April 2020 News



Louisiana Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Editor's Note: The content of the Louisiana Board of Pharmacy's Newsletter was finalized prior to the coronavirus disease 2019 (COVID-19) outbreak. Licensees should check the Board's website for the most up-to-date information.

Are You Entering the Correct Days Supply for Prescriptions? (20-04-631)

The Board has received complaints from multiple prescribers who are managing patients with controlled substances (CS). The prescribers have indicated some dispensing pharmacists are interfering with the prescribers' treatment goals of reducing opioid utilization when the pharmacist enters the incorrect number of days supply in the dispensing information system. Consider the hypothetical prescription: "#100 tablets, one tablet by mouth every six to eight hours as needed for pain; quantity must last 30 days." Although the mathematical calculation using the quantity and dose would ordinarily yield a 25-day supply, the prescriber's instruction also indicates the quantity must last 30 days. Therefore, the correct days supply for the hypothetical prescription is 30 days and not 25 days.

Dispensing data for CS prescriptions are reported to the state prescription monitoring program (PMP). The advanced analytics available from the PMP includes a patient's morphine milligram equivalent (MME) calculation. Prescribers use MME information in their patient treatment plans. The PMP uses MME information in prescriber report cards and other statewide reports. The reporting of an incorrect days supply will result in an inaccurate MME calculation that can adversely impact patient care and can also yield inaccurate PMP reports.

Dispensing pharmacists should consider the entire prescriber instruction, not just a part of it. As a reminder, the Board's rules require pharmacies to maintain accurate records. An inaccurate days supply is not an accurate record and is not compliant with the Board's rules.

Renewal of Pharmacy Technician Certificates (20-04-632)

The renewal cycle for pharmacy technicians will open on May 1, 2020, and conclude on June 30, 2020. The Board will mail a renewal reminder mailer just prior to May 1, 2020. 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.
- 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.
- 3. Send a written request to the Board office (mail, fax, or email) with your name, certificate number, and current mailing address, requesting the Board to mail a paper application form to you.

Any address changes received at the Board office after April 17, 2020, will not be reflected on your renewal reminder mailer. In the event the postal service fails to deliver your renewal reminder mailer by May 15, 2020, then it becomes your responsibility to obtain an application form or renew your certificate online. Certificates renewed online will be mailed within one to two business days; 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, 2020, and to deactivate at midnight on June 30, 2020. 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 to complete that duty. If you choose to wait until the last

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National Pharmacy Compliance News



April 2020

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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations* (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy "s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, Framing Opioid Prescribing Guidelines for Acute Pain:

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

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day and the website is not available, then you will be responsible for the consequences of 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, 2020, regardless of the date of issue. 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 in 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, 2020, 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 that you use the mail tracking service of your choice. With more than 7,000 pharmacy technician certificates to be renewed, the staff will not be able to respond to your request to confirm mail deliveries.

Renewal of Other Credentials (20-04-633)

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, 2020;
- ♦ 425 emergency drug kit (EDK) permits, which expire June 30, 2020;
- ◆ 9,000 controlled dangerous substances (CDS) licenses for facilities and practitioners, which expire between May 1, 2020, and July 31, 2020; and
- ♦ 625 durable medical equipment (DME) permits, which expire August 31, 2020.

The AMS, EDK, and CDS credentials must be renewed using paper application forms. The Board will mail those pre-printed application forms prior to May 1, 2020, 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 using paper application forms. The Board will mail the renewal reminder mailer prior to July 1, 2020, and timely renewals must be accomplished on or before August 31, 2020. Penalties will apply to the renewal of expired credentials.

