February 2014

Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Fifty-Year Pharmacists

The Alabama State Board of Pharmacy wishes to congratulate the following Alabama pharmacists that have completed 50 years in the practice of pharmacy. Thank you for your service and dedication to the pharmacy profession.

Clifton Freeman Minter, Jr	Robert Lynwood Golden
Richard Calvin Lee	Terry Ross Bennett
Howard Parker Aaron	Joshua Sparks Collins
Charles L. Cook	Willard Swank McDonald
Theodore F. Knight	Wilbur Leslie Macon
Paul Reeder Kimbrough	Donald Lee Williams
Joseph Lamar Vaughn	James R. Peacock
Johnny Keyes White	James Edward Heritage
Mustafa Issa Elayan	Arthur Boyce Webb
Raymond Valentine Wojtyna	Jerome Eugene Esneul
Van Philip East, Jr	Ronnie Wayne Richardson
Jack Gates Bendall	James Ferrell Hamrick
Harold Eugene Aycock	Henry Alexander Frazer
Robert Howard Foote	Jesse Larkus Mitchell
Donald Clyde Lenz	James Chandler Stapleton
John Barnett Dunbar III	Joe Earl Jones
Larry Maurice Crawford	Paul Henry Felgner
Howard Kichler	William Batson Holley, Jr
Danny Ross Posey	Charles Dart
John Colquitt Logan, Sr	Eugene Thames Fulton, Jr
Paul Wendell Turner	John Richard Patterson

David Darby Elected New Board Member

David Darby was elected by a majority of the votes cast by all Alabama pharmacists. He will serve a five-year term that shall begin on January 1, 2014, and expire on December 31, 2018.

Mr Darby, a 1982 graduate of Auburn University Harrison School of Pharmacy (AUHSOP), is owner of Darby's Village Pharmacy and Darby's Medical Center Pharmacy in Andalusia, AL. Prior to opening his first store in 1997, he worked with Harco Drug as a pharmacist, store manager, and district manager. He has served on committees on the state and national level and has held numerous offices in the Alabama Pharmacy Association including president, and is currently serving as district trustee. He serves on the AUHSOP Dean's Advisory Council as well the Blue Cross Pharmacy Advisory Committee. He has received the Bowl of Hygeia, as well as the Distinguished Service Award from the AUHSOP, the Lester White Good Government Award, and the National Community Pharmacists Association Leadership Award. Darby's Village Pharmacy was named Small Business of the Year by the Andalusia Chamber of Commerce in 2012. He serves as a guest speaker at AUHSOP and Andalusia High School.

Alabama Medicaid Rule No. 560-X-16-.20(5) Quantity Limitations

> (5) Maintenance medications are those generally used to treat chronic conditions or illnesses and are ordered/prescribed and taken regularly and continuously. Medicaid recipients can obtain a three month supply of maintenance medications as designated by the Agency. The patient must first have demonstrated stability for at least 60 days (same strength and dose) on a given maintenance medication. Only one co-pay is collected and only one dispensing fee is paid for the three month supply. A list of maintenance medications is available on the Medicaid website.

Medicaid has disseminated and posted guidance to the Alabama Medicaid Agency website, which is very clear in that pharmacists should always follow both state and federal pharmacy law. The Alabama Medicaid Agency guidance is available on its website at *www.medicaid.alabama.gov/documents/4.0_Programs/4.5_Pharmacy_Services/4.5.4_Drug_Info/4.5.4_Maintenance_Supply_Guidance_Revised_9-5-13.pdf* and states the following: "Alabama State Board of Pharmacy law prohibits the quantity of a prescription to be changed without prescriber approval. Approval from the prescriber must be attained prior to dispensing a maintenance supply."

Information provided by Kelli Littlejohn Newman, PharmD, RPh, director, clinical services and support, Alabama Medicaid Agency.

Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 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. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

Drug Inspector George T. Grubbs

The Board is sad to announce that former Drug Inspector George T. Grubbs passed away on November 6, 2013, at the age of 80. Mr Grubbs was employed as a drug inspector with the Board for 26 years before his retirement and his many honors included the Lester E. Hosto Inspector Distinguished Service Award, which was awarded by the National Association of Boards of Pharmacy®. The Board extends its deepest sympathy to his entire family.

Verify DEA Number, Physician's Name Before Uploading to the Prescription Drug Monitoring Program

The Alabama Board of Medical Examiners has passed a board rule creating standards for pain management services. According to the rule, physicians must sign up with the Prescription Drug Monitoring Program (PDMP) and are encouraged to verify controlled substance prescriptions written by them. This includes physicians at "a physician practice in which any of the providers of pain management services are rated in the top ten percent of practitioners who prescribe controlled substances in Alabama" as determined by the PDMP on an annual basis.

Numerous physicians have contacted the Board office, complaining that pharmacists are inputting wrong prescription information, showing the physician as being the prescriber when in fact it is another physician. As part of your record-keeping requirements, correct prescription information should be entered into the system. Please verify the Drug Enforcement Administration (DEA) number, as well as the physician's name before entering and uploading to the PDMP.

