

1 AN ACT relating to prescription drugs.

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

3 ➔Section 1. KRS 205.529 is amended to read as follows:

- 4 (1) The Department for Medicaid Services or a managed care organization contracted
5 to provide services pursuant to this chapter shall provide a program for
6 synchronization of medications when it is agreed among the member, a provider,
7 and a pharmacist that synchronization of multiple prescriptions for the treatment of
8 a chronic illness is in the best interest of the patient for the management or
9 treatment of a chronic illness provided that the medications:
- 10 (a) Are covered by the Department for Medicaid Services or a managed care
11 organization contracted to provide services pursuant to this chapter;
 - 12 (b) Are used for treatment and management of chronic conditions that are subject
13 to refills;
 - 14 (c) Are not a Schedule II controlled substance~~[or a Schedule III controlled~~
15 ~~substance containing hydrocodone]~~;
 - 16 (d) Meet all prior authorization criteria specific to the medications at the time of
17 the synchronization request;
 - 18 (e) Are of a formulation that can be effectively split over required short fill
19 periods to achieve synchronization; and
 - 20 (f) Do not have quantity limits or dose optimization criteria or requirements that
21 would be violated in fulfilling synchronization.
- 22 (2) When applicable to permit synchronization, the Department for Medicaid Services
23 or a managed care organization contracted to provide services pursuant to this
24 chapter shall apply a prorated daily cost-sharing rate to any medication dispensed
25 by a network pharmacy pursuant to this section.
- 26 (3) Any dispensing fee shall not be prorated and shall be based on an individual
27 prescription filled or refilled.

1 ➔Section 2. KRS 218A.010 is amended to read as follows:

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

- 3 (1) "Administer" means the direct application of a controlled substance, whether by
4 injection, inhalation, ingestion, or any other means, to the body of a patient or
5 research subject by:
- 6 (a) A practitioner or by his or her authorized agent under his or her immediate
7 supervision and pursuant to his or her order; or
- 8 (b) The patient or research subject at the direction and in the presence of the
9 practitioner;
- 10 (2) "Anabolic steroid" means any drug or hormonal substance chemically and
11 pharmacologically related to testosterone that promotes muscle growth and includes
12 those substances classified as Schedule III controlled substances pursuant to KRS
13 218A.020 but does not include estrogens, progestins, and anticosteroids;
- 14 (3) "Cabinet" means the Cabinet for Health and Family Services;
- 15 (4) "Carfentanil" means any substance containing any quantity of carfentanil, or any of
16 its salts, isomers, or salts of isomers;
- 17 (5) "Certified community based palliative care program" means a palliative care
18 program which has received certification from the Joint Commission;
- 19 (6) "Child" means any person under the age of majority as specified in KRS 2.015;
- 20 (7) "Cocaine" means a substance containing any quantity of cocaine, its salts, optical
21 and geometric isomers, and salts of isomers;
- 22 (8) "Controlled substance" means methamphetamine, or a drug, substance, or
23 immediate precursor in Schedules I through V and includes a controlled substance
24 analogue;
- 25 (9) (a) "Controlled substance analogue," except as provided in paragraph (b) of this
26 subsection, means a substance:
- 27 1. The chemical structure of which is substantially similar to the structure

- 1 of a controlled substance in Schedule I or II; and
- 2 2. Which has a stimulant, depressant, or hallucinogenic effect on the
- 3 central nervous system that is substantially similar to or greater than the
- 4 stimulant, depressant, or hallucinogenic effect on the central nervous
- 5 system of a controlled substance in Schedule I or II; or
- 6 3. With respect to a particular person, which such person represents or
- 7 intends to have a stimulant, depressant, or hallucinogenic effect on the
- 8 central nervous system that is substantially similar to or greater than the
- 9 stimulant, depressant, or hallucinogenic effect on the central nervous
- 10 system of a controlled substance in Schedule I or II.
- 11 (b) Such term does not include:
- 12 1. Any substance for which there is an approved new drug application;
- 13 2. With respect to a particular person, any substance if an exemption is in
- 14 effect for investigational use for that person pursuant to federal law to
- 15 the extent conduct with respect to such substance is pursuant to such
- 16 exemption; or
- 17 3. Any substance to the extent not intended for human consumption before
- 18 the exemption described in subparagraph 2. of this paragraph takes
- 19 effect with respect to that substance;
- 20 (10) "Counterfeit substance" means a controlled substance which, or the container or
- 21 labeling of which, without authorization, bears the trademark, trade name, or other
- 22 identifying mark, imprint, number, or device, or any likeness thereof, of a
- 23 manufacturer, distributor, or dispenser other than the person who in fact
- 24 manufactured, distributed, or dispensed the substance;
- 25 (11) "Dispense" means to deliver a controlled substance to an ultimate user or research
- 26 subject by or pursuant to the lawful order of a practitioner, including the packaging,
- 27 labeling, or compounding necessary to prepare the substance for that delivery;

