

November 2007



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

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Published to promote voluntary compliance of pharmacy and drug law.

## Next Board Vacancy

The next South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy member term begins July 1, 2008, and ends June 30, 2014. Any pharmacist interested in running as a candidate must:

- ◆ reside in the Fourth Congressional District;
- ◆ be licensed and actively practicing pharmacy in South Carolina; and
- ◆ before December 1, 2007, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fourth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- ◆ prepare and mail ballots by January 15, 2008, to all pharmacists who certified on their last renewal application that they reside in the Fourth Congressional District; and
- ◆ certify as true and valid all ballots postmarked before February 15, 2008, and received by the Board office before February 25, 2008.

Before March 1, 2008, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election along with the name of the person who the nominee replaces 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.

## South Carolina Prescription Monitoring Program

*By Wilbur L. Harling, RPh, Director, South Carolina Department of Health and Environmental Control Bureau of Drug Control*

The South Carolina Prescription Monitoring Program (PMP) Act, passed by the South Carolina Legislature on June 14, 2006, will now require dispensers to submit information regarding controlled substance (CS) prescriptions dispensed. The data will be submitted between the first and 15<sup>th</sup> of each month for **Schedules II-IV** CS prescriptions dispensed the previous month. The data collection agent, Health Information Designs, Inc (HID), will verify, compile, and load the data onto a secure server.

“Dispenser” includes pharmacies, as well as practitioners who dispense directly to patients. “Dispenser” does not include hospital pharmacies that dispense CS for inpatients, or that dispense CS at time of discharge; practitioners who administer CS; or wholesale distributors.

Dispensers will transmit prescription data to HID, via Web upload, diskette, CD, DVD, secure e-mail, tape, modem, or by

paper reports, if granted a waiver by Department of Health and Environmental Control (DHEC).

Reports will be generated from the data that may be obtained by authorized users, who will be provided login accounts for Web access. Authorized users who do not have, or choose not to use Web access, will request reports via fax or mail. DHEC anticipates that the majority of requests will be via Web access.

Reports will show CS prescriptions that an individual has received for a specified time period, as well as the practitioner who prescribed them and the dispenser who dispensed them. These reports will be available to individuals with access rights, including:

- a. a practitioner or pharmacist for providing treatment to a bona fide patient;
- b. a state, federal, or local law enforcement or prosecutorial official for a specific drug-related investigation, involving a designated person;
- c. a Department of Labor, Licensing, and Regulation board that is involved in a bona fide specific investigation involving an individual licensed by the particular board;
- d. the South Carolina Department of Health and Human Services regarding a Medicaid recipient; or
- e. a grand jury pursuant to a subpoena issued for the records.

Reports **cannot be shared with anyone else** except by court order.

A dispenser who knowingly fails to report is guilty of a misdemeanor and will be subject to a fine of up to \$2,000, or imprisonment for up to two (2) years.

A person who is authorized to have data, and discloses it in violation of the Act, or who uses it in a manner or for a purpose in violation of the Act, is guilty of a felony and will be subject to a fine of up to \$10,000, or imprisonment for up to ten (10) years.

The goals of the PMP are **not** designed to prevent individuals from getting CS, or to decrease the number of doses dispensed. The goals of the PMP **are** to provide a tool to help address the problem of prescription drug abuse and diversion by providing a source of information for practitioners and pharmacists and an investigative tool for law and regulatory enforcement.

Pharmacies and dispensing practitioners have received, or will receive early this month, a cover letter and a user manual from HID. The manual will provide information regarding format, account setup, data delivery, and transmission requirements. The manual will also provide an e-mail address and a phone number for **technical assistance**, and an e-mail address and phone number for **administrative assistance**.

If you do not receive the manual by the middle of this month, please contact Steve Espy via e-mail at [steve.espy@hidinc.com](mailto:steve.espy@hidinc.com).

Data collection is anticipated to begin **January 1, 2008**.





## Nonsterile Compounding and Sterile Compounding

At the Board of Pharmacy's September 2007 meeting the decision was made to clarify the Board's stance on the implementation of United States Pharmacopeia (USP) Chapter 795 "Pharmaceutical Compounding – Nonsterile Preparations" and USP Chapter 797 "Pharmaceutical Compounding – Sterile Preparations." USP Chapter 795 and USP Chapter 797 are recognized as the current standards for professional practice in South Carolina. Licensed pharmacists should be in compliance today with all sections, except those requiring construction. Construction requirements should be initiated now and completed by June 2008.

To review the inspection reports that will be used for nonsterile and sterile compounding pharmacies, you may go to the Board Web site at [www.lhr.state.sc.us/pol/pharmacy](http://www.lhr.state.sc.us/pol/pharmacy) under the Applications/Forms link. Also, review the statutes in 40-43-86(CC) and 40-43-88.

For **nonsterile compounding pharmacies** the pharmacist-in-charge and pharmacists involved in making and checking compounding must be qualified by having continuing education, advanced training, and studying literature in the art and science of compounding.

For **sterile compounding pharmacies** there must be evidence of training and/or continuing education in compounding of sterile products annually for all pharmacists and/or technicians involved in the process. The results for each person of a media fill test sufficient for risk level of compounded products must be available. Personnel must be gowned and gloved appropriately. Policies and procedures shall address standard operating procedures, cleaning and maintenance, patient monitoring and adverse drug reactions, quality assurance programs reviewed annually, and product testing and validation. Logs should include cleaning logs (hoods, floors, shelves, and walls), environmental testing, temperature and humidity, calibration/verification of equipment, nonsterile to sterile products, repackaging, in-house and/or outside testing, pyrogen, and sterility and potency validation when appropriate.

Pharmacists and compounding facilities should review both USP Chapter 795 and USP Chapter 797 as applicable and review issues concerning expiration dates, facility requirements, and personnel training as future inspections of facilities will center around these issues as it relates to these chapters.

## Community Pharmacy Technician Certificate Online Program

A Web-based online Community Pharmacy Technician Certificate program will be offered through the Airport Campus of Midlands Technical College beginning spring semester 2008. This program is accredited by the American Society of Health-System Pharmacists (ASHP) and meets criteria for the pharmacy technician state certification requirements mandated by the South Carolina Board of Pharmacy. This program has been developed to accommodate the individual who has current work experience in a community retail pharmacy setting and needs to become a South Carolina state-certified pharmacy technician. Additionally, this program is open for enrollment to the individual who desires to pursue a career as a pharmacy technician in a community retail pharmacy setting only and who has no prior work experience.

The program will be two semesters with the spring semester classes beginning January 14, 2008, and will run until April 28, 2008. Summer semester classes will begin May 19, 2008, and will run until August 1, 2008. A program orientation session will be scheduled on the Airport Campus prior to the beginning of spring and summer semesters. Attendance at orientation will be mandatory.

If you have any questions, please refer to the Midlands Technical College Web site at [www.midlandstech.edu/pharmacy](http://www.midlandstech.edu/pharmacy) or contact the program director:

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