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Louisiana Board of Pharmacy News

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Election of Officers (10-01-337)

The Louisiana Board of Pharmacy conducted its annual election of officers during its November 18, 2009 meeting held in Baton Rouge, LA. The following members were elected:

Carl W. Aron, Monroe..... President
T. Morris Rabb, Monroe.....First Vice President
Marty R. McKay, Woodworth ... Second Vice President
Joseph L. Adams, Mandeville ..... Third Vice President
Reuben R. Dixon, New Orleans.....Secretary

Board Meeting Dates for 2010 (10-01-338)

The Board has set the following tentative meeting dates for 2010:

February 2-4	August 10-12
May 4-6	November 8-10

All meetings are planned to be held at the Board office in Baton Rouge, LA.

Board Member Appointments (10-01-339)

Board member appointments are made in accordance with La. R.S. 37:1175, which provides that whenever a vacancy occurs among the members representing one of the eight districts, the pharmacists who are bona fide residents of the district in which the vacancy occurs shall nominate, from among their number, a representative to the Board. Whenever the vacancy will occur by reason of an expiring term, the nominations shall be made by mail at least 60 days in advance of the expiration date of the term.

The Board secretary is responsible for mailing a ballot, by United States mail, to each pharmacist holding an active license and residing in the district in which the vacancy will occur, at the last known address as indicated in the Board's records. The ballot, or another enclosed communication, will state the date, time, and place for counting ballots. At a gathering open to the public, the secretary and/or more persons designated by him or her will open and count the ballots. The secretary will then certify to the governor the names of the three nominees in each district receiving the highest number of votes.

The terms of five current Board members will expire on August 24, 2010. The ballots with the necessary information will be mailed to pharmacists in the respective districts during the week of May 3, 2010. The ballots will be opened and counted during the week of June 7, 2010; information about the exact time and place will be included with the ballot.

Board member terms that will expire on August 24, 2010, and their districts, are as follows:

1. Michele P. Alderman, Metairie (District 1 – composed of the parishes of Jefferson and St Tammany).
2. Reuben R. Dixon, New Orleans (District 2 – composed of the parishes of Orleans, Plaquemines, and St Bernard).
3. J. Douglas Boudreaux, Shreveport (District 4 – composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster).
4. John O. LeTard, Zachary (District 6 – composed of the parishes of East Baton Rouge, East Feliciana, Livingston, St Helena, Tangipahoa, Washington, and West Feliciana).
5. Allen W. Cassidy, Jr, Jennings (District 7 – composed of the parishes of Acadia, Calcasieu, Cameron, Jefferson Davis, Lafayette, and Vermilion).

Should any pharmacist need a list of pharmacists in his or her own district for purposes related to this nomination election, the Board office will supply one complimentary list upon written request by the pharmacist.

Proposed Changes to Board Regulations (10-01-340)

The Board is currently in the process of adopting changes to certain regulations. In particular, the Board is managing four separate regulatory projects:

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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- *Regulatory Project 2009-1 ~ Drugs of Concern:* This proposal seeks to amend the definition of the term "drugs of concern" found in Chapter 29 – Prescription Monitoring Program. The proposal will identify two drug products and include them in the definition: tramadol and butalbital/acetaminophen. The practical effect of this change would add all eligible prescription transactions for these drug products to the reporting requirement to the Board's prescription monitoring program (PMP). The PMP law requires all eligible prescription transactions for controlled substances and drugs of concern to be reported to the program. To date, the Board has only required controlled substances to be reported. This proposal will identify the first two drugs of concern, which will then require the reporting of their eligible transactions to the PMP.
- *Regulatory Project 2009-2 ~ Pharmacy Interns:* This proposal will identify the scope of practice for pharmacy interns, and further, will specify the maximum intern-to-pharmacist ratio in all practice settings. The proposal seeks to establish a 1:1 ratio, except for those pharmacists instructing interns within academic rotation settings, where that ratio shall not exceed three interns to one pharmacist (3:1).
- *Regulatory Project 2009-3 ~ Prescription Transfers:* This proposal will allow those pharmacies sharing a common electronic prescription file to streamline their prescription transfer procedures by eliminating the requirement to physically or electronically transfer prescriptions for information dispensing purposes, but only if there are complete and adequate records of all prescriptions dispensed.
- *Regulatory Project 2009-4 ~ Digital Imaging of Prescriptions:* This proposal will allow those pharmacies utilizing an electronic prescription imaging system to simplify their prescription filing procedures. Provided the imaging system complies with the standards identified in the proposal, the pharmacy may then choose to file the hard copy prescriptions in order of date scanned as opposed to prescription number sequence.

