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Louisiana Board of Pharmacy News

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The Board Has Moved (11-07-381)

The Louisiana Board of Pharmacy has moved its office operations to a new location, the address of which is noted in the masthead of this *Newsletter*. As you recall, the Board launched its new Web site last summer; that URL remains unchanged – *www.pharmacy.la.gov*. The Board's general e-mail account remains unchanged – info@pharmacy.la.gov. The Board's telephone number remains unchanged – 225/925-6496. The Board's facsimile number remains unchanged – 225/925-6499. However, the previous separate facsimile number for the controlled dangerous substance (CDS) program was discontinued. Please update your records to reflect these changes.

E-Prescribing of Controlled Substances (11-07-382)

While it is true the United States Drug Enforcement Administration (DEA) published a rule last year permitting the electronic signature and prescribing of controlled substances, the rule conditioned such approval upon the compliance of prescriber and dispenser software systems with the substantial security requirements contained in that rule, as documented by one or more certification agencies. At press time, there were no such systems certified as compliant with DEA security requirements; therefore, no document purporting to be an electronic prescription for a controlled substance may be dispensed by a pharmacist within Louisiana. A pharmacist receiving such a document should recognize it is not legitimate. The pharmacist may contact the prescriber and obtain a verbal order, transcribe that order as required in Board rules, and then dispense the medication pursuant to that transcribed verbal order. Unfortunately, there are multiple vendors of e-prescribing systems who appear to have misled prescribers and dispensers into believing their systems have been approved for controlled substances. Please remember the dispensing pharmacist is accountable for ensuring the prescription is a legitimate one.

Overstock Brokers (11-07-383)

The Board has become aware of companies soliciting pharmacies to designate part or all of their overstock available for purchase by other pharmacies. The broker suggests these activities are permitted as long as such transactions account for less than 5% of their total inventory transactions. While it is true that pharmacies are permitted to distribute a small portion of their inventory (as opposed to dispensing) so long as such distributions are to occasional customers (eg, physician offices) without obtaining a distributor's license, the deliberate intent to sell products (including overstock) to other pharmacies falls within the definition of distribution, an activity that requires a license from the Louisiana State Board of Wholesale Drug Distributors. Therefore, pharmacies electing to participate in such overstock broker arrangements shall first obtain a distributor's license from that agency before engaging in such activities.

Gentle Reminders (11-07-384)

- All of the Board's licensees in the Pharmacy Program (pharmacists, interns, technicians, and technician candidates) are required to notify the Board, in writing, of their current mailing address as well as all pharmacies within which they practice. Form No. 90 is available on the Board's Web site to help you comply with those rules.
- For those pharmacists in possession of a medication administration registration, please remember that registration shall expire when your life safety (CPR) card expires. The extension of the expiration date requires a copy of the updated card; you may send that document by mail, e-mail, or fax. The Board does not send another registration; however, you may print a verification of that credential from the Board's Web site. Please remember your continuing education requirements for that credential; you are subject to audit at any time.
- Since the beginning of this year, the Board has issued several electronic-only notifications to its licensees. These e-mail alerts are sent to the e-mail address associated with the credential. For instance, the Board has been sending alerts to pharmacies regarding physicians who have lost their prescriptive authority due to disciplinary action from the Board of Medical Examiners. The Board also sent an e-mail alert announcing its office relocation to all of its licensees. In the event you wish to receive such electronic alerts, please make sure the Board has an e-mail address associated with your particular credential, and further, you may wish to "whitelist" the Board's e-mail address in your e-mail system, so the Board's messages can be authorized to pass through your firewalls or other security systems.

Disciplinary Actions (11-07-385)

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

During its February 16-17, 2011 meeting and hearing, the Board took final action in the following matters:

Charles Edward Baxter (CDS.024062-MD): Formal Hearing – CDS license suspended for an indefinite period of time, effective April 7, 2011.

Regan Elizabeth Holliday (CPT.009376): Formal Hearing – Certificate revoked, effective April 7, 2011, and further, assessed a fine of $5,000 plus costs.

