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Louisiana Board of Pharmacy News

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Correction (16-04-511)

In the January 2016 edition of the *Newsletter,* and more specifically the article concerning Louisiana Board of Pharmacy member appointments, the Board indicated the expiration date of the terms of the new appointees would be June 20, 2022. The correct expiration date is June 30, 2022. The Board regrets the error and any inconvenience it may have caused.

Renewal of Pharmacy Technician Certificates (16-04-512)

The renewal cycle for pharmacy technicians will open on May 1 and conclude on June 30. The Board no longer mails renewal application forms; instead, the Board office will mail a renewal reminder mailer just prior to May 1. The mailer will remind you of 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, then complete and mail the application form with the appropriate fee using a check or money order; or
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 15, 2016, 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, 2016, then 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; 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 and to deactivate at midnight on June 30, 2016. 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 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 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 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 almost 7,000 certificates to be renewed, the staff will not be able to respond to your request to confirm mail deliveries.

Renewal of Other Credentials (16-04-513)

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

- 500 Automated Medication System (AMS) registrations expire June 30;
- 500 Emergency Drug Kit (EDK) permits expire June 30;
- 7,000 Controlled Dangerous Substance (CDS) licenses for physicians expire July 1; and
- 600 Durable Medical Equipment (DME) permits expire August 31.

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, and timely

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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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 just prior to July 1, and timely renewals must be accomplished on or before August 31; penalties will apply to the renewal of expired credentials.

Status Report on Rulemaking Activities (16-04-514)

The Board continues to promulgate new rules as well as revisions of existing rules. For its clients who have provided their email addresses, the Board sends electronic *Notices of Rulemaking Activity* about these issues.

Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians. During the Board's February 24, 2016 meeting, the Board reviewed the language for the proposed revision that will put pharmacists on notice as to the absence of clear federal authority for pharmacists to compound veterinary preparations for office use for veterinarians. The Board approved the proposed language and directed a public hearing to receive comments and testimony on that proposed revision. That public hearing has been tentatively scheduled for April 19, 2016. The Board also canceled the previously issued emergency rule and issued a new emergency rule. The new emergency rule contains the proposed revision and it was made effective immediately. The Board distributed that emergency rule electronically to all pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates.

You can follow the progress of all the Board's rulemaking activities at the Board's website at *www.pharmacy.la.gov.*

Legislative Proposals for the Regular Session of the 2016 Legislature (16-04-515)

During its February 24 meeting, the Board approved three legislative proposals for consideration during the Regular Session of the 2016 Louisiana State Legislature, which convened on March 14 and must adjourn no later than June 6.

- *Legislative Proposal 2016-A ~ CDS Schedule Update* will amend the state's list of controlled substances (CS). It is the Board's goal to harmonize the state's list as much as possible with the federal list. Since the state legislature must make the adjustments, the Board compiles all Drug Enforcement Administration (DEA) scheduling actions since the previous legislative session, then sponsors the legislation to update the list. This year's bill removes two items from Schedule II and adds a new drug to Schedule IV. This proposal has been pre-filed as House Bill (HB) 688.
- *Legislative Proposal 2016-B ~ PMP Record Retention* will amend the state prescription monitoring program (PMP) law to direct the Board to promulgate standards for the retention, archiving, and destruction of prescription transaction records in the PMP database. This proposal has been pre-filed as Senate Bill 56.
- *Legislative Proposal 2016-C ~ Application Fee for Marijuana Pharmacy Permit* will amend the Board's list of authorized fees to establish a non-refundable application fee for the marijuana pharmacy permit. The Board is still writing rules for the marijuana pharmacy program; the rules should be finalized before the end of calendar year 2016. This proposal has been pre-filed as HB 446.

You can follow the progress of all legislation at the legislature's website at *www.legis.la.gov.*

Disciplinary Actions (16-04-516)

During its February 24 meeting, the Board took final action in the following matters.

Tracey Deshawn Green (PTC.023681): For her failure to disclose her entire criminal history on her application for a new pharmacy technician candidate registration, the Board authorized the issuance of the registration, suspended it for 18 months and stayed the execution of the suspension, then placed the newly issued registration on probation for 18 months, effective February 25, 2016, subject to certain terms enumerated in the consent agreement.

Samantha Arylene Kirby (PTC Applicant): For her failure to disclose her criminal history, the Board denied her application and refused to issue the registration.

Progressive Acute Care Oakdale, LLC, dba Oakdale Community Hospital Pharmacy (PHY.006214): For its failure to appoint a replacement pharmacist-in-charge (PIC) in a timely manner and for its continued operation of the pharmacy without a PIC for approximately 60 days, the Board assessed a fine of $10,000 plus administrative and investigative costs.

Hotbar, LLC, dba Monroe Clinic Drugs/Aspire Rx (PHY.006121): For its failure to apply for a new pharmacy permit when the ownership changed more than 50% in calendar year 2010 and for its continued operation without a valid pharmacy permit since then, the Board assessed a fine of $30,000 plus administrative and investigative costs.

