

1 AN ACT relating to opioid overdose reversal agents.

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

3 ➔Section 1. KRS 15.291 is amended to read as follows:

4 (1) There is hereby established the Kentucky Opioid Abatement Advisory Commission.
5 The commission shall be attached to the Department of Law for administrative
6 purposes.

7 (2) (a) The commission shall consist of the following voting members:

- 8 1. The Attorney General or his or her designee, who shall act as chair;
- 9 2. The State Treasurer or his or her designee;
- 10 3. The secretary of the Cabinet for Health and Family Services or his or her
11 designee;
- 12 4. One (1) member appointed by the University of Kentucky from the
13 HEALing Communities Study Team;
- 14 5. One (1) member appointed by the Attorney General representing victims
15 of the opioid crisis;
- 16 6. One (1) member appointed by the Attorney General representing the
17 drug treatment and prevention community;
- 18 7. One (1) member appointed by the Attorney General representing law
19 enforcement; and
- 20 8. Two (2) citizens at large appointed by the Attorney General.

21 (b) The commission shall consist of the following nonvoting members who shall
22 serve at the pleasure of their appointing authority:

- 23 1. One (1) member appointed by the Speaker of the House of
24 Representatives; and
- 25 2. One (1) member appointed by the President of the Senate.

26 (3) (a) Members of the commission appointed under subsection (2)(a)1. to 3. of this
27 section shall serve terms concurrent with holding their respective offices or

1 positions.

2 (b) The remaining members of the commission shall serve staggered two (2) year
3 terms as follows:

4 1. Members of the commission appointed under subsection (2)(a)4. to 6. of
5 this section shall serve an initial term of two (2) years; and

6 2. Members of the commission appointed under subsection (2)(a)7. to 8. of
7 this section shall serve an initial term of one (1) year.

8 (c) Members of the commission shall not receive compensation for their services
9 but may be reimbursed for necessary travel and lodging expenses incurred in
10 the performance of their duties.

11 (4) (a) Meetings of the commission shall be conducted according to KRS 61.800 to
12 61.850.

13 (b) The commission shall meet at least twice within each calendar year.

14 (c) Five (5) voting members of the commission shall constitute a quorum for the
15 transaction of business.

16 (d) Each member of the commission shall have one (1) vote, with all actions
17 being taken by an affirmative vote of the majority of members present.

18 (5) The commission shall award moneys from the opioid abatement trust fund
19 established in KRS 15.293 to reimburse prior expenses or to fund projects
20 according to the following criteria related to opioid use disorder (OUD) or any co-
21 occurring substance use disorder or mental health (SUD/MH) issues:

22 (a) Reimbursement for:

23 1. Any portion of the cost related to outpatient and residential treatment
24 services, including:

25 a. Services provided to incarcerated individuals;

26 b. Medication-assisted treatment;

27 c. Abstinence-based treatment; and

- 1 d. Treatment, recovery, or other services provided by community
- 2 health centers or not-for-profit providers;
- 3 2. Emergency response services provided by law enforcement or first
- 4 responders; or
- 5 3. Any portion of the cost of administering *an opioid overdose reversal*
- 6 *agent, as defined in Section 2 of this Act*~~[naloxone]~~; or
- 7 (b) Provide funding for any project which:
- 8 1. Supports intervention, treatment, and recovery services provided to
- 9 persons:
- 10 a. With OUD or co-occurring SUD/MH issues; or
- 11 b. Who have experienced an opioid overdose;
- 12 2. Supports detoxification services, including:
- 13 a. Medical detoxification;
- 14 b. Referral to treatment; or
- 15 c. Connections to other services;
- 16 3. Provides access to opioid-abatement-related housing, including:
- 17 a. Supportive housing; or
- 18 b. Recovery housing;
- 19 4. Provides or supports transportation to treatment or recovery programs or
- 20 services;
- 21 5. Provides employment training or educational services for persons in
- 22 treatment or recovery;
- 23 6. Creates or supports centralized call centers that provide information and
- 24 connections to appropriate services;
- 25 7. Supports crisis stabilization centers that serve as an alternative to
- 26 hospital emergency departments for persons with OUD and any co-
- 27 occurring SUD/MH issues or persons that have experienced an opioid

