

HOUSE OF REPRESENTATIVES

KENTUCKY GENERAL ASSEMBLY AMENDMENT FORM
2017 REGULAR SESSION
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Amend printed copy of **SB 14/HCS 1**

On page 1, line 3, and continuing through page 27, line 5, by deleting the entirety, and inserting in lieu thereof:

"➔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 in KRS 218A.090(5) but does not include estrogens, progestins, and anticosteroids;
- (3) "Cabinet" means the Cabinet for Health and Family Services;
- (4) **"Carfentanil" means any substance containing any quantity of carfentanil, or any of its salts, isomers, or salts of isomers;**
- (5) "Child" means any person under the age of majority as specified in KRS 2.015;
- ~~(6)~~(5) "Cocaine" means a substance containing any quantity of cocaine, its salts, optical and

Amendment No. HFA 2

Rep. Rep. Joseph M. Fischer

Committee Amendment _____

Signed: _____

Floor Amendment _____

LRC Drafter: Nardy, Dale

Adopted: _____

Date: _____

Rejected: _____

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geometric isomers, and salts of isomers;

~~(7)(6)~~ "Controlled substance" means methamphetamine, or a drug, substance, or immediate precursor in Schedules I through V and includes a controlled substance analogue;

~~(8)(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;

~~(9)(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;

~~(10)~~~~(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;

~~(11)~~~~(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;

~~(12)~~~~(11)~~ "Distribute" means to deliver other than by administering or dispensing a controlled substance;

~~(13)~~~~(12)~~ "Dosage unit" means a single pill, capsule, ampule, liquid, or other form of administration available as a single unit;

~~(14)~~~~(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;

(15) "Fentanyl" means a substance containing any quantity of fentanyl, or any of its salts, isomers, or salts of isomers;

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(16) "Fentanyl derivative" means a substance containing any quantity of any chemical compound, except compounds specifically scheduled as controlled substances by statute or by administrative regulation pursuant to this chapter, which is structurally derived from 1-ethyl-4-(N-phenylamido) piperidine:

(a) By substitution:

1. At the 2-position of the 1-ethyl group with a phenyl, furan, thiophene, or ethyloxotetrazole ring system; and
2. Of the terminal amido hydrogen atom with an alkyl, alkoxy, cycloalkyl, or furanyl group; and

(b) Which may be further modified in one (1) or more of the following ways:

1. By substitution on the N-phenyl ring to any extent with alkyl, alkoxy, haloalkyl, hydroxyl, or halide substituents;
2. By substitution on the piperadine ring to any extent with alkyl, allyl, alkoxy, hydroxy, or halide substituents at the 2-, 3-, 5-, and/or 6- positions;
3. By substitution on the piperadine ring to any extent with a phenyl, alkoxy, or carboxylate ester substituent at the 4- position; or
4. By substitution on the 1-ethyl group to any extent with alkyl, alkoxy, or hydroxy substituents;

(17)~~(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;

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~~(18)~~~~(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;

~~(19)~~~~(16)~~ "Heroin" means a substance containing any quantity of heroin, or any of its salts, isomers, or salts of isomers;

~~(20)~~~~(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;

~~(21)~~~~(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;

~~(22)~~~~(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;

~~(23)~~~~(20)~~ "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;

~~(24)~~~~(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;

~~(25)~~~~(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 **that is in the possession, custody, or control of a person who holds**

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a license issued by the Department of Agriculture permitting that person to cultivate, handle, or process industrial hemp [as defined in KRS 260.850];

(b) Industrial hemp products that do not include any living plants, viable seeds, leaf materials, or floral materials;

(c) [(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]

(d) [(e)] 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;

(e) A cannabidiol product derived from industrial hemp, as defined in KRS 260.850;
or

(f) A cannabidiol product approved as a prescription medication by the United States Food and Drug Administration;

(26) [(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;

(27) [(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;

(28) [(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;

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~~(29)~~~~(26)~~ "Methamphetamine" means any substance that contains any quantity of methamphetamine, or any of its salts, isomers, or salts of isomers;

~~(30)~~~~(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;

~~(31)~~~~(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.030, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms;

~~(32)~~~~(29)~~ "Opium poppy" means the plant of the species papaver somniferum L., except its seeds;

