

1 AN ACT relating to statewide mobile food units.

2 ***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

3 ➔Section 1. KRS 217.015 is amended to read as follows:

4 For the purposes of KRS 217.005 to 217.215:

- 5 (1) "Advertisement" means all representations, disseminated in any manner or by any
6 means, other than by labeling, for the purpose of inducing, or which are likely to
7 induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;
- 8 (2) "Bread" and "enriched bread" mean only the foods commonly known and described
9 as white bread, white rolls, white buns, enriched white bread, enriched rolls, and
10 enriched white buns, as defined under the federal act. For the purposes of KRS
11 217.136 and 217.137, "bread" or "enriched bread" also means breads that may
12 include vegetables or fruit as an ingredient;
- 13 (3) "Cabinet" means the Cabinet for Health and Family Services or its designee;
- 14 (4) "Color" means but is not limited to black, white, and intermediate grays;
- 15 (5) "Color additive" means a material that:
- 16 (a) Is a dye, pigment, or other substance made by a process of synthesis or similar
17 artifice, or extracted, isolated, or otherwise derived, with or without
18 intermediate or final change of identity, from a vegetable, animal, mineral, or
19 other source. Nothing in this paragraph shall be construed to apply to any
20 pesticide chemical, soil or plant nutrient, or other agricultural chemical solely
21 because of its effect in aiding, retarding, or otherwise affecting, directly or
22 indirectly, the growth or other natural physiological process of produce of the
23 soil and thereby affecting its color, whether before or after harvest; or
- 24 (b) When added or applied to a food, drug, or cosmetic, or to the human body or
25 any part thereof, is capable, alone or through reaction with another substance,
26 of imparting color. "Color additive" does not include any material that has
27 been or may in the future be exempted under the federal act;

- 1 (6) "Contaminated with filth" means any food, drug, device, or cosmetic that is not
2 securely protected from dust, dirt, and as far as may be necessary by all reasonable
3 means, from all foreign or injurious contaminants;
- 4 (7) "Cosmetic" means:
- 5 (a) Articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into,
6 or otherwise applied to the human body or any part thereof for cleansing,
7 beautifying, promoting attractiveness, or altering the appearance; and
- 8 (b) Articles intended for use as a component of those articles, except that the term
9 shall not include soap;
- 10 (8) "Device," except when used in subsection (50)~~[(48)]~~ of this section, KRS
11 217.035(6), KRS 217.065(3), KRS 217.095(3), and KRS 217.175(10), means
12 instruments, apparatus, and contrivances, including their components, parts, and
13 accessories, intended:
- 14 (a) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease
15 in man or other animals; or
- 16 (b) To affect the structure or any function of the body of man or other animals;
- 17 (9) "Dispense" means to deliver a drug or device to an ultimate user or research subject
18 by or pursuant to the lawful order of a practitioner, including the packaging,
19 labeling, or compounding necessary to prepare the substance for that delivery;
- 20 (10) "Dispenser" means a person who lawfully dispenses a drug or device to or for the
21 use of an ultimate user;
- 22 (11) "Drug" means:
- 23 (a) Articles recognized in the official United States pharmacopoeia, official
24 homeopathic pharmacopoeia of the United States, or official national
25 formulary, or any supplement to any of them;
- 26 (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or
27 prevention of disease in man or other animals;

- 1 (c) Articles, other than food, intended to affect the structure or any function of the
2 body of man or other animals; and
- 3 (d) Articles intended for use as a component of any article specified in this
4 subsection but does not include devices or their components, parts, or
5 accessories;
- 6 (12) "Enriched," as applied to flour, means the addition to flour of vitamins and other
7 nutritional ingredients necessary to make it conform to the definition and standard
8 of enriched flour as defined under the federal act;
- 9 (13) "Environmental Pesticide Control Act of 1972" means the Federal Environmental
10 Pesticide Control Act of 1972, Pub. L. 92-516, and all amendments thereto;
- 11 (14) "Fair Packaging and Labeling Act" means the Fair Packaging and Labeling Act as it
12 relates to foods and cosmetics, 15 U.S.C. secs. 1451 et seq., and all amendments
13 thereto;
- 14 (15) "Federal act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. secs. 301
15 et seq., 52 Stat. 1040 et seq., or amendments thereto;
- 16 (16) "Filled milk" means any milk, cream, or skimmed milk, whether or not condensed,
17 evaporated, concentrated, frozen, powdered, dried, or desiccated, to which has been
18 added, or which has been blended or compounded with, any fat or oil other than
19 milk fat, except the fat or oil of contained eggs and nuts and the fat or oil of
20 substances used for flavoring purposes only, so that the resulting product is an
21 imitation or semblance of milk, cream, skimmed milk, ice cream mix, ice cream, or
22 frozen desserts, whether or not condensed, evaporated, concentrated, frozen,
23 powdered, dried, or desiccated, whether in bulk or in containers, hermetically sealed
24 or unsealed. This definition does not mean or include any milk or cream from which
25 no part of the milk or butter fat has been extracted, whether or not condensed,
26 evaporated, concentrated, powdered, dried, or desiccated, to which has been added
27 any substance rich in vitamins, nor any distinctive proprietary food compound not

1 readily mistaken for milk or cream or for condensed, evaporated, concentrated,
2 powdered, dried, or desiccated milk or cream, if the compound is prepared and
3 designed for the feeding of infants or young children, sick or infirm persons, and
4 customarily used on the order of a physician, and is packed in individual containers
5 bearing a label in bold type that the contents are to be used for those purposes; nor
6 shall this definition prevent the use, blending, or compounding of chocolate as a
7 flavor with milk, cream, or skimmed milk, desiccated, whether in bulk or in
8 containers, hermetically sealed or unsealed, to or with which has been added,
9 blended or compounded no other fat or oil other than milk or butter fat;

10 (17) "Flour" means only the foods commonly known as flour, white flour, wheat flour,
11 plain flour, bromated flour, self-rising flour, self-rising white flour, self-rising
12 wheat flour, phosphated flour, phosphated white flour, and phosphated wheat flour,
13 defined under the federal act;

14 (18) "Food" means:

15 (a) Articles used for food or drink for man or other animals;

16 (b) Chewing gum; and

17 (c) Articles used for components of any such article;

18 (19) "Food additive" means any substance the intended use of which results or may be
19 reasonably expected to result, directly or indirectly, in its becoming a component or
20 otherwise affecting the characteristics of any food, including any substance intended
21 for use in producing, manufacturing, packing, processing, preparing, treating,
22 packaging, transporting, or holding food; and including any source of radiation
23 intended for any of these uses, if the substance is not generally recognized, among
24 experts qualified by scientific training and experience to evaluate its safety, as
25 having been adequately shown through scientific procedures or, in the case of a
26 substance used in a food prior to January 1, 1958, through either scientific
27 procedures or experience based on common use in food to be safe under the

