits on prescriptions for opiate medications. Act 82 of the 2017 Legislature imposed a seven-day supply limit on the issuance of prescriptions for opiate medications issued to adults in outpatient settings with acute medical

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National Pharmacy Compliance News

January 2018

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 Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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conditions. However, that law also waived the seven-day supply limit in four situations:

- For the treatment of chronic pain;
- For the treatment of pain associated with a cancer diagnosis or palliative care;
- When the medication is designed for the treatment of substance abuse or opioid dependence; or
- When the prescriber's professional judgment dictates more than a seven-day supply is required to treat the patient's acute medical condition.

It is the last of these four exceptions that some pharmacists seem to have forgotten. When a prescriber has exercised that professional judgment in issuing a prescription for more than a seven-day supply and the pharmacist refuses to dispense more than a seven-day supply merely because of "a new law," it would appear the pharmacist has inappropriately substituted his or her judgment for that of the prescriber. It is important to remember the seven-day limit is directed to the prescriber and not the dispenser.

Status Report on Rulemaking Activities (18-01-563)

The Board completed two regulatory projects that became effective on January 1, 2018.

Regulatory Project 2015-9 ~ Pharmacy Technicians. This project amended several sections of Chapter 9 – Pharmacy Technicians of the Board's rules.

- There are now three eligibility options for pharmacy technician candidate (PTC) registration.
  1. Proof of enrollment in a nationally-accredited and Board-approved pharmacy technician training program;
  2. Proof of completion of a high school approved by a state department of education, plus proof of successful completion of a Board-approved technician certification examination; **or**
  3. Proof of credentialing as a pharmacy technician by another state board of pharmacy, plus proof of practice as a pharmacy technician for at least one year in that state, plus proof of successful completion of a Board-approved technician certification examination.
- The PTC registration is now valid for 24 months instead of the previous 18 months, but it is still not renewable.
- To qualify for the pharmacy technician certificate, the applicant must demonstrate practical experience as well as successful completion of a Board-approved technician certification examination.
  a. The amount of practical experience depends on how the candidate obtained his or her PTC registration. If the registration was obtained on the basis of enrollment in an accredited training program, the candidate must obtain the number of hours prescribed by the program's curriculum. If the registration was obtained on any other basis, the candidate must obtain at least 600 hours in a pharmacy in Louisiana.
  b. The Board now recognizes two pharmacy technician certification examinations: the test administered by the Pharmacy Technician Certification Board (PTCB) since January 2000 and the Exam for the Certification of Pharmacy Technicians (ExCPT) administered by the National Healthcareer Association since January 2018. PTCB tests taken prior to January 2000 and ExCPT tests taken prior to January 2018 are not valid.
- Another change in the rule was to the section on scope of practice. Pharmacy technicians are no longer prohibited from compounding high-risk sterile preparations as defined by United States Pharmacopeia.
- Finally, the continuing education (CE) rule was amended to require technicians to maintain their CE records through CPE Monitor®, a collaborative service provided by the National Association of Boards of Pharmacy® and the Accreditation Council for Pharmacy Education (ACPE).

Regulatory Project 2017-1 ~ Pharmacy Internship Requirements. This project amended two sections of Chapter 7 – Pharmacy Interns of the Board's rules.

- Intern registrations issued to students enrolled in ACPE-accredited schools of pharmacy will continue to expire one year after the date of graduation; however, intern registrations issued to foreign pharmacy graduates now expire two years after the date of issuance.
- The amount of professional experience required for licensure was increased from 1,500 hours to 1,740 hours, which is consistent with contemporary pharmacy school accreditation standards.
- The requirement for preceptors of pharmacy interns to be licensed pharmacists was amended to allow the use of licensed practitioners such as physicians, as long as their professional license is not on probation.
- The amount of credit awarded by the Board for professional experience programs in schools of pharmacy increased from 1,000 to 1,740. The effect of this change is that students will no longer be required to earn hours of experience separate and apart from their curriculum.
- In the event an applicant for pharmacist licensure is unable to demonstrate the 1,740 hours with a pharmacy school dean's certificate of graduation, then the applicant must demonstrate 1,740 hours of pre-licensure practical experience in a licensed pharmacy.
- Finally, hours of practical experience credited by the Board now expire two years after the expiration date of the intern registration, instead of the previous one year.

Disciplinary Actions (18-01-564)

During its November 15-16, 2017 meeting and administrative hearing, the Board took final action in the following matters:

Marsheka LaShun Bailey (Applicant for PTC Registration): For her failure to disclose the entirety of her arrest records on her application, the Board denied the application and refused to issue the registration.

Yashcia Sherell Hamilton (PTC.026248): In consideration of her criminal history disclosed on her application for PTC registration, the Board authorized the issuance of the registration, suspended it for 18 months and stayed the execution of the suspension, then placed it on probation for 18 months, effective November 16, 2017, subject to certain terms enumerated in the consent agreement.

