



Louisiana Board of Pharmacy

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Renewal Time for Pharmacists and Pharmacies (17-10-553)

The renewal cycle for pharmacist licenses, pharmacy permits, and controlled dangerous substance (CDS) licenses for pharmacies will open on November 1, 2017. Just prior to that date, you should receive a reminder notice from the Louisiana Board of Pharmacy office; the mailer will remind you of the three options you have to renew your credentials:

1. Visit the Board's website at www.pharmacy.la.gov and renew your credentials online using the username and password printed on the reminder notice and a credit card for payment of the fee;
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, to the Board office; or
3. Send a written request to the Board office (mail, fax, or email) with your name, credential number, and mailing address, requesting the Board mail an application form to you.

Any address changes received at the Board office after Friday, October 20, 2017, will not be reflected on your renewal reminder. In the event the postal service fails to deliver your reminder mailer by November 15, 2017, it becomes your responsibility to retrieve an application form on the Board's website or renew your credentials online. Credentials renewed online will be mailed within one or two business days; credentials renewed with paper application forms will be mailed within two to four weeks, depending on the volume of paper applications received.

The online renewal module on the Board's website is programmed to automatically activate at 12:01 AM on November 1, 2017, and to automatically deactivate at midnight on December 31, 2017. While the Board makes every effort to maintain the online convenience during the renewal cycle, the Board's service provider may experience weather-related or other unforeseen technical difficulties from time to time. Such service disruptions have already happened more than once during the few years the Board has been offering the online option, including the final day of the

renewal cycle. You have 60 days to renew your credential, and it is your choice as to when you complete that duty. In the event you choose to wait until the last day and the website is not available, you will be responsible for the consequences of your failure to renew your credential in a timely manner. The Board does not waive the penalty fees in that situation. Why take a chance? Please do not wait until the last minute of the last day.

In the event you elect or are required to use paper application forms, the Board suggests you submit your completed application forms and fees to the Board office no later than December 1, 2017, especially if you require a renewed license on or before January 1, 2018. Please do not forget to answer all the questions and sign and date the application form. If the forms are incomplete, or if there is no supporting documentation when required, the Board may return your application form to you, resulting in a delay in the renewal of your credential.

As required by Act 298 of the 2015 Louisiana State Legislature, the Board is required to assess the pharmacy education support (PES) fee of \$100 on the renewal of every pharmacist license and pharmacy permit issued by the Board. The law also provides an option for the pharmacist and pharmacy to decline to pay the fee. You will notice the default position is for the fee to be included on your invoice; you must "opt out" if you wish to decline to pay the PES fee.

If it is important for you to know when your paper application forms are received at the Board office, the Board suggests you use a mailing service with tracking options, eg, United States Postal Service, FedEx, DHL, or United Parcel Service. This year, the Board anticipates the renewal of approximately 12,000 credentials in this two-month renewal cycle. Because of the volume of mail, the Board may not be able to respond in a timely manner to requests for delivery confirmation.

- ◆ Current pharmacist licenses expire at midnight on December 31, 2017. There is no "grace period," and a pharmacist shall not practice with an expired license.
- ◆ The fee for the timely renewal of a pharmacist license is \$100. Unless opted out, the PES fee of \$100 will be

Continued on page 4

.Pharmacy Domain Signals Safety on the Web



With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: *www.safe.pharmacy*. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply*.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture



*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*.*

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- ◆ educate patients about safe use of prescription opioids;
- ◆ remind patients to store medications out of children’s reach in a safe place; and
- ◆ talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal*. Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR_xE®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhbsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- ◆ A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- ◆ A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- ◆ A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and

18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- ◆ A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide*, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

added to the total cost. The renewal of an expired license will incur a 50% penalty fee of \$50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, then a \$200 reinstatement fee will also be required.

Please remember the pharmacy permit and CDS license for the pharmacy are separate credentials and must be renewed on separate application forms. There is no change in the fee, and you may write one check for one or more credentials, but the application forms are separate. In the event you send multiple applications with one check and there is a problem with one of the applications, all of the applications covered by that check will be delayed until all of the applications paid for with that check can be processed. If renewing online, those credentials have separate application forms and are available for access at the same time. Both must be completed in order to renew both credentials. You can elect to renew and pay for them in separate transactions or, alternatively, you may place both applications on the same invoice prior to payment.