- 1 conditions of its intended use; except that the term does not include:
- 2 (a) A pesticide chemical in or on a raw agricultural commodity;
- 3 (b) A pesticide chemical to the extent that it is intended for use or is used in the
- 4 production, storage, or transportation of any raw agricultural commodity;
- 5 (c) A color additive; or
- 6 (d) Any substance used in accordance with a sanction or approval granted prior to
- 7 the enactment of the Food Additives Amendment of 1958, pursuant to the
- 8 federal act; the Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq.; or
- 9 the Meat Inspection Act of 1907; and amendments thereto;
- 10 (20) "Food processing establishment" means any commercial establishment in which
- 11 food is manufactured, processed, or packaged for human consumption, but does not
- 12 include retail food establishments, home-based processors, ~~for~~ home-based
- 13 microprocessors, **or statewide mobile food units**;
- 14 (21) "Food service establishment" means any fixed or mobile commercial establishment
- 15 that engages in the preparation and serving of ready-to-eat foods in portions to the
- 16 consumer, including but not limited to: restaurants; coffee shops; cafeterias; short
- 17 order cafes; luncheonettes; grills; tea rooms; sandwich shops; soda fountains;
- 18 taverns; bars; cocktail lounges; nightclubs; roadside stands; industrial feeding
- 19 establishments; private, public or nonprofit organizations or institutions routinely
- 20 serving food; catering kitchens; commissaries; charitable food kitchens; **statewide**
- 21 **mobile food units**; or similar places in which food is prepared for sale or service on
- 22 the premises or elsewhere with or without charge. It does not include food vending
- 23 machines, establishments serving beverages only in single service or original
- 24 containers, or retail food stores which only cut, slice, and prepare cold-cut
- 25 sandwiches for individual consumption;
- 26 (22) "Food storage warehouse" means any establishment in which food is stored for
- 27 subsequent distribution;

- 1 (23) "Immediate container" does not include package liners;
- 2 (24) "Imminent health hazard" means a significant threat or danger to health that is
3 considered to exist when there is evidence sufficient to show that a product,
4 practice, circumstance, or event creates a situation that requires immediate
5 correction or cessation of operation to prevent illness or injury based on:
- 6 (a) The number of potential illnesses or injuries; or
7 (b) The nature, severity, and duration of the anticipated illness or injury;
- 8 (25) "Interference" means threatening or otherwise preventing the performance of lawful
9 inspections or duties by agents of the cabinet during all reasonable times of
10 operation;
- 11 (26) "Label" means a display of written, printed, or graphic matter upon the immediate
12 container of any article; and a requirement made by or under authority of KRS
13 217.005 to 217.215 that any word, statement, or other information appearing on the
14 label shall not be considered to be complied with unless the word, statement, or
15 other information also appears on the outside container or wrapper, if any there be,
16 of the retail package of the article, or is easily legible through the outside container
17 or wrapper;
- 18 (27) "Labeling" means all labels and other written, printed, or graphic matter:
- 19 (a) Upon an article or any of its containers or wrappers; or
20 (b) Accompanying the article;
- 21 (28) "Legend drug" means a drug defined by the Federal Food, Drug and Cosmetic Act,
22 as amended, and under which definition its label is required to bear the statement
23 "Caution: Federal law prohibits dispensing without prescription.";
- 24 **(29) "Local government" means any county, city, urban-county, charter county,**
25 **consolidated local government, or unified local government;**
- 26 **(30)**~~(29)~~ "Meat Inspection Act" means the Federal Meat Inspection Act, 21 U.S.C. secs.
27 71 et seq., 34 Stat. 1260 et seq., including any amendments thereto;

1 ~~(31)~~[(30)] "New drug" means:

2 (a) Any drug the composition of which is such that the drug is not generally
3 recognized among experts qualified by scientific training and experience to
4 evaluate the safety of drugs as safe for use under the conditions prescribed,
5 recommended, or suggested in the labeling thereof; or

6 (b) Any drug the composition of which is such that the drug, as a result of
7 investigations to determine its safety for use under prescribed conditions, has
8 become so recognized, but which has not, otherwise than in the investigations,
9 been used to a material extent or for a material time under the conditions;

10 ~~(32)~~[(31)] "Official compendium" means the official United States pharmacopoeia,
11 official homeopathic pharmacopoeia of the United States, official national
12 formulary, or any supplement to any of them;

13 ~~(33)~~[(32)] "Person" means an individual, firm, partnership, company, corporation,
14 trustee, association, or any public or private entity;

15 ~~(34)~~[(33)] "Pesticide chemical" means any substance that alone in chemical combination,
16 or in formulation with one or more other substances, is an "economic poison"
17 within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act and
18 amendments thereto, and that is used in the production, storage, or transportation of
19 raw agricultural commodities;

20 ~~(35)~~[(34)] "Poultry Products Inspection Act" means the Federal Poultry and Poultry
21 Products Inspection Act, 21 U.S.C. secs. 451 et seq., Pub. L. 85-172, 71 Stat. 441,
22 and any amendments thereto;

23 ~~(36)~~[(35)] "Practitioner" means medical or osteopathic physicians, dentists, chiropractors,
24 and veterinarians who are licensed under the professional licensing laws of
25 Kentucky to prescribe and administer drugs and devices. "Practitioner" includes
26 optometrists when administering or prescribing pharmaceutical agents authorized in
27 KRS 320.240(12) to (14), advanced practice registered nurses as authorized in KRS

1 314.011 and 314.042, physician assistants when administering or prescribing
2 pharmaceutical agents as authorized in KRS 311.858, and health care professionals
3 who are residents of and actively practicing in a state other than Kentucky and who
4 are licensed and have prescriptive authority under the professional licensing laws of
5 another state, unless the person's Kentucky license has been revoked, suspended,
6 restricted, or probated, in which case the terms of the Kentucky license shall
7 prevail;

8 ~~(37)~~[(36)] "Prescription" means a written or oral order for a drug or medicine, or
9 combination or mixture of drugs or medicines, or proprietary preparation, that is
10 signed, given, or authorized by a medical, advanced practice registered nurse,
11 dental, chiropody, veterinarian, or optometric practitioner, and intended for use in
12 the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other
13 animals;

14 ~~(38)~~[(37)] "Prescription blank" means a document that conforms with KRS 217.216 and
15 is intended for prescribing a drug to an ultimate user;

16 ~~(39)~~[(38)] "Raw agricultural commodity" means any food in its raw or natural state,
17 including all fruits that are washed, colored, or otherwise treated in their unpeeled
18 natural form prior to marketing;

19 ~~(40)~~[(39)] "Retail food establishment" means any food service establishment, retail food
20 store, or a combination of both within the same establishment, **but does not include**
21 **a statewide mobile food unit**;

22 ~~(41)~~[(40)] "Retail food store" means any fixed or mobile establishment where food or
23 food products, including prepackaged, labeled sandwiches or other foods to be
24 heated in a microwave or infrared oven at the time of purchase, are offered for sale
25 to the consumer, and intended for off-premises consumption, but does not include
26 establishments which handle only prepackaged, snack-type, nonpotentially
27 hazardous foods, markets that offer only fresh fruits and vegetables for sale, food

1 service establishments, food and beverage vending machines, vending machine
2 commissaries, food processing establishments, or home-based processors, **but does**
3 **not include a statewide mobile food unit;**

4 ~~(42)~~~~((41))~~ "Salvage distributor" means a person who engages in the business of
5 distributing, peddling, or otherwise trafficking in any salvaged merchandise;

