AN ACT relating to the monitoring of controlled substances.

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

➔Section 1. 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 or her authorized agent under his or her immediate supervision and pursuant to his or her 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 ***as Schedule III controlled substances pursuant to KRS 218A.020*** ~~[in KRS 218A.090(5)]~~ but does not include estrogens, progestins, and anticosteroids;

(3) "Cabinet" means the Cabinet for Health and Family Services;

(4) "Child" means any person under the age of majority as specified in KRS 2.015;

(5) "Cocaine" means a substance containing any quantity of cocaine, its salts, optical and geometric isomers, and salts of isomers;

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

(7) (a) "Controlled substance analogue," except as provided in paragraph (b) of this subsection, 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;

(8) "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;

(9) "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;

(10) "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;

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

(12) "Dosage unit" means a single pill, capsule, ampule, liquid, or other form of administration available as a single unit;

(13) "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;

(14) "Good faith prior examination," as used in KRS Chapter 218A and for criminal prosecution only, means an in-person medical examination of the patient conducted by the prescribing practitioner or other health-care professional routinely relied upon in the ordinary course of his or her practice, at which time the patient is physically examined and a medical history of the patient is obtained. "In-person" includes telehealth examinations. This subsection shall not be applicable to hospice providers licensed pursuant to KRS Chapter 216B;

(15) "Hazardous chemical substance" includes any chemical substance used or intended for use in the illegal manufacture of a controlled substance as defined in this section or the illegal manufacture of methamphetamine as defined in KRS 218A.1431, which:

(a) Poses an explosion hazard;

(b) Poses a fire hazard; or

(c) Is poisonous or injurious if handled, swallowed, or inhaled;

(16) "Heroin" means a substance containing any quantity of heroin, or any of its salts, isomers, or salts of isomers;

(17) "Hydrocodone combination product" means a drug with:

(a) Not more than three hundred (300) milligrams of dihydrocodeinone, or any of its salts, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; or

(b) Not more than three hundred (300) milligrams of dihydrocodeinone, or any of its salts, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(18) "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 or methamphetamine, the control of which is necessary to prevent, curtail, or limit manufacture;

(19) "Intent to manufacture" means any evidence which demonstrates a person's conscious objective to manufacture a controlled substance or methamphetamine. Such evidence includes but is not limited to statements and a chemical substance's usage, quantity, manner of storage, or proximity to other chemical substances or equipment used to manufacture a controlled substance or methamphetamine;

(20) "Isomer" means the optical isomer, except ***the Cabinet for Health and Family Services may include the optical, positional, or geometric isomer to classify any substance pursuant to KRS 218A.020***[~~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~~];

(21) "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 or her administering or dispensing of a controlled substance in the course of his or her professional practice;

(b) By a practitioner, or by his or her 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 or her dispensing of a controlled substance in the course of his or her professional practice;

(22) "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. The term "marijuana" does not include:

(a) Industrial hemp as defined in KRS 260.850;

(b) The substance cannabidiol, when transferred, dispensed, or administered pursuant to the written order of a physician practicing at a hospital or associated clinic affiliated with a Kentucky public university having a college or school of medicine; or

(c) For persons participating in a clinical trial or in an expanded access program, a drug or substance approved for the use of those participants by the United States Food and Drug Administration;

(23) "Medical history," as used in KRS Chapter 218A and for criminal prosecution only, means an accounting of a patient's medical background, including but not limited to prior medical conditions, prescriptions, and family background;

(24) "Medical order," as used in KRS Chapter 218A and for criminal prosecution only, means a lawful order of a specifically identified practitioner for a specifically identified patient for the patient's health-care needs. "Medical order" may or may not include a prescription drug order;

(25) "Medical record," as used in KRS Chapter 218A and for criminal prosecution only, means a record, other than for financial or billing purposes, relating to a patient, kept by a practitioner as a result of the practitioner-patient relationship;

(26) "Methamphetamine" means any substance that contains any quantity of methamphetamine, or any of its salts, isomers, or salts of isomers;

(27) "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;

(28) "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.020*** ~~[218A.030]~~, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms;

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

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

(31) "Physical injury" has the same meaning it has in KRS 500.080;

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

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

(34) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific investigator, optometrist as authorized in KRS 320.240, advanced practice registered nurse as authorized under KRS 314.011, or other person licensed, registered, or otherwise permitted by state or federal law to acquire, 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, veterinarian, or advanced practice registered

nurse authorized under KRS 314.011 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;

(35) "Practitioner-patient relationship," as used in KRS Chapter 218A and for criminal prosecution only, means a medical relationship that exists between a patient and a practitioner or the practitioner's designee, after the practitioner or his or her designee has conducted at least one (1) good faith prior examination;

(36) "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, optometric practitioner, or advanced practice registered nurse, and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

