May 2014

Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

New Alabama Legislation Gives Controlled Drug Prescribing Authority to Certified Nurse Practitioners and Midwives

According to the Alabama Board of Medical Examiners & Medical Licensure Commission of Alabama, "The Alabama Legislature has passed Act 2013-223 which confers to Certified Registered Nurse Practitioners and Certified Nurse Midwives authority to prescribe controlled substances in Schedules, III, IV, and V. The [Alabama Medical] Board will act as the certifying board and issue Qualified Alabama Controlled Substances (QACSC) certificates in much the same way that Physician Assistants are issued QACSCs, that is, a CRNP/CNM in a collaborative agreement with a physician may apply for a QACSC to prescribe controlled substances in Schedules III, IV and V without a collaborating physician's review or signature, provided such is agreed to in the collaborative practice agreement." Beginning October 1, 2013, applicants may apply for a QACSC.

To qualify for a QACSC, a certified registered nurse practitioner (CRNP) or certified nurse midwife (CNM) must:

- Be in a collaborative practice with a physician who holds a valid, unrestricted Alabama Controlled Substances Certificate.
- Submit documentation of attendance at an eight-credit, Board-approved course entitled, "Prescribing Controlled Drugs," plus attendance at four credits of advanced pharmacology and controlled substance (CS) prescribing trends. These courses became available this past summer for those interested.
- Provide documentation of a minimum of 12 months of active clinical practice pursuant to an approved collaborative.

Once the required information is submitted to the Alabama Medical Board, the applicant must submit a form to Drug Enforcement Administration (DEA). DEA will confirm with the Alabama Medical Board that the person is approved for authority to prescribe CS and will provide the nurse with a DEA number. Look for the nurse's DEA number on prescriptions you receive from the nurse. Unlike physician assistants, no limitations were legislated on the prescribing rights of CRNPs or CNMs. There is not a limit for the number of doses prescribed or the number of refills allowed other than those already in the law for physicians.

680-X-2-.07 Mail Order Prescriptions (Amended)

(1) Every applicant for a Mail Order Permit or Permits pursuant to the provisions of Code of Alabama 1975, §§34-23-30, 34-23-31, shall obtain a permit biennially. On the first registration by a Pharmacy located outside of the State of Alabama, the provisions of Code of Alabama 1975, §34-23-30 shall apply to such first registration.

(2) Registration. No Nonresident Pharmacy shall ship, mail or deliver prescription drugs and/or devices to a patient in this state unless registered by the Alabama State Board of Pharmacy.

(3) Agent of Record. Each Nonresident Pharmacy that ships, mails, or delivers prescription drugs and/or devices to a patient in the state of Alabama shall designate a resident agent in Alabama for service of process. Any such Nonresident Pharmacy that does not so designate a registered agent and that ships, mails or delivers prescription drugs and/or devices in the state of Alabama shall be deemed an appointment by such Nonresident Pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceedings against such pharmacy growing out of or arising from such delivery. A copy of any such service of process shall be mailed to the Nonresident Pharmacy by the complaining party by certified mail, return receipt requested, postage prepaid, at the address of such Nonresident Pharmacy as designated on the pharmacy's application for registration in this state. If any such pharmacy is not licensed in this state, service on the Secretary of State of Alabama only shall be sufficient service.

(4) Conditions of Registration. As conditions of receiving a permit, the Nonresident Pharmacy or a renewal if applicable must comply with the following:

(a) Be registered and in a good standing in the State in which such pharmacy is located;

(b) Maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Alabama patients;

(c) Supply upon request, all information needed by the Alabama Board of Pharmacy to carry out the Board's responsibilities under the statutes and regulations pertaining to Nonresident Pharmacies;

(d) Maintain pharmacy hours that permit the timely dispensing of drugs to Alabama patients and provide reasonable access for the Alabama patients to consult with a licensed pharmacist about such patients' medications.

(e) Provide toll-free telephone communication consultation between an Alabama patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container;.

(f) Designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy. The supervising pharmacist shall be responsible for ensuring that the holder of the permit referenced herein complies with the requirements of this rule and all applicable statutory provisions and rules.

(g) If there is a change of the designated Supervising Pharmacist, the permit holder shall notify the Board by filing the "Notice of Change of Supervising Pharmacist" form provided by the Board. If the permit holder is un-

Continued on page 4

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, Illinois 60056

ALABAMA STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

Continued from page 1

able to maintain a designated supervising pharmacist, the permit holder shall notify the Board within ten (10) days with an action plan to designate another pharmacist as supervising pharmacist. A permit holder without a designated supervising pharmacist after the ninety (90) day action plan has expired may contact the Board for additional time.

(5) Compliance. Each nonresident Pharmacy shall comply with the following:
   (a) All statutory and regulatory requirements of the State of Alabama for controlled substances, including those that are different from federal law or regulation.
   (b) All the statutory and regulatory requirements of the state of Alabama regarding drug product selection laws.
   (c) Labeling of all prescriptions dispensed, to include but not limited to identification of the product and quantity dispensed.
   (d) All the statutory and regulatory requirements of the State of Alabama for the dispensing of prescriptions in accordance with the quantities indicated by the prescriber.

(6) Policy and Procedure Manual. Each Nonresident Pharmacy shall develop and provide the resident board of pharmacy with a policy and procedure manual that sets forth:
   (a) Normal delivery protocols and times;
   (b) The procedure to be followed if the patient's medication is not available at the Nonresident Pharmacy, or if delivery will be delayed beyond the normal delivery time;
   (c) The procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the Nonresident Pharmacy at the earliest possible time (i.e. courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time;
   (d) The procedure to be followed when the Nonresident Pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

(7) Disciplinary Action. Except in emergencies that constitute an immediate threat to public health and require prompt action by the Board, the Alabama Board of Pharmacy shall file a complaint against any Nonresident Pharmacy that violates any statute or regulation of Alabama for conduct which causes serious bodily or psychological injury to a resident of this state. This complaint shall be filed with the Board in which the Nonresident Pharmacy is located. If the Board in the state in which the Nonresident Pharmacy is based fails to resolve the violation complained of within a reasonable time, (not less than forty-five (45) days from the date that the complaint is filed), disciplinary proceedings may be instituted in Alabama before the Board.

Amended March 19, 2014; Effective June 1, 2014.

Underlined text represents new language.

Suboxone Prescriptions

Suboxone® is a Schedule III CS prescription and can be called in. However, it does have necessary requirements in order to be valid. If the prescription is for opioid addiction, the prescriber must be a qualified physician and provide a DEA number with an "X" in front of it to confirm the prescriber has certified authorization. If it is for the treatment of pain, the physician's DEA number is required.

Clarification of Schedule II Prescriptions

The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to CS prescriptions.

The pharmacist is never permitted to make changes to the patient's name, CS prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Addendum by the Alabama State Board of Pharmacy: pharmacists in Alabama cannot change the "fill by date" or the "do not fill before date" even after consultation with the prescriber. Board Policy 20100825; adopted August 25, 2010.

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.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

Susan Alverson, PharmD, Secretary - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager