April 2014

Louisiana Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Printed Newsletters Coming to an End (14-04-458)

In an effort to contain rising costs, the Louisiana Board of Pharmacy decided to convert the *Newsletter* to an electronic edition. This edition of the *Newsletter* will be the last edition printed and mailed to Board licensees. Going forward, the Board will send electronic messages to its licensees advising them of the electronic edition of the *Newsletter* posted on its website. There are still a few licensees for whom the Board does not have valid e-mail addresses; the Board encourages you to provide that information to the Board so that it can ensure you receive these messages and other time-sensitive information.

Renewal of Pharmacy Technician Certificates (14-04-459)

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 will mail a renewal reminder mailer just prior to May 1. The renewal reminder mailer will contain your login identification and password to access your account on the Board's website. The mailer will remind you of the three options to renew your certificate:

1. Visit the Board's website at *www.pharmacy.la.gov* and renew your certificate 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 e-mail) 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 18, 2014, 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, 2014, then it becomes your responsibility to obtain an application form or renew your credential 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 automatically timed to activate at 12:01 AM on May 1, and to deactivate at midnight on June 30. While the Board makes every effort to maintain the online convenience during the renewal period, 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 shall 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 a certificate is $50. The renewal of an expired certificate will incur an additional $25 penalty as well as an additional $200 reinstatement fee. Applications bearing a postal service postmark of July 1, or later must be accompanied by the additional fees 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. Given the volume of renewal applications, the staff will not be able to respond to your request to confirm mail deliveries.

Renewal of Other Credentials (14-04-460)

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

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding.* Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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- Automated Medication System (AMS) registrations expire June 30.
- Emergency Drug Kit (EDK) permits expire June 30.
- Durable Medical Equipment (DME) permits expire August 31.

All of these credentials must be renewed with paper applications. The Board will mail the renewal reminder mailers for the AMS and EDK credentials just prior to May 1, and timely renewals must be accomplished on or before June 30; penalties will apply to the renewal of expired credentials. The Board will mail the renewal reminder mailers for the DME permits just prior to July 1, and timely renewals must be accomplished on or before August 31; penalties will apply to the renewal of expired permits.

Status Report on Rulemaking Activities (14-04-461)

The Board continues to promulgate new rules as well as revisions to existing rules. For its clients who have given the Board their e-mail addresses, the Board sends electronic *Notices of Rulemaking Activity* about these activities.

- *Regulatory Project 2013-1 ~ Compounding for Prescriber Use*. The Board has republished the emergency rule that places limits on the amount of compounding for prescriber use a pharmacy may prepare without a patient-specific prescription. The Board's Regulation Revision Committee is working on a proposal that includes new legislative language and includes some of the comments and testimony from the public hearing. You can follow the progress of that proposal in the Public Notices section of the Board's website.
- *Regulatory Proposal 2014-A ~ PMP Delegates*. The Board gave preliminary approval to this proposal, which will authorize prescribers and dispensers to appoint delegates for the purpose of retrieving information about their patients from the Prescription Monitoring Program (PMP) database, but only according to rules promulgated by the Board for that purpose. The Board will conduct a public hearing to receive comments and testimony on the proposal. Look for the electronic *Notice of Rulemaking Activity* for the specific date of the hearing. You can follow the progress of this proposal in the Public Notices section of the Board's website.
- *Regulatory Proposal 2014-B ~ Veterinarian Exclusion from PMP*. The Board gave preliminary approval to this proposal, which will exclude veterinarians from participating in the PMP. The Board will conduct a public hearing to receive comments and testimony on the proposal. Look for the electronic *Notice of Rulemaking Activity* for the specific date of the hearing. You can follow the progress of this proposal in the Public Notices section of the Board's website.

Disciplinary Actions (14-04-462)

During its November 2013 meeting, the Board took final action in the following matters:

Charlene Marie Fletcher (CPT.004539): *Formal Hearing* – Revoked the certificate, and further, assessed a fine of $5,000 plus administrative, investigative, and hearing costs; for seven counts, including diversion of controlled substances (CS) from her employer pharmacy.

Javondra Marie Raby (CPT.008519): *Formal Hearing* – Revoked the certificate, and further, assessed a fine of $5,000 plus administrative, investigative, and hearing costs; for seven counts, including diversion of CS from her employer pharmacy.