All four of the regulatory proposals were drafted with stakeholder input and then approved for promulgation by the Board during calendar year 2009. The Board published the required notice of intent for all four proposals in the December 20, 2009 edition of the *Louisiana Register*. The next step in the promulgation process is the receipt of public comments by all interested parties. The Board will receive written comments until the date of the public hearing, which is set for 9 AM on Wednesday, January 27, 2010, at the Board office. The deadline for all comments for all four proposals is noon that same day. The Board will analyze all comments and then determine whether any amendments of any of the proposals are necessary. Following that determination, the Board will submit its report, including findings and recommendations to the Joint Legislative Oversight Committee on Health and Welfare. Depending on the outcome of the legislative review, the Board may – or may not – publish the proposals as a final rule. If one or more of the proposals is published as a final rule in the *Louisiana Register*, then the effective date of that new rule will be noted in that publication. Depending on the timing of that event, the Board may use a future edition of this *Newsletter*, or perhaps a bulletin, to notify all pharmacies, pharmacists, and interns.

If you have an interest in one or more of these regulatory proposals, we encourage you to review the proposed language and other documents available on the Board's Web site. In particular, you should select the Meetings & Notices link on the home page, and then select the Regulatory Projects link. If you wish to submit written comments about the proposals to the Board, you should send those communications to the Board office, directed specifically to Malcolm J. Broussard, executive director for the Board. He is the person responsible for collecting and responding to all comments submitted to the Board about the regulatory proposals.

New Licensing Software for Board Office (10-01-341)

The current software used by the Board office to maintain licensure records was purchased and installed in the 1970s. We have recently purchased a replacement product that will significantly enhance the Board's record keeping functionality. We have already begun the process of mapping the current data to the new system and we are currently configuring the new system to meet our current and future needs. As part of the configuration process, we have adopted a standardized format for all of the credentials issued by the Board. The credential number will be preceded by a three-letter prefix, and may in some cases be followed by a two- or three-letter suffix. PST refers to a pharmacist, PNT to a pharmacy intern, CPT to a certified pharmacy technician, PTC to a pharmacy technician candidate, PHY to a pharmacy, EDK to an emergency drug kit, AMS to an automated medication system, and CDS to a controlled dangerous substance license.

Disciplinary Actions (10-01-342)

Although every effort is made to ensure this information is correct, you should contact the Board office at 225/925-6496 or labp@labp.com to verify the accuracy of any listing before making any decision based on this information.

During its August 6, 2009 formal administrative hearing, the Board took final action in the following matters:

Triel Regions Pharmacy (PHY.5581): Permit revoked; and further, assessed $5,000 plus administrative and hearing costs.

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Kirsten N. Carter (CPT.8502): Certificate revoked; and further, assessed $1,000 plus administrative and hearing costs.

Curtis Lee Beauregard (CDS.33691.MD): License suspended for an indefinite period of time.

Maria Carmen Palazzo (CDS.12566.MD): License suspended for an indefinite period of time.

Misty Dawn McCarty (CPT.7221): Certificate suspended for an indefinite period of time; and further, assessed $500 plus administrative and hearing costs.

Complete Vital Care (PHY.4436): Permit revoked; and further, assessed $10,000 plus administrative and hearing costs.

During its November 18-19, 2009 meetings, the Board took final action in the following matters:

Alesha Renee Cleary (Applicant for Candidate Registration): Board denied the application and refused to issue the registration.

Katie Lisa Anne Layssard (Applicant for Candidate Registration): Consent Order: Board approved the issuance of the registration, suspended it for five years, and stayed the execution thereof, and then placed the registration on probation for five years, subject to certain terms enumerated in the order.

Roy Kirk Fisher (PST.18600): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective September 8, 2009.

Kimiko Tiesha Austin (CPT.5676): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective October 14, 2009.

Michael Thomas Savario (PST.16568): Consent Order: Granted request for reinstatement of the previously suspended license, suspended it for 10 years and stayed the execution thereof, then placed it on probation for 10 years, subject to certain terms as enumerated in the order.

Jason Conrad Dove (PST.15811): Consent Order: Granted request for reinstatement of the previously suspended license, contingent upon the completion of certain terms, then placed the special work permit, and subsequently reinstated license on probation for 10 years, subject to certain terms as identified in the order.