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

(38) "Presumptive probation" means a sentence of probation not to exceed the maximum term specified for the offense, subject to conditions otherwise authorized by law, that is presumed to be the appropriate sentence for certain offenses designated in this chapter, notwithstanding contrary provisions of KRS Chapter 533. That presumption shall only be overcome by a finding on the record by the sentencing court of substantial and compelling reasons why the defendant cannot be safely and effectively supervised in the community, is not amenable to community-based treatment, or poses a significant risk to public safety;

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

(40) "Recovery program" means an evidence-based, nonclinical service that assists individuals and families working toward sustained recovery from substance use and other criminal risk factors. This can be done through an array of support programs and services that are delivered through residential and nonresidential means;

(41) "Salvia" means Salvia divinorum or Salvinorin A and includes all parts of the plant presently classified botanically as Salvia divinorum, whether growing or not, the seeds thereof, any extract from any part of that plant, and every compound, manufacture, derivative, mixture, or preparation of that plant, its seeds, or its extracts, including salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation of that plant, its seeds, or extracts. The term shall not include any other species in the genus salvia;

(42) "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 or her 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;

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

(44) "Serious physical injury" has the same meaning it has in KRS 500.080;

(45) "Synthetic cannabinoids or piperazines" means any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, that

contains Benzylpiperazine (BZP); Trifluoromethylphenylpiperazine (TFMPP); 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210); 1-Butyl-3-(1-naphthoyl)indole; 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211); or any compound in the following structural classes:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to JWH-167, JWH-250, JWH-251, and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to AM-630, AM-2233, AM-694, Pravadoline (WIN 48,098), and RCS-4;

(d) Cyclohexylphenols: Any compound containing a 2-(3-

hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to JWH-175, JWH-184, and JWH-185;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to JWH-030, JWH-145, JWH-146, JWH-307, and JWH-368;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl)indene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to JWH-176;

(h) Tetramethylcyclopropanoylindoles: Any compound containing a 3-(1-tetramethylcyclopropoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not further substituted in the tetramethylcyclopropyl ring to any extent. Examples of this structural class include but are not limited to UR-144 and XLR-11;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring system to any extent. Examples of this structural class include but are not limited to AB-001 and AM-1248; or

(j) Any other synthetic cannabinoid or piperazine which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law;

(46) "Synthetic cathinones" means any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law (not including bupropion or compounds listed under a different schedule) structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in one (1) or more of the following ways:

(a) By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further

substituted in the ring system by one (1) or more other univalent substituents. Examples of this class include but are not limited to 3,4-Methylenedioxycathinone (bk-MDA);

(b) By substitution at the 3-position with an acyclic alkyl substituent. Examples of this class include but are not limited to 2-methylamino-1-phenylbutan-1-one (buphedrone);

(c) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure. Examples of this class include but are not limited to Dimethylcathinone, Ethcathinone, and α-Pyrrolidinopropiophenone (α-PPP); or

(d) Any other synthetic cathinone which is not approved by the United States Food and Drug Administration or, if approved, is not dispensed or possessed in accordance with state or federal law;

(47) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones;

(48) "Telehealth" has the same meaning it has in KRS 311.550;

(49) "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:

(a) Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

(b) Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; and

(c) Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

(50) "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;

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

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

➔Section 2. KRS 218A.020 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall administer this chapter and may by ***administrative*** regulation add substances to or delete or reschedule all substances enumerated in the schedules ***authorized under*** ~~[set forth in]~~ this chapter. In making a determination regarding a substance, the Cabinet for Health and Family Services may consider the following:

(a) The actual or relative potential for abuse;

(b) The scientific evidence of its pharmacological effect, if known;

(c) The state of current scientific knowledge regarding the substance;

(d) The history and current pattern of abuse;

(e) The scope, duration, and significance of abuse;

(f) The risk to the public health;

(g) The potential of the substance to produce psychic or physiological dependence liability; and

(h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(2) After considering the factors enumerated in subsection (1) of this section, the Cabinet for Health and Family Services may adopt a regulation controlling the substance if it finds the substance has a potential for abuse.

(3) If any substance is designated ***or*** ~~[,]~~ rescheduled ~~[, or deleted]~~ as a controlled substance under ***the*** federal ***Controlled Substances Act, the drug shall be***

***considered to be controlled at the state level in the same numerical schedule corresponding to the federal schedule. However, the Cabinet for Health and Family Services may file an amendment to the administrative regulations promulgated pursuant to this section to control the substance in a more restrictive numerical schedule than the federal schedule. Any amendment filed by administrative regulation pursuant to this subsection shall be filed with the Legislative Research Commission no later than ninety (90) days from publication in the Federal Register of a final order designating a substance as a controlled substance or rescheduling a controlled substance***~~[law and notice thereof is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under this chapter by regulation]~~.

(4) The Cabinet for Health and Family Services shall exclude any nonnarcotic substance from a schedule if the substance may be lawfully sold over the counter without prescription under the provisions of the Federal Food, Drug and Cosmetic Act, or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, or the Kentucky Revised Statutes (for the purposes of this section the Kentucky Revised Statutes shall not include any regulations issued thereunder).

