



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

*Published to promote compliance of pharmacy and drug law*

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## **Joint Advisory Opinion Issued by the South Carolina State Boards of Medical Examiners, Nursing, and Pharmacy Regarding Methadone Clinics**

The Healthcare Collaborative Committee met on October 23, 2015, at which time a quorum of designated representatives from the South Carolina State Board of Medical Examiners, South Carolina State Board of Nursing, and South Carolina State Board of Pharmacy was present.

Representatives from the Board of Pharmacy staff and the South Carolina Department of Health and Environmental Control (SC DHEC) Bureau of Drug Control advised the Committee of multiple regulatory compliance concerns arising from inspections of methadone clinics around the state.

The compliance challenges identified include, but are not limited to, scope of practice issues for pharmacists and nurses working in the methadone clinic, potential disparities between applicable state and federal laws, verification of a patient's identity, verification and compliance with a valid prescription by a prescriber, concerns about labeling of non-patient-specific doses for on-site administration, and the distinction between "administration" and "dispensing" of medication as defined by the South Carolina Pharmacy Practice Act. Testimony established that a pharmacist most often is not present during all dosing hours of a methadone clinic, but that a pharmacist's presence during all dosing hours would resolve most of the concerns identified.

The Committee recommended that the Boards of Medical Examiners, Nursing, and Pharmacy adopt a joint advisory opinion clarifying that methadone clinics should have a pharmacist on site during all hours when methadone is dispensed for either administration on site or at home. Dispensing occurs any time product selection, which includes dosage selection, occurs. The administration or dispensing of methadone without a

pharmacist present in the methadone clinic may result in disciplinary action against licensed professionals employed by the methadone clinic. The boards agree with this opinion.

The Board of Medical Examiners approved this recommendation at its meeting on November 2, 2015. The Board of Pharmacy approved this recommendation at its meeting on November 18, 2015. The Board of Nursing approved this recommendation at its meeting on November 19, 2015.

## **Pharmacy Technician Renewals**

The 2016 renewal notices were mailed to pharmacy technicians on or about April 15. The renewal notice you receive will contain a **user ID** and **password** to access the online renewal website. **If you are a state-certified pharmacy technician and your national certificate (from the Pharmacy Technician Certification Board) has expired, you must mail a copy of your current national certificate to the Board.**

If you choose not to renew online, you may download the renewal application and renew by mailing the completed form and proper fees to the Board office. **Applications need to be received in the Board office by June 1, 2016. Pharmacy technicians who do not renew prior to June 30, 2016, will be assessed penalties and cannot work as pharmacy technicians until a 2016-2017 registration is in hand or disciplinary action may result.** If you do not renew online, please document the date the application is mailed. **The Board recommends the paper renewal be sent via certified mail with a return receipt requested.**

## **Facility Permit Renewals**

The permit renewal notices and forms were mailed out in mid-April 2016 to the last known address on file in the Board office. If you are a permit holder and have not received your permit renewal application, contact the Board office immediately. The renewal notice you

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## **FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths**

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm).

## **Selected Medication Safety Risks to Manage in 2016**



*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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication

errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News*.  
**Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record**

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.<sup>1</sup>

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.<sup>1,2</sup> Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.<sup>3</sup> In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.<sup>4</sup>

## **Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records**

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: “Insulin glargine (Lantus) 100 units/mL,” followed on the next line with “6 units subcutaneous daily every evening.”

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

#### References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc.* 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med.* 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc.* 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health.* 2014; 73(10):322-328.

### **FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy**

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 decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

### **Reading Medicine Labels Helps Reduce Acetaminophen Overdoses**

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at [www.knowyourdose.org](http://www.knowyourdose.org).

### **Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings**

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, [www.perrigo.com](http://www.perrigo.com), under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).

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

FDA's Division of Drug Information, CDER, presents a series of continuing education 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. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at [www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm).

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receive will contain a **user ID** and **password** to access the online renewal website.

If you choose not to renew your permit online, you may download a renewal form from the Board's website. Mail the completed form, along with proper fees, to the Board at PO Box 11927, Columbia, SC 29211. All applications must be received at the Board's office prior to June 1, 2016, or a \$50 late fee will be assessed. After June 30, 2016, the facility permit will lapse.

Upon application for reinstatement, the facility will be assessed a penalty of \$10 a day until the permit is reinstated, plus the \$50 late fee and a new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to South Carolina Code Annotated §40-43-83, resulting in discipline.

In response to the Drug Quality and Security Act, the Board has approved two new permit classifications: outsourcing facility for 503B facilities and third-party logistics provider (3PL). In-state 3PLs will be issued non-dispensing drug outlet permits. Out-of-state 3PLs previously permitted as nonresident wholesalers/distributors will now receive the new 3PL permit. Facilities registered with Food and Drug Administration as a 503B outsourcing facility must obtain an outsourcing facility permit as well as a pharmacy permit or a wholesale/distributor/manufacturer (non-dispensing drug outlet permit for in-state facilities) permit.

### ***Update on Initial Applications for Pharmacy Technicians and Interns***

Board staff is pleased to announce that electronic initial applications are available on the Board website under Applications and Forms for pharmacy technicians and pharmacy interns. Once all the required support

documentation is received, this will improve the processing and turnaround time for issuance of licenses, registrations, and certifications.

### ***Theft or Loss of Drugs and/or Devices***

Licensees are reminded that they must comply with all requirements regarding the reporting of the theft or loss of drugs and devices. Drug Enforcement Administration (DEA) requires the reporting of the theft or loss of controlled substances utilizing the electronic DEA Form 106, but the Board and SC DHEC Bureau of Drug Control also have reporting requirements.

According to §40-43-91(A)(1) of the South Carolina Pharmacy Practice Act, "A permit holder shall report to the Board of Pharmacy within thirty working days of the discovery of the occurrence of theft or loss of drugs or devices."

According to South Carolina Code of Regulations, Chapter 61, Section 4, Controlled Substances 408, "Theft reports (DEA Form 106) as required by this regulation shall be filed with the Bureau of Drug Control not later than 30 days following the discovery of the theft."

Please be mindful of the statutes and regulations for reporting the theft or loss of drugs and devices. SC DHEC Bureau of Drug Control's fax number is 803/896-0627 and its office phone number is 803/896-0636. The Board's fax number is 803/896-4596.

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