



Louisiana Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Board Members (18-10-583)

The terms of five members of the Louisiana Board of Pharmacy expired on June 30, 2018. Governor John B. Edwards reappointed two members and named three new members to the Board.

- ◆ For District 3, Mr Blake P. Pitre, from Houma, LA, was reappointed to another term.
- ◆ For District 4, Mr Rhonny K. Valentine, from Natchitoches, LA, was reappointed to another term.
- ◆ For District 5, Mr J. Robert Cloud, from Chatham, LA, was appointed to replace Mr T. Morris Rabb, from West Monroe, LA, who completed 22 years of service to the Board.
- ◆ For District 7, Mr Kevin LaGrange, from Lafayette, LA, was appointed to replace Ms Chris B. Melancon, from Carencro, LA, who completed 12 years of service to the Board.
- ◆ For District 8, Mr Robert C. LeBas, from Opelousas, LA, was appointed to replace Mr Brian A. Bond, from Jena, LA, who completed 18 years of service to the Board.

The Board extends its appreciation to the three alumni members for their collective 52 years of service to the Board, and welcomes the new members. The terms for all five members appointed will expire on June 30, 2024.

Renewal Time for Pharmacists and Pharmacies (18-10-584)

The renewal cycle for pharmacist licenses, pharmacy permits, and controlled dangerous substance (CDS) licenses for pharmacies will open on November 1, 2018. Just prior to that date, you should receive a reminder notice from the Board office; the mailer will remind you of the following three options to renew your credentials:

1. Visit the Board's website at www.pharmacy.la.gov to renew your credentials online using the username and password printed on your reminder notice and a credit card for payment of the fee;
2. Visit the same website to download and print an application form, then complete and mail the application form with the appropriate fee, using a check or money order, to the Board office; or
3. Send a written request to the Board office (mail, fax, or email) with your name, credential number, and mailing address, requesting the Board to mail an application form to you.

Any address changes received at the Board office after Friday, October 19, 2018, will not be reflected on your renewal reminder. In the event the postal service fails to deliver your reminder mailer by November 15, 2018, then it becomes your responsibility to retrieve an application form on the Board's website or renew your credentials online. Credentials renewed online will be mailed within one or two business days; credentials renewed with paper application forms will be mailed within two to four weeks, depending on the volume of paper applications received.

The online renewal module on the Board's website is programmed to automatically activate at 12:01 AM on November 1, 2018, and to automatically deactivate at midnight on December 31, 2018. While the Board makes every effort to maintain the online convenience during the renewal cycle, the Board's service provider may experience weather-related or other unforeseen technical difficulties from time to time. Such service disruptions have already happened more than once during the several years the Board has been offering the online option, including on the final day of the renewal cycle.

You have 60 days to renew your credential, and it is your choice as to when you complete that duty. In the event you choose to wait until the last day and the website is not available, then you will be responsible for the consequences of your failure to renew your credential in a timely manner. The Board does not waive the penalty fees in that situation. Why take a chance? Please do not wait until the last minute of the last day.

In the event that you elect to use or you are required to use paper application forms, the Board suggests that you submit your completed application forms and fees to the Board office no later than December 1, 2018 – especially if you require a renewed license on or before January 1, 2019. Please do not forget to answer all the questions and sign and date the application form. If the forms are incomplete, or if there is no supporting documentation when required, the Board may return the application form to you, resulting in a delay in the renewal of your credential.

As required by Act 298 of the 2015 Louisiana Legislature, the Board is required to assess the pharmacy education support (PES) fee of \$100 on the renewal of every pharmacist license and pharmacy permit issued by the Board. The law also provides an option for the pharmacist and pharmacy to decline to pay the fee. You will notice the default position is for the fee to be included on your invoice; you must "opt out" if you wish to decline to pay the PES fee.

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National Pharmacy Compliance News

October 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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder*. The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*, which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at www.samhsa.gov.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, will help to:

- ◆ ensure that compounded drugs are made under appropriate quality standards;
- ◆ provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and

- ◆ respond to stakeholder feedback requesting guidance on the meaning of “facility” under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, “Four more EU Member States benefit from EU-US mutual recognition agreement for inspections,” can be found in the News and Events section at www.ema.europa.eu.

