

August 2014

News



Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

111 Village St • Birmingham, AL 35242 • Tel: 205/981-2280 • Fax: 205/981-2330

New Address for Board Office

The Alabama State Board of Pharmacy would like to announce that its mailing address has changed. The Board has not moved, but it has stopped the use of a PO Box, and is now using its street address. So, if you are sending anything to the Board office via mail, please use its street address, which is 111 Village St, Birmingham, AL 35242.

License Renewal Schedule for This Fall

While on the topic of office logistics, you need to know that this fall is the time for renewal of permits/controlled substance (CS) registrations for pharmacists, pharmacies, manufacturers/wholesalers/distributors, etc. Pharmacists may start renewals on September 1, 2014, and pharmacy facilities may begin renewal on September 15, 2014.

You may or may not know that the Board has been implementing a new computer system over the past 14 months. Although you have submitted renewals electronically before, the Board office did not have a system that would input that data into your specific record. That meant that any information that the Board received from you and that was an update to your file had to be recorded manually by Board staff. As you can imagine, every fall pushed the capacity of the office: technicians one year, pharmacists and pharmacies the next year. The Board had a system in place last fall to renew all technicians electronically, and it worked well for renewing 12,000 licenses. The Board hopes to do the same this year with all other registrants.

As you all know, no system is perfect. Although the Board is testing and reworking, it knows there will be something that malfunctions. The Board asks for your patience, and commits to correcting anything that might fail. If you have an issue with pharmacist registration, please e-mail Lynn Martin at lmartin@albop.com, and for any issue with facilities, e-mail Diane Decker at ddecker@albop.com. It is important for you to know that there is a monetary penalty for renewals that arrive after December 31, 2014. Also, after December 31, 2014, your license expires if you have not renewed it. That means, should you happen to be inspected, you could be charged with practicing without a license if you practice or operate a business after that time.

The most frequently asked question about renewals is continuing education (CE). Pharmacists are required to obtain 15 hours of CE each year; three of those hours must be "live" CE. For the upcoming renewal period, each pharmacist will be responsible for 30 hours, and six of those must be live. Consultant pharmacists must acquire six live hours of CE each year that are designated or approved as consultant-relevant. Those six hours count as part of the annual 15 hours. Likewise, sterile product certification CE counts as part of the annual 15 hours. Since CE hours are now reported to Accreditation Council for Pharmacy Education/National Association of Boards of Pharmacy® (NABP®) CPE Monitor®, the Board is now able to access a report of the CE hours acquired by each pharmacist during a registra-

tion period. The Board will review renewals for compliance with CE requirements. Usually, the Board requires additional hours and perhaps a monetary fine for not meeting CE obligations. What many pharmacists do not realize, however, is that if the Board makes any charge, including a charge of being non-compliant with CE hours, that charge must be reported to the National Practitioner Data Bank, an agency of the United States Department of Health and Human Services (HHS). There are free opportunities online to obtain CE hours, even live hours, should you need to supplement your hours.

DEA Classifies Tramadol a CS

In describing the conclusions of an analysis of abuse potential of tramadol, Drug Enforcement Administration (DEA) stated, "Abuse of tramadol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III." After assessment and public hearings, DEA and HHS made the determination to move tramadol to a Class IV scheduled drug. The following notice appeared the week of July 7, in *NABP e-News*.

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance (CS). Starting August 18, 2014, Drug Enforcement Administration (DEA) will require manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino) methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014." National Association of State Controlled Substances Authorities notes that several states have already classified tramadol as a CS. To "provide a reasonable time for registrants to comply with the handling requirements" for a Schedule IV CS, DEA established the effective date of the final rule as 45 days from the date of publication.

Additional details are included in the Final Rule available at www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm.

Alabama Board Inspects for Compliance With USP Chapter <795>

United States Pharmacopeia (USP) is a collection of standards that pharmacists realize impacts some aspect of their practice. The chapters that have had the most notoriety recently are USP <795>

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled “Red Flags,” encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described “red flags” as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWARE_xE® Prescription Drug Safety website at www.AWARERX.ORG/pharmacists.

Root Causes: A Roadmap to Action

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for carbamazepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of carbamazepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient’s medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child’s carbamazepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.¹

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy*. The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event**.

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation’s standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event**. For more information and to access the **free** workbook, visit www.ismp.org/tools/rca/.

