

218A.1446 Requirements for dispensing of certain nonprescription drugs -- Log or other electronic recordkeeping mechanism -- Exemption request -- Exceptions -- Preemption of local laws.

- (1) Any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers shall be dispensed, sold, or distributed only by a registered pharmacist, a pharmacy intern, or a pharmacy technician.
- (2) Any person purchasing, receiving, or otherwise acquiring any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers shall:
 - (a) Produce a government issued photo identification showing the date of birth of the person; and
 - (b) Sign a written log or record showing the:
 1. Date of the transaction;
 2. Name, date of birth, and address of the person making the purchase; and
 3. The amount and name of the compound, mixture, or preparation.

An electronic recordkeeping mechanism may be used in lieu of the written log or record described in paragraph (b) of this subsection, provided the mechanism is approved by the Office of Drug Control Policy.

- (3) A log, as described in subsection (2) of this section, shall be kept of each day's transactions. The registered pharmacist, a pharmacy intern, or a pharmacy technician shall initial the entry of each sale in the log, evidencing completion of each transaction. The log shall be:
 - (a) Kept for a period of two (2) years;
 - (b) Subject to random and warrantless inspection by city, county, or state law enforcement officers; and
 - (c) An electronic recordkeeping mechanism may be required in lieu of the written log or record described in subsection (2)(b) of this section if the costs of establishing and maintaining the mechanism are borne by the Commonwealth of Kentucky. Pursuant to administrative regulations promulgated by the Drug Enforcement and Professional Standards Branch and the Office of Drug Control Policy, pharmacies requesting an exemption to electronic reporting may file an exemption request to the above listed agencies. Any exemption may be granted upon a showing of imposition of additional cost by the pharmacy.
- (4) (a) Intentional failure of a registered pharmacist, a pharmacy intern, or a pharmacy technician to make an accurate entry of a sale of a product or failure to maintain the log records as required by this section may subject him or her to a fine of not more than one thousand dollars (\$1,000) for each violation and may be evidence of a violation of KRS 218A.1438.

- (b) If evidence exists that the pharmacist's, the pharmacy intern's, or the pharmacist technician's employer fails, neglects, or encourages incorrect entry of information by improper training, lack of supervision or oversight of the maintenance of logs, or other action or inaction, the employer shall also face liability under this section and any other applicable section of this chapter.
- (c) It shall be a defense to a violation of this section that the person proves that circumstances beyond the control of the registered pharmacist, pharmacy intern, or pharmacy technician delayed or prevented the making of the record or retention of the record as required by this section. Examples of circumstances beyond the control of the registered pharmacist, pharmacy intern, or pharmacy technician include but are not limited to:
 - 1. Fire, natural or manmade disaster, loss of power, and similar events;
 - 2. Robbery, burglary, shoplifting, or other criminal act by a person on the premises;
 - 3. A medical emergency suffered by the registered pharmacist, pharmacy intern, or pharmacy technician, another employee of the establishment, a customer, or any other person on the premises; or
 - 4. Some other circumstance that establishes that an omission was inadvertent.
- (5) No person shall purchase, receive, or otherwise acquire any product, mixture, or preparation or combinations of products, mixtures, or preparations containing more than nine (9) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers within any thirty (30) day period provided this limit shall not apply to any quantity of product, mixture or preparation dispensed pursuant to a valid prescription. In addition to the nine (9) gram restriction, no person shall purchase, receive, or otherwise acquire more than three (3) packages of any product, mixture, or preparation containing ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers during each transaction.
- (6) A person under eighteen (18) years of age shall not purchase or attempt to purchase any quantity of a ephedrine, pseudoephedrine, or phenylpropanolamine product as described in subsection (1) of this section. No person shall aid or assist a person under eighteen (18) years of age in purchasing any quantity of a ephedrine, pseudoephedrine, or phenylpropanolamine product as described in subsection (1) of this section.
- (7) The requirements of this section shall not apply to any compounds, mixtures, or preparation containing ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers which are in liquid, liquid capsule, or gel capsule form or to any compounds, mixtures, or preparations containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or optical isomers which are deemed to be not subject to abuse upon joint review and agreement of the Office of Drug Control Policy, the Board of Pharmacy, and the Cabinet for Health and Family Services.

- (8) The provisions of this section shall not apply to a:
- (a) Licensed manufacturer manufacturing and lawfully distributing a product in the channels of commerce;
 - (b) Wholesaler lawfully distributing a product in the channels of commerce;
 - (c) Pharmacy with a valid permit from the Kentucky Board of Pharmacy;
 - (d) Health care facility licensed pursuant to KRS Chapter 216B;
 - (e) Licensed long-term care facility;
 - (f) Government-operated health department;
 - (g) Physician's office;
 - (h) Publicly operated prison, jail, or juvenile correctional facility, or a private adult or juvenile correctional facility under contract with the Commonwealth;
 - (i) Public or private educational institution maintaining a health care program; or
 - (j) Government-operated or industrial medical facility serving its own employees.
- (9) The provisions of this section shall supersede and preempt all local laws, ordinances, and regulations pertaining to the sale of any compounds, mixtures, or preparation containing ephedrine, pseudoephedrine, phenylpropanolamine, their salts or optical isomers, or salts of optical isomers.

Effective: June 26, 2007

History: Amended 2007 Ky. Acts ch. 124, sec. 12, effective June 26, 2007. -- Created 2005 Ky. Acts ch. 150, sec. 6, effective June 20, 2005.

Legislative Research Commission Note (6/20/2005). 2005 Ky. Acts chs. 11, 85, 95, 97, 98, 99, 123, and 181 instruct the Reviser of Statutes to correct statutory references to agencies and officers whose names have been changed in 2005 legislation confirming the reorganization of the executive branch. Such a correction has been made in this section.