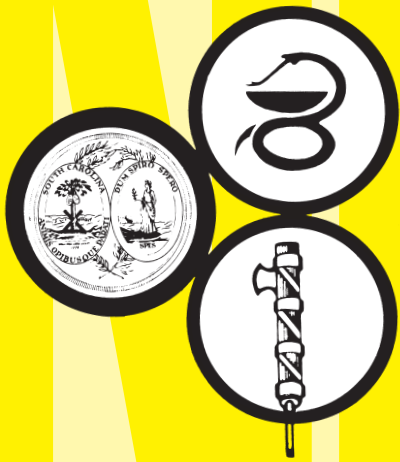


August 2007



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

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Congratulations to Board Appointee

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy would like to congratulate Hugh Mobley, RPh, of Lancaster, SC, on his recent appointment to the Board by Governor Mark Sanford. His six-year term expires on June 30, 2013. Mr Mobley represents the Fifth Congressional District and replaces Marvin A. Hyatt, Sr, RPh. He will provide valuable expertise on compounding, durable medical equipment, and independent community pharmacy practice settings. We welcome Mr Mobley, and we offer our sincere appreciation to Mr Hyatt for his dedicated service to the citizens of South Carolina and to the profession of pharmacy.

Board Elections

At the June 2007 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy members elected Dock Henry Rose, RPh, as their new chairman. Mr Rose is the pharmacist representative serving the Fourth Congressional District. Davis C. Hook, Jr, RPh, of West Columbia, representing the Second Congressional District, was elected as vice chairman. Each will serve a one-year term from July 1, 2007 until June 30, 2008.

E-Prescribing Law Passes

Senate Bill 610 was signed into law by Governor Sanford on June 13, 2007. Chapter 117, Title 44 of the 1976 Code was amended by adding the following:

Section 44-117-310. As used in this article:

- (1) “Board” means the State Board of Pharmacy.
- (2) “Confidential information” has the same meaning as provided in Section 40-43-30(8).
- (3) “Digital signature” means an electronic signature based upon cryptographic methods of originator authentication and computed by using a set of rules and set of parameters so that the identity of the signer and the integrity of the data can be verified.

- (4) “Electronic signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.
- (5) “Electronic transmission” means transmission of information by electronic means, including computer to computer, computer to facsimile machine, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment.
- (6) “Practitioner” means a health care professional licensed in this State who is authorized by law to issue prescription drug orders.
- (7) “Prescription” or “prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacist.
- (8) “Routing company” means a business that electronically receives a prescription or any other confidential information from a prescriber and transmits the prescription or confidential information to or from the pharmacy specified by the patient in accordance with a contract between the routing company and the prescriber or a company that provides computer software for the management of the prescriber’s practice.

Section 44-117-320.

- (A) A practitioner may electronically transmit a prescription to a pharmacy if all of these conditions are met:
 - (1) A valid practitioner-patient relationship must exist.
 - (2) The prescription must identify the transmitter’s phone number, the time and date of transmission, and the pharmacy intended to receive the transmission and any other information required by federal or state law.

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manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- ◆ **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6).
- ◆ **Product availability.** Ensure that oral syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- ◆ **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- ◆ **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- ◆ **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, www.fda.gov/buyonline/accutane, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called

Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide.

- (3) The prescription must be transmitted by the authorized practitioner or the practitioner's designated agent to the pharmacy of the patient's choice, and the prescription must be received only by a pharmacy, with no intervening person or entity having access to view, read, manipulate, alter, store, or delete the electronic prescription prior to its receipt at the pharmacy.
 - (4) The prescription must be transmitted to the pharmacy of the patient's choice. If the pharmacy of the patient's choice is not equipped with the capability to accept an electronic prescription, the practitioner shall provide the patient with a written prescription, telephone an oral prescription, or transmit via facsimile to the pharmacy of the patient's choice.
 - (5) The prescription must have the practitioner's electronic or digital signature or key code.
 - (6) The prescription must be sent directly from the practitioner to the receiving pharmacy of the patient's choice. If an electronic prescription is printed out, it must possess an original handwritten signature before being delivered to a patient. If a prescription is a hard-copy prescription drug order generated from electronic media, a prescribing practitioner's electronic or manual signature must be present. Prescriptions with electronic signatures must be applied to paper that utilizes security features that will ensure the prescription drug order is not subject to any form of copying or alteration.
- (B) An electronically transmitted prescription is deemed the original prescription drug order if it meets the requirements of this article and other applicable laws and regulations.
- (C) (1) Nothing in this article may be construed to prohibit a practitioner from using a routing company to transmit a prescription pursuant to this article, except that a routing company shall provide its tax identification number to the Board of Pharmacy before offering its services in this State.
- (2) A routing company:
- (a) may, for the purpose of verifying an audit conducted of the routing company, store any prescription or other confidential information it receives or transmits pursuant to this article in a form that is secure and ensures the confidentiality of the information in compliance with federal and state privacy law; and