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- ~~(33)~~~~(30)~~ "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity;
- ~~(34)~~~~(31)~~ "Physical injury" has the same meaning it has in KRS 500.080;
- ~~(35)~~~~(32)~~ "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing;
- ~~(36)~~~~(33)~~ "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy;
- ~~(37)~~~~(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;
- ~~(38)~~~~(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;
- ~~(39)~~~~(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;

~~(40)~~~~(37)~~ "Prescription blank," with reference to a controlled substance, means a document that meets the requirements of KRS 218A.204 and 217.216;

~~(41)~~~~(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;

~~(42)~~~~(39)~~ "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance;

~~(43)~~~~(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;

~~(44)~~~~(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*;

~~(45)~~~~(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

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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;

~~(46)~~~~(43)~~ "Sell" means to dispose of a controlled substance to another person for consideration or in furtherance of commercial distribution;

~~(47)~~~~(44)~~ "Serious physical injury" has the same meaning it has in KRS 500.080;

~~(48)~~~~(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) Naphthoypyrroles: 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.

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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;

~~(49)~~~~(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, alkylendioxy, 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;

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~~(50)~~~~(47)~~ "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones;

~~(51)~~~~(48)~~ "Telehealth" has the same meaning it has in KRS 311.550;

~~(52)~~~~(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;

~~(53)~~~~(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;

~~(54)~~~~(51)~~ "Transfer" means to dispose of a controlled substance to another person without consideration and not in furtherance of commercial distribution; and

~~(55)~~~~(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 regulation add substances to or delete or reschedule all substances enumerated in the schedules 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, rescheduled, or deleted as a controlled substance under federal 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 **any substance that would meet the criteria to be scheduled pursuant to this chapter**~~[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.050 is amended to read as follows:

Unless otherwise rescheduled by administrative regulation of the Cabinet for Health and Family Services, the controlled substances listed in this section are included in Schedule I:

- (1) Any material, compound, mixture, or preparation which contains any quantity of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, or salts is possible within the specific chemical designation: Acetylfentanyl; Acetylmethadol; Allylprodine; Alphacetylmethadol; Alphameprodine; Alphamethadol; Benzethidine; Betacetylmethadol; Betameprodine; Betamethadol; Betaprodine; Clonitazene; Dextromoramide; Dextrophan; Diampromide; Diethylthiambutene; Dimenoxadol; Dimepheptanol; Dimethylthiambutene; Dioxaphetyl butyrate; Dipipanone; Ethylmethylthiambutene; Etonitazene; Etoxadine; Furethidine; Hydroxypethidine; Ketobemidone; Levomoramide; Levophenacymorphan; Morpheridine; Noracymethadol; Norlevorphanol; Normethadone; Norpipanone; Phenadoxone; Phenampromide; Phenomorphan; Phenoperidine; Piritramide; Proheptazine; Properidine; Propiram; Racemoramide; Trimeperidine; 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]-benzenesulfonamide (W-18); 4-chloro-N-[1-(2-phenylethyl)-2-piperidinylidene]-benzenesulfonamide (W-15); ***or any fentanyl derivative;***
- (2) Any material, compound, mixture, or preparation which contains any quantity of the following opium derivatives, including their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, or salts of isomers is

- possible within the specific chemical designation: Acetorphine; Acetyldihydrocodeine; Benzylmorphine; Codeine methylbromide; Codeine-N-Oxide; Cyprenorphine; Desomorphine; Dihydromorphine; Etorphine; Heroin; Hydromorphenol; Methyldesorphine; Methyldihydromorphine; Morphine methylbromide; Morphine methylsulfonate; Morphine-N-Oxide; Myrophine; Nicocodeine; Nicomorphine; Normorphine; Pholcodine; Thebacon;
- (3) Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers, or salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation: 3, 4-methylenedioxyamphetamine; 5-methoxy-3, 4-methylenedioxy amphetamine; 3, 4, 5-trimethoxyamphetamine; Bufotenine; Diethyltryptamine; Dimethyltryptamine; 4-methyl-2, 5-dimethoxyamphetamine; Ibogaine; Lysergic acid diethylamide; Marijuana; Mescaline; Peyote; N-ethyl-3-piperidyl benzilate; N-methyl-3-piperidyl benzilate; Psilocybin; Psilocyn; Tetrahydrocannabinols; Hashish; Phencyclidine, 2 Methylamino-1-phenylpropan-1-one (including but not limited to Methcathinone, Cat, and Ephedrone); synthetic drugs; or salvia;
- (4) Any material, compound, mixture, or preparation which contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, or salts of isomers is possible within the specific chemical designation: gamma hydroxybutyric acid; and
- (5) Any material, compound, mixture, or preparation which contains any quantity of the following substances:
- (a) 2-(2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5H-NBOMe);
 - (b) 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5I-NBOMe);

- (c) 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5B-NBOMe); or
- (d) 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5C-NBOMe).