- 1 overdose;
- 2 8. Improves oversight of opioid treatment programs to ensure evidence-
- 3 based and evidence-informed practices;
- 4 9. Provides scholarships and support for certified addiction counselors and
- 5 other mental and behavioral health providers, including:
- 6 a. Training scholarships;
- 7 b. Fellowships;
- 8 c. Loan repayment programs; or
- 9 d. Incentives for providers to work in rural or underserved areas of
- 10 the Commonwealth;
- 11 10. Provides training on medication-assisted treatment for health care
- 12 providers, students, or other supporting professionals;
- 13 11. Supports efforts to prevent over-prescribing and ensures appropriate
- 14 prescribing and dispensing of opioids;
- 15 12. Supports enhancements or improvements consistent with state law for
- 16 prescription drug monitoring programs;
- 17 13. Supports the education of law enforcement or other first responders
- 18 regarding appropriate practices and precautions when dealing with
- 19 opioids or individuals with OUD or co-occurring SUD/MH issues;
- 20 14. Supports opioid-related emergency response services provided by law
- 21 enforcement or first responders;
- 22 15. Treats mental health trauma issues resulting from the traumatic
- 23 experiences of opioid users or their family members;
- 24 16. Engages nonprofits, the faith community, and community coalitions to
- 25 support prevention and treatment, and to support family members in
- 26 their efforts to care for opioid users in their family;
- 27 17. Provides recovery services, support, and prevention services for women

- 1 who are pregnant, may become pregnant, or who are parenting with
2 OUD or co-occurring SUD/MH issues;
- 3 18. Trains healthcare providers that work with pregnant or parenting women
4 on best practices for compliances with federal requirements that children
5 born with Neonatal Abstinence Syndrome get referred to appropriate
6 services and receive a plan of care;
- 7 19. Addresses Neonatal Abstinence Syndrome, including prevention,
8 education, and treatment of OUD and any co-occurring SUD/MH issues;
- 9 20. Offers home-based wrap-around services to persons with OUD and any
10 co-occurring SUD/MH issues, including parent-skills training;
- 11 21. Supports positions and services, including supportive housing and other
12 residential services relating to children being removed from the home or
13 placed in foster care due to custodial opioid use;
- 14 22. Provides public education about opioids or opioid disposal;
- 15 23. Provides drug take-back disposal or destruction programs;
- 16 24. Covers the cost of administering opioid overdose reversal agents, as
17 defined in Section 2 of this Act~~[naloxone]~~;
- 18 25. Supports pre-trial services that connect individuals with OUD and any
19 co-occurring SUD/MH issues to evidence-informed treatment and
20 related services;
- 21 26. Supports treatment and recovery courts for persons with OUD and any
22 co-occurring SUD/MH issues, but only if they provide referrals to
23 evidence-informed treatment;
- 24 27. Provides evidence-informed treatment, recovery support, harm
25 reduction, or other appropriate services to individuals with OUD and
26 any co-occurring SUD/MH issues who are incarcerated, leaving jail or
27 prison, have recently left jail or prison, are on probation or parole, are

1 under community corrections supervision, or are in re-entry programs or
2 facilities;

3 28. Meets the criteria included in any settlement agreement or judgment
4 between the parties listed in KRS 15.293(3)(a); or

5 29. Any other project deemed appropriate for opioid-abatement purposes by
6 the commission.

7 (6) The commission may identify additional duties or responsibilities, including:

8 (a) Reporting on projects and programs related to addressing the opioid epidemic;

9 (b) Developing priorities, goals, and recommendations for spending on the
10 projects and programs;

11 (c) Working with state agencies or outside entities to develop measures for
12 projects and programs that address substance use disorders; or

13 (d) Making recommendations for policy changes on a state or local level,
14 including statutory law and administrative regulations.

