



Louisiana Board of Pharmacy

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Board Elects Officers for 2017 (17-01-532)

During the November 16, 2016 Louisiana Board of Pharmacy meeting, Board members conducted their annual election of officers, with the following results:

- ◆ President – Carl W. Aron, from Monroe, LA, in District 5
- ◆ First Vice President – T. Morris Rabb, from Monroe, in District 5
- ◆ Second Vice President – Marty R. McKay, from Woodworth, LA, in District 8
- ◆ Third Vice President – Chris B. Melancon, from Carencro, LA, in District 7
- ◆ Secretary – Brian A. Bond, from Jena, LA, in District 8

Board Meeting Dates for Calendar Year 2017 (17-01-533)

The Board has announced the first meeting of the year will be held on January 25-26, as well as the following tentative dates for the rest of the year: May 10-11, August 23-24, and November 15-16. All meetings are planned for the Board office in Baton Rouge, LA.

Board Issues Emergency Rules (17-01-534)

During the November 16, 2016 meeting, the Board reviewed the emergency rule for accreditation of pharmacy technician training programs, noting the implementation date of January 1, 2017. Acknowledging the larger than usual number of proposed rules in various stages of process, the Board determined it appropriate to delay the implementation for one additional year. It revised the previous emergency rule by changing the implementation date from 2017 to 2018 and then issued a new, revised emergency rule effective immediately.

The Board also reviewed the emergency rule that was issued in August 2016 for distribution of naloxone pursuant to standing orders. With the rulemaking process under way and the development of a statewide standing order also under way, the Board authorized the emergency rule to be reissued in December 2016.

The Board also reviewed a proposal from the Board's Reinstatement Committee to streamline the reinstatement of controlled dangerous substance (CDS) licenses from

certain practitioners whose primary professional licenses had been disciplined. The Board approved the proposed rule change, and given the potential impact on patient care, also adopted a Declaration of Emergency to implement the change immediately while the rulemaking process was under way.

Copies of all these emergency rules were distributed to all pharmacies and pharmacists for whom the Board has email addresses on file. You can track the progress of those rulemaking projects on the Board's website.

Change of Pharmacist-in-Charge in a Pharmacy (17-01-535)

The Board's rules require three licensees to send written notice to the Board whenever there is a change in the pharmacist-in-charge (PIC) position: (1) The departing PIC shall give the owner of the permit and the Board at least 10 days written notice before his or her departure; (2) The owner of the permit shall notify the Board no later than 10 days after the departure of the prior PIC; and (3) The new PIC shall give notice to the Board no later than 10 days after his or her arrival. Form No. 61 documents the essential data elements for the proper notice of a change in the PIC for a pharmacy.

When the departing PIC fails to give proper notice to the Board, he or she is held accountable until the new PIC arrives, no matter how long that might be, and even if he or she is not present. The Board strongly suggests that the departing PIC document his or her final duty (CDS inventory), sign and date the form, send a copy of that form immediately to the Board office (fax, email, or mail), and keep a copy for his or her personal records.

The ability of a pharmacist to accept the PIC position in a pharmacy requires the pharmacist to first obtain a PIC privilege. The acquisition of a PIC privilege requires: (1) experience as a licensed pharmacist for at least two years in any jurisdiction within the United States, and (2) completion of the PIC affidavit form (No. 62). The form is only needed one time; once the PIC privilege is issued, it renews automatically with the pharmacist license, and there is no fee.

Disciplinary Actions (17-01-536)

During its August 11, 2016 administrative hearing, the Board took final action in the following matters:

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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at www.ecfr.gov.

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf. FDA provides more information online at www.fda.gov/Drugs/DrugSafety/ucm524320.htm.

Selected Medication Risks to Manage in 2017

 *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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.¹ Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.^{1,2} This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.^{1,2}

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.^{3,4} Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.⁴ Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.⁴ Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.⁴ Medication rooms should provide illumination at 100 fc.⁴ Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy³ and should be used on mobile medication carts (including those used with bar code medication verification systems)⁴ and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

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

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at www.dea.gov/divisions/hq/2016/hq100416.shtml and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) 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. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at www.fda.gov/Drugs/DrugSafety/ucm526206.htm.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s 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.