➔Section 4. KRS 218A.1410 is amended to read as follows:

- (1) A person is guilty of importing heroin, *carfentanil, fentanyl, or fentanyl derivatives* when he or she knowingly and unlawfully transports any quantity of heroin, *carfentanil, fentanyl, or fentanyl derivatives* into the Commonwealth by any means with the intent to sell or distribute the heroin, *carfentanil, fentanyl, or fentanyl derivatives*.
- (2) The provisions of this section are intended to be a separate offense from others in this chapter, and shall be punished in addition to violations of this chapter occurring during the same course of conduct.
- (3) Importing heroin, *carfentanil, fentanyl, or fentanyl derivatives* is a Class C felony, and the defendant shall not be released on probation, shock probation, conditional discharge, or parole until he or she has served at least fifty percent (50%) of the sentence imposed.

➔Section 5. KRS 218A.1412 is amended to read as follows:

- (1) A person is guilty of trafficking in a controlled substance in the first degree when he or she knowingly and unlawfully traffics in:
- (a) Four (4) grams or more of cocaine;
- (b) Two (2) grams or more of ~~heroin, fentanyl, or~~ methamphetamine;
- (c) Ten (10) or more dosage units of a controlled substance that is classified in Schedules I or II and is a narcotic drug, or a controlled substance analogue;
- (d) Any quantity of *heroin, fentanyl, carfentanil, or fentanyl derivatives*; lysergic acid diethylamide; phencyclidine; gamma hydroxybutyric acid (GHB), including its salts, isomers, salts of isomers, and analogues; or flunitrazepam, including its salts,

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- isomers, and salts of isomers; or
- (e) Any quantity of a controlled substance specified in paragraph (a), (b), or (c) of this subsection in an amount less than the amounts specified in those paragraphs.
- (2) The amounts specified in subsection (1) of this section may occur in a single transaction or may occur in a series of transactions over a period of time not to exceed ninety (90) days that cumulatively result in the quantities specified in this section.
- (3) (a) Any person who violates the provisions of subsection (1)(a), (b), (c), or (d) of this section shall be guilty of a Class C felony for the first offense and a Class B felony for a second or subsequent offense.
- (b) Any person who violates the provisions of subsection (1)(e) of this section:
- 1. Shall be guilty of a Class D felony for the first offense and a Class C felony for a second or subsequent offense; and
 - 2. a. Except as provided in subdivision b. of this subparagraph, where the trafficked substance was heroin and the defendant committed the offense while possessing more than one (1) items of paraphernalia, including but not limited to scales, ledgers, instruments and material to cut, package, or mix the final product, excess cash, multiple subscriber identity modules in excess of the number of communication devices possessed by the person at the time of arrest, or weapons, which given the totality of the circumstances indicate the trafficking to have been a commercial activity, shall not be released on parole until he or she has served at least fifty percent (50%) of the sentence imposed.
 - b. This subparagraph shall not apply to a person who has been determined by a court to have had a substance use disorder relating to a controlled substance at the time of the offense. "Substance use disorder" shall have

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the same meaning as in the current edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

- (c) Any person convicted of a Class C felony offense or higher under this section shall not be released on probation, shock probation, parole, conditional discharge, or other form of early release until he or she has served at least fifty percent (50%) of the sentence imposed in cases where the trafficked substance was heroin, *fentanyl, carfentanil, or fentanyl derivatives.*

➔Section 6. KRS 218A.142 is amended to read as follows:

- (1) A person is guilty of aggravated trafficking in a controlled substance in the first degree when he or she knowingly and unlawfully traffics in:
- (a) One hundred (100) grams or more of heroin;
 - (b) *Twenty-eight (28) grams or more of fentanyl; or*
 - (c) *Ten (10) grams or more of carfentanil or fentanyl derivatives.*
- (2) Aggravated trafficking in a controlled substance in the first degree is a Class B felony, and the defendant shall not be released on probation, shock probation, conditional discharge, or parole until he or she has served at least fifty percent (50%) of the sentence imposed.

