August 2018

News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Farewell to Chief Drug Inspector/Administrator

Lee Ann F. Bundrick, RPh, has retired, effective June 30, 2018, as chief drug inspector/administrator of the South Carolina Department of Labor, Licensing & Regulation – Board of Pharmacy after almost 21 years of service with the Board and almost 33 years of service to the state of South Carolina.

At the June 13, 2018 Board meeting, Senator Ronnie Cromer presented Lee Ann with a Senate resolution in recognition of her distinguished and dedicated service. The resolution also stated that her leadership, vision, and guidance have set an outstanding example for all pharmacists in South Carolina.

The Board offers its sincere appreciation to Lee Ann for her dedicated service to the Board, the citizens of South Carolina, and the profession of pharmacy. The Board wishes her continued success in all future endeavors.

Board Elects Officers

At its June 2018 meeting, the Board elected Spencer Morris, PharmD, RPh, of Georgetown, SC, as its chairperson. Morris is the pharmacist representing the Seventh Congressional District.

Eric Strauss, PharmD, RPh, of Greenville, SC, representing the Fourth Congressional District, was elected vice chairperson. Each will serve a one-year term from July 1, 2018, until June 30, 2019.

Congratulations to Board Appointees

The Board would like to congratulate Lauren B. Thomas, PharmD, RPh, of John's Island, SC, on her recent appointment to the Board, and Rebecca Long Gillespie, PharmD, RPh, of Columbia, SC, and Terry A. Blackmon, RPh, of New Zion, SC, on their recent reappointments to the Board by Governor Henry McMaster.

Thomas' six-year term will expire on June 30, 2023. She represents the First Congressional District and replaces Carole S. Russell, RPh. Thomas works as a floater for CVS Pharmacy and as a consultant pharmacist at Charleston Rx Consulting. She will provide valuable expertise in chain pharmacy and consulting.

Gillespie was reappointed to the Board on April 25, 2018, to serve as the pharmacist-at-large with a term coterminous with the appointing governor. She will continue to provide valuable expertise on compounding, durable medical equipment, and independent pharmacy.

Blackmon was reappointed to the Board and represents the Sixth Congressional District. His six-year term will expire on June 30, 2024. Blackmon will continue to provide valuable expertise in independent community pharmacy practice.

The Board welcomes its new members and offers sincere appreciation to Russell for her dedicated service to the citizens of South Carolina and to the profession of pharmacy.

2018 Retail Clinic Clarification

The Board has recently received inquiries as to whether clinics that store legend drugs are required to maintain a non-dispensing drug outlet permit. At its March 14, 2018 meeting, the Board noted that subject to limited exceptions, a permit is required for the sale, distribution, **possession,** or dispensing of drugs bearing the legend "Caution: Federal law prohibits dispensing without a prescription" including, but not limited to, pharmacies (institutional or community, public or private), nursing homes, hospitals, convalescent homes, extended care facilities, family planning clinics, **public or private health clinics,** infirmaries, wholesalers, correctional institutions, industrial health clinics, mail-order vendors, and manufacturers within or outside this state (South Carolina Code Annotated §40-43-83(I)).

Additionally, S.C. Code of Regulations 99-43(B) provides that a non-dispensing drug outlet permit is required for facilities including, but not limited to, **clinics,** wholesalers, manufacturers, and distributors.

Thus, any facility storing legend drugs that is not subject to an exception, must have a non-dispensing drug outlet permit. This includes clinics providing primary care that are located in a retail setting that also houses a permitted pharmacy.

The Board recognizes that this may be a change from current practice for some clinics and offers this guidance to help clinics operate in compliance with the South Carolina Pharmacy Practice Act.

2018 Patient-Specific Wholesale

The Board held its regularly scheduled Board meeting on March 14, 2018. One item on the agenda was the request to clarify if a facility permitted as a wholesale distributor could drop-ship patient-specific medical devices. Based on the below statutes, the Board made the determination that a facility permitted and/or classified as a wholesale distributor cannot dispense patient-specific medications or devices.

