

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

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Published to promote voluntary compliance of pharmacy and drug law.

New Prescription Transfer Law

Governor Mark Sanford signed into law the South Carolina Board of Pharmacy's proposed amendment to the South Carolina Pharmacy Practice Act regarding the transfer of prescriptions on February 15, 2005. The major changes are that prescription transfers can now occur between **in- or out-of-state** pharmacies, all refills for non-controlled substances can be transferred, and any refills remaining at the transferring pharmacy must be voided. Even though the law implies that only a pharmacist may perform the transfer of non-controlled prescriptions, a state-certified pharmacy technician or pharmacy intern or extern may perform these duties if the supervising pharmacist acknowledges that the individual is competent in this area.

H.3226 Transfer of Prescriptions and Refills Between Pharmacies

SECTION 1. Section 40-43-86(G) of the 1976 Code is amended to read:

(G)(1) The transfer of original prescription information for the purpose of dispensing refills is permissible between licensed or permitted pharmacies subject to these requirements:

(a) The transfer must be communicated directly between two pharmacists and not by one pharmacist accessing an information file containing data for several locations, unless all locations accessed are under common ownership or accessed pursuant to contractual agreement of the pharmacies.

(b) The transferring pharmacist shall void any remaining refills and so mark the face of the prescription retained by the transferring pharmacist or record information electronically.

(c) The transferring pharmacist shall record the name and address of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information on the reverse side of the transferred prescription or record information electronically.

(2) The transferring pharmacist shall record in writing the date of the transfer and the name of the pharmacist transferring the information or record information electronically.

(3) The transferring pharmacist shall record on the prescription transferred or record information electronically that the receiving pharmacist is authorized to dispense all remaining refills based on the original prescription, if such is the case.

(4) The pharmacist receiving the transferred prescription information shall record in writing or electronically the following:

- (a) the word 'transfer' on the face of the transferred prescription;
- (b) any information required to be on a prescription, including:
 - (i) the date of issuance of the original prescription;

(ii) the date and time of transfer;

(iii) the pharmacy's name, address, and original prescription number from which the prescription information was transferred;

(c) the name of the transferring pharmacist;

(d) the manufacturer or brand name of drug dispensed; and

(e) documentation that the receiving pharmacist shall dispense refills based on the transferring pharmacist's certification under subsection (G)(3).

(5) The requirements of this section may be facilitated by use of a computer, data, or facsimile.

(6) All records pertinent to this section must be readily available.

(7) Both the original and transferred prescription drug order must be maintained for a period of two years from the date of last refill.

(8) The transfer must be in compliance with current state and federal laws on controlled substances.

(9) The transfer of prescription information for the purpose of dispensing authorized refills is permissible between pharmacies where all pharmacies are under common ownership and access prescription information through a common computerized data system, subject to subsection (G)(1)(c), (G)(2), (G)(5), (G)(6), (G)(7), and (G)(8).

Clarification Regarding the Transfer of Controlled Substance Prescription Information for Refill Purposes

Recent amendments to the South Carolina Pharmacy Practice Act have resulted in changes regarding the transfer of controlled substance prescription information for refill purposes.

Transfers are no longer limited to pharmacies in South Carolina.

Transfers of original prescription information for controlled substances are on a one-time basis only, and all refills are transferred and may be filled by the receiving pharmacy. The transferring pharmacy must void any remaining refills.

If the receiving pharmacy is a chain pharmacy that shares a common database with other pharmacies, a transferred controlled substance prescription may not be filled by another pharmacy in the chain. This is because the receiving pharmacy does not have the original prescription.

A prescription initially filled by a pharmacy that shares a common database may be transferred to other pharmacies sharing the database as many times as there are authorized refills.