6 ~~(43)~~~~((42))~~ "Salvage processing plant" means an establishment operated by a person
7 engaged in the business of reconditioning, labeling, relabeling, repackaging,
8 recoopering, sorting, cleaning, culling or who by other means salvages, sells, offers
9 for sale, or distributes for human or animal consumption or use any salvaged food,
10 beverage, including beer, wine and distilled spirits, vitamins, food supplements,
11 dentifrices, cosmetics, single-service food containers or utensils, containers and
12 packaging materials used for foods and cosmetics, soda straws, paper napkins, or
13 any other product of a similar nature that has been damaged or contaminated by fire,
14 water, smoke, chemicals, transit, or by any other means;

15 ~~(44)~~~~((43))~~ "Second or subsequent offense" has the same meaning as it does in KRS
16 218A.010;

17 ~~(45)~~~~((44))~~ "Secretary" means the secretary of the Cabinet for Health and Family
18 Services;

19 ~~(46)~~ **"Statewide mobile food unit" means a mobile self-contained food service**
20 **establishment that operates from a fully enclosed vehicle or other conveyance. It**
21 **does not include food service establishments on a motor vehicle or a trailer from**
22 **which a vendor, from within the frame of the vehicle, serves ice cream, attracts**
23 **patrons by traveling through a residential area and signaling the truck's presence**
24 **in the area, including playing music, and may stop to serve ice cream at the**
25 **signal of the patron;**

26 ~~(47)~~~~((45))~~ "Temporary food service establishment" means any food service
27 establishment which operates at a fixed location for a period of time, not to exceed

1 fourteen (14) consecutive days, **but does not include a statewide mobile food unit;**

2 ~~(48)~~~~(46)~~ "Traffic" has the same meaning as it does in KRS 218A.010;

3 ~~(49)~~~~(47)~~ "Ultimate user" has the same meaning as it does in KRS 218A.010;

4 ~~(50)~~~~(48)~~ If an article is alleged to be misbranded because the labeling is misleading, or

5 if an advertisement is alleged to be false because it is misleading, in determining

6 whether the labeling or advertisement is misleading, there shall be taken into

7 account, among other things, not only representations made or suggested by

8 statement, word, design, device, sound, or in any combination thereof, but also the

9 extent to which the labeling or advertisement fails to reveal facts that are material in

10 the light of the representations or material with respect to consequences which may

11 result from the use of the article to which the labeling or advertisement relates under

12 the conditions of use prescribed in the labeling or advertisement thereof or under

13 the conditions of use as are customary or usual;

14 ~~(51)~~~~(49)~~ The representation of a drug in its labeling or advertisement as an antiseptic

15 shall be considered to be a representation that it is a germicide, except in the case of

16 a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet

17 dressing, ointment, dusting powder, or other use involving prolonged contact with

18 the body;

19 ~~(52)~~~~(50)~~ The provisions of KRS 217.005 to 217.215 regarding the selling of food,

20 drugs, devices, or cosmetics shall be considered to include the manufacture,

21 production, processing, packing, exposure, offer, possession, and holding of those

22 articles for sale, the sale, dispensing, and giving of those articles, and the supplying

23 or applying of those articles in the conduct of any food, drug, or cosmetic

24 establishment;

25 ~~(53)~~~~(51)~~ "Home" means a primary residence occupied by the processor, that contains

26 only two (2) ranges, ovens, or double-ovens, and no more than three (3)

27 refrigerators used for cold storage. This equipment shall have been designed for

1 home use and not for commercial use, and shall be operated in the kitchen within
2 the residence;

3 ~~(54)~~~~(52)~~ "Formulated acid food product" means an acid food in which the addition of a
4 small amount of low-acid food results in a finished equilibrium pH of 4.6 or below
5 that does not significantly differ from that of the predominant acid or acid food;

6 ~~(55)~~~~(53)~~ "Acidified food product" means a low-acid food to which acid or acidic food
7 is added and which has a water activity value greater than 0.85, and a finished
8 equilibrium pH of 4.6 or below;

9 ~~(56)~~~~(54)~~ "Low-acid food" means foods, other than alcoholic beverages, with a finished
10 equilibrium pH greater than 4.6, and a water activity value greater than 0.85;

11 ~~(57)~~~~(55)~~ "Acid food" means foods that have a natural pH of 4.6 or below;

12 ~~(58)~~~~(56)~~ "Home-based processor" means a person who in his or her home, produces or
13 processes non-potentially hazardous foods, including but not limited to dried herbs,
14 spices, nuts, candy, dried grains, whole fruit and vegetables, mixed-greens, jams,
15 jellies, sweet sorghum syrup, preserves, fruit butter, bread, fruit pies, cakes, or
16 cookies, and who has a gross income of no more than sixty thousand dollars
17 (\$60,000) annually from the sale of the products;

18 ~~(59)~~~~(57)~~ "Home-based microprocessor" means a farmer who, in the farmer's home or
19 certified or permitted kitchen, produces or processes foods, including but not
20 limited to acid foods, formulated acid food products, acidified food products, or
21 low-acid canned foods, and who has a gross income of no more than sixty thousand
22 dollars (\$60,000) annually from the sale of the product;

23 ~~(60)~~~~(58)~~ "Certified" means any person or home-based microprocessor who:

24 (a) Has attended the Kentucky Cooperative Extension Service's microprocessing
25 program or pilot microprocessing program and has been identified by the
26 Kentucky Cooperative Extension Service as having satisfactorily completed
27 the prescribed course of instruction; or

1 (b) Has attended some other school pursuant to 21 C.F.R. sec. 114.10;
2 ~~(61)~~~~(59)~~ "Farmer" means a person who is a resident of Kentucky and owns or rents
3 agricultural land pursuant to subsection (9) of KRS 132.010 or horticultural land
4 pursuant to subsection (10) of KRS 132.010. For the purposes of KRS 217.136 to
5 217.139, "farmer" also means any person who is a resident of Kentucky and has
6 grown the primary horticultural and agronomic ingredients used in the home-based
7 microprocessed products which they have produced; and

8 ~~(62)~~~~(60)~~ "Farmers market temporary food service establishment" means any temporary
9 food service establishment operated by a farmer who is a member of the market
10 which operates within the confines of a farmers market registered with the
11 Kentucky Department of Agriculture for the direct-to-consumer marketing of
12 Kentucky-grown farm products from approved sources for a period of time not to
13 exceed two (2) days per week for any consecutive six (6) months period in a
14 calendar year.

15 ➔Section 2. KRS 217.125 is amended to read as follows:

16 (1) The authority to promulgate regulations for the efficient administration and
17 enforcement of KRS 217.005 to 217.215 is hereby vested in the secretary. The
18 secretary may make the regulations promulgated under KRS 217.005 to 217.215
19 consistent with those promulgated under the federal act and the Fair Packaging and
20 Labeling Act. Regulations promulgated may require permits to operate and include
21 provisions for regulating the issuance, suspension, and reinstatement of permits.
22 The authority to promulgate regulations pursuant to KRS 217.005 to 217.205 is
23 restricted to the Cabinet for Health and Family Services.