➔Section 7. KRS 218A.205 is amended to read as follows:

- (1) As used in this section:
- (a) "Reporting agency" includes:
 - 1. The Department of Kentucky State Police;
 - 2. The Office of the Attorney General;
 - 3. The Cabinet for Health and Family Services; and
 - 4. The applicable state licensing board; and
 - (b) "State licensing board" means:
 - 1. The Kentucky Board of Medical Licensure;

2. The Kentucky Board of Nursing;
 3. The Kentucky Board of Dentistry;
 4. The Kentucky Board of Optometric Examiners;
 5. The State Board of Podiatry; and
 6. Any other board that licenses or regulates a person who is entitled to prescribe or dispense controlled substances to humans.
- (2) (a) When a reporting agency or a law enforcement agency receives a report of improper, inappropriate, or illegal prescribing or dispensing of a controlled substance it may, to the extent otherwise allowed by law, send a copy of the report within three (3) business days to every other reporting agency.
- (b) A county attorney or Commonwealth's attorney shall notify the Office of the Attorney General and the appropriate state licensing board within three (3) business days of an indictment or a waiver of indictment becoming public in his or her jurisdiction charging a licensed person with a felony offense relating to the manufacture of, trafficking in, prescribing, dispensing, or possession of a controlled substance.
- (3) Each state licensing board shall, **in consultation with the Kentucky Office of Drug Control Policy**, establish the following by administrative regulation for those licensees authorized to prescribe or dispense controlled substances:
- (a) Mandatory prescribing and dispensing standards related to controlled substances, the requirements of which shall include the diagnostic, treatment, review, and other protocols and standards established for Schedule II controlled substances and Schedule III controlled substances containing hydrocodone under KRS 218A.172 and which may include the exemptions authorized by KRS 218A.172(4);
 - (b) **In accord with the CDC Guideline for Prescribing Opioids for Chronic Pain published in 2016, a prohibition on a practitioner issuing a prescription for a**

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Schedule II controlled substance for more than a three (3) day supply of a Schedule II controlled substance if the prescription is intended to treat pain as an acute medical condition, with the following exceptions:

1. The practitioner, in his or her professional judgment believes that more than a three (3) day supply of a Schedule II controlled substance is medically necessary to treat the patient's pain as an acute medical condition and the practitioner adequately documents the acute medical condition and lack of alternative treatment options which justifies deviation from the three (3) day supply limit established in this subsection in the patient's medical records;
2. The prescription for a Schedule II controlled substance is prescribed to treat chronic pain;
3. The prescription for a Schedule II controlled substance is prescribed to treat pain associated with a valid cancer diagnosis;
4. The prescription for a Schedule II controlled substance is prescribed to treat pain while the patient is receiving hospice or end-of-life treatment;
5. The prescription for a Schedule II controlled substance is prescribed as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;
6. The prescription for a Schedule II controlled substance is prescribed to treat pain following a major surgery or the treatment of significant trauma, as defined by the state licensing board in consultation with the Kentucky Office of Drug Control Policy;
7. The Schedule II controlled substance is dispensed or administered directly to an ultimate user in an inpatient setting; or
8. Any additional treatment scenario deemed medically necessary by the state

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**licensing board in consultation with the Kentucky Office of Drug Control
Policy.**

**Nothing in this paragraph shall authorize a state licensing board to promulgate
regulations which expand any practitioner's prescriptive authority beyond that
which existed prior to the effective date of this Act;**

- (c)** A prohibition on a practitioner dispensing greater than a forty-eight (48) hour supply of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone unless the dispensing is done as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;
- (d)**~~(e)~~ A procedure for temporarily suspending, limiting, or restricting a license held by a named licensee where a substantial likelihood exists to believe that the continued unrestricted practice by the named licensee would constitute a danger to the health, welfare, or safety of the licensee's patients or of the general public;
- (e)**~~(d)~~ A procedure for the expedited review of complaints filed against their licensees pertaining to the improper, inappropriate, or illegal prescribing or dispensing of controlled substances that is designed to commence an investigation within seven (7) days of a complaint being filed and produce a charging decision by the board on the complaint within one hundred twenty (120) days of the receipt of the complaint, unless an extension for a definite period of time is requested by a law enforcement agency due to an ongoing criminal investigation;
- (f)**~~(e)~~ The establishment and enforcement of licensure standards that conform to the following:
1. A permanent ban on licensees and applicants convicted after July 20, 2012, in this state or any other state of any felony offense relating to controlled substances from prescribing or dispensing a controlled substance;