(5) The Office of Drug Control Policy may request that the Cabinet for Health and Family Services schedule a substance substantially similar to a synthetic cannabinoid or piperazine or a synthetic cathinone. The cabinet shall consider the request utilizing the criteria established by this section and shall issue a written response within sixty (60) days of the scheduling request delineating the cabinet's decision to schedule or not schedule the substance and the basis for the cabinet's decision. The cabinet's response shall be provided to the Legislative Research Commission and shall be a public record.

➔Section 3. KRS 218A.202 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall establish ***and maintain*** an

electronic system for monitoring Schedules II, III, IV, and V controlled substances~~[ that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy]~~. The cabinet may contract for the design, upgrade, or operation of this system if the contract preserves all of the rights, privileges, and protections guaranteed to Kentucky citizens under this chapter and the contract requires that all other aspects of the system be operated in conformity with the requirements of this or any other applicable state or federal law.

(2) A practitioner or a pharmacist authorized to prescribe***, administer,*** or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every ***practitioner or pharmacist***~~[dispenser within the Commonwealth]~~ who is licensed, permitted, or otherwise authorized to ***administer***~~[prescribe]~~ or dispense a controlled substance to a person ***in Kentucky, or for delivery to a person at an address*** in Kentucky shall report to the Cabinet for Health and Family Services the data required by this section, except that reporting shall not be required for:

(a) A drug administered directly to a patient ***receiving inpatient care*** in a hospital, a resident of a health care facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility; ***or***

(b) ~~[A drug, other than any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, dispensed by a practitioner at a facility licensed by the cabinet, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48)~~

~~hours; or~~

~~(c) ]~~A drug administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.

(4) ***In addition to the data required by subsection (5) of this section, a Kentucky-licensed acute care hospital or critical access hospital shall report to the Cabinet for Health and Family Services all positive toxicology screens performed by the hospital's emergency department to evaluate a suspected drug overdose of a patient prior to the patient's admission to the hospital.***

***(5)*** Data for each controlled substance that is ***administered or*** dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) National drug code of the drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

***(6)***~~[(5)]~~ The data shall be provided in the electronic format specified by the Cabinet for Health and Family Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.

***(7)***~~[(6)]~~ The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) Employees of the Office of the Inspector General of the Cabinet for Health and Family Services who have successfully completed training for the electronic system and who have been approved to use the system, ***federal prosecutors,*** Kentucky Commonwealth's attorneys and assistant Commonwealth's attorneys, county attorneys and assistant county attorneys, a peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal ***agent***~~[peace officer]~~ whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program in conformity with subsection ***(8)***~~[(7)]~~ of this section;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who~~[ requests information and]~~ certifies that the requested information is for

the purpose of:

1. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient;~~[ or]~~

2. ***Reviewing data on controlled substances that have been administered or dispensed to the birth mother of an infant who is currently being treated by the practitioner for neonatal abstinence syndrome; or has symptoms that suggest prenatal drug exposure; or***

***3.*** Reviewing and assessing the individual prescribing or dispensing patterns of the practitioner or pharmacist or to determine the accuracy and completeness of information contained in the monitoring system;

(f) The chief medical officer of a hospital or long-term-care facility, an employee of the hospital or long-term-care facility as designated by the chief medical officer and who is working under his or her specific direction, or a physician designee if the hospital or facility has no chief medical officer, if the officer, employee, or designee certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective patient or resident in the hospital or facility;

(g) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing or dispensing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate

prescribing or dispensing may be occurring in that area;

(h) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced practice registered nurse who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing or dispensing practices;
2. Associated in a partnership or other business entity with an advanced practice registered nurse who is already under investigation by the Board of Nursing for improper prescribing practices;
3. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or
4. In a designated geographic area for which a report on a physician or another advanced practice registered nurse in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;

(i) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program; or

(j) A medical examiner engaged in a death investigation pursuant to KRS 72.026.

***(8)*** ~~[(7)]~~ The Department for Medicaid Services shall use any data or reports from the system for the purpose of identifying Medicaid providers or recipients whose prescribing, dispensing, or usage of controlled substances may be:

(a) Appropriately managed by a single outpatient pharmacy or primary care

physician; or

(b) Indicative of improper, inappropriate, or illegal prescribing or dispensing practices by a practitioner or drug seeking by a Medicaid recipient.