- ◆ Current pharmacy permits and CDS licenses for pharmacies expire at midnight on December 31, 2017. There is no “grace period” and a pharmacy shall not operate with an expired permit or CDS license. Recent history reveals the usual fine for this violation is \$5,000.
- ◆ The fee for the timely renewal of a pharmacy permit is \$150, which includes the \$25 Prescription Monitoring Program assessment. Unless opted out, the PES fee of \$100 will be added to the total cost. The renewal of an expired permit will incur a 50% penalty fee of \$62.50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, then a \$200 reinstatement fee will also be required.
- ◆ The fee for the timely renewal of a CDS license for a pharmacy is \$25. The renewal of an expired CDS license for a pharmacy will incur a 50% penalty fee of \$12.50 for the first 30 days after the expiration date. If renewed more than 30 days after the expiration date, then a \$200 reinstatement fee will also be required.

Pharmacist Responsibility (17-10-554)

If you are the pharmacist-in-charge (PIC) of a pharmacy, it is your responsibility to ensure that all personnel you allow to perform professional functions in your pharmacy are properly credentialed with an active and current credential. If you are a staff pharmacist or a relief pharmacist, it is your responsibility to ensure that all personnel you allow to assist you in the pharmacy are properly credentialed with an active and current credential. Remember that you can verify the status of any credential at the Board’s website.

In the event a compliance officer discovers anyone performing professional functions without the necessary credentials, all of the pharmacists present as well as the PIC will be identified in the resulting investigative report filed by the compliance officer. Further, in the event of a formal inquiry by the Board, all of those pharmacists so identified will bear the risk of potential disciplinary action for aiding and abetting the unlicensed practice of pharmacy.

Disciplinary Actions (17-10-555)

During its August 23, 2017 meeting and administrative hearing, the Board took final action in the following matters:

B & B Pharmacy Enterprises, LLC, dba Highland Health Mart Pharmacy (Baton Rouge, LA) (PHY.006687):

For its failure to follow proper closure procedures, the Board assessed a fine of \$2,500 plus administrative and investigative costs.

Christopher Wesley Kidwell (CPT.007999): For his practice of pharmacy in the absence of pharmacist supervision despite specific prior guidance to the contrary, the Board issued a letter of reprimand, and further, assessed administrative and investigative costs.

Ashley Simon Seiber (CPT.013762): For her unlawful acquisition of controlled substances (CS) without a prescription, the Board suspended the certificate for one year and stayed the execution thereof, then placed the certificate on probation for one year, effective August 23, 2017, subject to certain terms enumerated in the consent agreement, and further, assessed administrative costs.

K&B Louisiana Corporation, dba Rite Aid Pharmacy No. 7335 (Shreveport, LA) (PHY.003040):

For its failure to notify the Board of the departure of its PIC in a timely manner and for the continued operation of the pharmacy without a designated PIC for approximately six weeks, the Board assessed a fine of \$10,000 plus administrative and investigative costs.

Caremark, LLC, dba CVS Specialty Pharmacy (Redlands, CA) (PHY.005877):

For its failure to designate a replacement PIC in a timely manner and for the continued operation of the pharmacy without a designated PIC for approximately five months, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Talisha Lachel Causey (CPT.010234): For her alleged diversion of CS from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Steven’s Pharmacy, Inc, dba Steven’s Pharmacy (Port Allen, LA) (PHY.004535 and CDS.038660-PHY – Case No. 17-0106):

For his failure to renew the pharmacy’s CDS license following its expiration on December 31, 2016, and for the pharmacy’s dispensing of 2,203 prescriptions for CS from January 1 through March 24, 2017, all of which activity occurred while the pharmacy permit and CDS license were on probation with the Board, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Steven’s Pharmacy, Inc, dba Steven’s Pharmacy (Port Allen) (PHY.004535 and CDS.038660-PHY – Case No. 16-0219):

For its failure to properly comply with the terms of its 2012 Probation Board Order mandating a perpetual inventory for all Schedule II CS, and for shortages of multiple CS pursuant to a drug accountability audit, the Board suspended the permit and CDS license for five years and stayed the execution thereof, then placed the permit and CDS license on probation for five years, to begin when the currently existing term of probation ends on October 1, 2017, and terminating on October 1, 2022, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of \$25,000 plus administrative and investigative costs.

