218A.1446 Requirements for dispensing of ephedrine-based products -- Log or recordkeeping mechanism â€“ Thirty-day and one-year quantity limitations on ephedrine-based products -- Exceptions -- Preemption of local laws â€“ Blocking mechanism â€“ Annual report.

(1) Any 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 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.

Only an electronic logging or recordkeeping mechanism approved by the Office of Drug Control Policy may be utilized to meet the requirements of this subsection. No pharmacy may dispense or sell any compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers unless the electronic logging or recordkeeping mechanism required by this section is provided at no cost to the pharmacy.

(3) An electronic log or record, 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; and

(b) Subject to random and warrantless inspection by city, county, or state law enforcement officers.

(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 seven and one-fifth (7.2) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers within any thirty (30) day period or twenty-four (24) grams within any one (1) year period, provided that either of these limits shall not apply to any quantity of product, mixture or preparation dispensed pursuant to a valid prescription. In addition to the thirty (30) day and the one (1) year restrictions, 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 nonprescription 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 nonprescription 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.

(10) To be approved for use under this section, a logging or recordkeeping system shall:

(a) Be designed to block the dispensing of any compound, mixture, or preparation containing ephedrine, pseudoephedrine, phenylpropanolamine, their salts or optical isomers, or salts of optical isomers, where the dispensing would exceed the quantity limitations established in this section or would be prohibited under KRS 218A.1440; and

(b) Allow unimpeded access by the Office of Drug Control Policy to any data stored in the system for statistical analysis purposes.

(11) The Office of Drug Control Policy shall prepare and submit to the Legislative Research Commission an annual statistical report on the sale of compounds, mixtures, or preparations containing ephedrine, pseudoephedrine, phenylpropanolamine, their salts or optical isomers, or salts of optical isomers, including state and county sale amounts and numbers of individual purchasers.

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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.