July 2016

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*

New State Laws From 2016 Legislature (16-07-519)

In the last issue of the *Louisiana Board of Pharmacy Newsletter,* the Board reported three legislative proposals it had filed for consideration during the state legislature's regular session that ended on June 6. Of the three bills, two were passed and signed into law and one failed to pass. In particular:

- **House Bill (HB) 446** would have established an application fee for the marijuana pharmacy permit that is currently under development by the Board. Although the bill cleared the House of Representatives, the bill failed to pass in the Senate.
- **HB 688** amends the state's list of controlled substances (CS) to remove naloxegol and ioflupane (with and without radioisotopes) from Schedule II and adds eluxadoline to Schedule IV, consistent with recent federal scheduling actions. The governor signed the bill into law as Act 62, with an effective date of August 1, 2016.
- **Senate Bill 56** amends the state's prescription monitoring program (PMP) law to allow the Board to establish standards for the retention, archiving, and destruction of prescription transaction information stored in the program's database. This will require the Board to develop those standards by the usual rulemaking process. The governor signed the bill into law as Act 189, with an effective date of August 1, 2016.

There were other bills affecting pharmacy practice sponsored by other organizations that were passed by the legislature. Some of these include the following:

- **Act 310** amends the Pharmacy Practice Act, more specifically Revised Statute 37:1226.3, which governs the process by which pharmacies serving offenders in state prisons are able to accept drug returns from those facilities and redispense the drugs to other offenders in those facilities. The new law expands the population to include correctional facilities operated by local law enforcement agencies, eg, parish jails. Pharmacies serving those facilities must be able to accept drug returns and redispense those drugs back to those same facilities. As a reminder, the Board requires any pharmacy serving that population to first acquire the penal pharmacy permit. Pharmacies with regular community pharmacy permits are not authorized to accept returns of prescription drugs for redispensing. This new law has an August 1, 2016 effective date and will require the Board to update its rules.
- **Act 192** amends the state CS law to provide an additional exception to the dispensing limitation on prescriptions for opiate derivatives listed in Schedules II or III when prescribed by practitioners not licensed in Louisiana. You may recall that **2014** legislation limited pharmacists to dispensing a maximum of a 10-day supply for such prescriptions, and further, required the dispensing pharmacist to notify the prescriber of the limited dispensing and the cancellation of any authorized refills, and further, prohibited the dispensing of that same medication to that same patient when prescribed by any non-Louisiana-licensed practitioner for the next 60 days. The **2015** legislature amended that law to provide that if the PMP information from the state where the prescriber is located is available to the dispensing pharmacist, then the limitation did not apply. This **2016** law provides an additional exception: if the practitioner indicates a diagnosis of cancer or terminal illness on that prescription for an opiate derivative listed in either Schedule II or III, then the dispensing limitation shall not apply. This exception is an additional exception and is independent of the first exception regarding the availability of PMP information. The governor signed this bill with an immediate effective date of May 26, 2016. The Board has previously notified all the pharmacies of this new law via the Pharmacy Alert email notice. **(Are you getting**

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, 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.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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the Pharmacy Alert emails? Make sure the Board has an email address on file for your pharmacy.)

- **Act 370** amends the law governing the dispensing of naloxone for the third year in a row. Although the bill was made effective immediately when the governor signed it on June 5, the legislation requires the Board to develop rules to fully implement this new law. When promulgated, the rule will allow a pharmacist to dispense naloxone or another opioid antagonist to anyone pursuant to a non-patient-specific standing order.
- **Act 96** amends the state's medical marijuana law to make some minor adjustments in the legislation from the previous year. The Board was in the process of developing its rules in response to last year's legislation, but paused when it saw the number of bills filed in this year's session that would have made substantial changes in the program adopted last year. The Board has resumed the rule development process; you can follow the progress of that effort by accessing the draft rules at *www.pharmacy.la.gov.* From the Board website's drop-down menu, select Public Library, then scroll down to click Public Notices, and then click Regulatory Proposals, where you will find Regulatory Proposal 2016-A.

Please look for the Board's traditional legislative bulletin that will be issued in mid-July detailing the bills passed that will affect your pharmacy practice.

Status Report on Rulemaking Activities (16-07-520)

The Board continues to promulgate new rules as well as revisions of existing rules. For its clients who have provided their email addresses, the Board sends electronic *Notices of Rulemaking Activity* about these issues.

- *Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians*. During its May 4, 2016 meeting, the Board reviewed the comments and testimony offered during the April 19, 2016 public hearing, determined no additional revisions were necessary, and directed the completion of the regulatory project. The Board submitted the entire project record to the Joint Legislative Oversight Committee on Health & Welfare. With no intervention by the legislature, the Board submitted the revised proposal for publication as a final rule. The *Louisiana Register* published the revised proposal as a final rule in the June 20, 2016 edition, with an immediate effective date. With the publication of the final rule, the revised emergency rule that was in effect was canceled.

The Board approved all three of the following original proposals during its February 24, 2016 meeting and directed the initiation of the promulgation process. The Board published the Notice of Intent in the April 2016 edition of the *Louisiana Register,* and then conducted a public hearing to receive comments and testimony on all three original proposals.