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2. Restrictions short of a permanent ban on licensees and applicants convicted in this state or any other state of any misdemeanor offense relating to prescribing or dispensing a controlled substance;
 3. Restrictions mirroring in time and scope any disciplinary limitation placed on a licensee or applicant by a licensing board of another state if the disciplinary action results from improper, inappropriate, or illegal prescribing or dispensing of controlled substances; and
 4. A requirement that licensees and applicants report to the board any conviction or disciplinary action covered by this subsection with appropriate sanctions for any failure to make this required report;
- ~~(g)~~~~(f)~~ A procedure for the continuous submission of all disciplinary and other reportable information to the National Practitioner Data Bank of the United States Department of Health and Human Services;
- ~~(h)~~~~(g)~~ If not otherwise required by other law, a process for submitting a query on each applicant for licensure to the National Practitioner Data Bank of the United States Department of Health and Human Services to retrieve any relevant data on the applicant; and
- ~~(i)~~~~(h)~~ Continuing education requirements beginning with the first full educational year occurring after July 1, 2012, that specify that at least seven and one-half percent (7.5%) of the continuing education required of the licensed practitioner relate to the use of the electronic monitoring system established in KRS 218A.202, pain management, or addiction disorders.
- (4) **For the purposes of pharmacy dispensing, the medical necessity for a Schedule II controlled substance as documented by the practitioner in the patient's medical record and the prescription for more than a three (3) day supply of that controlled substance are**

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presumed to be valid.

(5) A state licensing board shall employ or obtain the services of a specialist in the treatment of pain and a specialist in drug addiction to evaluate information received regarding a licensee's prescribing or dispensing practices related to controlled substances if the board or its staff does not possess such expertise, to ascertain if the licensee under investigation is engaging in improper, inappropriate, or illegal practices.

~~(6)(5)~~ Any statute to the contrary notwithstanding, no state licensing board shall require that a grievance or complaint against a licensee relating to controlled substances be sworn to or notarized, but the grievance or complaint shall identify the name and address of the grievant or complainant, unless the board by administrative regulation authorizes the filing of anonymous complaints. Any such authorizing administrative regulation shall require that an anonymous complaint or grievance be accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint or grievance is meritorious.

~~(7)(6)~~ Every state licensing board shall cooperate to the maximum extent permitted by law with all state, local, and federal law enforcement agencies, and all professional licensing boards and agencies, state and federal, in the United States or its territories in the coordination of actions to deter the improper, inappropriate, or illegal prescribing or dispensing of a controlled substance.

~~(8)(7)~~ Each state licensing board shall require a fingerprint-supported criminal record check by the Department of Kentucky State Police and the Federal Bureau of Investigation of any applicant for initial licensure to practice any profession authorized to prescribe or dispense controlled substances.

➔SECTION 8. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

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- (1) A person is guilty of trafficking in a misrepresented controlled substance when he or she knowingly and unlawfully sells or distributes any Schedule I controlled substance, carfentanil, or fentanyl while misrepresenting the identity of the Schedule I controlled substance, carfentanil, or fentanyl being sold or distributed as a legitimate pharmaceutical product.**
- (2) The provisions of this section are intended to be a separate offense from others in this chapter, and shall be punished in addition to violations of this chapter occurring during the same course of conduct.**
- (3) Trafficking in a misrepresented controlled substance is a Class D felony.**

➔Section 9. KRS 218A.180 is amended to read as follows:

- (1) Except when dispensed directly by a practitioner to an ultimate user, no ~~methamphetamine or~~ controlled substance **listed** in Schedule II may be dispensed without the written, facsimile, ~~or~~ **electronic, or oral** prescription of a practitioner. A prescription for a controlled substance **listed** in Schedule II may be dispensed by a facsimile prescription only as specified in administrative regulations promulgated by the cabinet. **A prescription for a controlled substance listed in Schedule II may be dispensed by oral prescription only for immediate administration to a patient enrolled in a hospice program or a resident in a long-term care facility, as defined in KRS 216.535, excluding a family care home or personal care home, and the practitioner determines that immediate administration is necessary, no appropriate alternative treatment is available, and it is not reasonably possible for the prescriber to provide a written prescription.** No prescription for a controlled substance in Schedule II shall be valid after sixty (60) days from the date issued. No prescription for a controlled substance in Schedule II shall be refilled. All prescriptions for controlled substances classified in Schedule II shall be maintained in a separate prescription file.