S.C. Code Section 40-43-30(89) defines a wholesale distributor as:

> a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. **Wholesale distributor does not include:**
>
> (a) intracompany sales, being defined as a transaction or transfer between a division, subsidiary, parent, or affiliated or

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National Pharmacy Compliance News

August 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

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

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related company under the common ownership and control of a corporate entity;

(b) the purchase or other acquisition by a hospital or other health care entity that is a member of a group-purchasing organization of a drug for its own use from the group-purchasing organization or from other hospitals or health care entities that are members of such organizations;

(c) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(d) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes the transfer of legend drugs by a licensed pharmacy to another licensed pharmacy or a practitioner licensed to possess prescription drugs to alleviate a temporary shortage, except that the gross dollar value of the transfers may not exceed five percent of the total legend drug sales revenue of either the transferor or the transferee pharmacy during a consecutive twelve-month period;

(f) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; or

(g) the sale, purchase, or trade of blood and blood components intended for transfusion. (emphasis added)

In addition, S.C. Code Section 40-43-89(A)(4) states, **"The board may suspend, revoke, deny, or refuse to renew the permit of wholesale drug distributors other than pharmacies dispensing or distributing drugs or devices directly to patients."** (emphasis added)

Therefore, all patient-specific drugs and legend devices must be dispensed by the pharmacy or facility holding the prescription or order with the appropriate licensure or permit that allows for patient-specific dispensing.

S.918 – Limitations on Initial Opioid Prescriptions

A new law passed that impacts your practice in South Carolina. S.918 passed the General Assembly on May 9, 2018, and was signed by the governor on May 15, 2018. The law establishes limitations on initial opioid prescriptions for acute pain management or postoperative pain management and designates exceptions to those limitations.

Be it enacted by the General Assembly of the State of South Carolina:

Initial opioid prescriptions, acute and postoperative pain

SECTION 1. Section 44-53-360 of the 1976 Code is amended by adding an appropriately lettered subsection at the end to read:

"( )(1) Initial opioid prescriptions for acute pain management or postoperative pain management must not exceed a seven-day supply, except when clinically indicated for cancer pain, chronic pain, hospice care, palliative care, major trauma, major surgery, treatment of sickle cell disease, treatment of neonatal abstinence syndrome, or medication-assisted treatment for substance use disorder. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new opioid prescription.

(2) This subsection does not apply to opioid prescriptions issued by a practitioner who orders an opioid prescription to be wholly administered in a hospital, nursing home, hospice facility, or residential care facility.

(3) A practitioner who acts in accordance with the limitation on prescriptions as set forth in this subsection is immune from any civil liability or disciplinary action from the practitioner's professional licensing board.

(4) As used in this subsection:

(A) 'Acute pain' means pain that a practitioner reasonably expects to last for three months or less, whether resulting from disease, accident, intentional trauma, or other cause. The term does not include 'chronic pain' or pain being treated as part of cancer care, chronic care, hospice care, palliative care, major trauma, major surgery, treatment of sickle cell disease, treatment of neonatal abstinence syndrome, or medication-assisted treatment for substance use disorder.

(B) 'Chronic pain' means pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.

(C) 'Postoperative pain' means acute pain experienced immediately after a surgical procedure.

(D) 'Surgical procedure' means a procedure performed for the purpose of altering the human body by incision or destruction of tissues as part of the practice of medicine such as diagnostic or therapeutic treatment of conditions or disease processes by use of instruments and includes lasers, ultrasound, ionizing, radiation, scalpels, probes, or needles that cause localized alteration or transportation of live human tissue by cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction for major dislocations and fractures, or otherwise altering by any mechanical, thermal, light-based, electromagnetic, or chemical means."

Practitioner prescription report cards

SECTION 2. Article 15, Chapter 53, Title 44 of the 1976 Code is amended by adding:

"Section 44-53-1655. (A) The department shall develop and maintain as part of the prescription monitoring program a system to provide prescription report cards to practitioners to inform the practitioner about certain prescribing trends. The report card must provide, at a minimum:

(1) a comparison of the practitioner's number of prescriptions issued per month by therapeutic class code or by specific substances to peer averages by specialty throughout the State;

(2) a comparison of the practitioner's number of milligrams prescribed per month by therapeutic class code over by specific substances to peer averages by specialty throughout the State;

(3) the total number of patients receiving ninety morphine milligram equivalents (MMEs) or more a day;

(4) the total number of patients receiving opioid medications for thirty days or more;

(5) the total number of patients receiving opioids and benzodiazepines medications at the same time;

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(6) the total number of patients issued prescriptions from three or more practitioners;

(7) the total number of patients filling prescriptions at three or more pharmacies;

(8) the total number of patients with controlled substance prescriptions whose dispensing dates overlap;

(9) the total number of patients obtaining refills on their prescriptions more than one week early; and

(10) the total number of prescription drug monitoring program queries made by the practitioner and a ratio of the queries to the number of patients or prescriptions issued.