***(9)*** ~~[(8)]~~ A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except as provided in this section, in another statute, or by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except that:

(a) A person specified in subsection ***(7)*** ~~[(6)]~~(b) of this section who is authorized to receive data or a report may share that information with any other persons specified in subsection ***(7)*** ~~[(6)]~~(b) of this section authorized to receive data or a report if the persons specified in subsection ***(7)*** ~~[(6)]~~(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each agency engaged in the investigation;

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection ***(7)*** ~~[(6)]~~(a) of this section, or with a law enforcement officer designated in subsection ***(7)*** ~~[(6)]~~(b) of this section;

(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B;

(d) If a state licensing board as defined in KRS 218A.205 initiates formal disciplinary proceedings against a licensee, and data obtained by the board is relevant to the charges, the board may provide the data to the licensee and his or her counsel, as part of the notice process required by KRS 13B.050, and

admit the data as evidence in an administrative hearing conducted pursuant to KRS Chapter 13B, with the board and licensee taking all necessary steps to prevent further disclosure of the data; and

(e) A practitioner, pharmacist, or employee who obtains data under subsection ***(7)***~~[(6)]~~(e) of this section may share the report with the patient or person authorized to act on the patient's behalf***. Any practitioner, pharmacist, or employee who obtains data under subsection (7)(e) of this section may***~~[ and]~~ place the report in the patient's medical record, ***in which case the***~~[with that]~~ individual report ***shall*** then ***be***~~[being]~~ deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record in lieu of the disclosure restrictions otherwise imposed by this section.

***(10)***~~[(9)]~~ The Cabinet for Health and Family Services, all peace officers specified in subsection ***(7)***~~[(6)]~~(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

***(11)***~~[(10)]~~ The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

***(12)***~~[(11)]~~ Intentional failure ***to comply with the reporting requirements of this section***~~[by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section]~~ shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.

***(13)***~~[(12)]~~ Intentional disclosure of transmitted data to a person not authorized by subsection ***(7)***~~[(6)]~~ to subsection ***(9)***~~[(8)]~~ of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide ***current or prospective patient or a bona fide*** specific investigation, shall be a Class

B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.

***(14)*** ~~[(13) (a) The Commonwealth Office of Technology, in consultation with the Cabinet for Health and Family Services, may submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot or continuing project to study, create, or maintain a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances.~~

~~(b) The pilot project shall:~~

~~1. Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and~~

~~2. Study the use of an interactive system that includes a relational data base with query capability.~~

~~(c) Funding to create or maintain a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances may be sought for a statewide system or for a system covering any geographic portion or portions of the state.~~

~~(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.~~

~~(15)]~~ The Cabinet for Health and Family Services may, by promulgating an administrative regulation, limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

***(15)*** ~~[(16)]~~ (a) The Cabinet for Health and Family Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or

dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.

(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

(c) The cabinet shall work with the Justice and Public Safety Cabinet for the development of a continuing education program for law enforcement officers about the purposes and uses of the electronic system for monitoring established in this section.

***(16)*** ~~[(17)]~~ If the cabinet becomes aware of a prescriber's or dispenser's failure to comply with this section, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser. The licensing board shall treat the notification as a complaint against the licensee.

***(17)*** ~~[(18)]~~ The cabinet shall promulgate administrative regulations to implement the provisions of this section. Included in these administrative regulations shall be:

(a) An error resolution process allowing a patient to whom a report had been disclosed under subsection ***(9)*** ~~[(8)]~~ of this section to request the correction of inaccurate information contained in the system relating to that patient; and

(b) ***A*** ~~[Beginning July 1, 2013, a]~~ requirement that data be reported to the system under subsection (3) of this section within one (1) day of dispensing.

➔Section 4. KRS 218A.240 is amended to read as follows:

(1) All police officers and deputy sheriffs directly employed full-time by state, county, city, urban-county, or consolidated local governments, the Department of Kentucky State Police, the Cabinet for Health and Family Services, their officers and agents, and of all city, county, and Commonwealth's attorneys, and the Attorney General,

within their respective jurisdictions, shall enforce all provisions of this chapter and cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.

(2) For the purpose of enforcing the provisions of this chapter, the designated agents of the Cabinet for Health and Family Services shall have the full power and authority of peace officers in this state, including the power of arrest and the authority to bear arms, and shall have the power and authority to administer oaths; to enter upon premises at all times for the purpose of making inspections; to seize evidence; to interrogate all persons; to require the production of prescriptions, of books, papers, documents, or other evidence; to employ special investigators; and to expend funds for the purpose of obtaining evidence and to use data obtained under KRS 218A.202~~[(7)]~~ in any administrative proceeding before the cabinet.

(3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health and Family Services.

(4) Designated agents of the Cabinet for Health and Family Services and the Kentucky Board of Pharmacy are empowered to remove from the files of a pharmacy or the custodian of records for that pharmacy any controlled substance prescription or other controlled substance record upon tendering a receipt. The receipt shall be sufficiently detailed to accurately identify the record. A receipt for the record shall be a defense to a charge of failure to maintain the record.

(5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter or to forfeit any property subject to forfeiture under KRS 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter.

(a) Any civil action against any person brought pursuant to this section may be

instituted in the Circuit Court in any county in which the person resides, in which any property owned by the person and subject to forfeiture is found, or in which the person has violated any provision of this chapter.