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- (2) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedules III, IV, and V, which is a prescription drug, shall not be dispensed without a written, facsimile, electronic, or oral prescription by a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date issued or be refilled more than five (5) times, unless renewed by the practitioner and a new prescription, written, electronic, or oral shall be required.
- (3) (a) To be valid, a prescription for a controlled substance shall be issued only for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. Responsibility for the proper dispensing of a controlled substance pursuant to a prescription for a legitimate medical purpose is upon the pharmacist who fills the prescription.
- (b) A prescription shall not be issued for a practitioner to obtain a controlled substance for the purpose of general dispensing or administering to patients.
- (4) All written, ~~and~~ facsimile, **and electronic** prescriptions for controlled substances shall be dated and signed by the practitioner on the date issued. **A computer-generated prescription that is printed out or faxed by the practitioner shall be manually signed. A prescription may be transmitted by facsimile only as specified in administrative regulations promulgated by the cabinet. Electronic prescriptions shall be created, signed, and transmitted in accordance with the requirements of 21 C.F.R. Part 1311** ~~and shall bear the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner~~.
- (5) All ~~oral, facsimile, or electronic~~ prescriptions **for controlled substances** shall include the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

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- (6) All oral prescriptions for controlled substances shall be immediately reduced to writing, dated, and signed by the pharmacist.
- (7) A pharmacist refilling any prescription shall record on the prescription or other equivalent record the date, the quantity, and the pharmacist's initials. The maintenance of prescription records under the federal controlled substances laws and regulations containing substantially the same information as specified in this subsection shall constitute compliance with this subsection.
- (8) The pharmacist filling a written, facsimile, electronic, or oral prescription for a controlled substance shall affix to the package a label showing the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner and directions for use and cautionary statements, if any, contained in such prescription or required by law.
- (9) Any person who violates any provision of this section shall:
 - (a) For the first offense, be guilty of a Class A misdemeanor.
 - (b) For a second or subsequent offense, be guilty of a Class D felony.

➔Section 10. KRS 218A.202 is amended to read as follows:

- (1) The Cabinet for Health and Family Services shall establish 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.

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- (2) A practitioner or a pharmacist authorized to prescribe 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 dispenser within the Commonwealth who is licensed, permitted, or otherwise authorized to prescribe or dispense a controlled substance to a person 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 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;
 - (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) Data for each controlled substance that is dispensed shall include but not be limited to the following:

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- (a) Patient identifier;
 - (b) National drug code of the drug dispensed;
 - (c) Date of dispensing;
 - (d) Quantity dispensed;
 - (e) Prescriber; and
 - (f) Dispenser.
- (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.
- (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, 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

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full-time peace officer of another state, or a federal 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 (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 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.

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- (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.
- (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 (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 (6)(b) of this section authorized to receive data or a report if the persons specified in subsection (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 (6)(a) of this section, or with a law enforcement officer designated in subsection (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;

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- (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 (6)(e) of this section may share the report with the patient or person authorized to act on the patient's behalf and place the report in the patient's medical record, with that individual report then 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.
- (9) The Cabinet for Health and Family Services, all peace officers specified in subsection (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.
- (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.
- (11) Intentional failure 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.
- (12) Intentional disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class B

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

- (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.
- (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

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- 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.
- (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.
- (18) **The Cabinet for Health and Family Services, Office of Inspector General, shall conduct quarterly reviews to identify patterns of potential improper, inappropriate, or illegal prescribing or dispensing of a controlled substance. The Office of Inspector General may independently investigate and submit findings and recommendations to the appropriate boards of licensure or other reporting agencies.**
- (19)** 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 (8) of this section to request the correction of inaccurate information contained in the system relating to that patient; and
- (b) 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."