

August 2011



# News

## SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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### **Congratulations to Board Appointees**

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy would like to congratulate Robert Hubbard, RPh, of Clemson, SC, Rebecca Long, PharmD, of Columbia, SC, and Carole Small Russell, RPh, of Charleston, SC, on their recent appointment to the Board of Pharmacy by Governor Nikki Haley.

Hubbard's six-year term expires on June 30, 2016. He represents the Third Congressional District and replaces Walter Allen Toole, RPh. He will provide valuable expertise on durable medical equipment and independent community pharmacy practice.

Long was appointed by Governor Haley to serve as the pharmacist at large with a term that is coterminous with that of the appointing governor. She replaces David M. Banks, RPh. She will provide valuable expertise on compounding, durable medical equipment, and independent community pharmacy practice.

Russell's six-year term expires on June 30, 2017. She represents the First Congressional District and replaces James Robert Bradham, RPh. She will provide valuable expertise in sterile compounding and hospital pharmacy.

The Board welcomes Mr Hubbard, Ms Long, and Mrs Russell and offers its sincere appreciation to Toole, Banks, and Bradham for their dedicated service to the citizens of South Carolina and to the profession of pharmacy.

### **Resignation**

Effective June 22, 2011, Hugh Mobley, RPh, resigned his position as the Fifth Congressional District Representative for the South Carolina Board of Pharmacy. The Board offers its sincere appreciation to Mobley for his dedicated service to the citizens of South Carolina and to the profession of pharmacy.

### **Board of Pharmacy Vacancies**

The Board of Pharmacy has a vacancy due to the resignation of Hugh Mobley. The term of the **Fifth Congressional** seat expires June 30, 2013. Any pharmacist interested in running as a candidate must:

- ◆ Reside in the Fifth Congressional District;
- ◆ Be licensed and actively practicing pharmacy in South Carolina; and
- ◆ Before September 15, 2011, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fifth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- ◆ Prepare and mail ballots by October 15, 2011, to all pharmacists who certified on their last renewal application that they reside in the Fifth Congressional District; and

- ◆ Certify as true and valid all ballots postmarked before November 15, 2011, and received by the Board office before November 25, 2011.

The Board of Pharmacy will conduct an election for the **Fourth Congressional** seat which expires June 30, 2014. Any pharmacist interested in running as a candidate must:

- ◆ Reside in the Fourth Congressional District;
- ◆ Be licensed and actively practicing pharmacy in South Carolina; and
- ◆ Before September 15, 2011, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fourth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- ◆ Prepare and mail ballots by October 15, 2011, to all pharmacists who certified on their last renewal application that they reside in the Fourth Congressional District; and
- ◆ Certify as true and valid all ballots postmarked before November 15, 2011, and received by the Board office before November 25, 2011

The Board will certify in writing to the governor the names of the three candidates receiving the most votes in each election along with the name of the person who the nominee replaces on the Board after the election results are tabulated.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

### **Board Elections**

At the June 2011 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy members elected Joseph D. Bushardt, Jr, RPh, of Lake City, SC, as its new chairman. Bushardt is the pharmacist representing the Sixth Congressional District. Dock Henry Rose, RPh, of Greer, SC, representing the Fourth Congressional District, was elected as vice chairman. Each will serve a one-year term from July 1, 2011 until June 30, 2012.

### **CPE Monitoring Service Launched**

NABP, in collaboration with the Accreditation Council for Pharmacy Education (ACPE), is launching a continuing pharmacy education (CPE) monitoring service. All pharmacists and pharmacy technicians should review the CPE Monitor™ article in the National Pharmacy Compliance News section of this *Newsletter*, "**Pharmacists Provide Feedback at APHA: 'It's About Time! What a Great Tool.'**" The Board of Pharmacy urges all pharmacy technicians and

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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](http://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](http://www.nabp.net/programs) or at [www.MyCPEmonitor.net](http://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-



Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

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 and 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](http://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](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto: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 until 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 on Benzocaine Use**

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. FDA also stresses that benzocaine products should not be used on children less than two (2) years of age, except under the advise of a health care provider. 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®, Hurracaine®, 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](http://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](http://www.fda.gov).

pharmacists to sign up for this valuable service. There is no charge to use this service for tracking ACPE-accredited CPE hours earned.

