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Louisiana Board of Pharmacy News

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Governor Appoints Five Members (13-01-422)

Governor Bobby Jindal appointed five members to the Louisiana Board of Pharmacy on September 27, 2012. Each of them will serve a term of six years, which terminates June 30, 2018.

- *Brian A. Bond*, from Jena, LA, represents District 8. He is a staff pharmacist at Christus Dubuis Hospital in Alexandria, LA, Promise Hospital of Miss Lou in Vidalia, LA, and HealthSouth Rehabilitation Hospital of Alexandria. He was reappointed to the Board for a third term.
- *Chris B. Melancon*, from Carencro, LA, represents District 7. She is a staff pharmacist at Cashway Pharmacy in Parks, LA, as well as an owner of Melancon Pharmacy in Carencro. She was reappointed to the Board for a second term.
- *Blake P. Pitre*, from Houma, LA, represents District 3. He is the owner of Pitre's Pharmacy in Larose, LA. He was reappointed to the Board for a second term. He also served previously on the Board from 1976 to 2000.
- *T. Morris Rabb*, from Monroe, LA, represents District 5. He is the director of pharmacy at Glenwood Regional Medical Center in West Monroe, LA. He was reappointed to the Board for a third term.
- *Rhonny K. Valentine*, from Mansfield, LA, represents District 4. He is the owner of Valentine's Pharmacy in Mansfield. He is a new member of the Board. He replaced Dr Lois R. Anderson from Shreveport, LA, who completed 12 years of service to the Board.

Board Meeting Dates for Calendar Year 2013 (13-01-423)

The Board has announced the following tentative meeting dates for calendar year 2013: March 6-7, May 29-30, August 14-15, and November 13-14. All meetings are planned for the Board office in Baton Rouge, LA.

Status Report for Regulatory Projects (13-01-424)

- *Regulatory Project 2012-5 ~ Institutional Pharmacies* includes two amendments to Chapter 17 of the Board's rules relative to institutional pharmacies. The first amendment clarifies the definition of an institutional pharmacy to specifically exclude hospital pharmacies and penal pharmacies, and further provides hospital pharmacies are regulated under Chapter 15 of the Board's rules and penal pharmacies are regulated under Chapter 18 of the Board's rules. The second amendment deletes §1727 – Medication Transfers to Penal Pharmacies, since that same language was already duplicated in Chapter 18. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.
- *Regulatory Project 2012-6 ~ Interstate Remote Processing* includes two amendments to Subchapter D – Off-Site Services, in Chapter 11 of the Board's rules. The first amendment changes the definition of the term Remote Processor to allow any permitted pharmacy to provide remote processing services for any other permitted pharmacy, regardless of location of either pharmacy. The second amendment places new requirements on hospital pharmacies soliciting remote processing services as well as on pharmacies providing remote processing services to a hospital pharmacy. In the event the pharmacy soliciting remote processing services is located within a hospital with more than 100 beds, there shall be at least one pharmacist on duty at all times. In the event the pharmacy providing remote processing services for the benefit of a hospital pharmacy, the performance of those services shall be limited to licensed pharmacists. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.
- *Regulatory Project 2012-7 ~ Security of Prescription Department* includes one amendment to §1103 – Prescription Department Requirements, of the Board's rules. In particular, the amendment provides an alternative security standard for prescription departments located within certain pharmacies typically owned by small businesses. The amendment stipulates as long as the facility housing the prescription department is closed and adequately secured, the enclosed prescription department would not need additional security measures. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.
- *Regulatory Project 2012-8 ~ Controlled Dangerous Substance (CDS) License for Nonresident Distributors* includes one amendment to Chapter 27 of the Board's rules. In particular, the requirement to obtain a Louisiana CDS license would be extended to those nonresident distributors who engage in the distribution of controlled substances to destinations within the state of Louisiana. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.
- *Regulatory Project 2012-9 ~ CDS in Emergency Drug Kits (EDK)* includes two amendments, both of which will authorize those pharmacies using EDK at long-term care facilities to place limited amounts of controlled substances within those kits. The rule govern-

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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ing EDK is found at §1713, and the permission to place controlled substances in such kits is proposed for insertion at §2743. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.

- *Regulatory Project 2012-10 ~ Prescription Monitoring Program (PMP)* includes several amendments to Chapter 29 of the Board's rules, all intended to implement the provisions of Acts 144 and 488 of the 2010 Legislature as well as Act 352 of the 2012 Legislature. The proposed amendments include (1) additional organization representatives on the PMP Advisory Council; (2) the requirement for dispensers to report prescription transaction data as soon as possible and no later than seven days after the dispensing date; (3) the modification of required data elements to include suffix numbers of Drug Enforcement Administration registration numbers where applicable, the use of National Provider Identifier numbers where applicable, and additional data elements for veterinary prescriptions; (4) permission for the Louisiana PMP to participate in a national network to share PMP data with similar programs in other states; and (5) permission for prescribers to make inquiries not only for their patients but also to verify their own prescribing records. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board was scheduled to consider those comments during its December 12, 2012 meeting before making a decision whether to move forward with the remainder of the rulemaking process.
- *Regulatory Project 2012-11 ~ Durable Medical Equipment (DME) Permit* would add a new chapter of rules (Chapter 24) and create a new classification of limited service pharmacy permits. The first use of the new classification will be for DME providers that do not stock any prescription drugs. The proposed rule identifies the products subject to the authority of the credential, establishes standards of practice, and enumerates the persons and firms exempted from the credentialing requirement. The Board published its Notice of Intent on November 20, 2012, and held a public hearing to receive comments on December 27, 2012. The Board will consider those comments before making a decision whether to move forward with the remainder of the rulemaking process.

Compounding of Sterile and Nonsterile Preparations (13-01-425)

Compounding means the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription drug orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding does not include the compounding of drug products that are essentially copies of a commercially available product. [La. R.S. 37:1164(5)]

In the wake of the morbidity and mortality related to cases of fungal meningitis traced last year to a compounding pharmacy in Massachusetts, the Board wishes to remind all of the pharmacies licensed by the Louisiana Board of Pharmacy – regardless of their location – that Louisiana requires compliance with the provisions of United States Pharmacopeia (USP) Chapter 797 for all activities related to the compounding of sterile preparations. Further, the Board requires compliance with the provisions of USP Chapter 795 for all activities related to the compounding of nonsterile preparations. A Louisiana pharmacy permit does not authorize manufacturing activities; Louisiana-licensed pharmacies engaged in such manufacturing activities in the absence of the appropriate federal credentials may be prosecuted. During the pharmacy permit renewal cycle at the end of 2012, the Board surveyed all the pharmacies to identify which of them were engaged in the compounding of sterile and nonsterile preparations. The Board's compliance officers have increased their surveillance of the compounding pharmacies to ensure compliance with the Board's compounding rules.

Calendar Notes (13-01-426)

The next Board meeting and administrative hearing will be March 6-7, 2013, at the Board office. The office will be closed January 21, for Martin Luther King, Jr, day; February 12, for Mardi Gras day; and March 29, for Good Friday.

Special Note (13-01-427)

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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