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration’s ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, www.hhs.gov/opioids, with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at www.surgeongeneral.gov.

Expanding Pharmacists’ Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention’s (CDC’s) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services*, describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC’s DHDSP can be found at www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability*, FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists’ unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ◆ consider how to most effectively use the skills of the staff and personnel available;
- ◆ provide and seek training where needed; and
- ◆ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP’s report and news release can be located at www.fip.org/news_publications.

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, “Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017,” can be accessed at <http://dx.doi.org/10.15585/mmwr.mm6709e1>.

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If it is important for you to know when your paper application forms are received at the Board office, the Board suggests you use a mailing service with tracking options, eg, United States Postal Service, FedEx, DHL, or United Parcel Service. This year, the Board anticipates the renewal of approximately 12,000 credentials in this two-month renewal cycle. Due to the volume of mail, the Board may not be able to respond in a timely manner to requests for delivery confirmation.

- ◆ Current pharmacist licenses expire at midnight on December 31, 2018. There is no “grace period” and a pharmacist shall not practice with an expired license.
- ◆ The fee for the timely renewal of a pharmacist license is \$100. Unless opted out, the PES fee of \$100 will be added to the total cost. The renewal of an expired license will incur a 50% penalty fee of \$50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, then a \$200 reinstatement fee will also be required.

Please remember that the pharmacy permit and CDS license for the pharmacy are separate credentials and must be renewed on separate application forms. There is no change in the fee, and you may write one check for one or more credentials, but the application forms are separate. In the event you send in multiple applications with one check and there is a problem with one of the applications, then all of the applications covered by that check will be delayed until all of the applications paid for with that check can be processed.

If renewing online, those credentials have separate application forms and are available for access at the same time. Both forms must be completed in order to renew both credentials. You can elect to renew and pay for them in separate transactions or, alternatively, you may place both applications on the same invoice prior to payment.

- ◆ Current pharmacy permits and CDS licenses for pharmacies expire at midnight on December 31, 2018. There is no “grace period” and a pharmacy shall not operate with an expired permit or CDS license. Recent history reveals the usual fine for this violation is \$5,000.
- ◆ The fee for the timely renewal of a pharmacy permit is \$150, which includes the \$25 prescription monitoring program assessment. Unless opted out, the PES fee of \$100 will be added to the total cost. The renewal of an expired permit will incur a 50% penalty fee of \$62.50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, a \$200 reinstatement fee will also be required.
- ◆ The fee for the timely renewal of a CDS license for a pharmacy is \$25. The renewal of an expired CDS license for a pharmacy will incur a 50% penalty fee of \$12.50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, a \$200 reinstatement fee will also be required.

Pharmacist Responsibility (18-10-585)

If you are the pharmacist-in-charge (PIC) of a pharmacy, it is your responsibility to ensure that all personnel you allow to perform professional functions in your pharmacy are properly credentialed with an active and current credential. If you are a

staff pharmacist or a relief pharmacist, it is your responsibility to ensure that all personnel you allow to assist you in the pharmacy are properly credentialed with an active and current credential. Remember that you can verify the status of any credential on the Board’s website.

In the event a compliance officer discovers anyone performing professional functions without the necessary credentials, all of the pharmacists present, as well as the PIC, will be identified in the resulting investigative report filed by the compliance officer. Further, in the event of a formal inquiry by the Board, all of those pharmacists identified will bear the risk of potential disciplinary action for aiding and abetting the unlicensed practice of pharmacy.

Disciplinary Actions (18-10-586)

During its August 15, 2018 meeting and administrative hearing, the Board took action in the following matters:

Winn Dixie Montgomery, LLC, dba Winn Dixie Pharmacy No. 1446 (Mandeville, LA) (PHY.006557): For its failure to comply with the Board’s rules for the permanent closure of a pharmacy, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Winn Dixie Montgomery, LLC, dba Winn Dixie Pharmacy No. 1411 (Metairie, LA) (PHY.006538): For its failure to comply with the Board’s rules for the permanent closure of a pharmacy, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Winn Dixie Montgomery, LLC, dba Winn Dixie Pharmacy No. 1448 (Covington, LA) (PHY.006533): For its failure to comply with the Board’s rules for the permanent closure of a pharmacy, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Intrathecal Compounding Specialists, LLC, dba Intrathecal Compounding Specialists (Scott, LA) (PHY.005856 – Case No. 17-0365): Pursuant to an inspection by the federal Food and Drug Administration in November 2017, as well as subsequent inspections by the Board for its failure to comply with the Board’s rules for the compounding of sterile and nonsterile preparations, the Board assessed a fine of \$50,000 plus administrative and investigative costs; and further, revoked the permit upon issuance of a new pharmacy permit pursuant to the pending application for same. **(Case No. 18-0190):** For its failure to obtain a new pharmacy permit and state controlled substance (CS) license when its ownership changed by more than 50% in December 2013, and for its continued operation with an invalid pharmacy permit and an invalid state CS license from January 2014 to August 2018, the Board assessed a fine of \$25,000 plus administrative and investigative costs.

Stuart Hall Burgess (PST.013189): As the PIC of Intrathecal Compounding Specialists in Scott, LA, for his failure to comply with the Board’s rules for the compounding of sterile and nonsterile preparations, and for his failure to properly supervise a pharmacy technician in the compounding process, the Board suspended the license for one year and stayed the execution of the suspension, then placed the license on probation for one year effective August 15, 2018, subject to certain terms enumerated in the consent agreement; and further, assessed a fine of \$5,000 plus administrative costs.

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LMC Medical Supplies, Inc, dba LMC Pharmacy (Boca Raton, FL) (PHY.006903): For its failure to designate a replacement PIC in a timely manner and for the continued operation of a pharmacy permit for approximately four months without a Louisiana-licensed PIC, the Board assessed a fine of \$10,000 plus administrative costs.

Eric Christopher Ament (PST.020768): 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 August 15, 2018, subject to certain terms enumerated in the consent agreement.

Terry James Veillon, Jr (PST.018988): 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 August 15, 2018, subject to certain terms enumerated in the consent agreement.

Justin Matthew Scalfano (PST.018787): The Board granted his request for modification of previous orders, then removed all probationary terms and restored the license to active and unrestricted status.

Jason Conrad Dove (PST.015811): The Board granted his request for modification of previous orders, then removed the restriction that had prevented him from accepting an appointment as the PIC of a pharmacy.

Amanda Elizabeth Shubert Balli (PST.019454): The Board denied her request for modification of previous orders.

Jessie James Grazier (PNT.047987): The Board suspended the intern registration and any subsequently issued credential for five years and stayed the execution of the suspension, then placed the intern registration and any subsequently issued credential on probation for five years effective August 15, 2018, subject to certain terms enumerated in the consent agreement.

Kendra Dian Wright (PST.021806): In consideration of the disciplinary action taken by the Oklahoma State Board of Pharmacy against the Oklahoma pharmacist license for conduct that constitutes a basis for action against a Louisiana pharmacist license, the Louisiana Board suspended the Louisiana pharmacist license for five months plus two days and stayed the execution of the suspension, then placed the license on probation for five months plus two days effective August 15, 2018, subject to certain terms enumerated in the consent agreement. The Board further noted the probationary period ordered was to run concurrently with the probationary period imposed by the Oklahoma State Board of Pharmacy, and further assessed administrative costs.

Jeffery Charles Pierre (PST.020332): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective July 11, 2018.

Aurdie Kent Bellard (PST.014340): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective July 11, 2018.

Brent Van Landry (PST.017440): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective July 30, 2018.

Jennifer Elizabeth Koruna (PST.016255): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective August 8, 2018.

During the same meeting, the Board issued a letter of warning to one pharmacy permit, and letters of reprimand to two pharmacists, one pharmacy technician, and two pharmacy permits. In addition, the Board granted one request for the reinstatement of an expired pharmacy technician certificate, contingent upon the satisfaction of certain requirements identified in the consent agreement.

Calendar Notes (18-10-587)

The Board office will be closed on November 22 in observance of Thanksgiving Day, November 23 for Acadian Day, December 25 for Christmas Day, and January 1, 2019, for New Year's Day.

Special Note (18-10-588)

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 (18-10-589)

"You will find that the truth is often unpopular and the contest between agreeable fancy and disagreeable fact is unequal. For, in the vernacular, we Americans are suckers for good news."
– Adlai Stevenson, 1958

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