### Electronic Prescriptions

The Board of Pharmacy has determined that it is acceptable for electronic prescriptions to be kept electronically and that it is not necessary to print out a hard copy of the electronic prescription. If there are any changes to an electronic prescription, the prescription must be printed out and all changes must be made on the hard copy.

### Guidelines for Assisted Living Chart Orders

The Board of Pharmacy passed the motion from the Practice Committee to view Assisted Living Centers as Extended Care Facilities with regard to medication therapy. *The guidelines are for chart orders for non-controlled medications that will be accepted in a setting where:*

1. A licensed nurse is responsible for receiving and transmitting medication orders to the pharmacy.
2. The resident's chart is maintained with current medication and treatment orders.
3. The attending physician reviews and renews medication and treatment on no less than a quarterly basis.
4. The resident's chart is reviewed on a quarterly basis by a consultant pharmacist who is currently in South Carolina.

### Board Meetings

The next Board of Pharmacy meeting will be 9 AM on September 15, 2011. The November meeting date has been changed to November 17, 2011.

### Compliance Tips

1. **Section 40-43-82** "A pharmacy technician who has failed to properly **renew a registration before July first shall immediately cease practice and refrain from performing any duties as a pharmacy technician.** Reinstatement of a registration must be granted upon the board receiving a renewal application and renewal and penalty fees." Many technicians have not renewed and according to **Section 40-43-86(B)(3) (a)** the pharmacist-in-charge is responsible for ensuring that all pharmacists, technicians, and interns employed at the pharmacy have a current license, certificate, or registration. Have your state certified pharmacy technicians sent a copy of their Pharmacy Technician Certification Board Certificate to the Board of Pharmacy to remain state certified?
2. **Section 40-43-86(A)(10)** A pharmacy at a minimum shall maintain storage areas at temperatures which shall ensure the integrity of the

drugs prior to their dispensing as stipulated by the United States Pharmacopeia-National Formulary and/or the manufacturer's or distributor's labeling requirements. The external temperatures have been quite high and some air conditioners have not been able to maintain the appropriate temperature for the storage of non-refrigerated drugs. The majority of labeling requirements for drugs state "Store at 20-25 degrees C (68-77 degrees F)" and if drugs are not stored properly, they may be adulterated and need to be destroyed. The manufacturers and Food and Drug Administration do allow medications to be stored at higher temperatures for short periods of time.

3. **Section 40-43-86(N) "Records of dispensing,** which are readily retrievable within twenty-four hours, for all drugs or devices are to be made and kept by pharmacies for two years and shall include, but are not limited to: . . . (4) **the identification of the pharmacist responsible for dispensing;"**

**Section 40-43-86 (I)(4)** "All drugs dispensed to ambulatory or outpatients shall contain a label **affixed to the container in which the drug is dispensed** including: . . . (h) **the name or initials of the dispensing pharmacist."**

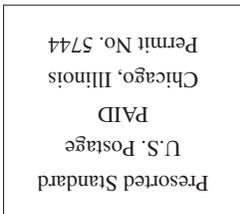
Upon inspection, it has been discovered that the prescription label and records do not always reflect all pharmacists involved in the dispensing process. A technician **cannot** input prescriptions under the name of a pharmacist that is not present during the process. In many instances, it has been observed that the name of the pharmacist on the label, records, or prescription does not reflect the pharmacist that performs the final checking process of dispensing. If the software system used by your pharmacy does not document all phases of the dispensing, the pharmacists shall initial the label and the prescription.

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