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

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

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

7 (15) "Drug" means:

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

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

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

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

17 It does not include devices or their components, parts, or accessories;

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

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

24 (a) By substitution:

25 1. At the 2-position of the 1-ethyl group with a phenyl, furan, thiophene, or
26 ethyloxotetrazole ring system; and

27 2. Of the terminal amido hydrogen atom with an alkyl, alkoxy, cycloalkyl,

1 or furanyl group; and

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

3 1. By substitution on the N-phenyl ring to any extent with alkyl, alkoxy,
4 haloalkyl, hydroxyl, or halide substituents;

5 2. By substitution on the piperadine ring to any extent with alkyl, allyl,
6 alkoxy, hydroxy, or halide substituents at the 2-, 3-, 5-, and/or 6-
7 positions;

8 3. By substitution on the piperadine ring to any extent with a phenyl,
9 alkoxy, or carboxylate ester substituent at the 4- position; or

10 4. By substitution on the 1-ethyl group to any extent with alkyl, alkoxy, or
11 hydroxy substituents;

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

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

23 (a) Poses an explosion hazard;

24 (b) Poses a fire hazard; or

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

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

- 1 (21) "Hydrocodone combination product" means a drug with:
- 2 (a) Not more than three hundred (300) milligrams of dihydrocodeinone, or any of
- 3 its salts, per one hundred (100) milliliters or not more than fifteen (15)
- 4 milligrams per dosage unit, with a fourfold or greater quantity of an
- 5 isoquinoline alkaloid of opium; or
- 6 (b) Not more than three hundred (300) milligrams of dihydrocodeinone, or any of
- 7 its salts, per one hundred (100) milliliters or not more than fifteen (15)
- 8 milligrams per dosage unit, with one (1) or more active, nonnarcotic
- 9 ingredients in recognized therapeutic amounts;
- 10 (22) "Immediate precursor" means a substance which is the principal compound
- 11 commonly used or produced primarily for use, and which is an immediate chemical
- 12 intermediary used or likely to be used in the manufacture of a controlled substance
- 13 or methamphetamine, the control of which is necessary to prevent, curtail, or limit
- 14 manufacture;
- 15 (23) "Industrial hemp" has the same meaning as in KRS 260.850;
- 16 (24) "Industrial hemp products" has the same meaning as in KRS 260.850;
- 17 (25) "Intent to manufacture" means any evidence which demonstrates a person's
- 18 conscious objective to manufacture a controlled substance or methamphetamine.
- 19 Such evidence includes but is not limited to statements and a chemical substance's
- 20 usage, quantity, manner of storage, or proximity to other chemical substances or
- 21 equipment used to manufacture a controlled substance or methamphetamine;
- 22 (26) "Isomer" means the optical isomer, except the Cabinet for Health and Family
- 23 Services may include the optical, positional, or geometric isomer to classify any
- 24 substance pursuant to KRS 218A.020;
- 25 (27) "Manufacture," except as provided in KRS 218A.1431, means the production,
- 26 preparation, propagation, compounding, conversion, or processing of a controlled
- 27 substance, either directly or indirectly by extraction from substances of natural

1 origin or independently by means of chemical synthesis, or by a combination of
2 extraction and chemical synthesis, and includes any packaging or repackaging of
3 the substance or labeling or relabeling of its container except that this term does not
4 include activities:

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

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

10 (c) By a pharmacist as an incident to his or her dispensing of a controlled
11 substance in the course of his or her professional practice;

