



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

Published to promote compliance of pharmacy and drug law

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Upcoming Board Vacancy

If you live in the First Congressional District and are interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you must meet the following requirements:

- ◆ Reside in the First Congressional District;
- ◆ Be licensed and actively practicing pharmacy in South Carolina; and
- ◆ Before December 1, 2016, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the First Congressional District. The term begins July 1, 2017, and ends June 30, 2023.

After receiving biographies and petitions, the Board administrator will:

- ◆ Prepare and mail ballots by January 15, 2017, to all pharmacists who have notified the Board that they reside in the First Congressional District; and
- ◆ Certify as true and valid all ballots postmarked before February 15, 2017, and received by the Board office before February 25, 2017.

Before March 1, 2017, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1 of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

Prescribing for Mid-Level Providers

Recently, the Board has received inquiries regarding what is required to be on the prescriptions of nurse practitioners and physician assistants. It appears that third-party auditors are denying reimbursement and/or claims to pharmacies for not having the name, address, and phone number of the physician on the prescription. The Board urges pharmacists to ensure all required information is included on the prescription. If licensed practitioners have questions, please refer them to the appropriate practice act.

Nurse Practitioners

South Carolina Code Annotated §40-33-34 states, in part (emphasis added):

- (F)(1) Authorized prescriptions by a nurse practitioner, certified nurse-midwife, or clinical nurse specialist with prescriptive authority:
- (a) must comply with all applicable state and federal laws;

- (b) is limited to drugs and devices utilized to treat common well-defined medical problems within the specialty field of the nurse practitioner or clinical nurse specialist, as authorized by the physician and listed in the approved written protocols. The Board of Nursing, Board of Medical Examiners, and Board of Pharmacy jointly shall establish a listing of classifications of drugs that may be authorized by physicians and listed in approved written protocols;
- (c) **do not include prescriptions for Schedule II controlled substances;** however, Schedules III through V controlled substances may be prescribed if listed in the approved written protocol and as authorized by Section 44-53-300;
- (d) must be signed by the NP, CNM, or CNS with the prescriber's identification number assigned by the board and all prescribing numbers required by law. **The prescription form must include the name, address, and phone number of the NP, CNM, or CNS and physician** and must comply with the provisions of Section 39-24-40. A prescription must designate a specific number of refills and may not include a nonspecific refill indication;
- (e) must be documented in the patient record of the practice and must be available for review and audit purposes.

The nurse practitioner must have a valid Drug Enforcement Administration (DEA) registration and South Carolina Department of Health and Environmental Control (SC DHEC) Bureau of Drug Control registration and must prescribe in accordance with state and federal laws. **Schedule II controlled substances (CS) cannot be prescribed.** Prescriptions must meet all other state and federal laws.

Physician Assistants

South Carolina Code Annotated §40-47-965(A) states the following requirements for writing prescriptions for drugs, CS, and medical devices (emphasis added).

- If the written scope of practice guidelines authorizes the physician's assistant to prescribe drug therapy:
- (1) prescriptions for authorized drugs and devices shall comply with all applicable state and federal laws;
 - (2) prescriptions must be limited to drugs and devices authorized by the supervising physician and set forth in the written scope of practice guidelines;


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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at <https://vaers.hhs.gov/professionals/index>.

Improper and Unsafe Vaccine Storage

 *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: isminfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up

involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter¹ contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.²

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

- (1) Read and follow the label.
- (2) Know which medicines contain acetaminophen.



- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, www.knowyourdose.org.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine[®]-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at www.fda.gov/MedWatch. Additional details are available on FDA's website at www.fda.gov/Safety/Recalls/ucm497812.htm.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution

distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia*, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. More information may be found in the safety alert on FDA's website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy[®] (NABP[®]) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- ◆ **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- ◆ **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- ◆ **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination[®] (NAPLEX[®]), Multistate Pharmacy Jurisprudence Examination[®] (MPJE[®]), Foreign Pharmacy Graduate Equivalency Examination[®] (FPGEE[®]), Pharmacy Curriculum Outcomes Assessment[®] (PCOA[®]), and Pharmacist Assessment for Remediation Evaluation[®] (PARE[®]).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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- (3) prescriptions must be signed by the physician assistant and must bear the physician assistant's identification number as assigned by the board and all prescribing numbers required by law. The preprinted prescription form shall include **both the physician assistant's and physician's name, address, and phone number** and shall comply with the provisions of Section 39-24-40;
- (4) drugs or devices prescribed must be specifically documented in the patient record;
- (5) the physician assistant may request, receive, and sign for professional samples of drugs authorized in the written scope of practice guidelines and may distribute professional samples to patients in compliance with appropriate federal and state regulations and the written scope of practice guidelines;
- (6) the physician assistant may authorize prescriptions for an orally administered Schedule II controlled substance, as defined in the federal Controlled Substances Act, pursuant to the following requirements:
 - (a) the authorization to prescribe is expressly approved by the supervising physician as set forth in the physician assistant's written scope of practice guidelines;
 - (b) the physician assistant has directly evaluated the patient;
 - (c) the authority to prescribe is limited to an initial prescription and must not exceed a seventy-two hour supply;
 - (d) any subsequent prescription authorization must be in consultation with and upon patient examination and evaluation by the supervising physician, and must be documented in the patient's chart; and
 - (e) any prescription for continuing drug therapy must include consultation with the supervising physician and must be documented in the patient's chart;
- (7) the physician assistant may authorize a medical order for parenteral administration of a Schedule II controlled substance, as defined in the federal Controlled Substances Act, pursuant to the following requirements:
 - (a) the authorization to write a medical order is expressly approved by the supervising physician as set forth in the physician assistant's written scope of practice guidelines;

- (b) the physician assistant is providing patient care in a hospital setting, including emergency and outpatient departments affiliated with the hospital;
- (c) an initial patient examination and evaluation has been performed by the supervising physician, or his delegate physician, and has been documented in the patient's chart; however, in a hospital emergency department, a physician assistant may authorize such a medical order if the supervising or delegate physician is unavailable due to clinical demands, but remains on the premises and is immediately available, and the supervising or delegate physician conducts the patient evaluation as soon as practicable and is documented in the patient's chart;
- (d) the physician assistant has directly evaluated the patient; and
- (e) the written medical order may not exceed a one-time administration within a twenty-four hour period.

The physician assistant must have a valid DEA registration and SC DHEC Bureau of Drug Control registration and must prescribe in accordance with state and federal laws. **Schedule II CS can be prescribed if set forth in the written scope of practice guidelines.** Prescriptions must meet all other state and federal laws.

Board of Medical Examiners Physician Assistant Prescribing Question Advisory Opinion

[28] [Physician Assistant] PRESCRIBING QUESTION ADVISORY OPINION - The Board of Medical Examiners (BME) does not interpret the language of the PA act as amended to impose an obligation upon the pharmacy in question to verify compliance with §40-47-965. Licensees under the BME, supervising physicians and physician assistants are expected to comply with the medical practice act and are 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.

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