Angela Nicole Hotard (PST.016604): For her failure as the owner of Hotbar, LLC, dba Monroe Clinic Drugs/Aspire Rx to apply for a new pharmacy permit in a timely manner and for the continued operation of the pharmacy without a valid pharmacy permit, 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 February 24, 2016, subject to certain terms enumerated in the consent agreement, and further, the Board assessed a fine of $250 plus administrative costs.

C and C Pharmacy, LLC, dba C and C Drugs (PHY.005637): For the repeated dispensing of more than 30 prescriptions without prescriber authorization to a single patient by multiple staff pharmacists over a period of 20 months, the Board assessed a fine of $1,000 plus administrative and investigative costs.

MasterPharm, LLC, dba MasterPharm (PHY.006466): For its dispensing of approximately 30 prescriptions to Louisiana residents with an expired pharmacy permit, and further, in recognition of the disciplinary action taken by the Michigan Board of Pharmacy wherein its resident pharmacy permit was placed on probation for three years for conduct that constitutes a basis for disciplinary action in this state, the Board suspended the pharmacy permit for two years, six months, and 19 days and stayed the execution of the suspension, then placed the permit on probation for two years, six months, and 19 days, effective February 24, 2016, and ending September 12, 2018 (concurrently with the probationary period imposed by the Michigan Board),

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and further, the Board assessed a fine of $10,000 plus administrative and investigative costs.

Cornerstone Compounding Pharmacy, Inc, dba Cornerstone Compounding Pharmacy (PHY.006896): For its failure to report approximately 140 CS prescription transactions to the state PMP, the Board assessed a fine of $5,000 plus administrative and investigative costs.

Louisiana CVS Pharmacy, LLC, dba CVS Pharmacy No. 1017 (PHY.006018): For allowing a person to practice in its pharmacy as a pharmacy technician candidate without the credential required to do so, the Board assessed a fine of $10,000 plus administrative costs.

LMC Medical Supplies, Inc, dba LMC Pharmacy (PHY.006903): For its dispensing of 139 prescriptions to Louisiana residents before acquiring the pharmacy permit required to do so, the Board assessed a fine of $15,000 plus administrative and investigative costs.

Donald Wayne Crawley (PST.010199): 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 19, 2015.

Hope Michelle Chabaud (CPT.012038): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective December 15, 2015.

William Coleman Honeycutt (PST.010643): 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 24, 2016, subject to certain terms enumerated in the consent agreement.

Andrea Katherine Bourque (PST.019587): The Board granted her request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective February 24, 2016, subject to certain terms enumerated in the consent agreement.

Ashley Elizabeth Reynolds (PST.020382): The Board denied her request for reinstatement of the suspended license, and further, conditioned the acceptance of any future application on certain terms enumerated in the consent agreement.

Sonya Darlene Coleman (PTC Applicant): For her extensive history and failure to provide additional information, the Board denied her application and refused to issue the registration.

Aurdie Kent Bellard (PST.014340): The Board granted his request for reinstatement of the lapsed license, suspended the license for 10 years and stayed the execution of the suspension, then placed the license on probation for 10 years, effective February 25, 2016, subject to certain terms enumerated in the consent agreement.

Marco Bisa Moran (PST.016442): The Board denied his request for reinstatement of the previously suspended license.

NMB Generics, Inc, dba NMB Generics (PHY.006889): The Board denied the request for reinstatement of the pharmacy permit, which lapsed by nonrenewal on December 31, 2014.

Anthony John Grzib, Jr (PST.018508): In recognition of the disciplinary action taken by the New Jersey State Board of Pharmacy wherein his resident pharmacist license was placed on probation for two years for conduct that constitutes a basis for disciplinary action in this state, the Board suspended the license for one year, eight months, and seven days and stayed the execution of the suspension, then placed the license on probation for one year, eight months, and seven days, effective February 24, 2016, and ending October 31, 2017 (concurrently with the probationary period imposed by the New Jersey Board), and further, the Board assessed administrative costs.

Latasha Monique King (CPT.008866): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective November 17, 2015.

Kacie Dore' Keith (PST.020248): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective January 20, 2016.

During the same meeting, the Board issued letters of reprimand to two pharmacies, 11 pharmacists, and three pharmacy technicians, as well as letters of warning to two pharmacies. In addition, the Board granted requests for reinstatement from one technician with an expired certificate, one pharmacist with a suspended license, and one pharmacy with an expired pharmacy permit. Finally, the Board suspended the CDS license for six physicians, one of whom had surrendered his federal DEA registration, another who had his medical license revoked, and four whose medical licenses had been suspended by the Louisiana Board of Medical Examiners.

Calendar Notes (16-04-517)

The Board office will be closed on May 30 in observance of Memorial Day and July 4 in observance of Independence Day.

Special Note (16-04-518)

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.

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