12 (28) "Marijuana" means all parts of the plant Cannabis sp., whether growing or not; the
13 seeds thereof; the resin extracted from any part of the plant; and every compound,
14 manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin
15 or any compound, mixture, or preparation which contains any quantity of these
16 substances. The term "marijuana" does not include:

17 (a) Industrial hemp that is in the possession, custody, or control of a person who
18 holds a license issued by the Department of Agriculture permitting that person
19 to cultivate, handle, or process industrial hemp;

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

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

26 (d) For persons participating in a clinical trial or in an expanded access program,
27 a drug or substance approved for the use of those participants by the United

- 1 States Food and Drug Administration;
- 2 (e) A cannabidiol product derived from industrial hemp, as defined in KRS
3 260.850;
- 4 (f) For the purpose of conducting scientific research, a cannabinoid product
5 derived from industrial hemp, as defined in KRS 260.850;
- 6 (g) A cannabinoid product approved as a prescription medication by the United
7 States Food and Drug Administration; or
- 8 (h) Medicinal cannabis as defined in KRS 218B.010;
- 9 (29) "Medical history," as used in KRS Chapter 218A and for criminal prosecution only,
10 means an accounting of a patient's medical background, including but not limited to
11 prior medical conditions, prescriptions, and family background;
- 12 (30) "Medical order," as used in KRS Chapter 218A and for criminal prosecution only,
13 means a lawful order of a specifically identified practitioner for a specifically
14 identified patient for the patient's health-care needs. "Medical order" may or may
15 not include a prescription drug order;
- 16 (31) "Medical record," as used in KRS Chapter 218A and for criminal prosecution only,
17 means a record, other than for financial or billing purposes, relating to a patient,
18 kept by a practitioner as a result of the practitioner-patient relationship;
- 19 (32) "Methamphetamine" means any substance that contains any quantity of
20 methamphetamine, or any of its salts, isomers, or salts of isomers;
- 21 (33) "Narcotic drug" means any of the following, whether produced directly or indirectly
22 by extraction from substances of vegetable origin, or independently by means of
23 chemical synthesis, or by a combination of extraction and chemical synthesis:
- 24 (a) Opium and opiate, and any salt, compound, derivative, or preparation of
25 opium or opiate;
- 26 (b) Any salt, compound, isomer, derivative, or preparation thereof which is
27 chemically equivalent or identical with any of the substances referred to in

- 1 paragraph (a) of this subsection, but not including the isoquinoline alkaloids
2 of opium;
- 3 (c) Opium poppy and poppy straw;
- 4 (d) Coca leaves, except coca leaves and extracts of coca leaves from which
5 cocaine, ecgonine, and derivatives of ecgonine or their salts have been
6 removed;
- 7 (e) Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- 8 (f) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; and
- 9 (g) Any compound, mixture, or preparation which contains any quantity of any of
10 the substances referred to in paragraphs (a) to (f) of this subsection;
- 11 (34) "Opiate" means any substance having an addiction-forming or addiction-sustaining
12 liability similar to morphine or being capable of conversion into a drug having
13 addiction-forming or addiction-sustaining liability. It does not include, unless
14 specifically designated as controlled under KRS 218A.020, the dextrorotatory
15 isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does
16 include its racemic and levorotatory forms;
- 17 (35) "Opium poppy" means the plant of the species *papaver somniferum* L., except its
18 seeds;
- 19 (36) "Person" means individual, corporation, government or governmental subdivision
20 or agency, business trust, estate, trust, partnership or association, or any other legal
21 entity;
- 22 (37) "Physical injury" has the same meaning it has in KRS 500.080;
- 23 (38) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing;
- 24 (39) "Pharmacist" means a natural person licensed by this state to engage in the practice
25 of the profession of pharmacy;
- 26 (40) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific
27 investigator, optometrist as authorized in KRS 320.240, advanced practice