24 **(2) The cabinet may promulgate administrative regulations pursuant to KRS Chapter**
25 **13A for the efficient administration and enforcement of Section 4 of this Act. Any**
26 **administrative regulation promulgated by the cabinet for the administration and**
27 **enforcement of Section 4 of this Act shall be narrowly tailored to address a**

1 demonstrable health or safety risk. Administrative regulations relating to
2 statewide mobile food units shall not:

3 (a) Require a statewide mobile food unit to operate a specific distance from the
4 perimeter of an existing commercial establishment or restaurant or to enter
5 into any agreement with an existing commercial establishment or
6 restaurant;

7 (b) Require a statewide mobile food unit to obtain licenses or permits for the
8 unit's employees;

9 (c) Address the operating hours of a statewide mobile food unit;

10 (d) Require a statewide mobile food unit that sells only prepackaged food to
11 have a handwashing sink in the unit;

12 (e) Require a statewide mobile food unit to associate with a commissary if the
13 unit carries all the equipment necessary to comply with this chapter;

14 (f) Limit the number of statewide mobile food units;

15 (g) Require a statewide mobile food unit to obtain any additional permits from
16 a local government, unless the unit seeks to operate in a public park;

17 (h) Require a statewide mobile food unit owner or employee to be fingerprinted,
18 pass a criminal background check, or install a GPS tracking device on the
19 unit;

20 (i) Require a statewide mobile food unit to stay in constant motion except when
21 serving customers;

22 (j) Require a statewide mobile food unit to maintain insurance that names the
23 local government as an additional insured unless the unit is serving
24 customers at an event sponsored by the local government or operating in a
25 public park;

26 (k) Require a statewide mobile food unit to maintain a bond that names the
27 local government as a beneficiary unless the unit is serving customers at an

1 *event sponsored by the local government or operating in a public park; and*
2 *(l) Require a statewide mobile food unit to submit to inspections in addition to*
3 *health inspections conducted by the cabinet or by a local government*
4 *collaborating with the cabinet, unless the cabinet is investigating a reported*
5 *foodborne illness.*

6 ~~(3)~~~~(2)~~ No person shall operate a food processing establishment, food storage
7 warehouse, salvage distributor, or salvage processing plant without having obtained
8 an annual permit to operate from the cabinet. An application for the permit to
9 operate shall be made to the cabinet upon forms provided by it and shall be
10 accompanied by the required fee as shall be provided by regulation. The secretary
11 shall promulgate administrative regulations to establish a fee schedule not to exceed
12 costs of the program to the cabinet. Fees collected by the cabinet shall be deposited
13 in the State Treasury and credited to a revolving fund account for use by the cabinet
14 in carrying out the provisions of KRS 217.025 to 217.390 and the regulations
15 adopted by the secretary pursuant thereto. The balance of the account shall lapse to
16 the general fund at the end of each biennium.

17 ~~(4)~~~~(3)~~ No person shall operate a retail food establishment *or statewide mobile food*
18 *unit* without having obtained a permit to operate from the cabinet. An application
19 for a permit to operate any retail food establishment *or statewide mobile food unit*
20 shall be made to the cabinet upon forms provided by it and shall contain the
21 information the cabinet may reasonably require.

22 ~~(5)~~~~(4)~~ (a) Except as otherwise provided in subsection ~~12~~~~(11)~~ of this section, each
23 application for a temporary food service establishment or for an annual permit
24 to operate a retail food establishment *or statewide mobile food unit* shall be
25 accompanied by the required fee. The secretary shall promulgate
26 administrative regulations to establish a fee schedule not to exceed costs to the
27 cabinet.

- 1 (b) The total fees for permitting and inspection:
- 2 1. Shall be the total of the operational and administrative costs of the
- 3 programs to the cabinet and to agencies as defined in KRS 211.185;
- 4 2. Beginning on March 17, 2020, until December 31, 2020, shall not
- 5 increase more than twenty-five percent (25%) of the fee amount on
- 6 March 17, 2020; and
- 7 3. Beginning on or after January 1, 2021, shall not increase more than five
- 8 percent (5%) for each year thereafter.

9 ~~(6)~~⁽⁵⁾ Except as otherwise provided in subsection ~~(12)~~⁽¹¹⁾ of this section, each

10 application for a farmers market temporary food service establishment shall be

11 accompanied by the required fee of at least fifty dollars (\$50). The secretary shall

12 establish a fee schedule by promulgation of administrative regulation. Fees

13 collected by the cabinet shall be used to carry out duties related to farmers market

14 temporary food service establishments, including but not limited to inspections and

15 the issuance of permits.

16 ~~(7)~~⁽⁶⁾ An applicant for a permit to operate a farmers market temporary food service

17 establishment must provide documentation of successful completion of a food

18 safety training program offered by either the state, a local health department, or

19 other entity approved by the cabinet to conduct food safety training. Each

20 certification of food safety training shall expire after a period of twenty-four (24)

21 months from the date of issuance. Permits issued shall be posted in a conspicuous

22 place in the establishment, and a person who has completed the food safety training

23 for farmers market temporary food service establishments shall be present at all

24 times during the operation of the establishment.

25 ~~(8)~~⁽⁷⁾ Upon expiration of a temporary food service establishment permit, any

26 subsequent permits shall not be issued to the same operator to operate at the same

27 location until a period of thirty (30) days has elapsed.

1 ~~(9)~~⁽⁸⁾ Upon receipt of an application for a permit to operate a food processing
2 establishment, food storage warehouse, salvage distributor, or salvage processing
3 plant, ~~or a~~ retail food establishment, ***or a statewide mobile food unit*** accompanied
4 by the required fee, the cabinet shall issue a permit if the establishment meets the
5 requirements of KRS 217.005 to 217.215 and regulations adopted by the cabinet.
6 Retail food establishments holding a valid and effective permit on January 1, 1973,
7 even though not fully meeting the construction requirements of KRS 217.005 to
8 217.215 and the regulations adopted pursuant thereto, may continue to be eligible
9 for permit renewal if in good repair and capable of being maintained in a safe and
10 sanitary manner.

11 ~~(10)~~⁽⁹⁾ Permits shall not be issued to operate a temporary food service establishment
12 and a farmers market temporary food service establishment simultaneously at the
13 same location and by the same operator.

14 ~~(11)~~⁽¹⁰⁾ In all instances of permit issuance for either a temporary food service
15 establishment permit or a farmers market temporary food service establishment
16 permit, any subsequent permits shall not be issued until a period of thirty (30) days
17 has elapsed.

18 ~~(12)~~⁽¹¹⁾ Private, parochial, and public school cafeterias or lunchroom facilities through
19 the twelfth grade, charitable food kitchens, and all facilities operated by the Cabinet
20 for Health and Family Services or Department of Corrections shall be exempt from
21 the payment of fees, but shall comply with all other provisions of KRS 217.005 to
22 217.215 and the state retail food establishment code. For this subsection, the term
23 "charitable food kitchens" means a not-for-profit, benevolent food service
24 establishment where more than one-half (1/2) of the employees are volunteers.

25 ~~(13)~~⁽¹²⁾ Each annual permit to operate a food processing establishment, food storage
26 warehouse, salvage distributor, or salvage processing plant, ~~or a~~ retail food
27 establishment, ***or a statewide mobile food unit*** unless previously suspended or

1 revoked, shall expire on December 31 following its date of issuance, and be
 2 renewable annually upon application accompanied by the required fee, except as
 3 otherwise provided in subsection (11) of this section, and if the establishment is in
 4 compliance with KRS 217.005 to 217.215 and regulations of the cabinet.

5 ~~(14)~~~~(13)~~ Each permit to operate a food processing establishment, food storage
 6 warehouse, salvage distributor, salvage processing plant, ~~for a~~ retail food
 7 establishment, **or a statewide mobile food unit** shall be issued only for the premises
 8 and person named in the application and shall not be transferable. Permits issued
 9 shall be posted in a conspicuous place in the establishment.