- (b) may not add a provision to, delete a provision from, or otherwise modify a prescription or any other confidential information that it receives or transmits pursuant to this article.

Section 44-117-330. All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission must have adequate security and system safeguards and must be maintained so as to ensure patient confidentiality and to ensure against unauthorized access or an intervening person or entity having access to view, read, manipulate, alter, store, or delete the electronic prescription prior to its receipt by the pharmacy of the patient's choice. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order consistent with existing federal or state laws and regulations. Once the drug has been dispensed, any alterations in prescription drug order data must be documented, including the identification of the pharmacist responsible for the alteration.

Section 44-117-340.

- (A) All laws and regulations applicable to oral prescription drug orders apply to all computer to computer, computer to facsimile machine, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment prescription orders.
- (B) A prescription order transmitted by computer to computer, computer to facsimile machine, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment must contain all prescription information required pursuant to Section 40-43-86(E) and federal and state law.
- (C) A practitioner or practitioner's agent shall note any generic substitution instructions on the electronic prescription order transmitted computer to computer, computer to facsimile machine, electronic device to computer or e-mail. Such electronic prescription order may follow the format provided for in Section 40-43-86(H)(3) or any other format that clearly indicates the generic substitution instructions.
- (D) A pharmacist may dispense prescription orders transmitted by computer to computer, computer to facsimile machine, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment only when a valid patient/physician relationship exists and the prescription has been signed by the prescribing practitioner and transmitted from the practitioner or a long-term care facility in compliance with all sections of this article.

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- (E) The original document must be assigned the number of the prescription dispensed and maintained in the pharmacy records for at least two years.
- (F) The facsimile machine receiving prescription drug orders must be in the prescription department of the pharmacy to protect confidentiality and security.

Section 44-117-350.

- (A) Prescription information and other patient health care information received by a pharmacy must be maintained in a manner that protects the integrity and confidentiality of such information as provided by the State Board of Pharmacy in regulation.
- (B) A pharmacy shall provide a mechanism to prevent the disclosure of any information, confidential or otherwise, about patients that was obtained or collected by a pharmacist or pharmacy incidental to the delivery of pharmaceutical care other than as authorized in regulation.
- (C) The pharmacist-in-charge shall:
 - (a) establish and maintain written policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information. All employees of the pharmacy with access to this information must be required to comply with the established policies and procedures.
 - (b) ensure that the requirements of this section are established and implemented.

Section 44-117-360. The board may refuse to issue or renew, or may suspend, revoke, restrict the license or the registration of, or fine its licensees, routing company, or other entity subject to their jurisdiction for each incident that allows the divulging or revealing of confidential information to a person other than a person authorized by this article or any other provision of law or for each incident allowing an intervening person or entity to have access to view, read, manipulate, alter, store, or delete the electronic prescription before it is received by the pharmacy. For all other licensees, the board must refer the matter to the board of appropriate jurisdiction.

Section 44-117-370. A pharmacist or pharmacy must not provide a computer modem or other similar electronic device to a prescriber, health care facility, or any other third party or provider entity for the purpose of providing an incentive to the practitioner, health care facility, or third party or provider entity that refers patients to a particular pharmacy or department. This does not prohibit a hospital from providing in-house equipment for the use of practitioners and the hospital pharmacy to communicate within the system.