1 registered nurse as authorized under KRS 314.011, physician assistant as authorized
2 under KRS 311.858, or other person licensed, registered, or otherwise permitted by
3 state or federal law to acquire, distribute, dispense, conduct research with respect to,
4 or to administer a controlled substance in the course of professional practice or
5 research in this state. "Practitioner" also includes a physician, dentist, podiatrist,
6 veterinarian, optometrist, physician assistant, or advanced practice registered nurse
7 ~~authorized under KRS 314.011~~ who is a resident of and actively practicing in a
8 state other than Kentucky and who is licensed and has prescriptive authority for
9 controlled substances under the professional licensing laws of another state, unless
10 the person's Kentucky license has been revoked, suspended, restricted, or probated,
11 in which case the terms of the Kentucky license shall prevail;

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

16 (42) "Prescription" means a written, electronic, or oral order for a drug or medicine, or
17 combination or mixture of drugs or medicines, or proprietary preparation, signed or
18 given or authorized by a medical, dental, chiropody, veterinarian, optometric
19 practitioner, or advanced practice registered nurse, and intended for use in the
20 diagnosis, cure, mitigation, treatment, or prevention of disease in man or other
21 animals;

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

24 (44) "Presumptive probation" means a sentence of probation not to exceed the maximum
25 term specified for the offense, subject to conditions otherwise authorized by law,
26 that is presumed to be the appropriate sentence for certain offenses designated in
27 this chapter, notwithstanding contrary provisions of KRS Chapter 533. That

- 1 presumption shall only be overcome by a finding on the record by the sentencing
2 court of substantial and compelling reasons why the defendant cannot be safely and
3 effectively supervised in the community, is not amenable to community-based
4 treatment, or poses a significant risk to public safety;
- 5 (45) "Production" includes the manufacture, planting, cultivation, growing, or harvesting
6 of a controlled substance;
- 7 (46) "Recovery program" means an evidence-based, nonclinical service that assists
8 individuals and families working toward sustained recovery from substance use and
9 other criminal risk factors. This can be done through an array of support programs
10 and services that are delivered through residential and nonresidential means;
- 11 (47) "Salvia" means *Salvia divinorum* or *Salvinorin A* and includes all parts of the plant
12 presently classified botanically as *Salvia divinorum*, whether growing or not, the
13 seeds thereof, any extract from any part of that plant, and every compound,
14 manufacture, derivative, mixture, or preparation of that plant, its seeds, or its
15 extracts, including salts, isomers, and salts of isomers whenever the existence of
16 such salts, isomers, and salts of isomers is possible within the specific chemical
17 designation of that plant, its seeds, or extracts. The term shall not include any other
18 species in the genus *salvia*;
- 19 (48) "Second or subsequent offense" means that for the purposes of this chapter an
20 offense is considered as a second or subsequent offense, if, prior to his or her
21 conviction of the offense, the offender has at any time been convicted under this
22 chapter, or under any statute of the United States, or of any state relating to
23 substances classified as controlled substances or counterfeit substances, except that
24 a prior conviction for a nontrafficking offense shall be treated as a prior offense
25 only when the subsequent offense is a nontrafficking offense. For the purposes of
26 this section, a conviction voided under KRS 218A.275 or 218A.276 shall not
27 constitute a conviction under this chapter;

- 1 (49) "Sell" means to dispose of a controlled substance to another person for
2 consideration or in furtherance of commercial distribution;
- 3 (50) "Serious physical injury" has the same meaning it has in KRS 500.080;
- 4 (51) "Synthetic cannabinoids or piperazines" means any chemical compound which is
5 not approved by the United States Food and Drug Administration or, if approved,
6 which is not dispensed or possessed in accordance with state and federal law, that
7 contains Benzylpiperazine (BZP); Trifluoromethylphenylpiperazine (TFMPP); 1,1-
8 Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210); 1-Butyl-3-(1-
9 naphthoyl)indole; 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211); or any
10 compound in the following structural classes:
- 11 (a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole
12 structure with substitution at the nitrogen atom of the indole ring by an alkyl,
13 haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-
14 piperidiny)methyl, or 2-(4-morpholiny)ethyl group, whether or not further
15 substituted in the indole ring to any extent and whether or not substituted in
16 the naphthyl ring to any extent. Examples of this structural class include but
17 are not limited to JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-
18 122, JWH-200, and AM-2201;
- 19 (b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole
20 structure with substitution at the nitrogen atom of the indole ring by an alkyl,
21 haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-
22 piperidiny)methyl, or 2-(4-morpholiny)ethyl group whether or not further
23 substituted in the indole ring to any extent and whether or not substituted in
24 the phenyl ring to any extent. Examples of this structural class include but are
25 not limited to JWH-167, JWH-250, JWH-251, and RCS-8;
- 26 (c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with
27 substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl,

