

November 2009



# Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **New Alabama State Board of Pharmacy Member**

**Mark T. Conradi, RPh, JD**

Appointed by Governor Bob Riley

Term of Service: January 1, 2010 to December 31, 2014 as the chain pharmacy representative.

Mark graduated from Auburn University Harrison School of Pharmacy in 1974 and Birmingham School of Law in 2000, and was admitted to the bar the same year. He is a CVS pharmacist and an adjunct professor for Harrison School of Pharmacy. At the Harrison School of Pharmacy he teaches pharmacy law and ethics. Mark has served as a "trustee at large" for the Alabama Pharmacy Association and served on various committees for the National Association of Boards of Pharmacy®. He and his wife Brenda live in Clanton, AL, and attend Friendship Baptist Church. His children are Lauren, Allen, and Thompson.

## **680-X-3-.08 Annual Inventory of Controlled Substances**

- (1) Every pharmacy shall take an initial inventory of all controlled substances on hand and shall take a new inventory of all stocks of controlled substances on hand on January 15<sup>th</sup> or the alternative fixed date approved by the Board of each year, following the date the initial inventory was taken.
- (4) The inventory by a pharmacy must be taken either as of the opening of business or as of the closing of business. The pharmacy shall indicate on the inventory records whether the inventory was taken as of the opening of business or as of the close of business, the date the inventory was taken, followed by the person responsible for taking the inventory.
- (5) In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the pharmacy shall do as follows:
  - (a) If the substance is listed in Schedule II, an exact count or measure of the contents shall be made.
  - (b) If the substance is listed in Schedule III, IV, or V, an estimated count or measure may be made of the contents unless the container holds more than 1000 tablets or capsules in which case an exact count of the contents must be made.

## **Prescribing of Controlled Substances by Physician Assistants**

*Author: Larry Dixon, Executive Director, Alabama Board of Medical Examiners*

A new law authorizes qualified, approved physician assistants (PAs) to prescribe controlled substances in Schedules III, IV, and V. The Alabama Board of Medical Examiners is in the process of developing

administrative rules that will specify the application procedures, fees, fines, punishments, and conduct of disciplinary hearings concerning the Qualified Alabama Controlled Substances Certificates (QACSC).

Pursuant to the new law (Act 2009-489), the Medical Board may grant a QACSC to a PA who:

- ◆ Is practicing with appropriate physician supervision
- ◆ Submits proof of successful completion of certain courses to include advanced pharmacology and controlled substances prescribing trends (the Medical Board is in the process of determining approved courses and number of hours required)
- ◆ Provides documentation of a minimum of 12 months of active, clinical employment with physician supervision following National Commission on Certification of Physician Assistants certification

PAs who are issued a QACSC by the Medical Board and a valid registration number from Drug Enforcement Administration (DEA) may prescribe, administer, authorize for administration, or dispense only those controlled substances in Schedules III, IV, and V in accordance with protocols and formularies approved by the supervising physician and the Medical Board. These protocols and formularies will specify which schedules and/or specific drugs the PA may prescribe. PAs may not use their QACSCs for purchasing, obtaining, maintaining, or ordering any stock supply or inventory of any controlled substance in any form. The law also states that a PA shall not prescribe, administer, or dispense any controlled substance to his or her own self, spouse, child, or parent.

The law sets out the grounds upon which the Medical Board may deny an initial or renewal QACSC application or initiate a disciplinary action. These grounds include the following:

- ◆ Fraud or deceit in applying for a QACSC
- ◆ Conviction of a crime relating to controlled substances
- ◆ Conviction of a crime or offense that affects the ability of the PA to practice with due regard for the health or safety of his or her patients
- ◆ Prescribing a drug or utilizing a QACSC in such a manner as to endanger the health of the patient
- ◆ Suspension or revocation of the PA's DEA registration number
- ◆ Excessive dispensing or prescribing of any drug to any person or patient of the PA
- ◆ Unfitness or incompetence due to the use of or dependence on alcohol, chemicals, or any mood altering drug to such an extent as to render the PA unsafe or unreliable to prescribe drugs or hold a QACSC

At this writing, the Medical Board has not yet established the application and renewal fees for QACSCs. This information, along with the administrative rules when they are published for public comment, will be available at the Medical Board's Web site. The Medical Board will commence accepting applications and issuing QACSCs in January 2010.

*Continued on page 4*



## **Pharmacy Security and Safety Prove Necessary Component in Pharmacists' Training**

Pharmacy robbery – no one ever thinks it will happen to them, but those who have experienced it know it **can** happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin®. They left with bags filled with OxyContin and Percocet®, having a retail value of nearly \$10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university's college of pharmacy alumni e-Newsletter. In the article Bryan states, "I crouched down hoping they hadn't seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery," he explains. "I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal."

In December 2008, a safety DVD, *Pharmacy Security – Robbery*, accompanied the shipments of the National Association of Boards of Pharmacy® 2009 Survey of Pharmacy Law that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management

course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

"One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber's appearance – clothes, height, weight – and not just focusing on the gun," states Cisneros. He was glad to have received the DVD, explaining that, "it was just the right length, added a lot to the class, and led to great discussions." Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol® Web site at [www.rxpatrol.org](http://www.rxpatrol.org). RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at [www.partnersagainstpain.com](http://www.partnersagainstpain.com) under Pain Education Center.