Dawne Chere Landry (PST.17223): Consent Order: Granted request for reinstatement of the previously suspended license, suspended it for five years, and stayed the execution thereof, and then placed it on probation for five years, subject to certain terms as enumerated in the order.

Raquelle Danielle Woodard (PNT.44998): Consent Order: Granted request for reinstatement of the previously suspended registration, suspended it and any subsequent license for five years, and stayed the execution thereof, and then placed the registration and any subsequent license on probation for five years, subject to certain terms as enumerated in the order.

Fred's Pharmacy No. 2336 (PHY.3127): Consent Order: Assessed $250 plus costs; and further, required documentation of quality assurance program by certain date; and further, required continuing education for entire staff for dispensing error.

Kevin Michael Dufour (PST.15941): Consent Order: Issued letter of reprimand; and further, assessed $500 plus costs, for improper access of information in the state prescription monitoring program.

CVS Pharmacy No. 5617 (PHY.5825): Consent Order: Assessed $2,500 plus costs, for allowing candidate with expired registration to continue to practice.

James Michael Bennett (PST.17989): Consent Order: Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective October 16, 2009.

Wal-Mart Pharmacy No. 10-3703 (PHY.5654): Consent Order: Assessed $2,500 plus costs, for dispensing error.

Walgreens Pharmacy No. 02468 (PHY.5481): Consent Order: Assessed $2,500 plus costs, for allowing candidate to practice without registration.

Walgreens Pharmacy No. 09086 (PHY.5566): Consent Order: Assessed $250 plus costs, for dispensing error.

Thrifty Way Pharmacy of Ville Platte (PHY.3139): Consent Order: Assessed $5,000 plus costs, for improper record keeping of controlled substances as well as audit shortages thereof.

Robert Andrew Launey (PST.11335): Consent Order: Assessed $5,000 plus costs; and further, license suspended for three years with execution thereof stayed, and then placed on probation for three years, subject to certain terms as enumerated in the order.

Polly A. Fontenot (CPT.4148): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective September 18, 2009.

Emily Noel Anders (CPT.1078): Consent Order: Certificate revoked, with permanent prohibition on application for reinstatement, for alleged diversion of controlled substances from employer pharmacy.

Miyoshi Annette Stinson (CPT.7786): Consent Order: Certificate revoked, with permanent prohibition on application for reinstatement, for alleged diversion of controlled substances from employer pharmacy.

Elisa Christine LaBat (CPT.7261): Consent Order: Certificate revoked, with permanent prohibition on application for reinstatement, for alleged diversion of controlled substances from employer pharmacy.

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LaBrenta Renee Shelton Hullaby (CPT.5146): Consent Order: Certificate revoked, with permanent prohibition on application for reinstatement, for alleged diversion of controlled substances from employer pharmacy.

Cory Joseph Landry (Applicant for Candidate Registration): Consent Order: Application denied with refusal to issue registration; and further, permanent prohibition on any future application for any credential, for alleged diversion of controlled substances from employer pharmacy.

Sharon Lind Bratton Hornbuckle Alexander (PST.11673): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective August 21, 2009.

Kathleen Mary McGill Hardin (CPT.4969): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective August 28, 2009.

Joia Crear-Perry (CDS.26387.MD): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective July 31, 2009.

Stephen Kuplesky (CDS.06319.MD): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective September 16, 2009.

Troy Renard Guilbeaux (PST.17854): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective October 5, 2009.

Michael Ray McElveen (CDS.20104.DVM): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective October 14, 2009.

Robert Eustis Fleming (PST.10867): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective October 28, 2009.

James Bruce Johnson (CDS.07946.MD): Accepted voluntary surrender, resulting in active suspension for an indefinite period of time, effective August 19, 2009.

On this same date, the Board also issued a letter of warning to one pharmacy permit owner as well as letters of reprimand to three pharmacy permit owners and two technician candidates. In addition, they granted requests for the reinstatement of lapsed credentials from three pharmacists and four technicians. With respect to participants in the Board's Practitioner Recovery Program, the Board granted requests for modification of probationary terms from one pharmacist and they also approved a partial modification of standard terms of probation for 19 pharmacists and one intern.

Calendar Notes (10-01-343)

The next Board meeting and administrative hearing will be February 2-4, 2010, at the Board office. The office will be closed January 18 in observance to Martin Luther King, Jr Day and February 16 for Mardi Gras Day.

Special Note (10-01-344)

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. We encourage 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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