1 alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-
2 piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether or not further
3 substituted in the indole ring to any extent and whether or not substituted in
4 the phenyl ring to any extent. Examples of this structural class include but are
5 not limited to AM-630, AM-2233, AM-694, Pravadoline (WIN 48,098), and
6 RCS-4;

7 (d) Cyclohexylphenols: Any compound containing a 2-(3-
8 hydroxycyclohexyl)phenol structure with substitution at the 5-position of the
9 phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl,
10 cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl
11 group whether or not substituted in the cyclohexyl ring to any extent.
12 Examples of this structural class include but are not limited to CP 47,497 and
13 its C8 homologue (cannabicyclohexanol);

14 (e) Naphthylmethylinroles: Any compound containing a 1H-indol-3-yl-(1-
15 naphthyl)methane structure with substitution at the nitrogen atom of the
16 indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl,
17 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether
18 or not further substituted in the indole ring to any extent and whether or not
19 substituted in the naphthyl ring to any extent. Examples of this structural class
20 include but are not limited to JWH-175, JWH-184, and JWH-185;

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

- 1 (g) Naphthylmethylindenes: Any compound containing a 1-(1-
2 naphthylmethyl)indene structure with substitution at the 3-position of the
3 indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl,
4 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group whether
5 or not further substituted in the indene ring to any extent and whether or not
6 substituted in the naphthyl ring to any extent. Examples of this structural class
7 include but are not limited to JWH-176;
- 8 (h) Tetramethylcyclopropanoylindoles: Any compound containing a 3-(1-
9 tetramethylcyclopropoyl)indole structure with substitution at the nitrogen
10 atom of the indole ring by an alkyl, haloalkyl, cycloalkylmethyl,
11 cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl
12 group, whether or not further substituted in the indole ring to any extent and
13 whether or not further substituted in the tetramethylcyclopropyl ring to any
14 extent. Examples of this structural class include but are not limited to UR-144
15 and XLR-11;
- 16 (i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole
17 structure with substitution at the nitrogen atom of the indole ring by an alkyl,
18 haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-
19 piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further
20 substituted in the indole ring to any extent and whether or not substituted in
21 the adamantyl ring system to any extent. Examples of this structural class
22 include but are not limited to AB-001 and AM-1248; or
- 23 (j) Any other synthetic cannabinoid or piperazine which is not approved by the
24 United States Food and Drug Administration or, if approved, which is not
25 dispensed or possessed in accordance with state and federal law;
- 26 (52) "Synthetic cathinones" means any chemical compound which is not approved by
27 the United States Food and Drug Administration or, if approved, which is not

1 dispensed or possessed in accordance with state and federal law (not including
2 bupropion or compounds listed under a different schedule) structurally derived from
3 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl,
4 or thiophene ring systems, whether or not the compound is further modified in one
5 (1) or more of the following ways:

6 (a) By substitution in the ring system to any extent with alkyl, alkylendioxy,
7 alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further
8 substituted in the ring system by one (1) or more other univalent substituents.
9 Examples of this class include but are not limited to 3,4-
10 Methylenedioxcathinone (bk-MDA);

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

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

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

22 (53) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic
23 cathinones;

24 (54) "Telehealth" has the same meaning it has in KRS 211.332;

25 (55) "Tetrahydrocannabinols" means synthetic equivalents of the substances contained
26 in the plant, or in the resinous extractives of the plant Cannabis, sp. or synthetic
27 substances, derivatives, and their isomers with similar chemical structure and

1 pharmacological activity such as the following:

- 2 (a) Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;
- 3 (b) Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; and
- 4 (c) Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

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

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

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

14 ➔Section 3. KRS 218A.172 is amended to read as follows:

15 (1) Administrative regulations promulgated under KRS 218A.205(3) shall require that,
16 prior to the initial prescribing or dispensing of any Schedule II controlled substance
17 ~~for a Schedule III controlled substance containing hydrocodone~~ to a human patient,
18 a practitioner shall:

- 19 (a) Obtain a medical history and conduct a physical or mental health examination
20 of the patient, as appropriate to the patient's medical complaint, and document
21 the information in the patient's medical record;
- 22 (b) Query the electronic monitoring system established in KRS 218A.202 for all
23 available data on the patient for the twelve (12) month period immediately
24 preceding the patient encounter and appropriately utilize that data in the
25 evaluation and treatment of the patient;
- 26 (c) Make a written plan stating the objectives of the treatment and further
27 diagnostic examinations required;

- 1 (d) Discuss the risks and benefits of the use of controlled substances with the
2 patient, the patient's parent if the patient is an unemancipated minor child, or
3 the patient's legal guardian or health care surrogate, including the risk of
4 tolerance and drug dependence; and
- 5 (e) Obtain written consent for the treatment.
- 6 (2) (a) Administrative regulations promulgated under KRS 218A.205(3) shall require
7 that a practitioner prescribing or dispensing additional amounts of Schedule II
8 controlled substances ~~for Schedule III controlled substances containing~~
9 ~~hydrocodone~~ for the same medical complaint and related symptoms shall:
- 10 1. Review, at reasonable intervals based on the patient's individual
11 circumstances and course of treatment, the plan of care;
- 12 2. Provide to the patient any new information about the treatment; and
- 13 3. Modify or terminate the treatment as appropriate.
- 14 (b) If the course of treatment extends beyond three (3) months, the administrative
15 regulations shall also require that the practitioner:
- 16 1. Query the electronic monitoring system established in KRS 218A.202
17 no less than once every three (3) months for all available data on the
18 patient for the twelve (12) month period immediately preceding the
19 query; and
- 20 2. Review that data before issuing any new prescription or refills for the
21 patient for any Schedule II controlled substance ~~or a Schedule III~~
22 ~~controlled substance containing hydrocodone~~.
- 23 (3) Administrative regulations promulgated under KRS 218A.205(3) shall require
24 that~~[,]~~ for each patient for whom a practitioner prescribes any Schedule II
25 controlled substance ~~for a Schedule III controlled substance containing~~
26 ~~hydrocodone,~~ the practitioner shall keep accurate, readily accessible, and complete
27 medical records which include, as appropriate:

- 1 (a) Medical history and physical or mental health examination;
- 2 (b) Diagnostic, therapeutic, and laboratory results;
- 3 (c) Evaluations and consultations;
- 4 (d) Treatment objectives;
- 5 (e) Discussion of risk, benefits, and limitations of treatments;
- 6 (f) Treatments;
- 7 (g) Medications, including date, type, dosage, and quantity prescribed or
- 8 dispensed;
- 9 (h) Instructions and agreements; and
- 10 (i) Periodic reviews of the patient's file.
- 11 (4) Administrative regulations promulgated under KRS 218A.205(3) may exempt, in
- 12 whole or in part, compliance with the mandatory diagnostic, treatment, review, and
- 13 other protocols and standards established in this section for:
 - 14 (a) A licensee prescribing or administering a controlled substance immediately
 - 15 prior to, during, or within the fourteen (14) days following an operative or
 - 16 invasive procedure or a delivery if the prescribing or administering is
 - 17 medically related to the operative or invasive procedure or the delivery and
 - 18 the medication usage does not extend beyond the fourteen (14) days;
 - 19 (b) A licensee prescribing or administering a controlled substance necessary to
 - 20 treat a patient in an emergency situation;
 - 21 (c) A licensed pharmacist or other person licensed by the Kentucky Board of
 - 22 Pharmacy to dispense drugs or a licensed pharmacy;
 - 23 (d) A licensee prescribing or dispensing a controlled substance:
 - 24 1. For administration in a hospital or long-term-care facility if the hospital
 - 25 or long-term-care facility with an institutional account, or a practitioner
 - 26 in those hospitals or facilities where no institutional account exists,
 - 27 queries the electronic monitoring system established in KRS 218A.202