- *Regulatory Project 2016-1 ~ Controlled Dangerous Substance (CDS) Prescriptions.* The Board received no comments or testimony on this proposal. The Board directed the continuation of the promulgation process. The Board submitted the entire project record to the Joint Legislative Oversight Committee on Health & Welfare on June 3. If there is no intervention required, the Board intends to publish the original proposal as a final rule in the July 2016 edition of the state register.
- *Regulatory Project 2016-2 ~ Pharmacist-in-Charge (PIC) of Nonresident Pharmacies.* The Board received one comment for this proposal. The Board will evaluate that comment during its next meeting on August 10 to determine whether any revisions to the original proposal is necessary.
- *Regulatory Project 2016-3 ~ Medication Synchronization.* The Board received one comment requesting a minor revision. The Board has no objection to the requested revision, but will conduct a second public hearing to receive public comments on that proposed revision; that public hearing has been scheduled for July 22. The Board will evaluate any comments submitted during that hearing during its next meeting scheduled on August 10.

Disciplinary Actions (16-07-521)

During its February 25 administrative hearing, the Board took final action in the following matters.

Sade Shanae Shuntae Thomas (CPT.012433): For her failure to disclose a prior arrest on her renewal application despite specific questioning thereof, and for her further failure to provide information about that incident to the Board when specifically requested to do so, the Board suspended her certificate for an indefinite period of time, effective February 25, 2016, and further, assessed a fine of $1,000 plus administrative, investigative, and hearing costs, and further, conditioned the acceptance of any future application upon the satisfaction of certain requirements identified in the order.

Ni'Esha Shantae Domingue (PTC.022688): For her written admission to the diversion of oxycodone from her employer pharmacy, the Board revoked the registration, effective February 25, 2016, and further, assessed a fine of $500 plus administrative, investigative, and hearing costs, and further, conditioned the acceptance of any future application upon the satisfaction of certain requirements identified in the order.

HealthScripts of America – Southeast Louisiana, LLC, dba HealthScripts of America – Southeast Louisiana (PHY.007064): For its failure to properly close the pharmacy permit, the Board revoked the permit, and further, assessed the permit owner a fine of $50,000 plus administrative, investigative, and hearing costs, and further, conditioned the acceptance of any future application upon the satisfaction of certain requirements identified in the order. *Continued on page 5*

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HealthScripts of America – North Shore, LLC, dba HealthScripts of America – North Shore (PHY.006874): For its failure to properly close the pharmacy permit, and for the transfer of its closing inventory to a closed pharmacy, the Board revoked the permit, and further, assessed the permit owner a fine of $75,000 plus administrative, investigative, and hearing costs, and further, conditioned the acceptance of any future application upon the satisfaction of certain requirements identified in the order.

During its May 4 meeting, the Board took final action in the following matters.

Quitney Raynard Toussaint (PTC.023973): For his failure to disclose his entire criminal history on his application for a new pharmacy technician candidate registration, the Board authorized the issuance of the registration, suspended it for one year and stayed the execution of the suspension, then placed the newly issued registration on probation for one year, effective May 4, 2016, subject to certain terms enumerated in the consent agreement.

Taquincion Diara Watson (PTC.023974): Due to the nature of the criminal history disclosed on her application for a new pharmacy technician candidate registration, the Board authorized the issuance of the registration, suspended it for 18 months and stayed the execution of the suspension, then placed the newly issued registration on probation for 18 months, effective May 5, 2016, subject to certain terms enumerated in the consent agreement.

Chasity Nicole Green (PTC.021688): For her written admission to the diversion of alprazolam, buprenorphine/naloxone, and promethazine with codeine syrup from her employer pharmacy, the Board revoked the registration, effective February 4, 2016, and further, permanently prohibited the acceptance of any future application for any credential issued by the Board.

Christi Lynn Louviere (CPT.006838): The Board approved her request for reinstatement of her expired certificate, contingent upon the satisfaction of certain requirements identified in the consent agreement, and further, her preliminary special work agreement as well as the subsequently reinstated certificate shall be suspended for five years with the execution thereof stayed, and then both credentials shall be placed on probation, effective on the date of issuance of the permit, subject to certain terms enumerated in the consent agreement.

Justin Matthew Scalfano (PST.018787): For his violation of previously imposed terms of probation, the Board extended the previously imposed period of probation for five years; the revised probationary period is now scheduled to conclude on August 16, 2021.

John Sherwood Bannister (PST.015778): The Board suspended the license for five years and stayed the execution thereof, then placed the license on probation for five years, effective May 4, 2016, subject to certain terms enumerated in the consent agreement.

Kimanh Thi Truong (CPT.010191): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective April 6, 2016.

Fairview Pharmacy Services, LLC, dba Fairview Specialty Services Pharmacy (PHY.006186): For its failure to appoint a replacement PIC in a timely manner, and for its continued operation of the pharmacy without a replacement, the Board assessed the permit owner a fine of $10,000 plus administrative, investigative, and attorney costs.

During the same meeting, the Board issued letters of reprimand to one pharmacy, two pharmacists, and two pharmacy technicians, as well as a letter of warning to one pharmacy. In addition, the Board suspended the CDS licenses for two physicians whose medical licenses had been suspended, one advanced practice registered nurse who had surrendered her Drug Enforcement Administration registration, and one dentist who had refused to resolve a dishonored check submitted for his renewal fee.

Calendar Notes (16-07-522)

The Board office will be closed on September 5 in observance of Labor Day.

Special Note (16-07-523)

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.

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