April 2017

Louisiana Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

3388 Brentwood Drive • Baton Rouge, LA 70809-1700 • *www.pharmacy.la.gov*

Board Announces Personnel Changes in Compliance Division (17-04-540)

The Louisiana Board of Pharmacy filled a long-standing vacancy in the chief compliance officer position by promoting Mr Benjamin Whaley from his former staff compliance officer position, effective October 31, 2016. Mr Whaley brings nine years of experience in his staff role, preceded by 11 years of pharmacy practice experience.

The Board is also pleased to announce the selection of a new staff compliance officer. Ms Nicole L. Gross joined the Board's staff on March 6, 2017. She brings 20 years of pharmacy practice experience, most recently in hospital practice in the Shreveport, LA area. Ms Gross will be responsible for conducting inspections and investigations in the northwest corner of the state.

The Board appreciates the professional courtesies extended to all of our compliance officers. Congratulations, Benjamin, on your promotion! Welcome to the family, Nicole!

Renewal of Pharmacy Technician Certificates (17-04-541)

The renewal cycle for pharmacy technicians will open on May 1, 2017, 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 14, 2017, 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, 2017, it then 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, 2017. 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, Board staff will not be able to respond to individual requests to confirm mail deliveries.

Renewal of Other Credentials (17-04-542)

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

- 500 automated medication system (AMS) registrations expire June 30;
- 475 emergency drug kit (EDK) permits expire June 30;
- 9,000 controlled dangerous substance (CDS) licenses for facilities and practitioners expire between May 1 and July 31; 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 renewals must

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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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.

Questions on Renewal Applications (17-04-543)

Application forms for the renewal of pharmacy permits, pharmacist licenses, and pharmacy technician certificates contain a series of questions requesting information concerning any legal issues or disciplinary actions taken against the applicant since the previous renewal. For each of those application forms, the instructions request two documents in the event of an affirmative answer: a certified copy of the decision document from the court or law enforcement agency, as well as the applicant's personal letter of explanation.

Two of these questions are commonly misinterpreted. The first question requests whether the applicant has been arrested, charged, arraigned, indicted, or convicted, or whether the applicant has been issued a citation or summons, or whether the applicant has pled guilty, no contest, nolo contendere, or any similar plea, or whether the applicant has been sentenced or pardoned for any criminal offense, including misdemeanors and felonies, in any court in any local, state, or federal jurisdiction. The instructions note that the only offenses not required to be reported are minor traffic violations, such as speeding or parking tickets. The common mistake on this question is not reporting an arrest. It does not matter whether the charges were not prosecuted, nor does it matter whether any prior convictions have been expunged. The question asks whether or not the action occurred; if it did, an affirmative reply is required. The applicant's personal letter of explanation is the vehicle to inform the Board of the outcome of the incident.

The second most common mistake relates to the question concerning civil or malpractice cases. The question asks whether the applicant has been named in such a case. Simply being named requires an affirmative answer. The applicant's personal letter of explanation is the vehicle to inform the Board of the outcome or status of the case.

Affirmative replies to these questions do not automatically result in disciplinary action by the Board. The Board considers each case on its own merits and takes an action it deems as appropriate. For the majority of the disciplinary actions taken related to these matters, the issue that the applicant failed to disclose is not the reason for the Board's action; instead, the action is usually taken for the failure to disclose the information requested. When the applicant fails to disclose information specifically requested and the Board issues the renewal, the result is the acquisition of a permit, license, or certificate by fraud or misrepresentation. As indicated in the certification section at the end of every application, the applicant agrees that such an act by the applicant provides a basis for disciplinary action by the Board and could possibly result in the revocation or suspension of the credential.

The Board encourages your careful review of these questions when renewing your credential.

Disciplinary Actions (17-04-544)

During its January 25-26, 2017 meeting and administrative hearing, the Board took final action in the following matters:

K&B Louisiana Corporation, dba Rite Aid No. 7335 (Shreveport) (PHY.003040): For allowing a pharmacy technician candidate to practice with an expired registration for approximately one month, the Board assessed a fine of $5,000 plus administrative and investigative costs.

Gulf States Health Partners, LLC, dba RX 2 Geaux (Baton Rouge, LA) (PHY.007095): 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 replacement for approximately two months, the Board assessed the permit owner a fine of $10,000 plus administrative and investigative costs.