10 ➔Section 3. KRS 217.126 is amended to read as follows:

11 (1) The cabinet shall suspend the permit to operate a retail food establishment **or**
 12 **statewide mobile food unit** immediately upon notice to the permit holder without a
 13 conference when:

14 (a) An inspection of an establishment reveals that any of the following conditions
 15 are present:

- 16 1. Sewage is standing in the food preparation, food storage, utensil
 17 washing, or storage areas;
- 18 2. Gross rodent or insect activity exists resulting in contamination of food
 19 or food equipment;
- 20 3. The water supply is contaminated or cut off with no approved alternative
 21 plan;
- 22 4. The establishment is operating in blatant disregard for safe cooking or
 23 holding temperatures for potentially hazardous foods; or
- 24 5. There is an infiltration of toxic or noxious gases, dust, or other irritants
 25 or contaminants causing apparent illness of employees or patrons; or

26 (b) The permit holder or authorized agent has interfered, as defined in KRS
 27 217.015~~(25)~~, with the cabinet in the performance of its duties, after its

1 agents have duly and officially identified themselves and the interference has
2 been verified by the inspector's supervisor;

3 (c) An inspection of an establishment reveals a rating score of less than sixty
4 (60); or

5 (d) An inspection reveals that an imminent health hazard as defined in KRS
6 217.015~~[(24)]~~ still exists and the hazard has been verified by the agent's
7 supervisor.

8 (2) In all other instances not covered by subsection (1) of this section, after notice to the
9 applicant or holder of a permit to operate and after an opportunity for a hearing as
10 provided by administrative regulations of the secretary, the cabinet or local health
11 department concerned may deny, suspend, or revoke a permit to operate in any case
12 where it finds that there has been a failure to comply with the requirements of KRS
13 217.005 to 217.215 or the administrative regulations of the secretary. Any
14 administrative hearing conducted under this section shall be conducted in
15 accordance with KRS Chapter 13B.

16 ➔SECTION 4. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED
17 TO READ AS FOLLOWS:

18 **(1) A local government shall not prohibit a statewide mobile food unit from lawfully**
19 **operating in its jurisdiction if the unit holds a permit to operate a statewide**
20 **mobile food unit and is in compliance with all other state and local laws not in**
21 **conflict with this chapter.**

22 **(2) A statewide mobile food unit shall follow all state and local laws governing**
23 **operations in the jurisdiction where the unit operates not in conflict with this**
24 **chapter.**

25 **(3) A statewide mobile food unit may operate in the following locations:**

26 **(a) On public property, so long as the unit is not parked within twenty (20) feet**
27 **of an intersection. Public property includes legal parking spaces, including**

- 1 metered spaces upon payment of appropriate fees, on the public right-of-
2 way. When operating on public property, a statewide mobile food unit is
3 subject to the same parking rules and restrictions as a commercial vehicle,
4 except that a local government may develop a permit and charge a fee that
5 allows a statewide mobile food unit to park at a meter beyond the time
6 allotted; and
- 7 (b) On private property if the property is in a zoning district where food service
8 establishments are permitted, and the unit has permission of the property
9 owner or his or her designee. A statewide mobile food unit may operate in a
10 residential zoning or traditional neighborhood zoning district if the unit has
11 been invited by a resident, property owner, lessor, or homeowner's
12 association in that district.
- 13 (4) A statewide mobile food unit shall not interfere with or obstruct the passage of
14 pedestrians or vehicles along any street, sidewalk, or parkway.
- 15 (5) Before serving food within the jurisdiction of a local government, a statewide
16 mobile food unit shall notify the local government in writing that food will be
17 served in that jurisdiction. The license holder shall mail the notice by first-class
18 mail or deliver the notice not less than four (4) business days before any food is
19 served or prepared for serving within the jurisdiction.
- 20 (6) When operating, a statewide mobile food unit shall:
- 21 (a) Maintain its unit in good operating order;
- 22 (b) Provide a waste receptacle for customers to use which is clearly marked and
23 request customers use it;
- 24 (c) Pick up, remove, and dispose of all refuse within twenty-five (25) feet of the
25 unit's operating area at the conclusion of service;
- 26 (d) Submit to and pass any required health inspections and fire inspections
27 pursuant to the procedures in this chapter; and

- 1 (e) Display its statewide mobile food unit license and inspection certificate in a
2 conspicuous location in its service window or on its unit for public view.
- 3 (7) At least one (1) person operating a statewide mobile food unit shall hold a current
4 food safety certification approved by the cabinet.
- 5 (8) Health inspections shall occur on a randomized basis and shall not exceed two
6 (2) inspections per year unless the cabinet is investigating a complaint of
7 foodborne illness or addressing an imminent public health or safety risk.
- 8 (9) Local governments may regulate statewide mobile food units in collaboration
9 with the cabinet in accordance with this chapter. In relation to the operations of a
10 statewide mobile food unit, a local government may:
- 11 (a) Restrict the operation of a noisemaking device that exceeds seventy-five (75)
12 decibels measured twenty-three (23) feet from the vehicle during specific
13 times of the day;
- 14 (b) Restrict a statewide mobile food unit from operating in a public park or
15 require a special permit and payment of fees to operate in a public park;
- 16 (c) Prohibit a statewide mobile food unit that is operating on private property
17 from blocking ingress to or egress from that property;
- 18 (d) Develop a mobile food unit metered parking pass for a fee that permits a
19 unit to operate from metered parking spaces for longer than the unit would
20 otherwise be permitted;
- 21 (e) Investigate reports of foodborne illnesses;
- 22 (f) Cite statewide mobile food units and issue penalties for violations of local
23 law not inconsistent with this chapter; and
- 24 (g) Report a statewide mobile food unit's suspected violations of this chapter to
25 the cabinet.
- 26 (10) In relation to the operations of a statewide mobile food unit, a local government
27 shall not:

- 1 (a) Prohibit or restrict a statewide mobile food unit from operating in a lawful
2 manner provided for in this chapter;
- 3 (b) Address the operating hours of a statewide mobile food unit unless the local
4 government also regulates the operating hours of restaurants;
- 5 (c) Require a statewide mobile food unit to receive any special permit from the
6 local government in addition to a permit to operate as a commercial vehicle,
7 unless the unit seeks to operate in a local public park;
- 8 (d) Require a statewide mobile food unit to obtain licenses or permits for the
9 unit's employees;
- 10 (e) Restrict the duration of time a statewide mobile food unit may operate on
11 private property in industrial or commercial zoning districts;
- 12 (f) Require a statewide mobile food unit to operate a specific distance from
13 restaurants or commercial establishments or to enter into any agreement
14 with a commercial establishment or restaurant;
- 15 (g) Regulate the equipment requirements for a statewide mobile food unit;
- 16 (h) Require a statewide mobile food unit to associate with a commissary;
- 17 (i) Require a statewide mobile food unit owner or employee to be fingerprinted,
18 pass a criminal background check to operate, or to install a GPS tracking
19 device on its unit;
- 20 (j) Require a statewide mobile food unit to stay in constant motion except when
21 serving customers;
- 22 (k) Require a statewide mobile food unit to maintain an insurance policy that
23 names the local government as an additional insured unless the unit is
24 attending an event sponsored by the local government or operating in a
25 local public park;
- 26 (l) Require a statewide mobile food unit to maintain a bond that names the
27 local government as a beneficiary unless the unit is attending an event

1 sponsored by the local government or operating in a local public park; and
 2 (m) Require a statewide mobile food unit to submit to inspections beyond health
 3 inspections conducted by the cabinet or a local government collaborating
 4 with the cabinet, unless the local government is investigating a reported
 5 foodborne illness.

