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

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Published to promote voluntary compliance of pharmacy and drug law.

## ***It is Time for Permit Renewals***

If you are a permit holder and have not received your permit renewal application, contact the South Carolina Board of Pharmacy office immediately. Applications for renewal must be postmarked before June 1, 2004, as required by §40-43-90(D) of the Pharmacy Practice Act. If you do not submit a renewal application, your existing permit will expire on June 30, 2004. You cannot legally operate without a permit.

If the renewal application is received after June 1, 2004, and does not have an earlier postmark, the Department of Labor, Licensing, and Regulation must assess a \$50 late fee for the special handling of the late application. Postage meter imprints are not acceptable as proof of mailing. It is recommended that you send the applications via certified mail with return receipt requested, so that you will have proof of mailing by the deadline.

If the renewal application is not received by June 30, 2004, the pharmacy will be assessed a penalty of \$10 a day until the permit is reinstated, plus the \$50 late fee and the new application fee. Depending upon the circumstances, the pharmacy, the pharmacist-in-charge (PIC), and the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to Section 40-43-83. Sanctions can include civil penalties, reprimands, or requirements for additional continuing education (CE).

## ***Pharmacy Technicians and State-certified Pharmacy Technician Renewals***

The pharmacy technician renewal applications were mailed to all registered and state-certified technicians at their designated mailing address before May 1, 2004. The completed renewal application and fee must be received at the Board office no later than June 1, 2004. 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.

Registered pharmacy technicians and state-certified pharmacy technicians are reminded that they must submit evidence of CE for renewal of their 2004-2005 registrations. Each renewal applicant must be able to document participation in 10 hours of CE that must be Continuing Medical Education-1 or Accreditation Council for Pharmacy Education approved; four of these hours must be live or obtained in a workshop/seminar setting.

With the 2004-2005 renewal cycle, a new policy on late renewal has been established by the Board. Pharmacy technicians who renew prior to June 30, 2004, must pay a fee of \$25 to be submitted with their renewal application. Those technicians who do not renew prior to June 30 will be assessed a \$10 penalty. 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.

Those pharmacy technicians who have not renewed their registration for over two years will be required to submit the initial registration fee of \$40 and a renewal application with proof of the required CE for those lapsed years.

As a reminder, it is the responsibility of the PIC to ensure that all pharmacy technicians employed hold a current 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.

## ***New Intern Certificate Application***

The Board has approved a new application form for the intern certificate. This application will be available on the Board's Web site and should be utilized by anyone who wishes to obtain an intern certificate including students entering into a college of pharmacy program, reciprocity candidates who are planning on working in South Carolina while waiting on pharmacist licensure, and foreign graduates awaiting licensure. You can find out more at [www.llr.state.sc.us/POL/pharmacy](http://www.llr.state.sc.us/POL/pharmacy).

## ***Study Material for Exam Online***

The Board of Pharmacy will no longer mail exam packets to all exam applicants. This information is now available online in a special section of our Web site. Visit our Web site at [www.llr.state.sc.us/POL/pharmacy](http://www.llr.state.sc.us/POL/pharmacy) and click on the "Important Study Information for Examination" link on the main page. If a student does not have access to the Internet, he or she should contact the Board office for assistance and a study packet will be provided.

## ***Compounding Update***

A new policy was adopted by the Board at its March 2004 meeting regarding sterile compounding. The Board, in conjunction with the Compounding Task Force, will be implementing new guidelines for sterile compounding resulting in a new permit classification for those facilities that perform sterile compounding. This permit will be implemented in June 2005 concurrent with new inspection requirements for sterile compounding facilities. The proposed sterile compounding permit would allow a facility to do sterile compounding in all risk levels provided it has the proper policies and procedures in place for each risk level in which it compounds drugs. The overall key to compliance is process, personnel, and environmental validation. The Board anticipates CE to be available in the fall of 2004 to help educate pharmacists on the updated requirements and to assist pharmacists in becoming compliant.