15 (7) The commission shall:

16 (a) Create and maintain a Web site on which it shall publish its minutes,
17 attendance rolls, funding awards, and reports of funding by recipients; and

18 (b) Promulgate administrative regulations to implement this section. The
19 commission may promulgate emergency administrative regulations to take
20 effect immediately so that funds may be distributed more quickly and
21 efficiently to combat the opioid epidemic.

22 ➔Section 2. KRS 217.015 is amended to read as follows:

23 For the purposes of KRS 217.005 to 217.215:

24 (1) "Advertisement" means all representations, disseminated in any manner or by any
25 means, other than by labeling, for the purpose of inducing, or which are likely to
26 induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;

27 (2) "Bread" and "enriched bread" mean only the foods commonly known and described

1 as white bread, white rolls, white buns, enriched white bread, enriched rolls, and
2 enriched white buns, as defined under the federal act. For the purposes of KRS
3 217.136 and 217.137, "bread" or "enriched bread" also means breads that may
4 include vegetables or fruit as an ingredient;

5 (3) "Cabinet" means the Cabinet for Health and Family Services or its designee;

6 (4) "Color" means but is not limited to black, white, and intermediate grays;

7 (5) "Color additive" means a material that:

8 (a) Is a dye, pigment, or other substance made by a process of synthesis or similar
9 artifice, or extracted, isolated, or otherwise derived, with or without
10 intermediate or final change of identity, from a vegetable, animal, mineral, or
11 other source. Nothing in this paragraph shall be construed to apply to any
12 pesticide chemical, soil or plant nutrient, or other agricultural chemical solely
13 because of its effect in aiding, retarding, or otherwise affecting, directly or
14 indirectly, the growth or other natural physiological process of produce of the
15 soil and thereby affecting its color, whether before or after harvest; or

16 (b) When added or applied to a food, drug, or cosmetic, or to the human body or
17 any part thereof, is capable, alone or through reaction with another substance,
18 of imparting color. "Color additive" does not include any material that has
19 been or may in the future be exempted under the federal act;

20 (6) "Contaminated with filth" means any food, drug, device, or cosmetic that is not
21 securely protected from dust, dirt, and as far as may be necessary by all reasonable
22 means, from all foreign or injurious contaminants;

23 (7) "Cosmetic" means:

24 (a) Articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into,
25 or otherwise applied to the human body or any part thereof for cleansing,
26 beautifying, promoting attractiveness, or altering the appearance; and

27 (b) Articles intended for use as a component of those articles, except that the term

1 shall not include soap;

2 (8) "Device," except when used in subsection (48) of this section, KRS 217.035(6),
3 KRS 217.065(3), KRS 217.095(3), and KRS 217.175(10), means instruments,
4 apparatus, and contrivances, including their components, parts, and accessories,
5 intended:

6 (a) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease
7 in man or other animals; or

8 (b) To affect the structure or any function of the body of man or other animals;

9 (9) "Dispense" means to deliver a drug or device to an ultimate user or research subject
10 by or pursuant to the lawful order of a practitioner, including the packaging,
11 labeling, or compounding necessary to prepare the substance for that delivery;

12 (10) "Dispenser" means a person who lawfully dispenses a drug or device to or for the
13 use of an ultimate user;

14 (11) "Drug" means:

15 (a) Articles recognized in the official United States pharmacopoeia, official
16 homeopathic pharmacopoeia of the United States, or official national
17 formulary, or any supplement to any of them;

18 (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or
19 prevention of disease in man or other animals;

20 (c) Articles, other than food, intended to affect the structure or any function of the
21 body of man or other animals; and

22 (d) Articles intended for use as a component of any article specified in this
23 subsection but does not include devices or their components, parts, or
24 accessories;

25 (12) "Enriched," as applied to flour, means the addition to flour of vitamins and other
26 nutritional ingredients necessary to make it conform to the definition and standard
27 of enriched flour as defined under the federal act;

