



# Alabama State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Technician Renewals**

All registered pharmacy technicians are required to renew their registrations biennially with the fee being due on October 31, 2011, and delinquent after December 31, 2011.

In addition, every pharmacy technician shall, prior to registration, complete three hours of continuing education (CE) **annually**, one hour of which shall be a “live” presentation.

In order to satisfy the CE requirement, the hours must be accredited by the Accreditation Council for Pharmacy Education (ACPE) and designated for technicians.

There have been some changes made to the renewal application for 2012/2013.

1. The application is now two pages.
2. The renewal application (both online and those mailed to the office) will contain a section where each registrant must provide CE data for calendar years 2010 and 2011. The required information must include the date, place, name of CE provider, ACPE number, number of **live** hours, and number of **other** hours for each CE credit earned. (Renewals will not be processed unless the CE has been completed for 2010 and 2011.)

## **Code of Professional Conduct Amended**

The Code of Professional Conduct was amended effective June 6, 2011, to add the following paragraph:

- (h) A pharmacist should never offer or participate in the offering a financial award or benefit, not related to competitive retail pricing of any drug, to induce or encourage any individual to transfer a prescription from one pharmacy to another.

## **Repackaging Bill Passed**

Last year the Board began receiving anecdotal accounts describing a common scenario. A patient has a loved one

in a nursing home or like facility who receives needed medications in a 60- or 90-day supply; however, the facility requires medication to be in single dose units and no more than 30 at a time. The patient takes the bottle of medication to his or her pharmacist asking if he or she can make the single doses required in a 30-day supply and hold on to the remaining drugs for subsequent pick up every 30 days. Unfortunately, the law would not allow the pharmacist to do this and help the patient.

The Board sought a solution through an amendment to the Pharmacy Practice Act in a bill, which was passed during the 2011 Legislative Session. The amendment allows the Board to establish by rule protocols allowing a pharmacy in possession of a current retail permit to repackage, re-label, and store any **non-controlled** legend drugs for a patient residing in a residential care facility that does not have an on-premise pharmacy. Residential care facility is defined in the amendment to include, for example, nursing homes, extended care facilities, assisted living facilities, etc.

The Board has already begun working on the rules establishing the requirements for pharmacies to engage in the above described activities. The Board hopes to start the formal rulemaking process required by state law as soon as possible.

## **DEA Policy on the Proper Role of a Duly Authorized Agent**

Recently the Drug Enforcement Administration (DEA) issued a statement of policy relating to the role of authorized agents in the communication of controlled substance prescriptions to pharmacies. While the policy is available on the DEA Web site, the following is a summary of the most significant highlights.

Initially, it is important to remember that a medical determination of the need for a controlled substance prescription can never be delegated. While the regulations provide that a

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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 (depending on 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 60 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).

prescription **may be** prepared by an agent for the signature of the practitioner, the practitioner is responsible in the event the prescription does not conform in all essential respects. As a result, an authorized agent of the practitioner may prepare a controlled substance prescription only based on the practitioner's instructions as to the required elements and then provide the prescription to the practitioner to review. In other words, the agent does not have authority to make a medical determination.

Schedule III, IV, and V controlled substances may be dispensed pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except, of course, the signature of the practitioner. DEA allows an authorized agent to communicate such a prescription to a pharmacist; however, when the pharmacist has reason to believe that a prescription has been communicated by such an agent the pharmacist, in accordance with the responsibility for the proper dispensing of controlled substances, may have a duty to inquire into the legitimacy of the prescription. The appropriate level of inquiry is dictated by the particular circumstances involved.

While a prescription for a Schedule II controlled substance must be in writing, there are two exceptions. Either a practitioner or the practitioner's authorized agent may transmit a prescription for a Schedule II controlled substance to a pharmacy via facsimile for patients enrolled in a hospice care program properly certified and/or paid for by Medicare or hospice programs which are licensed by the state and for residents of long-term care facilities.

Finally, who qualifies as an agent is obviously important. The Federal Controlled Substances Act defines an agent as an authorized person who acts on behalf of or at the direction of a practitioner. This is the same definition found in the Alabama Uniform Controlled Substances Act. The question of whether an agency relationship exists is determined by state law; DEA cites the following as elements: the estab-

lishment of an agency relationship requires the prescriber to manifest assent for a certain person to act on his or her behalf, the agent reciprocates by manifesting assent to serve as an agent and that the agent acts subject to the practitioner's control. However, as noted earlier, there are certain duties that cannot be delegated to an agent in connection with the prescribing of controlled substances.

While DEA regulations make it clear that the legal responsibility for issuing a valid prescription rests upon the practitioner, the regulations also provide that a pharmacist has a corresponding responsibility for the proper prescribing and dispensing of controlled substances. Accordingly, "A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy who fills a prescription not prepared in the form required by DEA regulations." 21 CFR 1306.05(f)

### ***Do You Know a Pharmacist or Technician Who Needs Help?***

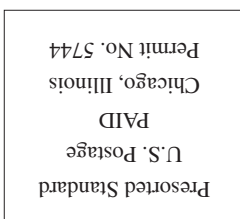
Call the Committee on Rehabilitating Impaired Pharmacists help-line at the voicemail of Steve Moore at 205/975-8548. All calls are confidential.

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