Pharmacy Law Update

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Disclosure

- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation

Definition of a Pharmacy Technician

- “Pharmacy technician” means an individual other than an intern or extern, who assists in preparing, compounding, and dispensing medicines under the personal supervision of a licensed pharmacist and who is required to register as a pharmacy technician.

Certified Technician

- “Certified pharmacy technician” means an individual who is a registered pharmacy technician and who has completed the requirements provided for in Section 40-43-82(B).

State Board of Pharmacy

- There is created the State Board of Pharmacy to be composed of nine members, appointed by the Governor with advice and consent of the Senate, one of whom must be a lay member from the State at large
  - one of whom must be a pharmacist from the State at large
  - seven of whom must be pharmacists representing each of the seven congressional districts.
- However, if no hospital pharmacist is selected to represent any of the seven congressional districts, the Governor shall appoint a hospital pharmacist as the pharmacist at large.

Learning Objectives

- Discuss the structure of the SC Board of Pharmacy
- Learn the SCBOP regulations for pharmacy technicians
- Discuss penalties for non-compliance of BOP regulation for registration renewal
- Learn PTCB requirements for Certification
- Discuss news updates from the FDA
Registration

- The Board of Pharmacy shall register pharmacy technicians who are performing pharmacy functions under the supervision of a pharmacist.
- A registration is valid from July one through June thirtieth and is renewable on dates as prescribed by the department with the consent of the board.
- A pharmacy technician who has failed to properly renew a registration before July first shall immediately cease practice and refrain from performing any duties as a pharmacy technician. Reinstatement of a registration must be granted upon the board receiving a renewal application and renewal and penalty fees.

Verification

- The pharmacist-in-charge shall verify compliance with the requirements of item (a) of subsection (B)(1) and maintained a record of this requirement in a readily retrievable manner for inspection.

Certified Pharmacy Technician

- A supervising pharmacist may authorize a certified pharmacy technician to:
  - (1) receive and initiate verbal telephone orders;
  - (2) conduct one time prescription transfers;
  - (3) check a technician’s refill of medications if the medication is to be administered by a licensed healthcare professional in an institutional setting;
  - (4) check a technician’s repackaging of medications from bulk to unit dose in an institutional setting

**Not allowed to take prescriptions for controlled substances over the phone**
Clarification for Taking Verbal Orders For Controls – DHEC Bureau of Drug Control

- According to § 40-43-82(C)(1) of the South Carolina Pharmacy Practice Act, a supervising pharmacist may authorize a state-certified pharmacy technician to receive and initiate verbal telephone orders. However, § 44-53-360(b) of the South Carolina Code of Laws specifically states, “a pharmacist may dispense a controlled substance included in Schedule III, IV, or V pursuant to an oral prescription, reduced promptly to writing and filed by the pharmacist.” Therefore, state-certified pharmacy technicians are not allowed to take verbal orders for controlled substances (CS).

Requirements of a Formal Academic Program - ASHP Accredited

(7) general education;
(a) medical terminology;
(b) interpersonal relations;
(c) communications;
(d) computers/keyboarding;
(8) problem solving/critical thinking;
(9) experiential training (practical experience)

Requirements of a Formal Academic Program

ASHP Accredited

(1) introduction to pharmacy and health care systems;
(2) pharmacy law and ethics;
(3) pharmacy calculations;
(4) pharmacology

(a) anatomy and physiology;
(b) therapeutic agents;
(c) prescription drugs;
(d) nonprescription drugs;

Requirements of a Formal Academic Program

(5) pharmacy operations;
(6) compounding;
(a) drug distribution systems;
(b) aseptic technique;
(c) ambulatory and institutional practice;
(b) nonsterile compounding;

Requirements of a Formal Academic Program

(7) general education;
(a) medical terminology;
(b) interpersonal relations;
(c) communications;
(d) computers/keyboarding;
(8) problem solving/critical thinking;
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List of ASHP Accredited Programs in South Carolina

<table>
<thead>
<tr>
<th>Name of Site</th>
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<tbody>
<tr>
<td>Aiken Technical College</td>
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BOP Fees

- Technician Registration Application $40
- Registration Renewal $15
- Reinstatement/Reactivation $40
- Duplicate Registration/Wallet Card $10
- License Verification $5
### Continuing Education Requirements

- Ten hours of ACPE or CME category 1 continuing education are required each license year for renewal.
- Of the 10 hours, a minimum of 4 hours must be “live” hours. CE must be taken before renewing a registration each year.
- There are no exemptions to the CE requirement for technicians.
- Technicians may take CE that is designated for pharmacists (P) or technicians (T).
- Use the ACPE UPN# to determine if a CE is live (L), home (H) or combination (C).
  
