



Louisiana Board of Pharmacy

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Renewal of Pharmacy Technician Certificates (19-04-600)

The renewal cycle for pharmacy technicians will open on May 1, 2019, and conclude on June 30, 2019. The Louisiana Board of Pharmacy no longer mails renewal application forms; instead, the Board office will mail a renewal reminder just prior to May 1. The renewal reminder will lay out the three options you have to renew your certificate:

1. Visit the Board's website at www.pharmacy.la.gov and renew your certificate online using a credit card.
2. Visit the same website to download and print an application form and complete and mail the application form with the appropriate fee using a check or money order.
3. Send a written request to the Board office via mail, fax, or email, with your name, certificate number, current mailing address, and a request for the Board to mail a paper application form to you.

Any address changes received at the Board office after April 18, 2019, will not be reflected on your renewal reminder. In the event that the postal service fails to deliver your renewal reminder by May 15, 2019, it becomes your responsibility to obtain an application form or renew your certificate online. Certificates renewed online will be mailed within one or two business days; and certificates renewed using paper application forms will be mailed within two to four weeks, depending on the volume of paper application forms received for processing.

The online renewal function of the website is programmed to activate at 12:01 AM on May 1, 2019, and to deactivate at midnight on June 30, 2019. While the Board makes every effort to maintain this online convenience during the renewal cycle, the Board's service provider may experience weather-related or other unforeseen technical difficulties from time to time. You have 60 days to renew your certificate, and it is your choice as to when you complete that duty. If 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 certificate in a timely manner. The Board does not waive late fees in that situation. Why take a chance? Please do not wait until the last minute of the last day.

All technician certificates expire on June 30, 2019, regardless of the issue date. You may not practice with an expired certificate. The fee for the timely renewal of an active certificate is \$50. For the first 30 days past the expiration date, the renewal of an expired certificate will incur an additional \$25 penalty fee, for a total fee of \$75. Applications received by the Board office more than 30 days after the expiration date will incur an additional \$200 reinstatement fee, for a total fee of \$275. Applications bearing a postal service mark of July 1, 2019, or later, must be accompanied by the additional fee(s), or the application package will be returned to the sender unprocessed. If it is important to you to know if or when the Board receives your paper application form, the Board suggests you use the mail tracking service of your choice. With more than 7,000 pharmacy technician certificates to be renewed, staff will not be able to respond to your request to confirm mail deliveries.

Renewal of Other Credentials (19-04-601)

In addition to the pharmacy technician cycle, the Board will also be renewing other credentials this spring and summer. These credentials include approximately:

- ◆ 500 automated medication system (AMS) registrations, which expire June 30;
- ◆ 450 emergency drug kit (EDK) permits, which expire June 30;
- ◆ 9,000 controlled dangerous substance (CDS) licenses for facilities and practitioners, which expire between May 1 and July 31; and
- ◆ 600 durable medical equipment (DME) permits, which expire August 31.

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National Pharmacy Compliance News

April 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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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The AMS, EDK, and CDS credentials must be renewed using paper application forms. The Board will mail those pre-printed application forms just prior to May 1, 2019, and timely renewals must be accomplished on or before the expiration date. Penalties will apply to the renewal of expired credentials.

The DME permits may be renewed either online or by using paper application forms. The Board will mail the renewal reminder just prior to July 1, 2019, and timely renewals must be accomplished on or before August 31, 2019. Penalties will apply to the renewal of expired credentials.

Guidance Document for CBD Oil Revised (19-04-602)

During its November 2018 meeting, the Board issued a guidance document related to the sale of cannabidiol (CBD) oil. That document referenced pertinent federal and state controlled substance (CS) laws. The relevant federal law changed in December 2018; however, the state law has not yet changed. In the interim, state law is more stringent than federal law. During its February 2019 meeting, the Board voted to revise the guidance document by removing the references to the federal law but left intact the references to state law. The ultimate guidance remains the same: the sale of CBD oil would violate the state CS law and place the licensee at risk for criminal and/or administrative sanctions. The Board distributed a notice of the revised guidance document to all licensees on February 23, 2019, and the document was also posted to the Board's website, under [Declaratory Statements, Advisory Opinions, & Policy Statements](#) in the Public Library section.

Veterinary Pharmacy (19-04-603)

The Board's rules require a pharmacy to maintain current reference materials pertinent to the nature of a pharmacy's practice. In the event that the pharmacy elects to dispense veterinary prescriptions, the pharmacy shall maintain current veterinary pharmacy reference materials and keep those materials readily available for pharmacists dispensing veterinary prescriptions.

The Board has received complaints from animal owners about pharmacy dispensing errors for veterinary prescriptions. Some common errors are described below.

- ◆ Levothyroxine prescriptions for canines require higher doses than for humans due to the reduced bioavailability and half-life for canines. Pharmacists should not automatically reduce the prescribed dosage without contacting the prescribing veterinarian first.
- ◆ While prednisone and prednisolone are considered therapeutically equivalent on a milligram-to-milligram basis in humans, this is not true for cats. Felines do not share the same metabolic pathways as humans.