(b) A final judgment rendered in favor of the Commonwealth in any criminal proceeding brought under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought pursuant to this section.

(c) The prevailing party in any civil proceeding brought pursuant to this section shall recover his or her costs, including a reasonable attorney's fee.

(d) Distribution of funds under this section shall be made in the same manner as in KRS 218A.420, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his or her percentage of the funds shall go to the agency initiating the forfeiture action.

(6) The Cabinet for Health and Family Services shall make or cause to be made examinations of samples secured under the provisions of this chapter to determine whether any provision has been violated.

(7) (a) The Cabinet for Health and Family Services shall proactively use the data compiled in the electronic system created in KRS 218A.202 for investigations, research, statistical analysis, and educational purposes and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the system shall be authorized access to the data and reports under this subsection. The cabinet shall notify a state licensing board listed in KRS 218A.205 if a report or analysis conducted under this subsection indicates that further investigation about improper, inappropriate or illegal prescribing or dispensing may be necessary by the board. The board shall consider each report and may, after giving due

consideration to areas of practice, specialties, board certifications, and appropriate standards of care, request and receive a follow-up report or analysis containing relevant information as to the prescriber or dispenser and his or her patients.

(b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure, the Board of Nursing, the Office of Drug Control Policy, and the Board of Pharmacy, to be used to generate public trend reports from the data obtained by the system. Meetings at which the criteria are developed shall be meetings, as defined in KRS 61.805, that comply with the open meetings laws, KRS 61.805 to 61.850. The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system. Except as provided in subsection (8) of this section, these trend reports shall not identify an individual prescriber, dispenser, or patient. Peace officers authorized to receive data under KRS 218A.202 may request trend reports not specifically published pursuant to this paragraph except that the report shall not identify an individual prescriber, dispenser, or patient.

(8) If the cabinet deems it to be necessary and appropriate, upon the request of a state licensing board listed in KRS 218A.205, the cabinet shall provide the requesting board with the identity of prescribers, dispensers, and patients used to compile a specific trend report.

(9) Any hospital or other health care facility may petition the cabinet to review data from the electronic system specified in KRS 218A.202 as it relates to employees of that facility to determine if inappropriate prescribing or dispensing practices are occurring. The cabinet may initiate any investigation in such cases as he or she determines is appropriate, and may request the assistance from the hospitals or health care facilities in the investigation.

➔Section 5. KRS 243.100 is amended to read as follows:

A natural person shall not become a licensee under KRS 243.020 to 243.670 if he or she:

(1) (a) Has been convicted of any felony until five (5) years have passed from the date of conviction, release from custody or incarceration, parole, or termination of probation, whichever is later;

(b) Has been convicted of any misdemeanor described under KRS ***218A.020***~~[218A.050]~~, ***218A.040,*** 218A.060,~~[ 218A.070,]~~ 218A.080,~~[ 218A.090,]~~ 218A.100, ***or***~~[218A.110,]~~ 218A.120~~[, or 218A.130]~~ in the two (2) years immediately preceding the application;

(c) Has been convicted of any misdemeanor directly or indirectly attributable to the use of alcoholic beverages in the two (2) years immediately preceding the application;

(d) Is under the age of twenty-one (21) years;

(e) Has had any license issued under this statute relating to the regulation of the manufacture, sale, and transportation of alcoholic beverages revoked for cause or has been convicted of a violation of any such statute, until the expiration of two (2) years from the date of the revocation or conviction; or

(f) Is not a citizen of the United States and has not had an actual, bona fide residence in this state for at least one (1) year before the date on which his or her application for a license is made. This subsection shall not apply to applicants for manufacturers' licenses, to applicants that are corporations authorized to do business in this state, or to persons licensed on March 7, 1938.

(2) A partnership, limited partnership, limited liability company, corporation, or governmental agency shall not be licensed if:

(a) Each member of the partnership or each of the directors, principal officers, or managers does not qualify under subsection (1)(a), (b), (c), and (d) of this section;

(b) It has had any license issued under this statute relating to the regulation of the manufacture, sale, and transportation of alcoholic beverages revoked for cause or has been convicted of a violation of any such statute, until the expiration of two (2) years from the date of the revocation or conviction; or

(c) It is a partnership or corporation, if any member of the partnership or any director, manager, or principal officer of the corporation has had any license issued under any statute relating to the regulation of the manufacture, sale, and transportation of alcoholic beverages, revoked for cause or has been convicted of a violation of any such statute, until the expiration of the later of two (2) years from the date of the revocation or two (2) years from the date of conviction.

(3) The provisions of subsection (1)(a) and (b) shall apply to anyone applying for a new license under this chapter after July 15, 1998, but shall not apply to those who renew a license that was originally issued prior to July 15, 1998, or an application for a supplemental license where the original license was issued prior to July 15, 1998.

➔Section 6. KRS 243.390 is amended to read as follows:

(1) In addition to other information as the board may by administrative regulation require, every application for a license under KRS 243.020 to 243.670 shall contain the following information, given under oath:

(a) The name, age, Social Security number, address, residence, and citizenship of each applicant;

(b) If the applicant is a partner, the name, age, Social Security number, address, residence, and citizenship of each partner and the name and address of the partnership;

(c) The name, age, Social Security number, address, residence, and citizenship of each person interested in the business for which the license is sought, together

with the nature of that interest, and, if the applicant is a corporation, limited partnership company, or limited liability company, the name, age, Social Security number, address, and residence of each officer, director, member, partner, and managerial employee and the citizenship of each, and the state under the laws of which the corporate applicant is incorporated or organized. The department may require the names of all the stockholders and the percentage of stock held by each;

(d) The premises to be licensed, stating the street and number, if the premises has a street number, and otherwise such a description that will reasonably indicate the location of the premises;

(e) A statement that neither the applicant nor any other person referred to in this section has been convicted of; any misdemeanor directly or indirectly attributable to alcoholic beverages; any violation of KRS ***218A.020***~~[218A.050]~~, ***218A.040,*** 218A.060,~~[ 218A.070,]~~ 218A.080,~~[ 218A.090,]~~ 218A.100, ***or***~~[218A.110]~~, 218A.120~~[, or 218A.130]~~ within the two (2) years immediately preceding the application; any felony, within five (5) years from the later of the date of parole or the date of conviction; or providing false information to the department preceding the application; and that the applicant or any other person referred to in this section has not had any license that has been issued to him under any alcoholic beverage statute revoked for cause within two (2) years prior to the date of the application; and

(f) A statement that the applicant will in good faith abide by every state and local statute, regulation, and ordinance relating to the manufacture, sale, use of, and trafficking in alcoholic beverages.

(2) If, after a license has been issued, there is a change in any of the facts required to be set forth in the application, a verified supplemental statement in writing giving notice of the change shall be filed with the board within ten (10) days after the

change.

(3) In giving any notice or taking any action in reference to a license, the board may rely upon the information furnished in the application or in the supplemental statement connected with the application. This information, as against the licensee or applicant, shall be conclusively presumed to be correct. The information required to be furnished in the application or supplemental statement shall be deemed material in any prosecution for perjury.

➔Section 7. KRS 243.500 is amended to read as follows:

Any license issued under KRS 243.020 to 243.670 may be revoked or suspended for the following causes:

(1) Conviction of the licensee or his agent or employee for selling any illegal beverages on the licensed premises.

(2) Making any false, material statements in an application for a license or supplemental license.

(3) Violation of the provisions of KRS 243.670.

(4) Conviction of the licensee or any of his clerks, servants, agents, or employees of:

(a) Two (2) violations of the terms and provisions of KRS Chapter 241, 243, or 244 or any act regulating the manufacture, sale, and transportation of alcoholic beverages within two (2) consecutive years;

(b) Two (2) misdemeanors directly or indirectly attributable to the use of intoxicating liquors within two (2 ) consecutive years; or

(c) Any felony.

(5) Failure or default of a licensee to pay an excise tax or any part of the tax or any penalties imposed by or under the provisions of any statutes, ordinances, or Acts of Congress relative to taxation, or for a violation of any administrative regulations promulgated by the Department of Revenue made in pursuance thereof.

(6) Revocation of any license or permit provided in KRS 243.060, 243.070, 243.600,

and 243.610, or granted under any Act of Congress relative to the regulation of the manufacture, sale, and transportation of alcoholic beverages. Any license issued under KRS 243.020 to 243.670 shall be revoked or suspended if the licensee sells the alcoholic beverages at a price in excess of the price set by federal or state regulations.

(7) Setting up, conducting, operating, or keeping, on the licensed premises, any gambling game, device, machine, contrivance, lottery, gift enterprise, handbook, or facility for betting or transmitting bets on horse races; or permitting to be set up, conducted, operated, kept, or engaged in, on the licensed premises, any such game, device, machine, contrivance, lottery, gift enterprise, handbook, or facility. This section shall not apply to contests in which eligibility to participate is determined by chance and the ultimate winner is determined by skill and the licensee has no direct interest, or to the sale of lottery tickets sold under the provisions of KRS Chapter 154A.

(8) Conviction of the licensee, his agents, servants, or employees for:

(a) The sale or use upon the licensed premises of those items described ***pursuant to***~~[in]~~ KRS ***218A.020***~~[218A.050 to 218A.130]~~ as controlled substances, including synthetic drugs;

(b) Knowingly permitting the sale or use by patrons upon the licensed premises of those items described ***pursuant to***~~[in]~~ KRS ***218A.020***~~[218A.050 to 218A.130]~~ as controlled substances, including synthetic drugs; or

(c) Knowingly receiving stolen property upon the licensed premises.

➔Section 8. KRS 314.011 is amended to read as follows:

As used in this chapter, unless the context thereof requires otherwise:

(1) "Board" means Kentucky Board of Nursing;

(2) "Delegation" means directing a competent person to perform a selected nursing activity or task in a selected situation under the nurse's supervision and pursuant to

administrative regulations promulgated by the board in accordance with the provisions of KRS Chapter 13A;

(3) "Nurse" means a person who is licensed or holds the privilege to practice under the provisions of this chapter as a registered nurse or as a licensed practical nurse;

(4) "Nursing process" means the investigative approach to nursing practice utilizing a method of problem-solving by means of:

(a) Nursing diagnosis, a systematic investigation of a health concern, and an analysis of the data collected in order to arrive at an identifiable problem; and

(b) Planning, implementation, and evaluation based on nationally accepted standards of nursing practice;

(5) "Registered nurse" means one who is licensed or holds the privilege under the provisions of this chapter to engage in registered nursing practice;

(6) "Registered nursing practice" means the performance of acts requiring substantial specialized knowledge, judgment, and nursing skill based upon the principles of psychological, biological, physical, and social sciences in the application of the nursing process in:

(a) The care, counsel, and health teaching of the ill, injured, or infirm;

(b) The maintenance of health or prevention of illness of others;

(c) The administration of medication and treatment as prescribed by a physician, physician assistant, dentist, or advanced practice registered nurse and as further authorized or limited by the board, and which are consistent either with American Nurses' Association Scope and Standards of Practice or with standards of practice established by nationally accepted organizations of registered nurses. Components of medication administration include but are not limited to:

1. Preparing and giving medications in the prescribed dosage, route, and frequency, including dispensing medications only as defined in

subsection (17)(b) of this section;

2. Observing, recording, and reporting desired effects, untoward reactions, and side effects of drug therapy;

3. Intervening when emergency care is required as a result of drug therapy;

4. Recognizing accepted prescribing limits and reporting deviations to the prescribing individual;

5. Recognizing drug incompatibilities and reporting interactions or potential interactions to the prescribing individual; and

6. Instructing an individual regarding medications;

(d) The supervision, teaching of, and delegation to other personnel in the performance of activities relating to nursing care; and

(e) The performance of other nursing acts which are authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally accepted organizations of registered nurses;

(7) "Advanced practice registered nurse" or "APRN" means a certified nurse practitioner, certified registered nurse anesthetist, certified nurse midwife, or clinical nurse specialist, who is licensed to engage in advance practice registered nursing pursuant to KRS 314.042 and certified in at least one (1) population focus;

(8) "Advanced practice registered nursing" means the performance of additional acts by registered nurses who have gained advanced clinical knowledge and skills through an accredited education program that prepares the registered nurse for one (1) of the four (4) APRN roles; who are certified by the American Nurses' Association or other nationally established organizations or agencies recognized by the board to certify registered nurses for advanced practice registered nursing as a certified nurse practitioner, certified registered nurse anesthetist, certified nurse midwife, or clinical nurse specialist; and who certified in at least one (1) population focus. The

additional acts shall, subject to approval of the board, include but not be limited to prescribing treatment, drugs, devices, and ordering diagnostic tests. Advanced practice registered nurses who engage in these additional acts shall be authorized to issue prescriptions for and dispense nonscheduled legend drugs as defined in KRS 217.905 and to issue prescriptions for but not to dispense Schedules II through V controlled substances as classified ***pursuant to***~~[in]~~ KRS ***218A.020,*** 218A.060,~~[ 218A.070,]~~ 218A.080,~~[ 218A.090,]~~ 218A.100, ***and***~~[218A.110,]~~ 218A.120~~[, and 218A.130,]~~ under the conditions set forth in KRS 314.042 and regulations promulgated by the Kentucky Board of Nursing on or before August 15, 2006.

(a) 1. Prescriptions issued by advanced practice registered nurses for Schedule II controlled substances classified under KRS 218A.060, except hydrocodone combination products as defined in KRS 218A.010, shall be limited to a seventy-two (72) hour supply without any refill.

2. Prescriptions issued by advanced practice registered nurses for hydrocodone combination products as defined in KRS 218A.010 shall be limited to a thirty (30) day supply without any refill.

3. Prescriptions issued under this subsection for psychostimulants may be written for a thirty (30) day supply only by an advanced practice registered nurse certified in psychiatric-mental health nursing who is providing services in a health facility as defined in KRS Chapter 216B or in a regional services program for mental health or individuals with an intellectual disability as defined in KRS Chapter 210.

(b) Prescriptions issued by advanced practice registered nurses for Schedule III controlled substances classified under KRS 218A.080 shall be limited to a thirty (30) day supply without any refill. Prescriptions issued by advanced practice registered nurses for Schedules IV and V controlled substances classified under KRS 218A.100 and 218A.120 shall be limited to the original

prescription and refills not to exceed a six (6) month supply.

(c) Limitations for specific controlled substances which are identified as having the greatest potential for abuse or diversion, based on the best available scientific and law enforcement evidence, shall be established in an administrative regulation promulgated by the Kentucky Board of Nursing. The regulation shall be based on recommendations from the Controlled Substances Formulary Development Committee, which is hereby created. The committee shall be composed of two (2) advanced practice registered nurses appointed by the Kentucky Board of Nursing, one (1) of whom shall be designated as a committee co-chair; two (2) physicians appointed by the Kentucky Board of Medical Licensure, one (1) of whom shall be designated as a committee co-chair; and one (1) pharmacist appointed by the Kentucky Board of Pharmacy. The initial regulation shall be promulgated on or before August 15, 2006, and shall be reviewed at least annually thereafter by the committee.

Nothing in this chapter shall be construed as requiring an advanced practice registered nurse designated by the board as a certified registered nurse anesthetist to obtain prescriptive authority pursuant to this chapter or any other provision of law in order to deliver anesthesia care. The performance of these additional acts shall be consistent with the certifying organization or agencies' scopes and standards of practice recognized by the board by administrative regulation;

(9) "Licensed practical nurse" means one who is licensed or holds the privilege under the provisions of this chapter to engage in licensed practical nursing practice;

(10) "Licensed practical nursing practice" means the performance of acts requiring knowledge and skill such as are taught or acquired in approved schools for practical nursing in:

(a) The observing and caring for the ill, injured, or infirm under the direction of a registered nurse, advanced practice registered nurse, physician assistant,

licensed physician, or dentist;

(b) The giving of counsel and applying procedures to safeguard life and health, as defined and authorized by the board;

(c) The administration of medication or treatment as authorized by a physician, physician assistant, dentist, or advanced practice registered nurse and as further authorized or limited by the board which is consistent with the National Federation of Licensed Practical Nurses or with Standards of Practice established by nationally accepted organizations of licensed practical nurses;

(d) Teaching, supervising, and delegating except as limited by the board; and

(e) The performance of other nursing acts which are authorized or limited by the board and which are consistent with the National Federation of Practical Nurses' Standards of Practice or with Standards of Practice established by nationally accepted organizations of licensed practical nurses;

(11) "School of nursing" means a nursing education program preparing persons for licensure as a registered nurse or a practical nurse;

(12) "Continuing education" means offerings beyond the basic nursing program that present specific content planned and evaluated to meet competency based behavioral objectives which develop new skills and upgrade knowledge;

(13) "Nursing assistance" means the performance of delegated nursing acts by unlicensed nursing personnel for compensation under supervision of a nurse;

(14) "Sexual assault nurse examiner" means a registered nurse who has completed the required education and clinical experience and maintains a current credential from the board as provided under KRS 314.142 to conduct forensic examinations of victims of sexual offenses under the medical protocol issued by the Justice and Public Safety Cabinet in consultation with the Sexual Assault Response Team Advisory Committee pursuant to KRS 216B.400(4);

(15) "Competency" means the application of knowledge and skills in the utilization of critical thinking, effective communication, interventions, and caring behaviors consistent with the nurse's practice role within the context of the public's health, safety, and welfare;

(16) "Credential" means a current license, registration, certificate, or other similar authorization that is issued by the board;

(17) "Dispense" means:

(a) To receive and distribute noncontrolled legend drug samples from pharmaceutical manufacturers to patients at no charge to the patient or any other party; or

(b) To distribute noncontrolled legend drugs from a local, district, and independent health department, subject to the direction of the appropriate governing board of the individual health department;

(18) "Dialysis care" means a process by which dissolved substances are removed from a patient's body by diffusion, osmosis, and convection from one (1) fluid compartment to another across a semipermeable membrane;

(19) "Dialysis technician" means a person who is not a nurse, a physician assistant, or a physician and who provides dialysis care in a licensed renal dialysis facility under the direct, on-site supervision of a registered nurse or a physician;

(20) "Population focus" means the section of the population within which the advanced practice registered nurse has targeted to practice. The categories of population foci are:

(a) Family and individual across the lifespan;

(b) Adult gerontology;

(c) Neonatal;

(d) Pediatrics;

(e) Women's health and gender-related health; and

(f) Psychiatric mental health; and

(21) "Conviction" means but is not limited to:

(a) An unvacated adjudication of guilt;

(b) Pleading no contest or nolo contendere or entering an Alford plea; or

(c) Entering a guilty plea pursuant to a pretrial diversion order;

Regardless of whether the penalty is rebated, suspended, or probated.

➔Section 9. The following KRS sections are repealed:

218A.030 Controlled substances -- How scheduled.

218A.050 Schedule I controlled substances.

218A.070 Schedule II controlled substances.

218A.090 Schedule III controlled substances.

218A.110 Schedule IV controlled substances.

218A.130 Schedule V controlled substances.