During its February 2014 meeting, the Board took final action in the following matters:

Monica Leigh Goux-Hahn (PTC Applicant): Denied the application for pharmacy technician candidate registration and refused to issue the credential.

Jaime Lea Anderson (PTC Applicant): Denied the application for pharmacy technician candidate registration and refused to issue the credential.

William Lee Pearson (PST Applicant): Denied the application for pharmacist license and refused to issue the license.

Lifechek Drug, Inc, and Lifechek Rosenberg GP, together dba Lifechek Drug #19 (PHY Applicant): Applicant executed a non-disciplinary agreement with the Board wherein the applicant is prohibited from applying for a Louisiana pharmacy permit for 10 years, and further, the applicant shall pay all attorney fees and costs associated with preparation for an administrative hearing that were accrued prior to its execution of the agreement.

Ackal's Community Pharmacy, Inc, dba Ackal's Community Pharmacy (PHY.005948): Suspended the permit for five years and suspended the execution of the suspension, then placed the permit on probation for five years, effective January 30, 2014, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $10,000 plus administrative and investigative costs; for 15 counts, including failure to perform drug utilization review and corresponding responsibility when dispensing prescriptions for CS.

Christine Adele Ackal (PST.015539): Suspended the license for five years and suspended the execution of the suspension, then placed the license on probation for five years, effective January 30, 2014, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $10,000 plus administrative costs; for 15 counts, as owner and pharmacist-in-charge (PIC) of Ackal's Community Pharmacy, including failure to perform drug utilization review and corresponding responsibility when dispensing prescriptions for CS.

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Walgreen Louisiana Co, Inc, dba Walgreen Pharmacy No. 110-06219 (PHY.001166): Assessed a fine of $2,500 plus administrative and investigative costs; for three counts, including allowing a pharmacy technician candidate with an expired registration to continue practicing in the prescription department.

Walgreen Louisiana Co, Inc, dba Walgreen Pharmacy No. 10399 (PHY.005672): Assessed a fine of $10,000 plus administrative costs; for two counts, including failure to appoint a replacement PIC in a timely manner and the subsequent operation of a pharmacy without a PIC for seven months.

Charmisha Renea East (CPT.010697): Accepted voluntary surrender, resulting in active suspension of the certificate for an indefinite period of time, effective December 12, 2013.

Apothecary Pharmacy, Inc, dba Ray's Apothecary Pharmacy (PHY.004444 and CDS.038642): Assessed a fine of $7,500 plus administrative and investigative costs; for 17 counts, including allowing unqualified pharmacists and pharmacy technicians to compound high-risk sterile preparations, failure to comply with multiple provisions of United States Pharmacopeia (USP) Chapter 797 (beyond-use dating and refrigerated storage), failure to remove expired products from active inventory, and improper distribution of compounded preparations to another pharmacy.

Robert Allen Ray (PST.011612): Assessed a fine of $5,000 plus administrative costs; for 11 counts, as owner of Ray's Apothecary Pharmacy and Ray's Pharmacy, including failure to employ qualified personnel to compound high-risk sterile preparations and failure to remove misbranded drug preparations (compounded preparations transferred from one pharmacy to another) from active inventory.

Noemi Amber Ray (CPT.003226): Assessed a fine of $250 plus administrative costs; for 12 counts, while practicing at Ray's Apothecary Pharmacy, including compounding high-risk sterile preparations and failure to comply with multiple provisions of USP Chapter 797.

Harmony Kay Ates (CPT.010435): Assessed a fine of $250 plus administrative costs; for 12 counts, while practicing at Ray's Apothecary Pharmacy, including compounding high-risk sterile preparations, and failure to comply with multiple provisions of USP Chapter 797.

Nicole Ann Simmons Spurlin (CPT.010935): Assessed a fine of $250 plus administrative costs; for 12 counts, while practicing at Ray's Apothecary Pharmacy, including compounding high-risk sterile preparations, and failure to comply with multiple provisions of USP Chapter 797.

Kimm Rogers (PST.013660): Accepted voluntary surrender, resulting in active suspension of the license for an indefinite period of time, effective November 14, 2013.