Shaknocka Lewis (CPT.013059): For her failure to disclose her previous arrest on her 2016-2017 renewal application, the Board revoked the certificate; and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

Scotty Paul Broussard (PST.015681): The Board granted his request for reinstatement of the previously suspended license, contingent upon the satisfaction of certain requirements identified in the consent agreement; and further, 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 special work permit and the subsequently reinstated license on probation for 15 years, effective on the date of issuance of the special work permit, subject to certain terms enumerated in the consent agreement.

Roy Allen Martin (PST.021385): In recognition of the disciplinary action taken by the Oklahoma State Board of Pharmacy, wherein his resident pharmacist license was placed on probation for five years for conduct that constitutes a basis for disciplinary action in this state, the Louisiana Board suspended the Louisiana license for four years plus four months plus 20 days and stayed the execution of the suspension, then placed the license on probation for four years plus four months plus 20 days, effective January 25, 2017, and ending June 15, 2021 (to run concurrently with the probationary period imposed by the Oklahoma Board), subject to certain terms enumerated in the consent agreement; and further, the Board assessed administrative costs.

Hillary Renee LeGros (CPT.011819): For her diversion of controlled substances (CS) from her employer pharmacy, the Board revoked the certificate, effective December 5, 2016; and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

Kalsey Rae-Jean Miller (CPT.012510): For her diversion of CS from her employer pharmacy, the Board revoked the certificate, effective December 8, 2016; and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

LeighAnn Nicole Hebert (CPT.008150): 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 14, 2016.

Bria Alessia Jenkins (CPT.011343): *Formal Hearing* – For her written admission to the diversion of alprazolam from her employer pharmacy, the Board revoked the certificate; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Krystal Renee Nawadny (CPT.009756): *Formal Hearing* – For her written admission to the unlawful possession of CS listed in Schedule I, the Board revoked the certificate; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application

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for the reinstatement of the certificate or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Jessica Gayle Donaldson (CPT.008112): *Formal Hearing* – For her written admission to the diversion of alprazolam from her employer pharmacy, the Board revoked her certificate; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Dana Rochelle Ingram (CPT.009074): *Formal Hearing* – For her alleged diversion of promethazine and codeine syrup from her employer pharmacy, and for her failure to provide information subsequently requested by the Board, the Board suspended the certificate for an indefinite period of time, effective January 25, 2017; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Holly Reneé Griffith (CPT.008637): *Formal Hearing* – For her written admission to dispensing prescriptions for hydrocodone pursuant to forged prescriptions that she prepared, the Board revoked her certificate; and further, assessed a fine of $500 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Larry Hoyt Hamilton, Jr (PST.016558): *Formal Hearing* – For his accountability as PIC at Sterling Pharmacy for the following shortages of CS (see table below) identified in the Board's audit for the two-year period ending April 16, 2015, the Board suspended the license for an indefinite period of time effective January 26, 2017; and further, assessed a fine of $5,000 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the license or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

Drug & Strength	Quantity Lost	Percentage Lost
Alprazolam 2 mg	1,600	100%
Hydrocodone/ acetaminophen (APAP) 10/325 mg	8,533	33.21%
Hydrocodone/APAP 5/500 mg	2,495	35.79%
Hydrocodone/APAP 7.5/500 mg	1,248	27.07%
Hydrocodone/APAP 10/500 mg	6,582	51.51%
Oxycodone/APAP 10/325 mg	756	12.92%

[redacted]

[redacted]

The Medicine Store Pharmacy, Inc, dba RXpress Pharmacy (Fort Worth, TX) (PHY.007083): *Formal Hearing* – For its failure to designate a replacement PIC in a timely manner, and for the continued operation of the pharmacy without a PIC for approximately six months until its permanent closure, the Board revoked the permit; and further, assessed a fine of $5,000 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future application for the reinstatement of the permit or any application for any other credential issued by the Board upon the satisfaction of certain requirements identified in the hearing order.

During the same meeting, the Board issued a letter of warning to one pharmacy technician candidate and letters of reprimand to three pharmacy technicians. In addition, the Board granted requests for reinstatement of lapsed credentials from two pharmacy technicians, contingent upon their satisfaction of certain requirements identified in their consent agreements.

Calendar Notes (17-04-545)

The Board office will be closed on April 14 in observance of Good Friday, May 29 in observance of Memorial Day, and July 4 in observance of Independence Day.

Special Note (17-04-546)

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 (17-04-547)

"A single lie destroys a whole reputation for integrity." – Baltasar Gracián in *The Art of Worldly Wisdom* (1647)

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Record expunged in accordance with Act 229 of the La. Legislature's 2025 Regular Session.