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Louisiana Board of Pharmacy News

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Rulemaking Activities (13-07-435)

The Louisiana Board of Pharmacy published a new edition of the *Louisiana Pharmacy Law Book* on April 15, 2013. The electronic version of that reference is available on the "Laws & Rules" page of the Board's Web site. For those who wish to purchase a printed copy of the updated law book, a product order form is also available on that same page of the Web site.

The Board continues to promulgate new rules as well as revisions to current rules. The Board sends electronic *Notices of Rulemaking Activity* to its clients about these activities.

- *Regulatory Project 2013-1 ~ Compounding for Prescriber Use.* The Board voted to issue an emergency rule on January 29, 2013, that places limits on the amount of compounding for prescriber use a pharmacy may prepare. Since that time, the Board has been working through the process to develop a permanent rule. During its May 29 meeting, the Board voted to reissue the same emergency rule to give the Board more time to complete the rulemaking process for a permanent rule.
- *Regulatory Project 2013-2 ~ Hospital Off-Site Satellite Pharmacy.* The Board added new language to Chapter 15 of the Board's rules, allowing for the establishment and operation of satellite pharmacies in hospitals, subject to the provisions contained in the new rule. This new rule became effective on May 20, 2013.
- *Regulatory Project 2013-3 ~ Pharmacy Technician Training Programs.* The Board published the Notice of Intent in the April edition of the *Louisiana Register* and convened a public hearing on May 30, to receive comments and testimony on the proposed revision to the current rules.

Finally, you can monitor the progress of all regulatory proposals and projects by visiting the "Public Library" section of the Board's Web site, selecting the "Public Notices" link, and then reviewing the appropriate links for "Regulatory Proposals" and "Regulatory Projects."

Disciplinary Actions (13-07-436)

During its May 2013 meeting, the Board took final action in the following matters:

Peggy Ann Robins (PTC Applicant): Denied the application for pharmacy technician candidate registration and refused to issue the credential.

David Wayne Spears (PST.010314): Suspended the license for two years and stayed the execution thereof, then placed the license on probation for two years, effective June 1, 2013, subject to certain terms enumerated in the consent agreement, and further assessed administrative and investigative costs; for 15 counts, including dispensing multiple prescriptions for controlled substances (CS) pursuant to forged prescriptions.

Kristi Ann Phillips (CPT.008552): Certificate suspended for an indefinite period of time, effective March 13, 2013; for failure to submit to medical evaluation as directed by the Board.

Kori Kiffe Wright (CPT.009060): Accepted voluntary surrender of the credential, resulting in active suspension of the certificate for an indefinite period of time, effective March 25, 2013.

Cortina LaShone Richardson (CPT.005255): Suspended the certificate for five years and stayed the execution of the suspension, then placed the certificate on probation for five years, effective June 1, 2013, subject to certain terms enumerated in the consent agreement; for five counts, including possession of a firearm while in unlawful possession of Schedule I CS.

Kimiko Tiesha Austin (CPT.005676): Granted request for reinstatement of the previously suspended certificate, converted the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, and then placed the license on probation for five years, effective May 29, 2013, subject to certain terms enumerated in the consent agreement.

Roy Kirk Fisher (PST.018600): Granted request for reinstatement of the previously suspended license, converted the suspensive period from an indefinite term to a term of 10 years and stayed the execution of the suspension, and then placed the license on probation for 10 years, effective May 29, 2013, subject to certain terms enumerated in the consent agreement.

David Collins Evans (PST.014181): Granted request for reinstatement of the previously suspended license, converted the suspensive period from an indefinite term to a term of 15 years and stayed the execution of the suspension, and then placed the license on probation for 15 years, effective May 29, 2013, subject to certain terms enumerated in the consent agreement.

Michael Thomas Savario (PST.016568): Granted request for reinstatement of the previously suspended license, converted the suspensive period from an indefinite term to a term of 15 years and stayed the execution of the suspension, and then placed the license on probation for 15 years, effective May 29, 2013, subject to certain terms enumerated in the consent agreement.

Leslie Eileen Rodgers (PST.016948): Granted request for termination of probationary period, returning the license to active and unrestricted status, effective May 29, 2013.