  **Example:** Live CE will have an “L” in the UPN number 430-000-092-021-L01.
- All CME-Category 1 hours are live hours.
- Hours completed in excess of requirements may be carried forward in the next registration year but may not be carried forward for more than one registration year.

### Pharmacist - loss of license

- A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is **not eligible to be registered as a pharmacy technician**.

### CE Providers - ASHP

- Over 20 hours of T-designated continuing education (CE)
- Meet all of your pharmacy technician continuing education requirements by subscribing to www.PharmacyTechCE.org.
- **Costs** - An individual purchase to PharmacyTechCE.org is only $60 per year. That is $60 for all the continuing education you need to maintain your certification status or for board license approval.

### SC State Organizations

**CE Providers**
- SCSHP  [www.scsph.com](http://www.scsph.com)
- SC AHEC  [http://www.scahec.net/ce/ce.html](http://www.scahec.net/ce/ce.html)

**Pharmacy Volunteer**

- An individual who works as an **unpaid volunteer** under the personal supervision of a licensed pharmacist or who handles legend drugs in a pharmacy department of a free medical clinic staffed by a licensed pharmacist **may be registered as a pharmacy technician and may perform pharmacy functions as a pharmacy technician without payment of a registration fee or filing with the board**, provided, that a register is maintained in the pharmacy department of the free medical clinic bearing the name of every such volunteer performing pharmacy functions as a pharmacy technician and documenting each volunteer’s period of service.

**Pharmacy Volunteer**

- This special registration is valid only in the free medical clinic. The register must be kept for a period of three years.
- For the purposes of this section, “free medical clinic” means a permitted facility that provides medical services, including the dispensing of legend drugs and other medications, free of any charge to members of the public.
Pharmacy Permit

- (I) A permit is required for the sale, distribution, possession, or dispensing of drugs bearing the legend “Caution: Federal law prohibits dispensing without a prescription” including, but not limited to, pharmacies (institutional or community, public or private), nursing homes, hospitals, convalescent homes, extended care facilities, family planning clinics, public or private health clinics, infirmaries, wholesalers, correctional institutions, industrial health clinics, mail order vendors, and manufacturers within or outside this State.

- (J) The board shall assess a civil penalty in the amount of $50.00 for failure to display a permit as required by this section.

Pharmacy Interns

- The board shall issue an intern certificate to a qualified applicant. No intern/extern may receive credit for practical experience unless he has been issued a certificate by the board. Such certificate must be granted only to individuals who have been accepted by or graduated from an approved college of pharmacy.

- An intern/extern may not represent himself as a pharmacist. The board shall issue to an intern/extern a certificate for purposes of identification and verification of his role as an intern/extern.

- Pharmacy interns/externs shall not be left in sole charge of a prescription department or other approved site at any time.

Identification Badges

- "the pharmacist-in-charge shall have the following responsibilities:
  (b) assuring that all pharmacists, technicians, and interns employed at the pharmacy are currently licensed, certified, or registered and that interns and technicians wear proper identification while on duty;"

- Board inspectors will be monitoring these requirements while conducting site inspections

Pharmacy Compounding

- Pharmacists may not offer compounded medications to other pharmacies for resale; however, pharmacists may compound products based on an order from a practitioner for use by practitioners for patient use in institutional or office settings

- The compounding of drugs in anticipation of receiving prescriptions without a historical basis or the distribution of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing

- Pharmacy technicians may assist the pharmacist in compounding. The pharmacist is responsible for training and monitoring the pharmacy technician. The pharmacy technician's duties must be consistent with the training received.

- Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats, jackets, aprons, gowns, hand or arm coverings, or masks must be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination
Loss or Theft of Drugs/Devices

- According to 40-43-91 (A) of the South Carolina Pharmacy Practice Act, "All permit holders shall report to the Board of Pharmacy within thirty working days of the discovery of the occurrence of:
  1) theft or loss of drugs or devices
  2) conviction of any employee of any state or federal drug laws."

- 40-43-86 (B)(3) states that "The pharmacist in-charge shall have the following responsibilities:
  (d) making or filing any reports required by state or federal laws and regulations.
  (e) Any time your pharmacy or drug outlet experiences a loss or theft of legend drugs or legend devices, the Board of Pharmacy requires a written notification.
  (f) Requires that a loss or theft of controlled substances must be reported to the DHEC Division of Drug Control, on a DEA Form 108, not later than 30 days after the discovery of the loss or theft.