Pharmacists should not automatically substitute prednisone when prednisolone is ordered without first contacting the prescribing veterinarian.

- ◆ The pharmacist should exercise care when responding to requests for over-the-counter (OTC) medications for osteoarthritis in cats and dogs. Acetaminophen is contraindicated in cats and poorly tolerated in dogs. Although nonsteroidal anti-inflammatory drugs are useful, veterinarians tend to avoid the OTC options due to their side effects. Aspirin should never be used unless the veterinarian has been consulted and is actively monitoring the patient.
- ◆ Insulin is the treatment of choice for dogs diagnosed with diabetes mellitus. The preferred insulin product for dogs is a U-40 (40 units/mL) insulin, and pharmacists should be aware that the use of a human U-100 (100 units/mL) insulin syringe may result in underdosing the animal by a factor of 2.5.

The Board encourages pharmacists dispensing veterinary prescriptions to consult appropriate veterinary pharmacy references and contact the prescribing veterinarian before making any substitutions or dosage adjustments.

Disciplinary Actions (19-04-604)

During its February 19, 2019 meeting, the Board took action on the following matters:

Emerald Kamisha Howard (applicant for pharmacy technician candidate registration): For her failure to disclose the entirety of her criminal history and for her extensive criminal history, the Board denied her application for a pharmacy technician candidate registration and refused to issue the credential.

Kristian Raymond Hahn (PST.016625): For his failure as the pharmacist-in-charge (PIC) of Galleria Medical Pharmacy, in Metairie, LA, to comply with United States Pharmacopeia Chapter <797> Pharmaceutical Compounding — Sterile Preparations, despite repeated inspection findings by the Board, and for his failure to cease all sterile compounding activity when directed to do so by the Board, 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 February 19, 2019, subject to certain terms enumerated within the consent agreement, and further, assessed a fine of \$5,000 plus administrative costs.

Blair Pope Wilbert (PST.017357): The Board granted his request to terminate a previously entered private agreement, then suspended the license for five years and stayed the execution of the suspension, then placed the license on probation for five years, effective

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February 19, 2019, subject to certain terms enumerated within the consent agreement.

Aurdie Kent Bellard (PST.014340): The Board granted his request to reinstate the previously suspended license, 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 February 19, 2019, subject to certain terms enumerated within the consent agreement.

Steven Walter Gough (PST.013199): The Board granted his request for modification of previous orders, then removed the restriction in his February 2018 probation order, which had prevented him from accepting an appointment as the PIC of a pharmacy; however, all other probationary terms shall continue.

Ashley Elizabeth Reynolds (PST.020382): The Board granted her request for modification of previous orders, then removed the restriction in her August 2016 probation order, which had prevented her from accepting an appointment as the PIC of a pharmacy; however, all other probationary terms shall continue.

Richard Jeffrey Gaudé (PST.015640): The Board granted his request for modification of previous orders, then removed all probationary terms and restored the license to active and unrestricted status.

David Collins Evans (PST.014181): For his violation of probationary terms, the Board summarily suspended his license for an indefinite period of time, effective January 15, 2019.

Tremekia Vaughn Brown (CPT.013758): For her alleged diversion of CS from her employer pharmacy by prescription forgery, the Board revoked her certificate, effective January 3, 2019, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Melissa Marie Bordelon (CPT.006229): For her alleged diversion of drugs from her employer pharmacy, the Board revoked her certificate, effective January 15, 2019, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Dallas Whitney Blade (PTC.026943): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the registration for an indefinite period of time, effective January 31, 2019.

Fred's Stores of Tennessee, Inc, dba Fred's Pharmacy No. 2722 (Franklin, LA) (PHY.006806): For its accountability for the significant loss of CS during the one-year

period ending in May 2017, the Board revoked the permit effective December 20, 2018, and further, assessed a fine of \$10,000 plus administrative and investigative costs.

Dave's Pharmacy, Inc, dba Dave's Pharmacy (Marro, LA) (CDS.039211-PHY): The Board accepted the voluntary surrender of the credential, resulting in the suspension of the CS license for an indefinite period of time, effective February 7, 2019.

340B Partners Pharmacy – Dallas, LLC, dba Avita Pharmacy (Dallas, TX) (PHY.006893): For its dispensing of approximately 50 prescriptions into Louisiana during an 11-month period ending in May 2017 while operating with an expired pharmacy permit, the Board assessed a fine of \$10,000 plus administrative costs.

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

The Board approved an application for reinstatement of a lapsed credential from one pharmacy technician, contingent upon the satisfaction of certain requirements identified within the consent agreement.

Calendar Notes (19-04-605)

The Board office will be closed on April 19 in observance of Good Friday, on May 27 for Memorial Day, and on July 4 for Independence Day.

Special Note (19-04-606)

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 (19-04-607)

“When you get to the end of your rope, tie a knot in it and hang on.” – Eleanor Roosevelt

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