Decisions From February 2020 Board Meeting (20-04-634)

During its February meeting, the Board took action on several items of business, including:

- ♦ Considered comments and testimony from the December 2019 public hearing on the 17 regulatory projects that were approved for promulgation during the previous Board meeting in November 2019. The Board determined a revision was necessary for Regulatory Project 2019-15 ∼ Drug Disposal by Pharmacies and directed the publication of that revision and a second public hearing to receive comments and testimony on that proposed revision. For the remaining projects, the Board directed the continuation of the promulgation process.
- ◆ Approval of three new regulatory proposals for promulgation:
 - ♦ Proposal 2019-G Pharmacy Benefit Managers;
 - ♦ Proposal 2020-A Marijuana Pharmacy; and
 - ♦ Proposal 2020-B Drugs of Concern.
- ♦ Approval of three legislative proposals for filing in the 2020 Legislature:
 - ♦ Proposal 2020-A Pharmacy Benefits Manager Permit Fee and Renewal of Licenses and Permits;
 - ♦ Proposal 2020-B CDS Update; and
 - ♦ Proposal 2020-C Collaborative Practice and Pharmacist Prescriptive Authority.

The progress of all these initiatives may be monitored on the Board's website by visiting www.pharmacy.la.gov, then selecting Public Library, and clicking on Rulemaking Activity.

Disciplinary Actions (20-04-635)

During its February meeting, the Board took action on several items of business, including:

Walgreen Louisiana Co, Inc, dba Walgreen Pharmacy No. 09526 (Pineville, LA) (PHY.005545): For its failure to report its December 2018 significant losses of alprazolam 1 mg and alprazolam 2 mg to the Board until May 2019, the Board assessed a fine of \$25,000 plus administrative and investigative costs.

Walgreen Louisiana Co, Inc, dba Walgreen Pharmacy No. 110-02980 (Baton Rouge, LA) (PHY.002865): For its failure to provide adequate security for its CS, as well as its accountability for losses of approximately 4,000 dosage units of hydrocodone in March 2019, the Board assessed a fine of \$10,000 plus administrative and investigative costs.

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Walgreen Louisiana Co, Inc, dba Walgreen Pharmacy No. 110-02995 (Baton Rouge) (PHY.002868): For its failure to provide adequate security for its CS, as well as its accountability for losses of approximately 1,200 dosage units of alprazolam, 900 units of hydrocodone, and 600 units of oxycodone, and for its failure to disclose those June 2019 losses to the Board until October 2019, the Board assessed a fine of \$10,000 plus administrative and investigative costs.

Pensacola Apothecary, Inc, dba Everwell Specialty Pharmacy (Pensacola, FL) (PHY.007114): For its failure to designate a Louisiana-licensed pharmacist-in-charge from January 2019 to September 2019, and for its continued operation of a pharmacy without an appropriately qualified professional, the Board assessed a fine of \$10,000 plus administrative and investigative costs.

Best Life Pharmacy and Restaurant, Inc, dba Best Life Pharmacy and Restaurant (New Orleans, LA) (PHY.006617): For its failure to provide adequate security for its CS as evidenced by five separate thefts/ losses from May 2018 through December 2019, and for its failure to conduct the required post-theft inventories of its CS after three of those losses, and for its failure to report those losses to United States Drug Enforcement Administration, the Board suspended the permit for two years and stayed the execution of the suspension, then placed the permit on probation for two years, effective February 5, 2020, subject to certain terms enumerated within the voluntary consent agreement; and further, assessed a fine of \$2,500 plus administrative and investigative costs.

Kristian Raymond Hahn (PST.016625): For his violation of the terms enumerated within his February 2019 Probation Board Order, the Board continued the previous emergency suspension imposed on November 4, 2019, converted the duration of the suspensive period to a five-year term and stayed the execution of the suspension, then placed the license on probation for five years, effective February 5, 2020, subject to certain terms enumerated within the voluntary consent agreement; and further, assessed administrative and investigative costs; and further, the lifetime restriction against his compounding of sterile or nonsterile preparations or supervising anyone else engaged in the compounding of sterile or nonsterile preparations shall survive the probationary period and may only be released by the Board pursuant to his application.