- 1 (13) "Environmental Pesticide Control Act of 1972" means the Federal Environmental
2 Pesticide Control Act of 1972, Pub. L. 92-516, and all amendments thereto;
- 3 (14) "Fair Packaging and Labeling Act" means the Fair Packaging and Labeling Act as it
4 relates to foods and cosmetics, 15 U.S.C. secs. 1451 et seq., and all amendments
5 thereto;
- 6 (15) "Federal act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. secs. 301
7 et seq., 52 Stat. 1040 et seq., or amendments thereto;
- 8 (16) "Filled milk" means any milk, cream, or skimmed milk, whether or not condensed,
9 evaporated, concentrated, frozen, powdered, dried, or desiccated, to which has been
10 added, or which has been blended or compounded with, any fat or oil other than
11 milk fat, except the fat or oil of contained eggs and nuts and the fat or oil of
12 substances used for flavoring purposes only, so that the resulting product is an
13 imitation or semblance of milk, cream, skimmed milk, ice cream mix, ice cream, or
14 frozen desserts, whether or not condensed, evaporated, concentrated, frozen,
15 powdered, dried, or desiccated, whether in bulk or in containers, hermetically sealed
16 or unsealed. This definition does not mean or include any milk or cream from which
17 no part of the milk or butter fat has been extracted, whether or not condensed,
18 evaporated, concentrated, powdered, dried, or desiccated, to which has been added
19 any substance rich in vitamins, nor any distinctive proprietary food compound not
20 readily mistaken for milk or cream or for condensed, evaporated, concentrated,
21 powdered, dried, or desiccated milk or cream, if the compound is prepared and
22 designed for the feeding of infants or young children, sick or infirm persons, and
23 customarily used on the order of a physician, and is packed in individual containers
24 bearing a label in bold type that the contents are to be used for those purposes; nor
25 shall this definition prevent the use, blending, or compounding of chocolate as a
26 flavor with milk, cream, or skimmed milk, desiccated, whether in bulk or in
27 containers, hermetically sealed or unsealed, to or with which has been added,

1 blended or compounded no other fat or oil other than milk or butter fat;

2 (17) "Flour" means only the foods commonly known as flour, white flour, wheat flour,
3 plain flour, bromated flour, self-rising flour, self-rising white flour, self-rising
4 wheat flour, phosphated flour, phosphated white flour, and phosphated wheat flour,
5 defined under the federal act;

6 (18) "Food" means:

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

8 (b) Chewing gum; and

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

10 (19) "Food additive" means any substance the intended use of which results or may be
11 reasonably expected to result, directly or indirectly, in its becoming a component or
12 otherwise affecting the characteristics of any food, including any substance intended
13 for use in producing, manufacturing, packing, processing, preparing, treating,
14 packaging, transporting, or holding food; and including any source of radiation
15 intended for any of these uses, if the substance is not generally recognized, among
16 experts qualified by scientific training and experience to evaluate its safety, as
17 having been adequately shown through scientific procedures or, in the case of a
18 substance used in a food prior to January 1, 1958, through either scientific
19 procedures or experience based on common use in food to be safe under the
20 conditions of its intended use; except that the term does not include:

21 (a) A pesticide chemical in or on a raw agricultural commodity;

22 (b) A pesticide chemical to the extent that it is intended for use or is used in the
23 production, storage, or transportation of any raw agricultural commodity;

24 (c) A color additive; or

25 (d) Any substance used in accordance with a sanction or approval granted prior to
26 the enactment of the Food Additives Amendment of 1958, pursuant to the
27 federal act; the Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq.; or

1 the Meat Inspection Act of 1907; and amendments thereto;

2 (20) "Food processing establishment" means any commercial establishment in which
3 food is manufactured, processed, or packaged for human consumption, but does not
4 include retail food establishments, home-based processors, or home-based
5 microprocessors;

6 (21) "Food service establishment" means any fixed or mobile commercial establishment
7 that engages in the preparation and serving of ready-to-eat foods in portions to the
8 consumer, including but not limited to: restaurants; coffee shops; cafeterias; short
9 order cafes; luncheonettes; grills; tea rooms; sandwich shops; soda fountains;
10 taverns; bars; cocktail lounges; nightclubs; roadside stands; industrial feeding
11 establishments; private, public or nonprofit organizations or institutions routinely
12 serving food; catering kitchens; commissaries; charitable food kitchens; or similar
13 places in which food is prepared for sale or service on the premises or elsewhere
14 with or without charge. It does not include food vending machines, establishments
15 serving beverages only in single service or original containers, or retail food stores
16 which only cut, slice, and prepare cold-cut sandwiches for individual consumption;

