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Alabama State Board of Pharmacy News

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Fifty-Year Pharmacists

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

John Milton Fitzpatrick	Sloan Jackson Harper
Edward Wayne Stallings	Esam Zopher Dajani
James Tweedie Dunn	Kenneth Wayne Wilkerson
Floyd Hayward Gunnin	Rebecca Ann Fox
James Robert Lowry	Charlene Callaway Vaughn
Robert Calvin Bottoms	Louis Emanuel Michetti
William Glen Dunaway	Barbara Duke McLeod
Stanley Lucien Malkemus	Marion Bice Lamon
Kreshel Jerome Mallory	Jane Burks Forbes
Crayton Mark Bowen	Ralph John Bennett
Roland Julian Nelson	John Barry Jacobs
Joseph H. Carstarphen	Melbourn Lloyd Sellers
Charles Kenneth Sanders	William Kenneth Jacobs
Thomas Edwin Holcombe	

Donna C. Yeatman Appointed New Board Member

Donna C. Yeatman was appointed by Governor Robert J. Bentley as the Board's chain pharmacist member. She will serve a five-year term, which began January 1, 2015, and will expire December 31, 2019.

She is a 1994 Samford University School of Pharmacy graduate. She is a third generation pharmacist, and grew up learning the rewards of practicing pharmacy in an independent pharmacy owned by her grandfather and father. She began her pharmacy practice at Children's Hospital before returning to retail community pharmacy with Big B Drugs. She is currently a district manager with CVS Health.

Donna is an affiliate clinical instructor of pharmacy practice for Samford University, served on Samford University's Leadership Council, and provides federal and state law reviews for CVS Health.

Donna has been married to her husband, Wes, for 20 years and has four children: Taylor, Lilly, Wesley, and Daniel. She is on the United Cerebral Palsy of Greater Birmingham Board of Directors and volunteers with VSA Arts of Alabama. She coaches Our Lady of the Valley Catholic School (OLV) girls' basketball and is a member of the OLV Basketball Board of Directors.

Limited Purpose Schedule II Permit for CRNPs, CNMs, and PAs Practicing in Alabama

Beginning January 1, 2015, qualified mid-level practitioners, specifically certified registered nurse practitioners (CRNPs), certified nurse midwives (CNMs), and physician assistants (PAs), may write prescriptions for limited, practice-specific Schedule II prescriptions in the state of Alabama. To do this, they must apply through the Alabama Board of Medical Examiners and receive a Limited Purpose Schedule II Permit (LPSP) number. The LPSP number will be the same as their Qualified Alabama Controlled Substances Certificate (QACSC) number, which was granted by the Board of Medical Examiners when they received permission to write for Schedule III through Schedule V prescriptions. In addition, each mid-level practitioner who can write for any controlled substance (CS) has his or her own Drug Enforcement Administration (DEA) number.

This new authority is not for all Schedule II drugs; it is limited to Schedule II drugs that are appropriate for the type of practice. For example, a CRNP who works for a physician who sees children with a diagnosis of attention deficient disorder might have permission to write prescriptions for Ritalin®. A PA who works with an orthopedic surgeon might have permission to write for hydrocodone, while a PA who works with an oncologist might have permission to write for fentanyl patches. To verify Alabama licensure status, licensing numbers, scope of practice, a list of Schedule II drugs allowed to be prescribed, and the name of the collaborating physician, check the Board of Medical Examiners website at *www.albme.org.* From the home screen, select the "Look up a licensee" quick link and follow the prompts.

