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- 1 AN ACT relating to purchase limits for pseudoephedrine. 2 Be it enacted by the General Assembly of the Commonwealth of Kentucky: 3 → Section 1. KRS 218A.1446 is amended to read as follows: 4 Any compound, mixture, or preparation containing any detectable quantity of (1)5 ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, 6 or salts of optical isomers shall be dispensed, sold, or distributed only by a 7 registered pharmacist, a pharmacy intern, or a pharmacy technician. 8 (2)Any person purchasing, receiving, or otherwise acquiring any nonprescription 9 compound, mixture, or preparation containing any detectable quantity of ephedrine, 10 pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of 11 optical isomers shall: 12 Produce a government-issued photo identification showing the date of birth of (a) 13 the person; and 14 (b) Sign a log or record showing the: 15 1. Date of the transaction; 16 2. Name, date of birth, and address of the person making the purchase; and 17 3. The amount and name of the compound, mixture, or preparation. 18 Only an electronic logging or recordkeeping mechanism approved by the Office of 19 Drug Control Policy may be utilized to meet the requirements of this subsection. No 20 pharmacy may dispense or sell any compound, mixture, or preparation containing 21 any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, 22 their salts or optical isomers, or salts of optical isomers unless the electronic 23 logging or recordkeeping mechanism required by this section is provided at no cost 24 to the pharmacy. 25 An electronic log or record, as described in subsection (2) of this section, shall be (3)26 kept of each day's transactions. The registered pharmacist, a pharmacy intern, or a
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pharmacy technician shall initial the entry of each sale in the log, evidencing

- 1 completion of each transaction. The log shall be:
- 2 (a) Kept for a period of two (2) years; and
- 3 (b) Subject to random and warrantless inspection by city, county, or state law
  4 enforcement officers.
- 5 (4) (a) Intentional failure of a registered pharmacist, a pharmacy intern, or a
  6 pharmacy technician to make an accurate entry of a sale of a product or failure
  7 to maintain the log records as required by this section may subject him or her
  8 to a fine of not more than one thousand dollars (\$1,000) for each violation and
  9 may be evidence of a violation of KRS 218A.1438.
- 10 (b) If evidence exists that the pharmacist's, the pharmacy intern's, or the 11 pharmacist technician's employer fails, neglects, or encourages incorrect entry 12 of information by improper training, lack of supervision or oversight of the 13 maintenance of logs, or other action or inaction, the employer shall also face 14 liability under this section and any other applicable section of this chapter.
- 15 (c) It shall be a defense to a violation of this section that the person proves that 16 circumstances beyond the control of the registered pharmacist, pharmacy 17 intern, or pharmacy technician delayed or prevented the making of the record 18 or retention of the record as required by this section. Examples of 19 circumstances beyond the control of the registered pharmacist, pharmacy 20 intern, or pharmacy technician include but are not limited to:
- 21 1. Fire, natural or manmade disaster, loss of power, and similar events;
- 22 2. Robbery, burglary, shoplifting, or other criminal act by a person on the
  23 premises;
- 243. A medical emergency suffered by the registered pharmacist, pharmacy25intern, or pharmacy technician, another employee of the establishment, a26customer, or any other person on the premises; or
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4. Some other circumstance that establishes that an omission was

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inadvertent.

2 No person shall purchase, receive, or otherwise acquire any product, mixture, or (5)3 preparation or combinations of products, mixtures, or preparations containing more 4 than seven and one-fifth (7.2) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers 5 within any thirty (30) day period [or twenty-four (24) grams within any one (1) year 6 period], provided that *this limit*[either of these limits] shall not apply to any 7 8 quantity of product, mixture or preparation dispensed pursuant to a valid 9 prescription. [In addition to the thirty (30) day and the one (1) year restrictions, no 10 person shall purchase, receive, or otherwise acquire more than three (3) packages of 11 any product, mixture, or preparation containing ephedrine, pseudoephedrine, or 12 phenylpropanolamine, their salts or optical isomers, or salts of optical isomers 13 during each transaction.]

14 A person under eighteen (18) years of age shall not purchase or attempt to purchase (6)15 of nonprescription ephedrine, pseudoephedrine, any quantity a or 16 phenylpropanolamine product as described in subsection (1) of this section. No 17 person shall aid or assist a person under eighteen (18) years of age in purchasing 18 quantity of nonprescription ephedrine, pseudoephedrine, any а or 19 phenylpropanolamine product as described in subsection (1) of this section.

20 (7)The requirements of this section shall not apply to any compounds, mixtures, or 21 preparation containing ephedrine, pseudoephedrine, or phenylpropanolamine, their 22 salts or optical isomers, or salts of optical isomers which are in liquid, liquid 23 capsule, or gel capsule form or to any compounds, mixtures, or preparations 24 containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts or 25 optical isomers which are deemed to be not subject to abuse upon joint review and 26 agreement of the Office of Drug Control Policy, the Board of Pharmacy, and the 27 Cabinet for Health and Family Services.

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1 (8)The provisions of this section shall not apply to a: 2 Licensed manufacturer manufacturing and lawfully distributing a product in (a) the channels of commerce; 3 (b) Wholesaler lawfully distributing a product in the channels of commerce; 4 5 (c) Pharmacy with a valid permit from the Kentucky Board of Pharmacy; 6 (d) Health care facility licensed pursuant to KRS Chapter 216B; 7 Licensed long-term care facility; (e) 8 (f) Government-operated health department; 9 Physician's office; (g) 10 (h) Publicly operated prison, jail, or juvenile correctional facility, or a private 11 adult or juvenile correctional facility under contract with the Commonwealth; 12 (i) Public or private educational institution maintaining a health care program; or 13 Government-operated or industrial medical facility serving its own (j) 14 employees. 15 (9)The provisions of this section shall supersede and preempt all local laws, 16 ordinances, and regulations pertaining to the sale of any compounds, mixtures, or 17 preparation containing ephedrine, pseudoephedrine, phenylpropanolamine, their 18 salts or optical isomers, or salts of optical isomers. 19 (10) To be approved for use under this section, a logging or recordkeeping system shall: 20 Be designed to block the dispensing of any compound, mixture, or preparation (a) 21 containing ephedrine, pseudoephedrine, phenylpropanolamine, their salts or 22 optical isomers, or salts of optical isomers, where the dispensing would 23 exceed the quantity limitations established in this section or would be 24 prohibited under KRS 218A.1440; and 25 (b) Allow unimpeded access by the Office of Drug Control Policy to any data 26 stored in the system for statistical analysis purposes. 27 (11) The Office of Drug Control Policy shall prepare and submit to the Legislative

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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.