17 (22) "Food storage warehouse" means any establishment in which food is stored for
18 subsequent distribution;

19 (23) "Immediate container" does not include package liners;

20 (24) "Imminent health hazard" means a significant threat or danger to health that is
21 considered to exist when there is evidence sufficient to show that a product,
22 practice, circumstance, or event creates a situation that requires immediate
23 correction or cessation of operation to prevent illness or injury based on:

24 (a) The number of potential illnesses or injuries; or

25 (b) The nature, severity, and duration of the anticipated illness or injury;

26 (25) "Interference" means threatening or otherwise preventing the performance of lawful
27 inspections or duties by agents of the cabinet during all reasonable times of

1 operation;

2 (26) "Label" means a display of written, printed, or graphic matter upon the immediate
3 container of any article; and a requirement made by or under authority of KRS
4 217.005 to 217.215 that any word, statement, or other information appearing on the
5 label shall not be considered to be complied with unless the word, statement, or
6 other information also appears on the outside container or wrapper, if any there be,
7 of the retail package of the article, or is easily legible through the outside container
8 or wrapper;

9 (27) "Labeling" means all labels and other written, printed, or graphic matter:

10 (a) Upon an article or any of its containers or wrappers; or

11 (b) Accompanying the article;

12 (28) "Legend drug" means a drug defined by the Federal Food, Drug and Cosmetic Act,
13 as amended, and under which definition its label is required to bear the statement
14 "Caution: Federal law prohibits dispensing without prescription.";

15 (29) "Meat Inspection Act" means the Federal Meat Inspection Act, 21 U.S.C. secs. 71 et
16 seq., 34 Stat. 1260 et seq., including any amendments thereto;

17 (30) "New drug" means:

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

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

26 (31) "Official compendium" means the official United States pharmacopoeia, official
27 homeopathic pharmacopoeia of the United States, official national formulary, or any

1 supplement to any of them;

2 (32) "Person" means an individual, firm, partnership, company, corporation, trustee,
3 association, or any public or private entity;

4 (33) "Pesticide chemical" means any substance that alone in chemical combination, or in
5 formulation with one or more other substances, is an "economic poison" within the
6 meaning of the Federal Insecticide, Fungicide and Rodenticide Act and amendments
7 thereto, and that is used in the production, storage, or transportation of raw
8 agricultural commodities;

9 (34) "Poultry Products Inspection Act" means the Federal Poultry and Poultry Products
10 Inspection Act, 21 U.S.C. secs. 451 et seq., Pub. L. 85-172, 71 Stat. 441, and any
11 amendments thereto;

12 (35) "Practitioner" means medical or osteopathic physicians, dentists, chiropractors, and
13 veterinarians who are licensed under the professional licensing laws of Kentucky to
14 prescribe and administer drugs and devices. "Practitioner" includes optometrists
15 when administering or prescribing pharmaceutical agents authorized in KRS
16 320.240(12) to (14), advanced practice registered nurses as authorized in KRS
17 314.011 and 314.042, physician assistants when administering or prescribing
18 pharmaceutical agents as authorized in KRS 311.858, and health care professionals
19 who are residents of and actively practicing in a state other than Kentucky and who
20 are licensed and have prescriptive authority under the professional licensing laws of
21 another state, unless the person's Kentucky license has been revoked, suspended,
22 restricted, or probated, in which case the terms of the Kentucky license shall
23 prevail;

24 (36) "Prescription" means a written or oral order for a drug or medicine, or combination
25 or mixture of drugs or medicines, or proprietary preparation, that is signed, given, or
26 authorized by a medical, advanced practice registered nurse, dental, chiropractor,
27 veterinarian, or optometric practitioner, and intended for use in the diagnosis, cure,

- 1 mitigation, treatment, or prevention of disease in man or other animals;
- 2 (37) "Prescription blank" means a document that conforms with KRS 217.216 and is
- 3 intended for prescribing a drug to an ultimate user;
- 4 (38) "Raw agricultural commodity" means any food in its raw or natural state, including
- 5 all fruits that are washed, colored, or otherwise treated in their unpeeled natural
- 6 form prior to marketing;
- 7 (39) "Retail food establishment" means any food service establishment, retail food store,
- 8 or a combination of both within the same establishment;
- 9 (40) "Retail food store" means any fixed or mobile establishment where food or food
- 10 products, including prepackaged, labeled sandwiches or other foods to be heated in
- 11 a microwave or infrared oven at the time of purchase, are offered for sale to the
- 12 consumer, and intended for off-premises consumption, but does not include
- 13 establishments which handle only prepackaged, snack-type, nonpotentially
- 14 hazardous foods, markets that offer only fresh fruits and vegetables for sale, food
- 15 service establishments, food and beverage vending machines, vending machine
- 16 commissaries, food processing establishments, or home-based processors;
- 17 (41) "Salvage distributor" means a person who engages in the business of distributing,
- 18 peddling, or otherwise trafficking in any salvaged merchandise;
- 19 (42) "Salvage processing plant" means an establishment operated by a person engaged in
- 20 the business of reconditioning, labeling, relabeling, repackaging, reconditioning,
- 21 sorting, cleaning, culling or who by other means salvages, sells, offers for sale, or
- 22 distributes for human or animal consumption or use any salvaged food, beverage,
- 23 including beer, wine and distilled spirits, vitamins, food supplements, dentifrices,
- 24 cosmetics, single-service food containers or utensils, containers and packaging
- 25 materials used for foods and cosmetics, soda straws, paper napkins, or any other
- 26 product of a similar nature that has been damaged or contaminated by fire, water,
- 27 smoke, chemicals, transit, or by any other means;

- 1 (43) "Second or subsequent offense" has the same meaning as it does in KRS 218A.010;
- 2 (44) "Secretary" means the secretary of the Cabinet for Health and Family Services;
- 3 (45) "Temporary food service establishment" means any food service establishment
- 4 which operates at a fixed location for a period of time, not to exceed fourteen (14)
- 5 consecutive days;
- 6 (46) "Traffic" has the same meaning as it does in KRS 218A.010;
- 7 (47) "Ultimate user" has the same meaning as it does in KRS 218A.010;
- 8 (48) If an article is alleged to be misbranded because the labeling is misleading, or if an
- 9 advertisement is alleged to be false because it is misleading, in determining whether
- 10 the labeling or advertisement is misleading, there shall be taken into account,
- 11 among other things, not only representations made or suggested by statement, word,
- 12 design, device, sound, or in any combination thereof, but also the extent to which
- 13 the labeling or advertisement fails to reveal facts that are material in the light of the
- 14 representations or material with respect to consequences which may result from the
- 15 use of the article to which the labeling or advertisement relates under the conditions
- 16 of use prescribed in the labeling or advertisement thereof or under the conditions of
- 17 use as are customary or usual;
- 18 (49) The representation of a drug in its labeling or advertisement as an antiseptic shall be
- 19 considered to be a representation that it is a germicide, except in the case of a drug
- 20 purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing,
- 21 ointment, dusting powder, or other use involving prolonged contact with the body;
- 22 (50) The provisions of KRS 217.005 to 217.215 regarding the selling of food, drugs,
- 23 devices, or cosmetics shall be considered to include the manufacture, production,
- 24 processing, packing, exposure, offer, possession, and holding of those articles for
- 25 sale, the sale, dispensing, and giving of those articles, and the supplying or applying
- 26 of those articles in the conduct of any food, drug, or cosmetic establishment;
- 27 (51) "Home" means a primary residence occupied by the processor, that contains only