¹<http://pediatrics.aappublications.org/content/113/2/406.abstract>



FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at www.fda.gov/Drugs/DrugSafety.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- ◆ The millimeter (mL) should be used as a standard unit of measurement.
- ◆ Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.

- ◆ Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, is available for download from the NCPDP website at <http://ncdp.org/Education/Whitepaper>.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum*, and may currently be viewed on the USP website at www.usp.org/usp-nf. Comments were accepted until July 31, 2014.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor[®] into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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Pharmaceutical Compounding—Nonsterile Preparations, and USP <797> Pharmaceutical Compounding—Sterile Preparations. For those not involved with compounding, it seemed that there has been little reason to focus on these chapters. It appeared that only pharmacies with a significant involvement in compounding needed to study the dictates of USP. In reality, however, Chapters <795> and <797> apply to any compounded product prepared by any pharmacy. That is the reason for this message to you.

The Board has been advising pharmacies about basic steps to implement USP Chapter <795> in any pharmacy that compounds any nonsterile product, no matter how infrequently. USP Chapter <795> has multiple components and standards, but the Board intends to start with the most basic.

The chapter requires that areas designated for compounding have adequate space to prevent mix-ups between ingredients, containers, etc., and are designed to prevent accidental cross contamination. The availability of potable water, washing facilities, and appropriate equipment is also discussed in this chapter. (Michael J. Gaunt, PharmD. “What Does USP <795> Mean to You?” *www.PharmacyTimes.com*)

The chapter was updated, expanded and republished in May 2011 to emphasize the importance of documenting all compounding procedures, labeling compounded drugs accurately with Active Pharmaceutical Ingredient (APIs) and beyond use dates, and using purified water for all mixing and cleaning related to nonsterile compounding. (Edward Lamb. “What Is Nonsterile Drug Compounding?” *www.pharmacy.about.com*)

As the Board has been inspecting pharmacies, it has informed pharmacists of the need for a designated compounding area that is of sufficient size for a person to prepare the compound safely and that the compounding area be clean; specifically that it have cleanable/washable counters, walls, ceiling, and floors. The water used for compounding should be purified (distilled or deionized), there should be a sink nearby with potable hot and cold running water, and the sink should be clean and free of unwashed items. At a minimum, the pharmacist should record on the prescription or a compounding sheet the name, quantity, lot number, and expiration date of each item used and show calculations.

These requirements are not new. Code of Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205, states in §34-23-152.

Designation and maintenance of compounding area:

Any pharmacy engaged in compounding shall have a specifically designated and adequate area or space for the orderly compounding of prescriptions. The area used for the compounding of drugs shall be maintained in a good state of repair. The compounding area shall have cleanable surfaces to include walls, ceilings, and floors. Adequate lighting and ventilation

shall be provided in all compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Areas used for compounding shall be maintained in a clean and sanitary condition. (Act 2003-389, p. 1094, §3; Act 2006-543, p. 1260, §1; Act 2006-573, p. 1506, §1.)

Board regulations also address equipment, records, compounding procedures, labeling, containers, and training. The Board is not charging pharmacies with violations of the regulations for noncompliance with USP Chapter <795>. Rather, it is attempting to educate pharmacists about the USP standards, and the Board anticipates that within the next year, or by the time of your next inspection, the pharmacies will have come into compliance with basic USP Chapter <795> standards.

Prescriptive Authority

Of the questions that come to the Board office, one of the most frequent is about the legal authority for a physician assistant or an advanced registered nurse practitioner (ie, CPNP, CRNP, CNM) to write prescriptions. Both groups are allowed to write prescriptions for non-controlled prescription drugs, and both are allowed to write prescriptions for Schedule III-V drugs if they are certified with Qualified Alabama Controlled Substances Certificate prescribing and they are in a collaborative practice with a physician. However, neither group is allowed to write for Schedule II drugs. Initial Schedule III-V drugs are limited to a 30-day supply with no refills. They may authorize one 30-day refill of CS if the original is initiated by the collaborating physician. The supervising physician’s name is required on oral and written prescriptions.

Reminder

Please notify the Board in writing of any change of address or employment within 10 days.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program helpline at 205/981-2273 or 251/866-5585. The Board Wellness Program e-mail address is bopwellness@gmail.com. All communications are confidential.

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