Catherine Powell Kain (PST.020150): Approved application for pharmacist licensure by reciprocity, authorized issuance of pharmacist license then immediately suspended that license for a period of time ending May 17, 2016, and stayed the execution of the suspension, then placed the license on probation for a period of time ending May 17, 2016, subject to certain terms enumerated in the consent agreement.

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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 an 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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

Pharmacists & Technicians:
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Michael Glenn Harlton (PTC Applicant): Approved application for pharmacy technician candidate registration, authorized issuance of the registration and then immediately suspended that registration for five years and stayed the execution of the suspension, then placed the registration on probation for five years, effective on the date of issuance of the registration, subject to certain terms enumerated in the consent agreement.

Bryant Paul Pierce, Jr (CPT.001594): Granted request for reinstatement of the expired certificate, conditioned upon the satisfaction of certain terms identified in the consent agreement, and further, suspended the special work permit and certificate for one year and stayed the execution of the suspension, then placed the special work permit and certificate on probation for one year, effective on the date of issuance of the special work permit, subject to certain terms enumerated in the consent agreement.

Adriel Peter Joseph (PST.017298): Granted request for reinstatement of the previously suspended license, conditioned upon satisfaction of certain terms identified in the consent agreement, and further, suspended the license for three years and stayed the execution of the suspension, then placed the license on probation for three years, effective on the date of issuance of the license, subject to certain terms enumerated in the consent agreement.

Medisca, Inc (CDS.025126): Suspended the license for three years and stayed the execution thereof, then placed the license on probation for three years, effective January 10, 2013, subject to certain terms enumerated in the consent agreement; for activities that prompted the disciplinary action taken by the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy on the distributor's resident permit.

Samantha Sellers Michelli (CPT.004416): Revoked the certificate, and further, permanently prohibited any future application for reinstatement of the certificate or for any other credential issued by the Board; for five counts, including diversion of CS from her employer pharmacy.

Advantage Pharmacy (PHY.006676): Suspended the pharmacy permit for 11 months and 17 days and stayed the execution of the suspension, then placed the permit on probation for 11 months and 17 days, effective June 1, 2013, subject to certain terms enumerated in the consent agreement; for activities that prompted the disciplinary action taken by the Mississippi Board of Pharmacy on the pharmacy's resident permit.

Mehrdad Hariri (PST.019770): Suspended the license for four years, seven months, and 25 days and stayed the execution of the suspension, then placed the license on probation for four years, seven months, and 25 days, effective June 1, 2013, subject to certain terms enumerated in the consent agreement; for two counts, including activities which prompted the disciplinary action taken by the Florida Board of Pharmacy on his resident pharmacist license.

Travellis Eugene Harrison, Sr (CPT.010618): Revoked the certificate, and further, permanently prohibited any future application for reinstatement of the certificate or for any other credential issued by the Board; for five counts, including alleged diversion of CS from his employer pharmacy.

Chantelle Denise Williams (CPT.004794): Revoked the certificate, and further, permanently prohibited any future application for reinstatement of the certificate or for any other credential issued by the Board; for five counts, including alleged diversion of CS from her employer pharmacy.

John Edward Bull (PST.010451): Accepted the voluntary surrender of the credential, resulting in active suspension of the license for an indefinite period of time, effective May 7, 2013.

Barry Joseph Robichaux (PST.010309): Accepted the voluntary surrender of the credential, resulting in active suspension of the license for an indefinite period of time, effective May 10, 2013.

During the same meeting, the Board granted approval for the reinstatement of an expired license for a pharmacist and an expired certificate for a technician, as well as conditional approval for the reinstatement of expired credentials for two pharmacists and one technician, pending satisfaction of certain terms enumerated in their consent agreements. The Board also issued a letter of warning to the owner of a pharmacy permit as well as letters of reprimand to two pharmacists and the owners of two pharmacy permits, and further, suspended the controlled dangerous substance licenses for five physicians whose medical licenses were suspended by the Louisiana State Board of Medical Examiners.

Calendar Notes (13-07-437)

The next Board meeting and administrative hearing will be August 14-15, 2013, at the Board office. The office will be closed September 2, in observance of Labor Day.

Special Note (13-07-438)

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.

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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