680-X-2-.41 Pharmacy Services Permits

(1) The Board may issue on a case by case basis a Pharmacy Services Permit for the limited purpose of allowing pharmacists and pharmacy technicians to provide pharmacy services to patients and clients. Nothing in this rule shall limit the board's ability to issue any Pharmacy Services Permit the Board deems appropriate.

(2) The Board has determined that, at a minimum, the holder of a Pharmacy Services Permit must designate a Supervising Pharmacist who shall be licensed by the Alabama State Board of Pharmacy, on site, who is responsible for ensuring that the processes and compliance standards are maintained within limits set by the Board for the permit holder.

(3) Nothing in this rule restricts the Board from setting pharmacist and technician ratios.

(4) Nothing in this rule shall authorize any individual to perform any activity beyond their scope of practice pursuant to any license or registration issued to them.

(5) In the event the application for a Pharmacy Services Permit is by a non-resident pharmacy, in addition to the requirements set out in Paragraphs (1) through (4) above, if applicable, the applicant must comply with to the following requirements:

(a) Complete an application furnished by the Board and be issued the referenced permit. Any application which is not full and complete will not be processed.

(b) Pay the fee set out in Code of Alabama, (1975) §34-23-30.

(c) The Pharmacy Services Permit issued by the Board shall become void on December 31st of even numbered years unless renewed in compliance with Code of Alabama, (1975) §34-23-30.

(d) Submit documentation from the applicant's home state verifying any applicable license or permit is valid and in good standing.

(e) Designate a resident agent in Alabama for service of process. The failure to include this information shall result in the denial of the application.

(f) In the event the applicant will be involved or participate in any remote order processing and not actually shipping, mailing or delivering any drug from its location to a citizen in this State, there shall also be compliance with the following:

1. All statutory and regulatory requirements of the State of Alabama relating to controlled substances, including those that are different from federal law or regulation.
2. All the statutory and regulatory requirements of the State of Alabama regarding drug product selection laws.
3. All Board of Pharmacy requirements for data submission related to volumes of orders processed as specified at the time of approval.

(g) Submission with the application a policy and procedure manual for Board approval which must, at a minimum, include the following:

1. Hours of operation.
2. On-Call Pharmacist. For the protection of patients, when orders are being processed remotely and no pharmacist is onsite at the resident Pharmacy, a pharmacist must be on-call to respond to situations that arise that cannot be addressed through remote services, such as patient needing a specific medication which is not available until the resident Pharmacy opens, or a healthcare provider urgently needing information that cannot be provided by the pharmacists performing remote order processing.
3. Procedures to be following in case of downtime.
4. The system to be used to identify and respond to medication errors arising from mistakes from remote order processing.
5. The system to be used to insure initial and ongoing quality of remote order processing.

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6. The means by which compliance with HIPAA [Health Insurance Portability and Accountability Act] requirements will be met.

(h) Designate a supervising pharmacist who shall be responsible for ensuring compliance with this rule and all applicable laws and rules.

(i) Compliance with any other requirement deemed necessary by the Board, to include but not limited to required technician to pharmacist ratios.

(History: Adopted: 26 September 2012; Effective 1 November 2012; Amended 23 October 2013; Effective 1 January 2014).

680-X-2-.42 Requirements for Return and Destruction of Drugs by Pharmacies

(1) This rule shall apply only to unused or expired non-controlled legend drugs. The return of controlled drugs shall not be authorized until the adoption of applicable regulations pursuant to the Secure and Responsible Drug Disposal Act of 2010, at which time there must be compliance with the provisions of any such regulation(s) or any subsequent amendments thereto.

(2) The following requirements shall apply whenever an individual desires to return unused or expired drugs to a pharmacy and if the pharmacy agrees to accept the return.

(a) Drugs may only be returned for the sole purpose of destruction.

(b) It shall be the pharmacist(s) responsibility to ensure compliance with the requirements of this Rule.

(c) The pharmacy shall maintain a separate log of all returned drugs which shall include the following information.

1. General description of returned drugs.
2. Date of return.
3. Date and method of destruction of drugs.
4. The above referenced log shall be available for inspection in the same manner as set forth in the Code of Alabama 1975, § 34-23-70(k).

(3) Any returned drug must be maintained and stored in an area within the pharmacy which is separate and apart from the regular inventory of the pharmacy.

(4) No returned drugs shall be dispensed for any purpose.

(5) Any returned drugs shall be destroyed within 180 days of their return to the pharmacy.

(History: Adopted: 20 November 2013; 1 January 2014)

680-X-2-.07 Mail Order Prescriptions

(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 <u>or a renewal if applicable</u> 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) <u>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</u>

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

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Permit No. 5744

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the requirements of this rule and all applicable statutory provisions and rules;

(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.

A public hearing will be held at 8 AM on February 19, 2014, at the Board office in Birmingham, AL, to amend the above indicated rule. The deadline for written comments is March 7, 2014. (Underlined words indicate proposed amendment.)

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 help-line 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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