- 1 two (2) ranges, ovens, or double-ovens, and no more than three (3) refrigerators
2 used for cold storage. This equipment shall have been designed for home use and
3 not for commercial use, and shall be operated in the kitchen within the residence;
- 4 (52) "Formulated acid food product" means an acid food in which the addition of a small
5 amount of low-acid food results in a finished equilibrium pH of 4.6 or below that
6 does not significantly differ from that of the predominant acid or acid food;
- 7 (53) "Acidified food product" means a low-acid food to which acid or acidic food is
8 added and which has a water activity value greater than 0.85, and a finished
9 equilibrium pH of 4.6 or below;
- 10 (54) "Low-acid food" means foods, other than alcoholic beverages, with a finished
11 equilibrium pH greater than 4.6, and a water activity value greater than 0.85;
- 12 (55) "Acid food" means foods that have a natural pH of 4.6 or below;
- 13 (56) "Home-based processor" means a person who in his or her home, produces or
14 processes non-potentially hazardous foods, including but not limited to dried herbs,
15 spices, nuts, candy, dried grains, whole fruit and vegetables, mixed-greens, jams,
16 jellies, sweet sorghum syrup, preserves, fruit butter, bread, fruit pies, cakes, or
17 cookies, and who has a gross income of no more than sixty thousand dollars
18 (\$60,000) annually from the sale of the products;
- 19 (57) "Home-based microprocessor" means a farmer who, in the farmer's home or
20 certified or permitted kitchen, produces or processes foods, including but not
21 limited to acid foods, formulated acid food products, acidified food products, or
22 low-acid canned foods, and who has a gross income of no more than sixty thousand
23 dollars (\$60,000) annually from the sale of the product;
- 24 (58) "Certified" means any person or home-based microprocessor who:
- 25 (a) Has attended the Kentucky Cooperative Extension Service's microprocessing
26 program or pilot microprocessing program and has been identified by the
27 Kentucky Cooperative Extension Service as having satisfactorily completed

1 the prescribed course of instruction; or

2 (b) Has attended some other school pursuant to 21 C.F.R. sec. 114.10;

3 (59) "Farmer" means a person who is a resident of Kentucky and owns or rents
4 agricultural land pursuant to subsection (9) of KRS 132.010 or horticultural land
5 pursuant to subsection (10) of KRS 132.010. For the purposes of KRS 217.136 to
6 217.139, "farmer" also means any person who is a resident of Kentucky and has
7 grown the primary horticultural and agronomic ingredients used in the home-based
8 microprocessed products which they have produced;~~and~~

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

15 (61) "Opioid overdose reversal agent" means a substance or device approved by the
16 United States Food and Drug Administration for the reversal of an opioid
17 overdose.

18 ➔Section 3. KRS 217.177 is amended to read as follows:

19 (1) No person engaged in sales at retail shall display hypodermic syringes or needles in
20 any portion of the place of business which is open or accessible to the public.

21 (2) Pharmacies offering retail sale of hypodermic syringes or needles shall make
22 available:

23 (a) Written or electronic educational materials on safe and proper disposal of
24 hypodermic needles and syringes;

25 (b) Written or electronic educational or referral information for syringe exchange
26 service programs and substance use disorder treatment; and

27 (c) A verbal, physical, or electronic offer to provide a ~~naloxone~~ prescription for

1 an opioid overdose reversal agent.

2 (3) Nothing in this section shall apply to the sale of hypodermic syringes or needles
3 dispensed as a prescription or in conjunction with a prescription medication that
4 requires reconstitution or administration with a syringe.

5 (4) Any physician, other licensed medical person, hospital, or clinic disposing of
6 hypodermic syringes or needles shall render the instrument incapable of further use.

7 ➔Section 4. KRS 217.186 is amended to read as follows:

8 (1) A licensed health-care provider who, acting in good faith, directly or by standing
9 order, prescribes or dispenses an opioid overdose reversal agent~~[the drug naloxone]~~
10 to a person or agency who, in the judgment of the health-care provider, is capable of
11 administering the drug for an emergency opioid overdose, shall not, as a result of
12 his or her acts or omissions, be subject to disciplinary or other adverse action under
13 KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute. As
14 used in this subsection, "licensed health-care provider" includes a pharmacist as
15 defined in KRS 315.010 who holds a separate certification issued by the Kentucky
16 Board of Pharmacy authorizing the initiation of the dispensing of an opioid
17 overdose reverse agent~~[naloxone]~~ under subsection (5) of this section.