Lauren Ashley Guess (CPT.010910): Accepted voluntary surrender, resulting in active suspension of the certificate for an indefinite period of time, effective December 4, 2013.

Hoa Thi Pham (PNT.046513): Accepted voluntary surrender, resulting in active suspension of the registration for an indefinite period of time, effective December 12, 2013.

Randy Wayne Owers (PST.018354): Accepted voluntary surrender, resulting in active suspension of the license for an indefinite period of time, effective December 18, 2013.

Noel Gerard Faucheux (PST.011765): Granted request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite period of time to a term of 10 years and suspended the execution of the suspension, then placed the license on probation for 10 years, effective February 12, 2014, subject to certain terms enumerated in the consent agreement.

Randi Lea Cassidy (CPT.010273): Board granted request for reinstatement of the previously suspended certificate, converted the duration of the suspensive period from an indefinite term to a term of five years and suspended the execution of the suspension, then placed the certificate on probation for five years, effective February 12, 2014, subject to certain terms enumerated in the consent agreement.

Douglas Christopher Montecino (PST.015620): Granted request for removal of all probationary terms and restored license to active and unrestricted status.

Leon Jacob Barker (PST.011293): Suspended the license for 10 years and suspended the execution of the suspension, then placed the license on probation for 10 years, effective February 12, 2014, subject to certain terms enumerated in the consent agreement.

Louis Charles Gambina (PST.011145): Granted request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of two years and suspended the execution of the suspension, then placed the license on probation for two years, effective February 12, 2014, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $2,500 plus investigative costs.

Charles Fredrick Bruce (PST.017793): Granted request for removal of prior prohibition on acceptance of PIC appointments and restored the license to active and unrestricted status.

Patrick Glen Andrus (PST.014226): Denied request for removal of probationary restrictions.

Orenthal James Carter (PST.018123): Suspended the license for four years, three months, and two days and suspended the execution of the suspension, then placed

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the license on probation for four years, three months, and two days, effective February 12, 2014, subject to certain terms enumerated in the consent agreement, and further, assessed administrative costs; for one count arising from disciplinary action taken by the Alabama State Board of Pharmacy against his Alabama pharmacist license.

Precision Pharmacy, LLC, dba Precision Pharmacy (PHY.006219-NR): Suspended the pharmacy permit for three years and suspended the execution of the suspension, then placed the pharmacy permit on probation for three years, effective February 12, 2012, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $10,000 plus administrative costs; for four counts, including shipping prescription medications to Louisiana without a permit.

Main Street Family Pharmacy, LLC, dba Main Street Family Pharmacy (PHY.006371-NR): Accepted voluntary surrender, resulting in active suspension of the pharmacy permit for an indefinite period of time, effective December 12, 2013.

Alex Anthony Capace (PST.013422): Accepted voluntary surrender, resulting in active suspension of the license for an indefinite period of time, effective December 12, 2013.

Tara Lynn LeBlanc (CPT.010220): Accepted voluntary surrender, resulting in active suspension of the certificate for an indefinite period of time, effective December 20, 2013.

Chelsey Andria Stevenson (CPT.011760): Accepted voluntary surrender, resulting in active suspension of the certificate for an indefinite period of time, effective February 7, 2014.

Starns Pharmacy, LLC, dba Starns Pharmacy (CDS.042068): Accepted voluntary surrender, resulting in active suspension of the controlled dangerous substances (CDS) license for an indefinite period of time, effective January 7, 2014.

During the same meeting, the Board granted approval for the reinstatement of an expired certificate for one technician, as well as conditional approval for the reinstatement of an expired license for one pharmacist, pending satisfaction of certain terms enumerated in their consent agreement. The Board also issued letters of reprimand to one pharmacist, one technician, and the owner of one pharmacy permit, and further, suspended the CDS licenses for three physicians whose medical licenses were suspended by the Louisiana State Board of Medical Examiners and for another physician who surrendered his federal Drug Enforcement Administration registration.

Calendar Notes (14-04-463)

The next Board meeting and administrative hearing will be held on May 7-8, 2014, at the Board office. The office will be closed April 18, in observance of Good Friday; May 26, in observance of Memorial Day; and July 4, in observance of Independence Day.

Special Note (14-04-464)

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.

The *Louisiana Board of Pharmacy News* is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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