Steven Walter Gough (PST.013199 – Case No. 16-0220):

As owner and PIC of Steven's Pharmacy in Port Allen, for his failure to properly comply with the terms of his 2012 Probation Board Order mandating a perpetual inventory for all Schedule II CS, and for shortages of multiple CS pursuant to a drug accountability audit, the Board suspended the license for an indefinite period of time, effective July 10, 2017, and further, assessed administrative costs, and further, conditioned the acceptance of any future application for reinstatement of the license upon the satisfaction of certain terms identified in the consent agreement.

Rx Care of LA, Inc, dba Benzer Pharmacy (Vivian, LA) (PHY.006524 and CDS.041725-PHY):

For its failure to adequately secure the prescription department when entrusting keys to the building and pharmacy and security access codes to non-pharmacist personnel, and for substantial shortages of CS pursuant to a drug accountability audit, the Board assessed a fine of \$10,000 plus administrative and investigative costs.

Stephanie Ann Richards (PST.015339):

Board granted request for reinstatement of the previously suspended license, then restored the license to active and unrestricted status.

James Edward Helou (PST.019129):

Board granted 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 August 23, 2017, subject to certain terms enumerated in the consent agreement.

Stephen Leonard Collins (PST.011311):

Board granted request for early termination of the probationary period originally scheduled to conclude on November 18, 2020, then placed the license on voluntary inactive status.

Kacie Doré Keith (PST.020248):

Board granted request for modification of her 2016 Probation Board Order by removing Article 2-e, which had prevented her from accepting an appointment as the PIC of a pharmacy.

Pattie Jo Bullard (CPT.013594):

Board suspended the certificate for five years and stayed the execution thereof, then placed the certificate on probation for five years, effective August 23, 2017, subject to certain terms enumerated in the consent agreement.

Charles Wendell Alford (PST.013050):

Board granted request for the reinstatement of the previously lapsed license, suspended it for two years and stayed the execution thereof, then placed the license on probation for two years, effective August 23, 2017, subject to certain terms enumerated in the consent agreement.

Harvey Lee Smith, Jr (PST.020467):

Board granted request for early termination of the probationary period originally scheduled to conclude on February 13, 2019, then restored the license to active and unrestricted status.

Kaitlyn Marie Zimmerman (PTC.025251):

Board accepted the voluntary surrender of the credential, resulting in the active suspension of the registration for an indefinite period of time, effective July 20, 2017.

Summer Michelle Eichelberger (PTC.025120):

Board accepted the voluntary surrender of the credential, resulting in the active suspension of the registration for an indefinite period of time, effective August 21, 2017.

Kristen Je'Nay Williams (PTC.021994) – Formal Hearing:

For her diversion of CS from her employer pharmacy, the Board suspended her registration for an indefinite period of time, effective August 23, 2017, and further, assessed administrative, investigative, and hearing costs, and further, conditioned the future acquisition of a pharmacy technician certificate upon the satisfaction of certain requirements identified in the hearing order.

Benecard Central Fill of PA, LLC, dba Benecard Central Fill (Mechanicsburg, PA) (PHY.006167) – Formal Hearing:

For its failure to comply with the provisions of the Medical Assistance Trust Fund Act, which requires pharmacies to file quarterly reports with the Louisiana Department of Health and to pay certain fees, the Board suspended the permit for an indefinite period of time, effective August 23, 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 permit upon the satisfaction of certain requirements identified in the hearing order.

During the same meeting, the Board issued a letter of warning to one pharmacist and additional letters of reprimand to one pharmacist and one technician. In addition, the Board granted one request to return a previously voluntary inactive pharmacist license to active status. Finally, the Board granted requests for reinstatement for one technician without further action and for one pharmacist conditioned upon the satisfaction of certain requirements identified in the consent agreement.

Calendar Notes (17-10-556)

The Board office will be closed on November 23 in observance of Thanksgiving Day, November 24 for Acadian Day, December 25 for Christmas Day, and January 1, 2018, for New Year's Day.

Special Note (17-10-557)

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 (17-10-558)

“The fool doth think he is wise, but the wise man knows himself to be a fool.” – William Shakespeare, *As You Like It*