Section 44-117-380. Entities that offer electronic services for a pharmacist or pharmacy must comply with

Section 40-43-86(F) of the South Carolina Pharmacy Practice Act.

Drug Control Legislation

Senate Bill 610 was signed into law by Governor Sanford on June 13, 2007. The following changes are now in effect:

Facsimile of Schedules III-V Prescriptions Permitted

A pharmacist may dispense a controlled substance (CS) included in Schedule III, IV, or V pursuant to either a written prescription signed by a practitioner, or a **facsimile of a written, signed prescription, transmitted by the practitioner or the practitioner's agent to the pharmacy**, or pursuant to an oral prescription, reduced promptly to writing and filed by the pharmacist. A prescription transmitted by facsimile must be received at the pharmacy as it was originally transmitted by facsimile and must include the name and address of the practitioner, the phone number for verbal confirmation, the time and date of transmission, and the name of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law.

Quantity/Time Limitations

Prescriptions for CS in Schedule II with the exception of transdermal patches, must not exceed a 31-day supply. Prescriptions for Schedule II substances must be dispensed within **90 days of the date of issue**, after which time they are void. Prescriptions for CS in Schedules III through V, inclusive, must not exceed a **90-day supply**.

Government Issued Photo Identification Required

A prescription for a CS in Schedules II through V may not be filled unless the dispenser knows the recipient or requires the recipient to produce **government-issued photo identification**, and the dispenser notes the identification source and number on the prescription, or in a readily retrievable log including:

- (1) prescription number;
- (2) date prescription filled;
- (3) number and type of identification;
- (4) initials of person obtaining and recording information.

Changes in ACPE Accreditation for Continuing Pharmacy Education Programs

Submitted by Michael Dunphy, South Carolina College of Pharmacy (USC Campus) Accreditation Council for Pharmacy Education Provider

Beginning August 1, a new "topic designator" will be added to the Universal Program Number (UPN). This designator will be "-05" and will tell you that the program contents are about patient safety.

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The list of “topic designator” will be:

- 01 Disease state management/drug therapy
- 02 AIDS therapy
- 03 Law (related to pharmacy practice)
- 04 General Pharmacy
- 05 Patient Safety: the prevention of health care errors, and the elimination or mitigation of patient injury caused by health care errors

Additionally, promotional material should clearly and explicitly identify the target audience that will benefit from the content of the continuing pharmacy education (CPE) activity. If a CPE activity includes pharmacists **and** pharmacy technicians in the same CPE activity, specific and separate learning objectives should be described for each pharmacist and pharmacy technician.

In order to identify the target audience, a new “topic designator” will be used as follows:

If the CPE activity’s target audience is exclusively for pharmacists, the designation “P” will be used as in this example:

Clinical Update on Hypertension UPN 062-000-07-055-L01-P

If the CPE activity’s target audience is exclusively for pharmacy technicians, the designation “T” will be used as in this example:

Law Update for Pharmacy Techs UPN 062-000-07-072-L03-T

For complete information on these changes go to www.acpe-accredit.org/pdf/CE_Definition_Pharmacy_Final_1006-2007.pdf.

Frequently Asked Questions

Question: What happens if a pharmacy technician attends and participates in a CPE activity designed for pharmacists (“P” designation)?

Answer: The pharmacy technician would receive a “P” designated statement of credit that should **not** be acceptable to the pharmacy technician’s regulatory body.

Question: What happens if a pharmacist attends and participates in a CPE activity designed for pharmacy technicians (“T” designation)?

Answer: The pharmacist would receive a “T” designated statement of credit that should **not** be acceptable for credit for relicensure.

Question: How will the UPN be depicted if a CPE activity is designed for both pharmacists **and** pharmacy technicians?

Answer: If the CPE activity is intended for **both** pharmacists and pharmacy technicians, providers must be able to demonstrate needs assessments, performance objectives, and learning assessments for the pharmacists **and** pharmacy technicians, respectively. The CPE activity will be assigned **two** UPNs specific to each audience. For example:

062-999-07-045-L04-P (for pharmacists)

062-999-07-045-L04-T (for technicians)

Question: When will these changes go into effect?

Answer: These changes will go into effect on August 1, 2007. A transition period will occur from August 1, 2007 to December 31, 2007.

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