Peter Manuel (PTC-Applicant): Formal Hearing – Application denied, and Board refused to issue the registration, and further, assessed costs.

During its May 4-5, 2011 meeting and hearing, the Board took final action in the following matters:

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Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts. Further, ISMP calls on FDA to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning: Benzocaine Use and Rare, But Serious Condition

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov*.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 30 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov*.

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Charissa Dawn Abshire (PST.015560): Pursuant to violation of probationary terms, license was revoked, with permanent prohibition on any future application for reinstatement, effective February 22, 2011.

St Mary's Pharmacy (PHY-Applicant): Board authorized issuance of pharmacy permit and CDS license, and then placed the pharmacy permit on probation until April 1, 2015, subject to certain terms enumerated in the consent agreement.

Ana Myra Garcia (PTC-Applicant): Application denied, and Board refused to issue the registration.

Amy Elizabeth Suarez (PTC-Applicant): Application denied, and Board refused to issue the registration.

Michelle Leigh Leonard (PTC-Applicant): Application denied, and Board refused to issue the registration.

Christopher Nathaniel Dispenza (CPT.010188): Board authorized issuance of technician certificate, and then placed certificate on probation for an indefinite period of time.

Richard Robert Heap (PST.010874): Suspended license for six months and stayed execution thereof, and then placed license on probation for six months, terminating October 1, 2011, and further, assessed a fine of $1,000 plus costs; for four counts, including theft of drugs from employer pharmacy for personal use.

Meshell's Home Respiratory Meds (PHY.005261): Permit revoked, effective March 11, 2011; for eight counts, including failure to properly close pharmacy permit.

Paragon Drug Store (PHY.003275): Permit suspended for five years with execution thereof stayed, and then placed on probation for five years, effective April 1, 2011, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $10,000 plus costs; for six counts, including significant unexplained losses of multiple controlled substances.

John Edward Broussard (PST.013303): License suspended for five years with execution thereof stayed, and then placed on probation for five years, effective April 1, 2011, subject to certain terms as enumerated in the consent agreement, and further, assessed a fine of $2,500 plus costs; for five counts, including theft of drugs from employer pharmacy for personal use.

Walgreens Tech Builder Training Program (PTTP.01023): Assessed a fine of $5,000 plus costs; for one count of assisting in the evasion of pharmacy laws or rules by another person.

Medicine Shoppe of Bayou Vista (PHY.002662): Added one year to the current term of probation, which will now terminate on September 22, 2012, and further, assessed a fine of $5,000 plus costs; for 16 counts, including operation of a pharmacy without a pharmacist.

Steve Patrick Michel (PST.011999): Added one year to the current term of probation, which will now terminate on May 8, 2014, and further, assessed a fine of $5,000 plus costs; for 17 counts, including ownership of Medicine Shoppe of Bayou Vista and operation of that pharmacy without a pharmacist.

Paige Elizabeth LeBlanc (PTC.017142): Registration revoked, with permanent prohibition on any future application for reinstatement of the registration, effective February 25, 2011; for five counts, including theft of controlled substances from employer pharmacy.

Sharonda Denise Russ (CPT.007386): Certificate revoked, with permanent prohibition on any future application for reinstatement of the certificate, effective April 28, 2011; for five counts, including theft of controlled substances from employer pharmacy.

Donald Rochon Parker (CDS.026578-MD): Accepted voluntary surrender, resulting in suspension of the CDS license for an indefinite period of time, effective May 3, 2011.

At the same meeting in May, the Board also issued letters of reprimand to four pharmacists and one pharmacy, as well as letters of warning to two pharmacies; and further, the Board granted five requests for probation modification; and further, the Board granted three requests for the reinstatement of previously lapsed credentials, contingent upon the completion of certain tasks.

Calendar Notes (11-07-386)

The next Board meeting and administrative hearing will be August 17-18, 2011, at the Board office. The office will be closed July 4, in observance of Independence Day.

Special Note (11-07-387)

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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