The report card also must provide data on the number of practitioners registered against which the comparisons of items (1) and (2) are being made and any other demographic data relating to the pool of practitioners and may include regional or nationwide prescribing comparison data that would be useful to the practitioner. Prescription report cards, data, documents, records, and any other information accessed or compiled in preparing prescription report cards, are confidential and not subject to discovery, subpoena, or introduction into evidence in any civil action, unless confidentiality is waived by the practitioner.

(B) The department shall coordinate with the Board of Medical Examiners and any other appropriate professional boards as part of the development and implementation of a prescription report card program. The department may contract with another agency of the State or with a private vendor, as necessary, to ensure effective operation of the report card program, as provided in Section 44-53-1660, and may apply for public or private grants or other funding to develop, implement, and maintain the program."

Prescription monitoring program confidentiality exceptions

SECTION 3. Section 44-53-1650(D) of the 1976 Code is amended by an appropriately numbered item at the end to read:

"( ) a practitioner in a prescription report card provided to practitioners in accordance with Section 44-53-1655."

Time effective

SECTION 4. SECTION 2 is effective six months after the effective date of this act. All other SECTIONS are effective upon approval by the Governor.

The Board does not interpret the language of S.918/Act 201 of 2018 (as now set forth in the revised S.C. Code Ann. Section 44-53-360) to impose an obligation upon the pharmacy in question to verify compliance with this section. Pharmacies may choose to implement their own verification procedures for prescriptions in accordance with the requirements of the Pharmacy Practice Act.

According to the South Carolina Department of Health and Environmental Control (SC DHEC) Bureau of Drug Control, pharmacists have the legal right to refuse to fill a prescription if they are concerned about the "legitimate" nature of the prescription. The new language in the Controlled Substances Act (CSA) 44-53-360 has led many pharmacists in the community to question the implementation of the language specified in the law. One concern is the legal ramifications should a pharmacist fill an initial opioid prescription that may exceed the seven-day supply limit based on the clinical status of a patient.

The concerns of the pharmacists in the community were communicated to SC DHEC for guidance. It is the Board's position that the pharmacist's role is not to determine if the prescription is within the legal confines of Section 44-53-360. It is the responsibility of the prescribing practitioner to comply with the CSA by ensuring that initial opioid prescriptions for acute or postoperative pain management that exceed a seven-day supply are clinically indicated.

The Board does not interpret the opioid limitation to impose an obligation upon the pharmacist in question to verify compliance, as the practitioners are expected to comply and may be subject to discipline if they do not. Pharmacies may choose to implement their own verification procedures for prescriptions in accordance with the requirements of the Pharmacy Practice Act.

S.506 – One-Time Emergency Prescription Refill During a State of Emergency Amended, Signed May 17, 2018

Section 40-43-170(A) of the 1976 Code was amended, related to a state of emergency, prerequisites to emergency refills, and the dispensing of medications by pharmacists not licensed in this state, and to allow for a one-time, 30-day emergency refill during a state of emergency.

Be it enacted by the General Assembly of the State of South Carolina:

Emergency refills, quantity increased

SECTION 1. Section 40-43-170(A)(1) of the 1976 Code is amended to read:

"(A) When the Governor issues a 'State of Emergency':

(1) A pharmacist may work in the affected county and may dispense a one-time emergency refill of up to a **thirty-day** supply of a prescribed medication if:

(a) the pharmacist has all prescription information necessary in order to accurately refill the prescription;

(b) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy;

(c) the pharmacist reduces the information to a written prescription marked 'Emergency Refill', files the prescription as required by law, and notifies the prescribing physician within fifteen days of the emergency refill; and

(d) the prescription is not for a controlled substance."

Time effective

SECTION 2. This act takes effect upon approval by the Governor. (emphasis added)

New Sterile Compounding Inspection Form

At its June 13, 2018 meeting, the Board approved a new sterile compounding inspection form to be utilized by pharmacist inspectors in the field upon the passage of Act 143 relating to compounding pharmacies. The implementation date will be **October 1, 2018.**

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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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