PTCB Requirements

- CPhTs can apply for recertification beginning 100 days prior to the certification expiration date. Applications should be submitted at least 30 days prior to the expiration date (the "renew by date") to ensure adequate time for processing.
- CPhTs apply online from within their PTCB Account. The fee to recertify is $40. A paper application is only available to those with a disability or hardship that precludes using the online application. Requests to use the paper application must be submitted in writing to PTCB, and include appropriate documentation of the disability or hardship.

Random Audit

- A certain number of CPhTs are randomly selected for an audit of their continuing education (CE). All applications are reviewed by PTCB in the order in which they are received and are typically processed within five business days.
- Once an application is approved, the verification database will be updated and a certificate will be made available for download and print.

PTCB Fees

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Below are definitions of all potential certification statuses:
- Active: Currently certified.
- Expiring: Not currently certified, but eligible for reinstatement.
- Uncertified: Not certified and must reapply.
- Suspended: Not Certified, Certification is suspended.
- Revoked: Not Certified.
- Certification has been revoked.

PTCB Approved CEs

- Medication distribution
- Inventory control systems
- Mathematics
- Biology
- Pharmaceutical sciences
- Pharmacy law
- Pharmacology/drug therapy
- Roles and duties of pharmacy technicians
PTCB Reinstatement

- CPhTs who fail to recertify by midnight Eastern Standard Time on the certification expiration date are no longer considered certified by PTCB and must immediately cease using the designation "CPhT" or "Certified Pharmacy Technician"

PTCB Reinstatement

- Cost of reinstatement - Former CPhTs who wish to reinstate, apply online from within their PTCB Account.
- The fee to reinstate is $80. Reinstatement applications are processed in the same manner as with recertification.
- In addition to completing the continuing education (CE) required for recertification, reinstatement candidates must complete one additional CE hour in pharmacy law.

PTCB Reinstatement

- A pharmacy technician whose certification has expired may apply for reinstatement within one year. Former CPhTs who do not reinstate must retake and pass the PTCE in order to regain certification.
- No special permission is required to retest unless a former CPhT has reached the retake limit.

Retaking the PTCE

- Candidates who fail the PTCE may retake it three more times, for a total of four attempts.
  - For the first two retakes, candidates are required to wait 60 days from the previous attempt.
  - For the third and final retake, candidates are required to wait six months.
  - After four attempts, candidates will need to petition PTCB in writing for additional attempts. Petitions will be reviewed and approved on a case-by-case basis.

PTCB Reinstatement

- Pharmacy technicians who do not recertify before their expiration date may apply for reinstatement within one year.
- Pharmacy technicians who successfully reinstate are again considered "Certified Pharmacy Technicians" and may resume using the "CPhT" designation.
- Reinstated CPhTs are granted an active certification for the balance of the recertification cycle.
News from the FDA-Hydrocodone

- The FDA is recommending to the U.S. Department of Health and Human Services (HHS) that hydrocodone combination products, such as Vicodin, be reclassified as a Schedule II product, placing tighter controls on the pain medications. Hydrocodone is currently a Schedule III drug, according to an FDA announcement.
- “This determination comes after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings,” stated Janet Woodcock, MD, director of the FDA’s Center for Drug Evaluation and Research.

See more at: http://drugtopics.modernmedicine.com/drug-topics/news/fda-calls-reclassification-hydrocodone-products-schedule-ii#sthash.8vow0WCW.dpuf

FDASIA

- On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA)
- Among other things, Title X of FDASIA directs the Food and Drug Administration (FDA or the Agency) to establish a task force on drug shortages to develop and submit to Congress a Strategic Plan to enhance FDA’s response to preventing and mitigating drug shortages.

FDA and Drug Shortages

- FDA helped prevent close to 200 drug shortages in 2011 and more than 280 in 2012. The total number of new shortages decreased from 251 in 2011 to 117 in 2012.

Sources

- SC Board of Pharmacy http://www.llr.state.sc.us/pol/pharmacy/
- PTCB www.ptcb.org
- ASHP www.ashp.org
- www.fda.gov

FDA and Drug Shortages

- Early notification about possible shortages, as requested in the President’s Executive Order 13588 and then codified into law by Congress, has enabled FDA to work with manufacturers to restore production of many lifesaving therapies.
- There has been a 6-fold increase in notifications to FDA since the Executive Order

At the Impatient Pharmacy

3/4/2014