6 (11) The cabinet or a local government may investigate a statewide mobile food unit
 7 upon reasonable suspicion the unit is violating the law or upon receipt of a
 8 health or safety complaint. Local governments shall report suspected violations of
 9 state law to the cabinet. Statewide mobile food units shall cooperate with the
 10 cabinet and local government during an investigation. Failure to cooperate with
 11 the cabinet or local government may result in suspension or revocation of a
 12 permit.

13 ➔Section 5. KRS 217.128 is amended to read as follows:

14 (1) The state fire marshal or other duly authorized agents or representatives or other
 15 authorized agents pursuant to KRS Chapter 227 shall administer and enforce all
 16 state fire regulations, laws, standards of safety, and regulations adopted by the
 17 commissioner of housing, buildings and construction relating to retail food
 18 establishments.

19 (2) The state fire marshal or other duly authorized agents or representatives or other
 20 authorized agents pursuant to KRS Chapter 227 shall not require a statewide
 21 mobile food unit that has passed a fire inspection within the previous year to pass
 22 an additional fire inspection within that year unless the unit poses an imminent
 23 public health or safety risk.

24 ➔Section 6. KRS 217.136 is amended to read as follows:

25 (1) A home-based processor shall be exempt from KRS 217.035 and 217.037 if the
 26 following conditions are met:

27 (a) All finished product containers are clean, sanitary, and properly labeled

- 1 pursuant to subsection (3) of this section;
- 2 (b) All home-processed foods produced under this exemption are neither
- 3 adulterated nor misbranded pursuant to subsection (4) of this section; and
- 4 (c) All glass containers for jams, jellies, preserves, fruit butter, and similar
- 5 products are provided with suitable rigid metal covers.
- 6 (2) A home-based processor shall not produce or process for sale acid foods, acidified
- 7 food products, formulated acid food products, or low-acid canned foods.
- 8 (3) A home-based processor shall label each of its food products and include the
- 9 following information on the label of each of its food products:
- 10 (a) The name and address of the home-based processing operation;
- 11 (b) The common or usual name of the food product;
- 12 (c) The ingredients of the food product, in descending order of predominance by
- 13 weight;
- 14 (d) The net weight and volume of the food product by standard measure, or
- 15 numerical count;
- 16 (e) The following statement in ten (10) point type: "This product is home-
- 17 produced and processed"; and
- 18 (f) The date the product was processed.
- 19 (4) Food products identified in *the definition of "home-based microprocessor" in*
- 20 KRS 217.015~~[(56)]~~ and not labeled in accordance with subsection (3) of this section
- 21 are deemed misbranded.
- 22 (5) Food products identified in *the definition of "home-based microprocessor" in*
- 23 KRS 217.015~~[(56)]~~ and produced, processed, and labeled in accordance with
- 24 subsection (3) of this section are acceptable food products that may only be offered
- 25 for sale directly to consumers within this state, including from the home-based
- 26 processor's home, whether by pick-up or delivery, at a market, roadside stand,
- 27 community event, or online. These food products may be used in preparing and

1 serving food.

2 (6) Food products identified in the definition of "home-based microprocessor" in
3 KRS 217.015~~[(56)]~~ and labeled in accordance with subsection (3) of this section
4 shall not be required to be tested in determining whether or not the food product is
5 an acid food, acidified food product, formulated acid food product, or low-acid
6 food.

7 (7) The processing facilities of a home-based processor may be inspected annually by
8 the cabinet.

9 (8) A home-based processor shall be subject to food sampling and inspection if it is
10 determined that its food product is misbranded pursuant to subsection (4) of this
11 section or adulterated, or if a consumer complaint has been received.

12 (9) If the cabinet has reason to believe that an imminent health hazard exists it may
13 invoke cessation of production until it deems that the hazardous situation has been
14 addressed to the satisfaction of the cabinet.

15 (10) The cabinet shall promulgate administrative regulations to further delineate which
16 food products are subject to the definition of home-based processor, as defined in
17 KRS 217.015~~[(56)]~~.

18 (11) No later than January 1, 2020, the cabinet shall develop and implement a
19 registration system for home-based processors.

20 (12) Beginning January 1, 2020, a home-based processor shall be registered with the
21 cabinet and include the following information:

22 (a) The name of the home-based processor and the physical address where
23 production or processing will occur; and

24 (b) A listing of the food products to be produced or processed.

25 ➔Section 7. KRS 217.137 is amended to read as follows:

26 (1) The secretary shall promulgate administrative regulations to accommodate the
27 specific circumstances of home-based microprocessors. In order to protect public

1 health while encouraging the marketing of home-processed foods, the
2 administrative regulations shall include, at a minimum, standards for:

- 3 (a) Installation, design, location, and maintenance of toilet rooms;
- 4 (b) Installation and maintenance of hand-washing facilities;
- 5 (c) Manual and mechanical cleaning and sanitizing processes;
- 6 (d) Installation and location of equipment;
- 7 (e) Construction and covering of floors; and
- 8 (f) Construction, materials, and maintenance of walls and ceilings.

9 (2) Food products that are produced or processed by a home-based microprocessor and
10 in compliance with administrative regulations promulgated pursuant to subsection
11 (1) of this section are acceptable food products that may only be offered for sale by
12 farmers markets, certified roadside stands, or on the processor's farm. These food
13 products may be used in preparing and serving food.

14 (3) The cabinet shall promulgate administrative regulations to further delineate which
15 food products are subject to the definition of home-based microprocessor, as
16 defined in KRS 217.015~~[(57)]~~.

17 ➔Section 8. KRS 304.17A-741 is amended to read as follows:

18 When an audit of the records of a pharmacy is conducted by an auditing entity, it shall be
19 subject to the following conditions:

- 20 (1) The auditing entity shall give at least thirty (30) days' written notice to the pharmacy
21 prior to conducting the audit for each audit to be conducted;
- 22 (2) An audit performed by the auditing entity that involves clinical or professional
23 judgment shall be conducted in consultation with a pharmacist;
- 24 (3) A pharmacy may use the records of a hospital, physician, or other practitioner as
25 defined in KRS 217.015~~[(35)]~~, or transmitted by any means of communication, for
26 purposes of validating pharmacy records with respect to orders or refills of a drug;
- 27 (4) An auditing entity shall not require a pharmacy to keep records for a period of time