18 (2) A prescription for an opioid overdose reversal agent~~[naloxone]~~ may include
19 authorization for administration of the drug to the person for whom it is prescribed
20 by a third party if the prescribing instructions indicate the need for the third party
21 upon administering the drug to immediately notify a local public safety answering
22 point of the situation necessitating the administration.

23 (3) A person or agency, including a peace officer, jailer, firefighter, paramedic, or
24 emergency medical technician or a school employee authorized to administer
25 medication under KRS 156.502, may:

26 (a) Receive a prescription for an opioid overdose reversal agent~~[the drug~~
27 ~~naloxone]~~;

- 1 (b) Possess *an opioid overdose reversal agent*~~[naloxone]~~ pursuant to this
2 subsection and any equipment needed for its administration; and
- 3 (c) Administer *an opioid overdose reversal agent*~~[naloxone]~~ to an individual
4 suffering from an apparent opiate-related overdose.
- 5 (4) A person acting in good faith who administers *an opioid overdose reversal*
6 *agent*~~[naloxone]~~ received under this section shall be immune from criminal and
7 civil liability for the administration, unless personal injury results from the gross
8 negligence or willful or wanton misconduct of the person administering the drug.
- 9 (5) (a) The Board of Pharmacy, in consultation with the Kentucky Board of Medical
10 Licensure, shall promulgate administrative regulations to establish
11 certification, educational, operational, and protocol requirements to
12 implement this section.
- 13 (b) Administrative regulations promulgated under this subsection shall:
- 14 1. Require that any dispensing under this section be done only in
15 accordance with a physician-approved protocol and specify the
16 minimum required components of any such protocol;
- 17 2. Include a required mandatory education requirement as to the
18 mechanism and circumstances for the administration of *an opioid*
19 *overdose reversal agent*~~[naloxone]~~ for the person to whom the *opioid*
20 *overdose reversal agent*~~[naloxone]~~ is dispensed; and
- 21 3. Require that a record of the dispensing be made available to a physician
22 signing a protocol under this subsection, if desired by the physician.
- 23 (c) Administrative regulations promulgated under this subsection may include:
- 24 1. A supplemental educational or training component for a pharmacist
25 seeking certification under this subsection; and
- 26 2. A limitation on the forms of *opioid overdose reversal agent*~~[naloxone]~~
27 and means of its administration that may be dispensed pursuant to this

1 subsection.

- 2 (6) (a) The board of each local public school district and the governing body of each
3 private and parochial school or school district may permit a school to keep
4 opioid overdose reversal agents~~[naloxone]~~ on the premises and regulate the
5 administration of an opioid overdose reversal agent~~[naloxone]~~ to any
6 individual suffering from an apparent opiate-related overdose.
- 7 (b) In collaboration with local health departments, local health providers, and
8 local schools and school districts, the Kentucky Department for Public Health
9 shall develop clinical protocols to address supplies of opioid overdose
10 reversal agents~~[naloxone]~~ kept by schools under this section and to advise on
11 the clinical administration of opioid overdose reversal agents~~[naloxone]~~.
- 12 (7) Notwithstanding any provision of law to the contrary, a pharmacist may utilize the
13 protocol established by this section to dispense an opioid overdose reversal
14 agent~~[naloxone]~~ to any person or agency who provides training on the mechanism
15 and circumstances for the administration of an opioid overdose reversal
16 agent~~[naloxone]~~ to the public as part of a harm reduction program, regardless of
17 whom the ultimate user of the opioid overdose reversal agent~~[naloxone]~~ may be.
18 The documentation of the dispensing of an opioid overdose reversal
19 agent~~[naloxone]~~ to any person or agency operating a harm reduction program shall
20 satisfy any general documentation or recording requirements found in
21 administrative regulations regarding legend drugs promulgated pursuant to this
22 chapter.