

TSBP Action August 5-6, 2008

Generic Substitution Rules

(A) When a prescription is issued for a brand name product that has no generic equivalent product, the pharmacist must dispense the brand name product. If a generic equivalent product becomes available, a pharmacist may substitute the generically equivalent product unless the practitioner has specified that the on the initial prescription that the brand name product is medically necessary.

(B) If a practitioner issues a prescription for a generic drug and specifies a particular manufacturer or that the same manufacturer always be dispensed, the pharmacist may not refill the prescription with another manufacturer's product without authorization, from the prescribing practitioner. *Withdrawn(may come back in November with different language)*

(C) If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute a generically equivalent drug product unless the pharmacist obtains verbal or written authorization from the practitioner, notes such authorization on the original prescription drug order, and notifies the patient in accordance with §309.4 of this title (relating to Patient Notification).

Security Rules- Changes since May Hearing

(i) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders when the pharmacy is closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless the pharmacy changes location. Change of location shall inclu; or other systems or technologies that will secure the pharmacy from unauthorized entrance de the relocation of the pharmacy within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change *Added – addressed the APRX position that the grandfather clause needed to be clarified to be sure that if a grandfathered pharmacy was purchased the above requirement would not kick in.*

(D) Only persons designated either by name or by title including such titles as “relief” or “floater” pharmacist, in writing by the pharmacist-in-charge may unlock the prescription department except in emergency situations. An additional key-added in yellow.

(A) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for short periods of time breaks and meal periods without added in place of highlighted below-closing the prescription department and

removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;
(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period; *deleted- was opposed by APRX in our May testimony.*

(iv) effective, June 1, 2010, shall be documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record on either the original hard-copy prescription, in the pharmacy's data processing system or in an electronic logbook; and- *Changed date*

Off Site Absence

The rules with regard to an offsite absence of a pharmacist which were opposed by APRX were adopted yesterday. In the May hearing the Board contended that due to existing law they could not allow techs to keep working during an off-site absence of the pharmacist as we had supported. In our May testimony we had stated that if the techs can keep working during an on-site absence by the pharmacist and they can deliver prescriptions to the patient after the RPh returns and checks the RX, they should be allowed to do the same during an off-site absence. Below I have attached an e-mail I received from Gay Dodson after the meeting yesterday.

Richard-- Here's the portion of the law that deals with supervision of Class A pharmacies.

Sec. 562.101. Supervision of Pharmacy.

- (a) A pharmacy is required to be under the supervision of a pharmacist as provided by this section.
- (b) A Class A or Class B pharmacy is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.**
- (c) A Class C pharmacy that is in an institution with more than 100 beds is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.
- (d) A Class C pharmacy that is in an institution with 100 beds or fewer is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.
- (e) A Class D pharmacy is required to be under the continuous supervision of a pharmacist whose services are required according to the needs of the pharmacy.
- (f) A Class E pharmacy is required to be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located to serve as the pharmacist-in-charge of the Class E pharmacy.
- (f-1) A Canadian pharmacy designated by the board as having passed inspection to dispense prescription drugs to residents in this state is required to be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of Canada or of the Canadian province in which the Canadian pharmacy is located to serve as the pharmacist-in-charge of the Canadian pharmacy.
- (g) For a pharmacy license classification established under [Section 560.053](#), the board shall adopt rules that provide for the supervision of the pharmacy by a pharmacist. Supervision under the board rules must require at least continuous supervision by a pharmacist according to the needs of the pharmacy.

Leg.H. Stats. 1999 76th Leg. Sess. Ch. 388, effective September 1, 1999; Stats. 2003 78th Leg. Sess. Ch. 941, effective September 1, 2003; Stats. 2005 79th Leg. Sess. Ch. 1345, effective Sept. 1, 2005.

The key word here seems to be on-site. As we discussed before, if we want that changed, we will have to do it during the legislative session, if you so desire.