Walgreen La Co, Inc, dba Walgreen Pharmacy No. 4998 (Shreveport, LA) (PHY.004176): For its dispensing of five prescriptions for Schedule II controlled substances (CS) that were ultimately determined to be forgeries, and for its failure to maintain those prescriptions in a readily retrievable format, the Board ordered the performance of an inventory reconciliation audit of all CS in the pharmacy for the one-year period beginning June 9, 2016 (performance of which was acknowledged by the Board), and further, assessed a fine of $5,000 plus administrative and investigative costs.

Gregory Tyrome Sweet (PST.019579): As the pharmacist-in-charge of Walgreen Pharmacy No. 4998 in Shreveport, for his

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failure to maintain CS prescriptions in a readily retrievable format, the Board ordered the acquisition of at least six hours of ACPE-accredited pharmacist-specific CE relative to the proper dispensing of CS prescriptions, and further, issued a letter of reprimand and ordered its publication in this *Newsletter,* and further, assessed administrative costs.

Laura Kaye Brantley (CPT.004700): In lieu of immediate administrative action on pending allegations, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective June 16, 2017.

Louisiana Medical Center & Heart Hospital, LLC, dba Louisiana Medical Center & Heart Hospital (Lacombe, LA) (PHY.006464): For its failure to properly close the pharmacy permit, the Board revoked the permit, effective November 15, 2017, and further, assessed administrative and investigative costs.

Danny Roy Myers (PST.018776): Board granted his request for reinstatement of the previously relinquished license, suspended it for nine years plus two days and stayed the execution of the suspension, then placed the license on probation for nine years plus two days, effective November 15, 2017, subject to certain terms enumerated in the consent agreement, noting the probationary period is to run concurrently with the probationary period previously ordered by the Mississippi Board of Pharmacy on his Mississippi pharmacist license.

Charles Paul Guidry (PST.020067): 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 15, 2017, subject to certain terms enumerated in the consent agreement.

Amanda Schubert Balli (PST.019454): Board suspended the license for five years and stayed the execution of the suspension, then placed the license on probation for five years, effective November 15, 2017, subject to certain terms enumerated in the consent agreement.

Sumitra B. Patel (PST.010943): Board denied her petition to return her voluntary inactive license to active status, and further, conditioned the acceptance of any future such petition upon the satisfaction of certain requirements identified in the consent agreement.

Christina Marshall Buhrman (PST.017495): In consideration of the probationary period imposed by the Maryland Board of Pharmacy on her Maryland pharmacist license for violation of that state's standards for the compounding of sterile preparations, noting such actions constitute a basis for action in this state, the Louisiana Board suspended the Louisiana pharmacist license for one month plus 13 days and stayed the execution of the suspension, then placed the license on probation for one month plus 13 days, subject to certain terms enumerated in the consent agreement, noting the probationary period is to run concurrently with the probationary period ordered by the Maryland Board of Pharmacy on her Maryland pharmacist license.

McKesson Corporation (Livonia, MI) (CDS.031429-DIS): In consideration of the suspension of its federal CS registration by the United States Drug Enforcement Administration (DEA), the Louisiana Board suspended the distributor's CS license until January 17, 2019, subject to certain terms enumerated in the consent agreement.

McKesson Corporation (Washington Court House, OH) (CDS.023883-DIS): In consideration of the suspension of its federal CS registration by DEA, the Board ordered the suspension of the distributor's CS license from January 18, 2019, through January 18, 2021.

Hailey Chyene Pittman (PTC.025001): In lieu of immediate administrative action on pending allegations, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the registration for an indefinite period of time, effective August 28, 2017.

Gina Maria Picone (PST.016021): In lieu of immediate administrative action on pending allegations, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective October 26, 2017.

Samantha Lee Landry (PTC.026251) – *Formal Hearing:* In consideration of the criminal history disclosed on her application for PTC registration, the Board authorized the issuance of the registration, then suspended it for an indefinite period of time and stayed the execution of the suspension, then placed the registration on probation for an indefinite period of time, effective November 17, 2017, and terminating on the expiration or cancellation of the registration, whichever shall occur first.

During the same meeting, the Board issued a letter of warning to one pharmacy and a letter of reprimand to one pharmacy. In addition, the Board granted one request from a pharmacist for modification of previously imposed probationary terms and denied one request from a pharmacist for modification of previously imposed probationary terms.

Calendar Notes (18-01-565)

The Board office will be closed on January 15 in observance of Martin Luther King, Jr Day, February 13 for Mardi Gras Day, and March 30 for Good Friday.

Special Note (18-01-566)

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 (18-01-567)

"If the blind lead the blind, both shall fall into the ditch." – *The Bible,* Matthew 15:14

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