CRNPs, CNMs, and PAs must have their DEA number and their QACSC/LPSP number on each prescription they prepare. The same is true for each Schedule III through Schedule V prescription they prepare. Since the QACSC is the same number as the LPSP, the only way to know if the person has extended privileges is to check the Board of Medical Examiners website. Be sure to use the CRNP, CNM, or PA identifiers so that the correct person is identified in the Alabama Prescription Drug Monitoring Program (PDMP) database. These mid-level practitioners will be tracked by the collaborating physician using the PDMP database, so it is vital that the correct data is submitted. Insurances should recognize and allow for a paid claim using the CRNP, CNM, or PA information. Additional information may be found under the Alabama Board of Medical Examiners Administrative Code Chapter 540-X-20 Limited Purpose Schedule II Permit (LPSP), available at *www.alabamaadministrativecode.state.al.us/docs/mexam/540-X-20.pdf.*

For more information on Qualified Alabama Controlled Substances Registration, see Code of Alabama 1975, Title 20, Chapter 2, Article 3A (20-2-60 through 20-2-69). A copy is available on the Board's website under the Statutes/Rules tab.

Schedule II Prescriptions From Out-of-State Mid-Level Practitioners

Alabama will allow Schedule II prescriptions to be filled within Alabama from out-of-state mid-level practitioners only if the CRNP, CNM, or PA is currently licensed to write Schedule II prescriptions within the state he or she practices and holds his or her own DEA number.

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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Quick Reference: Requirements for Alabama Mid-Level Practitioners to Legally Write a Schedule II Prescription

1. Must be registered with the Board of Medical Examiners with a DEA number and have the practice registration amended to include Schedule II prescriptions.
2. Must have a current collaborative practice agreement.
3. Must have an active QACSC, which allows the writing of Schedule III through Schedule V prescriptions.
4. Must have an active LPSP, which is an extension of the QACSC to include practice-specific Schedule II prescriptions. The permit number will be the same as the QACSC number.

Rule Change: Daily Reporting to PDMP Implementation Begins Immediately; Daily Reporting Overview

On October 20, 2014, Rule 420-7-2-.12 passed, requiring entities and practitioners (except veterinarians) that dispense Schedule II-V CS to report data to the CS database on **a daily** basis. The purpose of this new rule will assist with the identification, intervention, prevention, and education of abused, misused, and diverted CS within the state of Alabama.

Daily reporting implementation should begin immediately. The PDMP allowed a grace period to implement this change until **January 1, 2015,** at which time PMDP began collecting noncompliance data for the regulatory boards per state law. If you are already reporting to the CS database on a daily basis, please disregard this message.

Accordingly, this notification is solely intended to educate entities or practitioners that are currently reporting to the CS database on a **weekly** basis.

Daily Reporting Requirements

Entities and practitioners that dispense Schedule II-V CS must report data to the CS database on **a daily** basis.

Entities and practitioners required to report **daily** include, but are not limited to:

- Licensed pharmacies;
- Mail-order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing CS to residents of Alabama;
- Licensed physicians, dentists, podiatrists, and optometrists who dispense CS; and
- Veterinary practitioners shall submit reports at least once monthly by 11:59 PM on the last business day of the month.

For additional assistance regarding **daily** reporting to the CS database, contact the PDMP technical support desk at 1-800/225-6998 (option 8) or visit the PDMP website at *www.adph.org/pdmp* (click on the Dispenser Packets link).

Daily Reporting Submissions

- At least once **daily** by 11:59 PM.
  - ◊ Licensed pharmacies
  - ◊ Mail-order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing CS to residents of Alabama
  - ◊ Licensed physicians, dentists, podiatrists, and optometrists who dispense CS
- At least once **monthly** by 11:59 PM on the last business day of the month.
  - ◊ Veterinary practitioners
- If an entity or practitioner does not dispense a CS on a specific day, the entity or practitioner shall report that zero CS were dispensed.
- The **daily** reporting requirement does not apply on days that the entity or practitioner's business is closed.

Daily Reporting Penalties for Noncompliance/Non-Reporting

Mandatory reporting from weekly to **daily** will begin immediately. The PDMP began collecting data to report noncompliance to the regulatory boards on **January 1, 2015.**

For a complete copy of Rule 420-7-2-.12, visit the PDMP website at *www.adph.org/PDMP/Default.asp?id=1234.*

If you have any questions regarding this notification, please feel free to contact the PDMP at pdmp@adph.state.al.us.

Thank you in advance for your assistance in reducing prescription drug abuse, misuse, and diversion in the state of Alabama.

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 email 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.

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