All of this is in response to the recently adopted United States Pharmacopeia (USP) Chapter 797 that outlines special requirements and guidelines for sterile compounding. As of January 1, 2004, this became the standard of practice for pharmacy compounding practices in the US. In an effort to meet the intent of Chapter 797

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and to establish state guidelines for sterile compounding, the Board has adopted the following policy.

**Policy & Procedure #137**

A facility which is permitted by the Board of Pharmacy for Sterile product compounding should meet the intent and guidelines of the USP by the permit renewal period beginning January 2005 by obtaining Accreditation from an organization approved by the Board and/or giving evidence of personnel training, facility and equipment maintenance, and product testing and validation. Policies and procedures as well as logs and other documentation should be maintained by the facility to support compliance with the level of product compounding performed. In lieu of compliance by the date above, a facility may propose a written plan of action for compliance and be subject to re-inspection on an individual basis.

USP goes into great detail in describing sterile-compounding. "Compounding involves the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription." The organization explains that it "requires cleaner facilities, specific training, and testing of personnel in principles and practices of aseptic manipulations; air quality evaluation and maintenance; and sound knowledge of sterilization and solution stability principles and practices." USP Chapter 797 addresses specifically "the responsibility of the compounder; training requirements; compounding procedures and documentation; drug compounding facilities and equipment needed; packaging and drug product containers; and compounding controls for labeling."

The Board adopted **Policy & Procedure #132** in 2003, which states,

The minimum requirements for a compounding pharmacy upon inspection shall include the verification of the source of chemicals, the ability to ascertain that the level of products delivered and the duty are equal, and that the facility is in compliance with compounding laws with appropriate record keeping, i.e. logs, calibrations. If compounding of sterile products exist, the pharmacy shall be in compliance with the South Carolina Pharmacy Practice Act and review USP guidelines regarding the compounding of sterile products and keep abreast of any new changes.

The minimum expected compliance for a pharmacist selling compounded products to a physician or licensed practitioner is that the pharmacist have a contract with the physician or licensed practitioner specifying that the compounded medications are for office administration only, and that lot numbers and expiration dates shall be maintained and readily retrievable on patient's records/charts.

Testing requirements should center around the process in use as well as random product testing applicable to the practice site and specific product being compounded.

All sterile compounding personnel (pharmacy technicians and pharmacists) must have proof of personal competency in the art of sterile compounding completed on an annual basis.

For more information regarding sterile-compounding and the new USP guidelines, visit the following Web sites:

- USP ..... [www.usp.org](http://www.usp.org)
- International Journal of Pharmaceutical Compounding* ..... [www.ijpc.com](http://www.ijpc.com)
- Clean Rooms* ..... [www.cleanrooms.com](http://www.cleanrooms.com)
- Clinical IQ* ..... [www.clinicaliq.com](http://www.clinicaliq.com)

You can obtain a copy of USP Chapter 797 by calling 301/881-0666.

**Congratulations to Board Appointees**

The Board would like to congratulate Davis C. Hook, Jr, RPh, of West Columbia, and David M. Banks, RPh, of Simpsonville, on their recent reappointments to the Board. Mr Hook represents the Second Congressional District and heads up the Compounding Task Force as well as the Pharmacy Technician Committee of the Board. Mr Banks is the governor-appointed, coterminous member of the Board and serves as co-chair for the Technology Committee. We would like to extend our gratitude to these dedicated members of the pharmacy community for their continued hard work and commitment.

**Board Welcomes New Inspector**

The Board would like to welcome our newest staff member. Tom Porter, RPh, joined the Board in March 2004 as an inspector. He is a 1986 graduate of the University of South Carolina, College of Pharmacy. Tom has an extensive background in long-term care pharmacy and independent retail. He also worked with the Department of Health and Environmental Control, Environmental Services and Certification, for 13 years. Tom will be conducting facility inspections across the state. He and wife, Linda, live in Chapin; they have two children: Josh, 21, and Allison, 16. Tom enjoys music and plays the bass in a local jazz band. Welcome aboard, Tom!

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