- 1 longer than two (2) years, or as required by state or federal law or regulation;
- 2 (5) The recoupment of claims shall be based on the actual overpayment or
3 underpayment of claims unless the pharmacy agrees to a settlement to the contrary;
- 4 (6) A pharmacy shall be audited under the same standards and parameters as other
5 similarly situated pharmacies audited by the auditing entity;
- 6 (7) The period covered by the audit shall not exceed two (2) years from the date the
7 claim was submitted for payment except if a longer period is allowed by federal law
8 or if there is evidence of fraud;
- 9 (8) An audit shall not be scheduled during the first seven (7) calendar days of any
10 month, unless consented to by the pharmacy;
- 11 (9) A preliminary audit report shall be delivered to the pharmacy within one hundred
12 twenty (120) days after the exit interview;
- 13 (10) A final audit report shall be delivered to the pharmacy within six (6) months after
14 receipt of the preliminary audit report or after all appeals have been exhausted,
15 whichever is later;
- 16 (11) The auditing entity shall allow a pharmacy at least thirty (30) days following receipt
17 of the preliminary audit report to produce documentation to address any
18 discrepancies found during an audit;
- 19 (12) The final audit report shall provide claim-level detail of the amounts and reasons for
20 each claim recovery found due. If no amounts have been found due, the final audit
21 report shall so state;
- 22 (13) The auditing entity shall not receive payment based on the amount recovered in an
23 audit;
- 24 (14) The auditing entity shall conduct an exit interview at the close of the audit. The exit
25 interview shall be conducted at a time agreed to by the audited pharmacy. The
26 interview shall provide the audited pharmacy an opportunity to:
- 27 (a) Respond to questions from the auditing entity;

- 1 (b) Review and comment on the initial findings of the auditing entity; and
- 2 (c) Provide additional documentation to clarify the initial findings of the auditing
- 3 entity;
- 4 (15) If an audit results in the identification of any clerical or recordkeeping errors such as
- 5 typographical errors, scrivener's errors, omissions, or computer errors, the pharmacy
- 6 shall not be subject to recoupment of funds by the auditing entity unless the auditing
- 7 entity can provide proof of intent to commit fraud or the error results in an actual
- 8 overpayment to the pharmacy or the wrong medication being dispensed to the
- 9 patient. The pharmacy shall have the right to submit amended claims within thirty
- 10 (30) days of the discovery of an error to correct clerical or recordkeeping errors in
- 11 lieu of recoupment if the prescription was dispensed according to requirements set
- 12 forth in state or federal law;
- 13 (16) In the case of overpayment, the auditing entity may seek a refund or recoupment of
- 14 the overpayment in accordance with KRS 304.17A-712. The amount refunded or
- 15 recouped shall be limited to the amount paid to the pharmacy minus the amount that
- 16 should have been paid to the pharmacy absent the overpayment and shall not
- 17 include the dispensing fee if the correct medication was dispensed to the patient;
- 18 and
- 19 (17) Claims shall be paid pursuant to KRS 304.17A-702.
- 20 ➔Section 9. KRS 315.010 is amended to read as follows:
- 21 As used in this chapter, unless the context requires otherwise:
- 22 (1) "Administer" means the direct application of a drug to a patient or research subject
- 23 by injection, inhalation, or ingestion, whether topically or by any other means;
- 24 (2) "Administrative activities of a pharmacy" means the following functions performed
- 25 by a pharmacy adhering to all local, state, and federal patient privacy laws:
- 26 (a) Investigating and researching a patient's insurance benefits and updating the
- 27 patient profile regarding insurance coverage;

- 1 (b) Billing and collections activities, including:
- 2 1. Contacting patients for copayments and coinsurance payments; and
- 3 2. Communicating with insurance companies;
- 4 (c) Performing patient financial assistance activities and updating patient records
- 5 accordingly;
- 6 (d) Opening faxes and accessing electronic prescriptions for the purposes of
- 7 setting up patient demographic and insurance profiles, excluding height,
- 8 weight, and allergy information, so long as the activity does not involve the
- 9 entering of a prescription order into the dispensing or medication management
- 10 system;
- 11 (e) Initiating insurance prior authorizations for submission to the licensed
- 12 pharmacy, including communications with the prescribing physician to
- 13 collect, record, and transmit information to insurance companies, so long as
- 14 the activity does not include the authorization or receipt of new or refill
- 15 prescription orders;
- 16 (f) Answering and transferring telephone calls, whether or not such calls require
- 17 accessing a patient record, so long as the call does not involve the
- 18 interpretation, evaluation, or implementation of a drug order; and
- 19 (g) Communicating with patients via telephone or electronically regarding refill
- 20 reminders, so long as the communication does not involve the interpretation,
- 21 evaluation, or implementation of a drug order and a pharmacist is readily
- 22 available for patient consultation;
- 23 (3) "Association" means the Kentucky Pharmacists Association;
- 24 (4) "Board" means the Kentucky Board of Pharmacy;
- 25 (5) "Collaborative care agreement" means a written agreement between a pharmacist or
- 26 pharmacists and a practitioner or practitioners that outlines a plan of cooperative
- 27 management of patients' drug-related health care needs where:

- 1 (a) Patients' drug-related health care needs fall within the practitioner's or
2 practitioners' statutory scope of practice;
- 3 (b) Patients are referred by the practitioner or practitioners to the pharmacist or
4 pharmacists; and
- 5 (c) The agreement:
- 6 1. Identifies the practitioner or practitioners and the pharmacist or
7 pharmacists who are parties to the agreement;
- 8 2. Specifies the drug-related regimen to be provided, and how drug therapy
9 is to be monitored; and
- 10 3. Stipulates the conditions for initiating, continuing, or discontinuing drug
11 therapy and conditions which warrant modifications to dose, dosage
12 regimen, dosage form, or route of administration;
- 13 (6) "Compound" or "compounding" means the preparation or labeling of a drug
14 pursuant to or in anticipation of a valid prescription drug order, including but not
15 limited to packaging, intravenous admixture or manual combination of drug
16 ingredients. "Compounding," as used in this chapter, shall not preclude simple
17 reconstitution, mixing, or modification of drug products prior to administration by
18 nonpharmacists;
- 19 (7) "Confidential information" means information which is accessed or maintained by a
20 pharmacist in a patient's record, or communicated to a patient as part of patient
21 counseling, whether it is preserved on paper, microfilm, magnetic media, electronic
22 media, or any other form;
- 23 (8) "Continuing education unit" means ten (10) contact hours of board approved
24 continuing pharmacy education. A "contact hour" means fifty (50) continuous
25 minutes without a break period;
- 26 (9) "Dispense" or "dispensing" means to deliver one (1)
27 drug in a suitable container, appropriately labeled for subsequent administration to

- 1 or use by a patient or other individual entitled to receive the prescription drug;
- 2 (10) "Drug" means any of the following:
- 3 (a) Articles recognized as drugs or drug products in any official compendium or
- 4 supplement thereto;
- 5 (b) Articles, other than food, intended to affect the structure or function of the
- 6 body of man or other animals;
- 7 (c) Articles, including radioactive substances, intended for use in the diagnosis,
- 8 cure, mitigation, treatment or prevention of disease in man or other animals;
- 9 or
- 10 (d) Articles intended for use as a component of any articles specified in
- 11 paragraphs (a) to (c) of this subsection;
- 12 (11) "Drug regimen review" means retrospective, concurrent, and prospective review by
- 13 a pharmacist of a patient's drug-related history, including but not limited to the
- 14 following areas:
- 15 (a) Evaluation of prescription drug orders and patient records for:
- 16 1. Known allergies;
- 17 2. Rational therapy contraindications;
- 18 3. Appropriate dose and route of administration;
- 19 4. Appropriate directions for use; or
- 20 5. Duplicative therapies;
- 21 (b) Evaluation of prescription drug orders and patient records for drug-drug, drug-
- 22 food, drug-disease, and drug-clinical laboratory interactions;
- 23 (c) Evaluation of prescription drug orders and patient records for adverse drug
- 24 reactions; or
- 25 (d) Evaluation of prescription drug orders and patient records for proper
- 26 utilization and optimal therapeutic outcomes;
- 27 (12) "Immediate supervision" means under the physical and visual supervision of a