Latoya Ranisha Robinson (CPT.012478): For her written admission to the diversion of controlled substances (CS) from her employer pharmacy, the Board revoked her certificate; assessed a fine of \$1,000 plus administrative, investigative, and hearing costs; and further, conditioned the acceptance of any future reinstatement application upon the satisfaction of certain requirements identified in the hearing order.

Marco Bisa Moran (PST.016442): Pursuant to the Board's interview and deliberation on his application for the reinstatement of his previously suspended license, the Board denied his request. The pharmacist has appealed the Board's decision for judicial review.

During its November 15, 2016 meeting, the Board took final action in the following matters:

Kumisa René Walker (PTC Applicant): For her failure to disclose her entire criminal history on her application for a pharmacy technician candidate (PTC) registration, the Board denied the application and refused to issue the credential.

Kmart Corporation, dba Kmart Pharmacy No. 3016 (Bossier City, LA) (PHY.002058): For its failure to properly close the pharmacy, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Daanaa Raajih Richard (PNT.047724): For his written admission to the diversion of alprazolam and hydrocodone from his employer pharmacies, the Board suspended his intern registration for five years and stayed the execution of the suspension, then placed the registration and any subsequent credential on probation for five years, effective November 16, 2016, subject to certain terms enumerated in the consent agreement.

Apothecare, LLC, dba Apothecare (Meadville, MS) (PHY.007269): For its dispensing of approximately 3,600 prescriptions into Louisiana between August 2011 and November 2012 without a Louisiana pharmacy permit, the Board assessed a fine of \$50,000 plus administrative and investigative costs.

AmeriPharm, Inc, dba MedVantx Specialty Pharmacy (Louisville, KY) (PHY.007091): For its continued operation from June 15, 2015, to December 15, 2015, without a Louisiana-licensed PIC, the Board assessed a fine of \$5,000 plus administrative and investigative costs.

Tiffany Annette Pitre (CPT.001615): The Board granted her request for the reinstatement of the previously suspended certificate, 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 certificate on probation for five years, effective November 16, 2016, subject to certain terms enumerated in the consent agreement.

Leo Gerard Riche (PST.014961): The Board granted his request for early termination of probation, which was originally scheduled to conclude on August 5, 2019, then restored the license to active and unrestricted status.

Angela Nicole Hotard (PST.016604): The Board granted her request for early termination of probation, which was originally scheduled to conclude on February 24, 2017, then restored the license to active and unrestricted status.

Sandra Ann Charlot (CPT.011354): Pursuant to her arrest for the illegal possession of CS, the Board revoked the certificate, and further, permanently prohibited any future reinstatement application.

Charlene L. Simon (CPT.007131): For her diversion of alprazolam and diazepam from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited any future reinstatement application.

Alissa Marie Henry (CPT.010953): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective September 16, 2016.

Alvin Watts III (PST.018168): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective October 17, 2016.

Morris Albert Lottinger III (PST.013756): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective October 17, 2016.

Timothy Keith Freeman (PST.020918): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the license for an indefinite period of time, effective September 9, 2016.

During the same meeting, the Board issued a letter of warning to one pharmacy technician and letters of reprimand to eight pharmacy technicians. In addition, the Board granted requests for reinstatement of lapsed credentials from three pharmacy technicians, contingent upon their satisfaction of certain requirements identified in their consent agreements. Finally, the Board suspended the CDS licenses for eight physicians, one podiatrist, one advanced practice registered nurse, and one veterinarian. The suspensions were based on the suspension of their primary professional licenses or the surrender of their federal Drug Enforcement Administration registrations.

Calendar Notes (17-01-537)

The Board office will be closed on January 16 in observance of Martin Luther King, Jr Day, February 28 for Mardi Gras Day, and April 14 for Good Friday.

Special Note (17-01-538)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and PTCs 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 (17-01-539)

"Nature gave men two ends – one to sit on, and one to think with. Ever since then man's success or failure has been dependent on the one he used most." – George R. Kirkpatrick