## **Concerns with Patients' Use of More than One Pharmacy**



*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](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 a 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).*

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy



locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient's pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM's computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through Surescripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the \$4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbals, nutritional supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

## **CDC Launches Get Smart Web Site to Help Decrease Antibiotic Resistance**

Centers for Disease Control and Prevention (CDC) launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it. Because antibiotic resistance is one of the world's most pressing public health problems, CDC also held Get Smart Week on October 5-11 to emphasize its public health effort to decrease antibiotic resistance, including how pharmacists can become involved.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at [www.cdc.gov/getsmart/](http://www.cdc.gov/getsmart/).

## **FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1**

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements).

## **ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High**

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

## **FDA Takes Actions on Pain Medications Containing Propoxyphene**

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite "serious concerns . . .", the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time." Additional information can be found at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm).

The law also amends provisions concerning the Department of Public Health's Prescription Drug Monitoring Program (PDMP) database. PAs with QACSCs will be authorized to query the database, limited to information concerning a current or prospective patient, and physicians will be authorized to query the database concerning PAs under their supervision. As with the physicians' QACSCs, the Medical Board will be required to collect \$10 per year on each QACSC to be remitted to the health department for the operation and maintenance of the PDMP database.

**On the Net:**

♦ Act 2009-489: <http://arc-sos.state.al.us/PAC/SOSACPDF.001/A0007123.pdf>

♦ PDMP: [www.adph.org/PDMP/](http://www.adph.org/PDMP/)

**Amended Rule Changes**

**680-X-2-.14 The Role of Technicians in Pharmacies in Alabama**

(3) It is ruled by the Board of Pharmacy that three (3) technicians, one of which shall be certified through the Pharmacy Technician Certification Board (PTCB) or the Institute for the Certification of Pharmacy Technicians (ICPT), on duty are sufficient in the prescription area of a retail pharmacy or an institutional pharmacy for each full time licensed pharmacist on duty. Nothing in this rule shall prevent a pharmacy from employing technicians to perform supervised tasks not requiring professional judgment.

Author: Herb Bobo, RPh, Secretary

Statutory Authority: *Code of Alabama* 1975, §34-23-92

Amended September 4, 2009; Effective November 1, 2009.

**680-X-2-.18 Institutional Pharmacies**

(5) Drug Distribution and Control:

(b) All of the activities and operations of each Institutional Pharmacy shall be personally and directly supervised by its Supervising Pharmacist or a designated pharmacist. All functions and activities of technicians shall be personally and directly supervised by a registered pharmacist to insure that all functions and activities are performed competently, safely, and without risk of harm to patients. There shall be not more than three (3) technicians, at least one of which shall be certified through the Pharmacy Technician Certification Board (PTCB) or the Institute for the Certification of Pharmacy Technicians (ICPT), on duty in the preparation area for each full time licensed pharmacist on duty. Nothing in this rule shall prevent an institutional pharmacy from employing technicians to perform supervised tasks not requiring professional judgment.

Author: Herb Bobo, RPh, Secretary

Statutory Authority: *Code of Alabama* 1975, §34-23-92

Amended September 4, 2009; Effective November 1, 2009

**Note to Pharmacists**

Section 20-2-190 of the Code of Alabama 1975, was amended to delete the provision prohibiting the sale of products containing ephedrine or pseudoephedrine after October 1, 2009.

**Section 22-11A-9 – Tuberculosis Cases to Be Reported; Contents of Report; Reports Confidential**

Any physician who diagnoses or treats a case of active tuberculosis, the administrator of any hospital, dispensary, correctional facility or other institution in which there is a case of active tuberculosis, the person in charge of any laboratory performing a positive test for active or suspected active tuberculosis, and pharmacist dispensing anti-tuberculosis medication shall report this information to the State Health Officer, the county health officer, or their designee . . . These reports shall include, at a minimum, the name of the patient and the name and address of the physician. The reports required by this section shall be confidential and shall not be subject to public inspection, subpoena, or admission into evidence in any court except proceedings brought under this article to compel the examination, treatment, commitment or quarantine of any person or upon the written consent of the patient, or if the patient is a minor, his parent or legal guardian. (*Acts 1987, No. 87-574, p. 904, §9*)

**Prescriptive Authority of Health Care Professionals in Alabama**

Visit [www.albop.com](http://www.albop.com), and click on the Forms, Apps, and Publications section to download a full-size copy of the prescriptive authority pdf to post in your pharmacy.

**Special Notice about the Newsletter**

The *Alabama State Board of Pharmacy Newsletter* is an official method of notification to pharmacists licensed and pharmacy technicians registered by the Board. Board *Newsletters* serve in administrative hearings as proof of notification. Please read them carefully. We encourage you to keep them in the back of the *Alabama Pharmacy Law Book* for future reference.

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

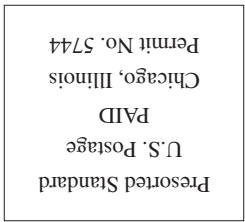
Call the Committee On Rehabilitating Impaired Pharmacists help line at the voicemail of Steve Moore at 205/975-8548. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary 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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