1 pharmacist;

2 (13) "Manufacturer" or "virtual manufacturer" of a product means:

3 (a) A person that holds an application approved under 21 U.S.C. sec. 355 or a
4 license issued under 42 U.S.C. sec. 262 for such product, or if such product is
5 not the subject of an approved application or license, the person who
6 manufactured the product;

7 (b) A co-licensed partner of the person described in paragraph (a) of this
8 subsection that obtains the product directly from a person described in this
9 paragraph or paragraph (a) of this subsection;

10 (c) An affiliate of a person described in paragraph (a) or (b) of this subsection
11 who receives the product directly from a person described in this paragraph or
12 in paragraph (a) or (b) of this subsection; or

13 (d) Any person, except a pharmacist compounding in the normal course of
14 professional practice;

15 (14) "Medical order" means a lawful order of a specifically identified practitioner for a
16 specifically identified patient for the patient's health care needs. "Medical order"
17 may or may not include a prescription drug order;

18 (15) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold
19 without a prescription and are prepackaged and labeled for use by the consumer in
20 accordance with the requirements of the statutes and regulations of this state and the
21 federal government;

22 (16) "Outsourcing facility" means a facility at one (1) geographic location or address
23 that:

24 (a) Is engaged in the compounding of human sterile drugs without a patient-
25 specific prescription;

26 (b) Has registered as an outsourcing facility with the secretary of the United
27 States Department of Health and Human Services, Food and Drug

1 Administration; and

2 (c) Complies with all applicable state and federal requirements;

3 (17) "Pharmacist" means a natural person licensed by this state to engage in the practice
4 of the profession of pharmacy;

5 (18) "Pharmacist intern" means a natural person who is:

6 (a) Currently certified by the board to engage in the practice of pharmacy under
7 the direction of a licensed pharmacist and who satisfactorily progresses
8 toward meeting the requirements for licensure as a pharmacist;

9 (b) A graduate of an approved college or school of pharmacy or a graduate who
10 has established educational equivalency by obtaining a Foreign Pharmacy
11 Graduate Examination Committee (FPGEC) certificate, who is currently
12 licensed by the board for the purpose of obtaining practical experience as a
13 requirement for licensure as a pharmacist;

14 (c) A qualified applicant awaiting examination for licensure as a pharmacist or
15 the results of an examination for licensure as a pharmacist; or

16 (d) An individual participating in a residency or fellowship program approved by
17 the board for internship credit;

18 (19) "Pharmacy" means every place where:

19 (a) Drugs are dispensed under the direction of a pharmacist;

20 (b) Prescription drug orders are compounded under the direction of a pharmacist;
21 or

22 (c) A registered pharmacist maintains patient records and other information for
23 the purpose of engaging in the practice of pharmacy, whether or not
24 prescription drug orders are being dispensed;

25 (20) "Pharmacy-related primary care" means the pharmacists' activities in patient
26 education, health promotion, and assistance in the selection and use of over-the-
27 counter drugs and appliances for the treatment of common diseases and injuries, as

1 well as those other activities falling within their statutory scope of practice;

2 (21) "Pharmacy technician" means a natural person who works under the immediate
3 supervision, or general supervision if otherwise provided for by statute or
4 administrative regulation, of a pharmacist for the purpose of assisting a pharmacist
5 with the practice of pharmacy;

6 (22) "Practice of pharmacy" means interpretation, evaluation, and implementation of
7 medical orders and prescription drug orders; responsibility for dispensing
8 prescription drug orders, including radioactive substances; participation in drug and
9 drug-related device selection; administration of medications or biologics in the
10 course of dispensing or maintaining a prescription drug order; the administration of
11 adult immunizations pursuant to prescriber-approved protocols; the administration
12 of immunizations to individuals nine (9) to seventeen (17) years of age pursuant to
13 prescriber-approved protocols with the consent of a parent or guardian; the
14 administration of immunizations to a child as defined in KRS 214.032, pursuant to
15 protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen
16 review; maintenance of patient pharmacy records; and provision of patient
17 counseling and those professional acts, professional decisions, or professional
18 services necessary to maintain and manage all areas of a patient's pharmacy-related
19 care, including pharmacy-related primary care as defined in this section;

20 (23) "Practitioner" has the same meaning given in KRS 217.015~~[(35)]~~;

21 (24) "Prescription drug" means a drug which:

22 (a) Under federal law is required to be labeled with either of the following
23 statements:

- 24 1. "Caution: Federal law prohibits dispensing without prescription";
- 25 2. "Caution: Federal law restricts this drug to use by, or on the order of, a
26 licensed veterinarian";
- 27 3. "Rx Only"; or

- 1 4. "Rx"; or
- 2 (b) Is required by any applicable federal or state law or administrative regulation
- 3 to be dispensed only pursuant to a prescription drug order or is restricted to
- 4 use by practitioners;
- 5 (25) "Prescription drug order" means an original or new order from a practitioner for
- 6 drugs, drug-related devices or treatment for a human or animal, including orders
- 7 issued through collaborative care agreements or protocols authorized by the board.
- 8 Lawful prescriptions result from a valid practitioner-patient relationship, are
- 9 intended to address a legitimate medical need, and fall within the prescribing
- 10 practitioner's scope of professional practice;
- 11 (26) "Society" means the Kentucky Society of Health-Systems Pharmacists;
- 12 (27) "Supervision" means the presence of a pharmacist on the premises to which a
- 13 pharmacy permit is issued, who is responsible, in whole or in part, for the
- 14 professional activities occurring in the pharmacy; and
- 15 (28) "Wholesaler" means any person who legally buys drugs for resale or distribution to
- 16 persons other than patients or consumers.

17 ➔Section 10. KRS 411.600 is amended to read as follows:

18 For purposes of KRS 411.600 to 411.640:

- 19 (1) "Claim" means any claim by or on behalf of a natural person, as well as any
- 20 derivative or other claim arising therefrom asserted by or on behalf of any other
- 21 person;
- 22 (2) "Food establishment" means:
- 23 (a) Any entity required to hold a permit pursuant to KRS 217.125; or
- 24 (b) Any other manufacturer, packer, distributor, carrier, holder, seller, marketer,
- 25 or advertiser of food as defined in KRS 217.015~~[(18)]~~ or 21 U.S.C. sec.
- 26 321(f);
- 27 (3) "Generally known condition allegedly caused by or allegedly likely to result from

1 long-term consumption" means a condition generally known to result or to likely
2 result from the cumulative effect of consumption, and not from a single instance of
3 consumption; and

4 (4) "Knowing and willful violation" means that the conduct constituting the violation
5 was committed with the intent to deceive or injure consumers or with actual
6 knowledge that the conduct was injurious to consumers, and the conduct
7 constituting the violation was not required by regulations, orders, rules, or other
8 pronouncements of, or any statutes administered by, a federal, state, or local
9 government agency.