CHAPTER 51

(HB 459)

AN ACT relating to health care practitioners.

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

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

For the purposes of KRS 217.005 to 217.215:

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

(2) "Bread" and "enriched bread" mean only the foods commonly known and described as white bread, white rolls, white buns, enriched white bread, enriched rolls, and enriched white buns, as defined under the federal act;

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

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

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

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

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

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

(7) "Cosmetic" means:

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

(b) Articles intended for use as a component of those articles, except that the term shall not include soap;

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

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

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

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

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

(11) "Drug" means:

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

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

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

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

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

(13) "Environmental Pesticide Control Act of 1972" means the Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, and all amendments thereto;

(14) "Fair Packaging and Labeling Act" means the Fair Packaging and Labeling Act as it relates to foods and cosmetics, 15 U.S.C. secs. 1451 et seq., and all amendments thereto;

(15) "Federal act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. secs. 301 et seq., 52 Stat. 1040 et seq., or amendments thereto;

(16) "Filled milk" means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, frozen, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, except the fat or oil of contained eggs and nuts and the fat or oil of substances used for flavoring purposes only, so that the resulting product is an imitation or semblance of milk, cream, skimmed milk, ice cream mix, ice cream, or frozen desserts, whether or not condensed, evaporated, concentrated, frozen, powdered, dried, or desiccated, whether in bulk or in containers, hermetically sealed or unsealed. This definition does not mean or include any milk or cream from which no part of the milk or butter fat has been extracted, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added any substance rich in vitamins, nor any distinctive proprietary food compound not readily mistaken for milk or cream or for condensed, evaporated, concentrated, powdered, dried, or desiccated milk or cream, if the compound is prepared and designed for the feeding of infants or young children, sick or infirm persons, and customarily used on the order of a physician, and is packed in individual containers bearing a label in bold type that the

contents are to be used for those purposes; nor shall this definition prevent the use, blending, or compounding of chocolate as a flavor with milk, cream, or skimmed milk, desiccated, whether in bulk or in containers, hermetically sealed or unsealed, to or with which has been added, blended or compounded no other fat or oil other than milk or butter fat;

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

(18) "Food" means:

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

(b) Chewing gum; and

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

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

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

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

(c) A color additive; or

(d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act; the Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq.; or the Meat Inspection Act of 1907; and amendments thereto;

(20) "Food processing establishment" means any commercial establishment in which food is manufactured, processed, or packaged for human consumption, but does not include retail food establishments;

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

containers, or retail food stores which only cut, slice, and prepare cold-cut sandwiches for individual consumption;

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

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

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

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

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

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

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

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

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

(b) Accompanying the article;

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

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

(30) "New drug" means:

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

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

(31) "Official compendium" means the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them;

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

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

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

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

(36) "Prescription" means a written or oral order for a drug or medicine, or combination or mixture of drugs or medicines, or proprietary preparation, that is signed, given, or authorized by a medical, dental, chiropody, veterinarian, or optometric practitioner, and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

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

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

(39) "Retail food establishment" means any food service establishment, retail food store, or a combination of both within the same establishment;

(40) "Retail food store" means any fixed or mobile establishment where food or food products, including prepackaged, labeled sandwiches or other foods to be heated in a microwave or infrared oven at the time of purchase, are offered for sale to the consumer, and intended for off-premises consumption, but does not include establishments which handle only prepackaged, snack-type, nonpotentially hazardous foods, markets that offer only fresh fruits and vegetables for sale, food service establishments, food and beverage vending machines, vending machine commissaries, or food processing establishments;

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

(42) "Salvage processing plant" means an establishment operated by a person engaged in the business of reconditioning, labeling, relabeling, repackaging, recoopering, sorting, cleaning, culling or who by other means salvages, sells, offers for sale, or distributes for human or animal consumption or use any salvaged food, beverage, including beer, wine and distilled spirits, vitamins, food supplements, dentifices, cosmetics, single-service food containers or

utensils, containers and packaging materials used for foods and cosmetics, soda straws, paper napkins, or any other product of a similar nature that has been damaged or contaminated by fire, water, smoke, chemicals, transit, or by any other means;

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

(44) "Secretary" means the secretary of the Cabinet for Health Services;

(45) "Temporary food service establishment" means any food service establishment which operates at a fixed location for a period of time, not to exceed fourteen (14) consecutive days;

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

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

(48) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts that are material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under the conditions of use as are customary or usual;

(49) The representation of a drug in its labeling or advertisement as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involving prolonged contact with the body; and

(50) The provisions of KRS 217.005 to 217.215 regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of those articles for sale, the sale, dispensing, and giving of those articles, and the supplying or applying of those articles in the conduct of any food, drug, or cosmetic establishment.

Section 2. KRS 217.814 is amended to read as follows:

The following words and phrases, as used in KRS 217.815 to 217.826, shall have the following meanings, unless the context requires otherwise:

(1) "Brand name" means the name that a manufacturer of a drug or pharmaceutical places on the container thereof at the time of packaging.

(2) "Generic name" means the chemical or established name of a drug or pharmaceutical.

(3) "Practitioner" ***has the same meaning as in Section 1 of this Act*** ~~[means any person licensed under the professional laws of this state to prescribe and administer medicine and drugs]~~.

(4) "Pharmacist" means any person licensed as such by the Kentucky Board of Pharmacy.

(5) "Equivalent drug product" means a product with the same generic name, active ingredients, strength, quantity and dosage form as the drug product identified in a prescription.

(6) "Board" means the Kentucky Board of Pharmacy.

(7) "Nonequivalent drug product formulary" means a formulary of drugs, drug products, and dosage formulations for which there are no equivalent drugs, drug products, or dosage formulations and which have been determined to be noninterchangeable or to have actual or potential bioequivalency problems by the United States Food and Drug Administration and are contained in a drug bioequivalence problems list as published in the United States Food and Drug Administration publication entitled "Approved prescription drug products with therapeutic equivalence evaluations" with supplements.

(8) "Dosage formulation" shall include, but not be limited to, those specific dosage forms which, by the nature of their physical manufacture are deemed to be nonequivalent to other similar formulations such as controlled release tablets, aerosol-nebulizer drug delivery systems and enteric coated oral dosage forms.

Section 3. KRS 218A.010 is amended to read as follows:

As used in this chapter:

(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or by his authorized agent under his immediate supervision and pursuant to his order; or

(b) The patient or research subject at the direction and in the presence of the practitioner.

(2) "Anabolic steroid" means any drug or hormonal substance chemically and pharmacologically related to testosterone that promotes muscle growth and includes those substances listed in KRS 218A.090(5) but does not include estrogens, progestins, and anticosteroids.

(3) "Cabinet" means the Cabinet for Health Services.

(4) "Controlled substance" means methamphetamine, or a drug, substance, or immediate precursor in Schedules I through V and includes a controlled substance analogue.

(5) (a) "Controlled substance analogue", except as provided in subparagraph (b), means a substance:

1. The chemical structure of which is substantially similar to the structure of a controlled substance in Schedule I or II; and

2. Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II; or

3. With respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.

(b) Such term does not include:

1. Any substance for which there is an approved new drug application;

2. With respect to a particular person, any substance if an exemption is in effect for investigational use for that person pursuant to federal law to the extent conduct with respect to such substance is pursuant to such exemption; or

3. Any substance to the extent not intended for human consumption before the exemption described in subparagraph 2. of this paragraph takes effect with respect to that substance.

(6) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

(7) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(8) "Dispenser" means a person who lawfully dispenses a Schedule II, III, IV, or V controlled substance to or for the use of an ultimate user.

(9) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(10) "Drug" means:

(a) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man or animals;

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

(d) Substances intended for use as a component of any article specified in this subsection.

It does not include devices or their components, parts, or accessories.

(11) "Immediate precursor" means a substance which is the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(12) "Isomer" means the optical isomer, except as used in KRS 218A.050(3) and 218A.070(1)(d). As used in KRS 218A.050(3), the term "isomer" means the optical, positional, or geometric isomer. As used in KRS 218A.070(1)(d), the term "isomer" means the optical or geometric isomer.

(13) "Manufacture", except as provided in KRS 218A.1431, means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container except that this term does not include activities:

(a) By a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(b) By a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale; or

(c) By a pharmacist as an incident to his dispensing of a controlled substance in the course of his professional practice.

(14) "Marijuana" means all parts of the plant Cannabis sp., whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin or any compound, mixture, or preparation which contains any quantity of these substances.

(15) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(b) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) of this subsection, but not including the isoquinoline alkaloids of opium;

(c) Opium poppy and poppy straw;

(d) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(e) Cocaine, its salts, optical and geometric isomers, and salts of isomers;

(f) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; and

(g) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (a) to (f) of this subsection.

(16) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under KRS 218A.030, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(17) "Opium poppy" means the plant of the species papaver somniferum L., except its seeds.

(18) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(19) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(20) "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy.

(21) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific investigator, optometrist as authorized in KRS 320.240, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state. ***"Practitioner" also includes a physician, dentist, podiatrist, or veterinarian who is a***

resident of and actively practicing in a state other than Kentucky and who is licensed and has prescriptive authority for controlled substances under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated in which case the terms of the Kentucky license shall prevail.

(22) "Prescription" means a written, electronic, or oral order for a drug or medicine, or combination or mixture of drugs or medicines, or proprietary preparation, signed or given or authorized by a medical, dental, chiropody, veterinarian, or optometric practitioner, and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

(23) "Prescription blank," with reference to a controlled substance, means a document that meets the requirements of KRS 218A.204 and 217.216.

(24) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(25) "Second or subsequent offense" means that for the purposes of this chapter an offense is considered as a second or subsequent offense, if, prior to his conviction of the offense, the offender has at any time been convicted under this chapter, or under any statute of the United States, or of any state relating to substances classified as controlled substances or counterfeit substances, except that a prior conviction for a nontrafficking offense shall be treated as a prior offense only when the subsequent offense is a nontrafficking offense. For the purposes of this section, a conviction voided under KRS 218A.275 or 218A.276 shall not constitute a conviction under this chapter.

(26) "Sell" means to dispose of a controlled substance to another person for consideration or in furtherance of commercial distribution.

(27) "Tetrahydrocannabinols" means synthetic equivalents of the substances contained in the plant, or in the resinous extractives of the plant Cannabis, sp. or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

1. Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;
2. Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;
3. Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers.

(28) "Traffic," except as provided in KRS 218A.1431, means to manufacture, distribute, dispense, sell, transfer, or possess with intent to manufacture, distribute, dispense, or sell a controlled substance.

(29) "Transfer" means to dispose of a controlled substance to another person without consideration and not in furtherance of commercial distribution.

(30) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

Section 4. KRS 315.121 is amended to read as follows:

(1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take

any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:

(a) Unprofessional or unethical conduct;

(b) Mental or physical incapacity that prevents the licensee, permit holder, or certificate holder from engaging in the practice of pharmacy or the wholesale distribution or manufacturing of drugs with reasonable skill, competence, and safety to the public;

(c) Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea, one (1) or more or the following:

1. A felony;

2. An act involving moral turpitude or gross immorality; or

3. A violation of the pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government;

(d) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician is incapable of engaging or assisting in the practice of pharmacy with reasonable skill, competence, and safety to the public and failing to report any relevant information to the board;

(e) Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate;

(f) Engaging in fraud in connection with the practice of pharmacy or the wholesale distribution or manufacturing of drugs;

(g) Engaging in or aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of "pharmacist," "pharmacist intern," or other term which might imply that the individual is a pharmacist or pharmacist intern;

(h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;

(i) Violation of any order issued by the board to comply with any applicable law or administrative regulation; or

(j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the board.

(2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist or pharmacist intern:

(a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;

(b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or

direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:

1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
2. Certified or licensed health-care personnel who are responsible for care of the patient;
3. Designated agents of the Cabinet for Health Services for the purposes of enforcing the provisions of KRS Chapter 218A;
4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;

(c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist or pharmacy intern knows or should have known of their intended use in illegal activities;

(d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;

(e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;

(f) Selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;

(g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;

(h) Obtaining any remuneration by fraud, misrepresentation, or deception; or

(i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care***; or***

(j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

(3) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.

(4) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all

reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.

(5) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.

(6) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.

(a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.

(b) No person may have his or her record expunged under this section more than once.

The board shall promulgate administrative regulations under KRS Chapter 13A to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person, or create a significant threat of such harm.

Approved March 12, 2003