Keep On Tech'n – It is Renewal Time

The pharmacy technician renewal applications were mailed to all registered and state-certified technicians at their designated mailing

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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address before May 1, 2005. The completed renewal application and \$25 fee must be received at the Board office no later than June 1, 2005. Those technicians who do not renew prior to June 30 will be assessed a \$10 late renewal fee. All renewal forms received after June 30 will be returned with a notice to the individual that the renewal will not be processed until the proper penalty fee is received. The 2004-2005 pharmacy technician and state-certified pharmacy technician registrations expire on June 30, 2005.

Registered pharmacy technicians and state-certified pharmacy technicians are reminded that they must have 10 hours of continuing education (CE) that must be Continuing Medical Education-1 or Accreditation Council for Pharmacy Education (ACPE) approved; four of these hours must be live or obtained in a workshop/seminar setting. All hours must be earned between January 1, 2003, and the date on which you submit your renewal. You must have your certificate in hand in order to count the CE course. If exempt from CE, proper documentation must be attached to the application. (See the Policy and Procedure #134 article below.) If you have registered as a pharmacy technician with the Board for the first time between January 1, 2005, and April 30, 2005, then you are exempt from CE for this renewal. **Do not send CE certificates to the Board office unless specifically requested to do so.** The South Carolina Board of Pharmacy will not be responsible for any CE certificates unless they have been requested.

As a reminder, it is the responsibility of the **pharmacist-in-charge (PIC)** to ensure that all pharmacy technicians employed hold a current registration. If you supervise an employee who functions as a pharmacy technician who is currently not registered, the Board reminds you that **all** technicians must be registered in the state of South Carolina prior to working. Depending on the circumstances, the permit holder, the PIC, the supervising pharmacist, and/or the pharmacy technician may be subject to disciplinary action if a pharmacy technician is found to be working without a registration. Technicians do not receive the *South Carolina Board of Pharmacy News*; however, the Board asks that you share this information with the technicians with whom you work.

Policy and Procedure #134 – Pharmacy Technician CE Exemptions

Any registered pharmacy technician attending accredited courses in a health-related field during the respective period of renewal may submit a transcript of such courses, which would exempt them from submitting CE for the renewal requirements.

Any registered pharmacy technician who holds a license in a health care field may also be exempt from submitting CE. He or

she should submit a copy of his or her current license with his or her renewal application.

Continuing Education Opportunities

If you are in need of CE prior to submitting your pharmacy technician renewal application, you are in luck. The following Web sites offer continuing education, **but** make sure that the courses have ACPE accreditation.

- ◆ www.rxschool.com
- ◆ www.uspharmacist.com
- ◆ www.powerpak.com
- ◆ www.ptcb.org
- ◆ www.continuingeducation.com/pharmtech
- ◆ www.cedrugstorenews.com
- ◆ www.acpe.com
- ◆ www.ashp.com

Confused About Technician Terminology?

Registered? Certified? What do these terms really mean? Let us clear it up.

Registered Pharmacy Technician – You have submitted a registration application to the Board and have paid your \$40 fee. Your South Carolina Registration says “Pharmacy Technician Registration.”

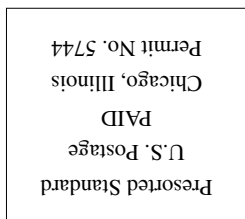
Nationally Certified Pharmacy Technician – You are a registered pharmacy technician **and** you have taken and passed the Pharmacy Technician Certification Board (PTCB) exam. You have a certificate from PTCB that states you merit the designation of “Certified Pharmacy Technician.” Your South Carolina Registration says “Pharmacy Technician Registration.”

State Certified Pharmacy Technician – You are a registered pharmacy technician and a nationally certified pharmacy technician. **In addition**, you have a diploma/certificate in pharmacy technician training from an American Society of Health-System Pharmacists-accredited program **and** you have completed at least 1,000 hours of practical work experience under the supervision of a licensed pharmacist in a licensed facility. Your South Carolina Registration says “Certified Pharmacy Technician Registration.”

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