Pharmaceutical Specialties, LLC, dba Pharmaceutical Specialties (Baton Rouge) (PHY.003625): For its

failure to obtain a new pharmacy permit and a new state CS license following a change of ownership by 50% or more in May 2016, and for its continued operation of the pharmacy without a valid pharmacy permit or valid state CS license through December 2019, the Board assessed a fine of \$15,000 plus administrative and investigative costs.

Chris' Pharmacy and Gifts, LLC, dba Chris' Pharmacy and Gifts (Maurepas, LA) (PHY.006032): For its dispensing of approximately 54 prescriptions without the prescriber's authority, the Board assessed administrative and investigative costs.

Matthew John Guarisco (PST.014303): For his violation of the terms enumerated within his November 2018 Probation Board Order, the Board suspended the license for 10 years and stayed the execution of the suspension, then placed the license on probation for 10 years, effective February 5, 2020, subject to certain terms enumerated within the voluntary consent agreement.

George Lamar Munn, Jr (PST.009445): Pursuant to its consideration of a medical evaluation favorable for his return to practice, 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 February 5, 2020, subject to certain terms enumerated within the voluntary consent agreement.

Jamie Courtney Smith (CPT.009224): Board granted her request for reinstatement of the certificate, which expired on June 30, 2012, contingent upon her satisfaction of the following requirements prior to February 5, 2022: (1) acquire 250 hours of updated and supervised practical experience under the authority of a special work permit; and (2) acquire 10 hours of Accreditation Council for Pharmacy Education (ACPE)-accredited technician-specific continuing pharmacy education (CPE).

Ruthy Lynn Paul (CPT.006591): Board granted her request for reinstatement of the certificate, which expired on June 30, 2013, contingent upon her satisfaction of the following requirements prior to February 5, 2022: (1) acquire 250 hours of updated and supervised practical experience under the authority of a special work permit; and (2) acquire 10 hours of ACPE-accredited technician-specific CPE.

Ashley Shandell Ferdinand (PTC.027503): For her diversion of CS from her employer pharmacy, the Board revoked the registration, effective November 13, 2019;

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and further, permanently prohibited the acceptance of any application for any credential issued by the Board.

Jamie Deshotels Pucheu (PST.018456): In lieu of immediate administrative action, the Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective November 18, 2019.

Kayla Christine Sibley (Powell) (PTC.026981): For her diversion of CS from her employer pharmacy, the Board revoked the registration, effective November 21, 2019; and further, permanently prohibited the acceptance of any future application for any credential issued by the Board.

William Andrew Fletcher (CPT.013721): Pursuant to a voluntary consent agreement from August 2005 relative to an allegation of practicing without a credential, the Board suspended the certificate for five years and stayed the execution of the suspension, then placed the certificate on probation for five years, effective February 5, 2020, subject to certain terms enumerated within the voluntary consent agreement.

Meds for Vets, LLC, dba Meds for Vets (Sandy, UT) (PHY.006258): In recognition of the administrative action taken by the Utah Board of Pharmacy in October 2019 against the pharmacy's resident permit in Utah for professional misconduct, which also constitutes a sufficient basis for action against the pharmacy's Louisiana permit, the Board suspended the Louisiana permit for one year plus eight months, 16 days, and stayed the execution of the suspension. The Board then placed the permit on probation for one year plus eight months and 16 days, effective February 5, 2020, and concluding October 21, 2021, subject to certain terms

enumerated within the voluntary consent agreement, noting the probationary period shall run concurrently with the probationary period imposed by the Utah Board of Pharmacy. Further, the Board imposed administrative costs.

During the same meeting, the Board issued a letter of reprimand to one pharmacist.

Calendar Notes (20-04-636)

The Board office will be closed on April 10 in observance of Good Friday and May 25 for Memorial Day.

Special Note (20-04-637)

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. Electronic copies dating back to 1998 are posted on the Board's website.

Louisiana Lagniappe (20-04-638)

"Some people go through life trying to find out what the world holds for them only to find out too late that it's what they bring to the world that really counts." – L. M. Montgomery

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