- 1 for all available data on the patient or resident for the twelve (12) month
2 period immediately preceding the query within twelve (12) hours of the
3 patient's or resident's admission and places a copy of the query in the
4 patient's or resident's medical records during the duration of the patient's
5 stay at the facility;
- 6 2. As part of the patient's hospice or end-of-life treatment;
- 7 3. For the treatment of pain associated with cancer or with the treatment of
8 cancer;
- 9 4. In a single dose to relieve the anxiety, pain, or discomfort experienced
10 by a patient submitting to a diagnostic test or procedure;
- 11 5. Within seven (7) days of an initial prescribing or dispensing under
12 subsection (1) of this section if the prescribing or dispensing:
- 13 a. Is done as a substitute for the initial prescribing or dispensing;
- 14 b. Cancels any refills for the initial prescription; and
- 15 c. Requires the patient to dispose of any remaining unconsumed
16 medication;
- 17 6. Within ninety (90) days of an initial prescribing or dispensing under
18 subsection (1) of this section if the prescribing or dispensing is done by
19 another practitioner in the same practice or in an existing coverage
20 arrangement, if done for the same patient for the same medical
21 condition; or
- 22 7. To a research subject enrolled in a research protocol approved by an
23 institutional review board that has an active federalwide assurance
24 number from the United States Department of Health and Human
25 Services, Office for Human Research Protections, where the research
26 involves single, double, or triple blind drug administration or is
27 additionally covered by a certificate of confidentiality from the National

1 Institutes of Health;

2 (e) The prescribing of a Schedule III, IV, or V controlled substance by a licensed
3 optometrist to a patient in accordance with the provisions of KRS 320.240; or

4 (f) The prescribing of a three (3) day supply of a Schedule III controlled
5 substance following the performance of oral surgery by a dentist licensed
6 pursuant to KRS Chapter 313.

7 (5) (a) A state licensing board promulgating administrative regulations under KRS
8 218A.205(3) may promulgate an administrative regulation in accordance
9 with KRS Chapter 13A authorizing exemptions supplemental or in addition to
10 those specified in subsection (4) of this section. Prior to exercising this
11 authority, the board shall:

12 1. Notify the Kentucky Office of Drug Control Policy that it is considering
13 a proposal to promulgate an administrative regulation authorizing
14 exemptions supplemental or in addition to those specified in subsection
15 (4) of this section and invite the office to participate in the board
16 meeting at which the proposal will be considered;

17 2. Make a factual finding based on expert testimony as well as evidence or
18 research submitted to the board that the exemption demonstrates a low
19 risk of diversion or abuse and is supported by the dictates of good
20 medical practice; and

21 3. Submit a report to the Governor and the Legislative Research
22 Commission of its actions, including a detailed explanation of the
23 factual and policy basis underlying the board's action. A copy of this
24 report shall be provided to the regulations compiler.

25 (b) Within one (1) working day of promulgating an administrative regulation
26 authorizing an exemption under this section, the promulgating board shall
27 email~~te-mail~~ to the Kentucky Office of Drug Control Policy:

- 1 1. A copy of the administrative regulation as filed, and all attachments
- 2 required by KRS 13A.230(1); and
- 3 2. A request from the board that the office review the administrative
- 4 regulation in the same manner as would the Commission on Small
- 5 Business Innovation and Advocacy under KRS 11.202(1)(e), and submit
- 6 its report or comments in accordance with the deadline established in
- 7 KRS 13A.270(1)(c). A copy of the report or comments shall be filed
- 8 with the regulations compiler.

9 ➔Section 4. KRS 218A.182 is amended to read as follows:

- 10 (1) Notwithstanding KRS 218A.180 or any other state law to the contrary, beginning
- 11 January 1, 2021, no practitioner shall issue any prescription for a controlled
- 12 substance unless the prescription is made by electronic prescription from the
- 13 practitioner issuing the prescription to a pharmacy, except for prescriptions issued:
- 14 (a) By veterinarians;
- 15 (b) In circumstances where electronic prescribing is not available due to
- 16 temporary technological or electrical failure;
- 17 (c) By a practitioner to be dispensed by a pharmacy located outside the state;
- 18 (d) When the prescriber and dispenser are the same entity;
- 19 (e) That include elements that are not supported by the most recently
- 20 implemented version of the National Council for Prescription Drug Programs
- 21 Prescriber/Pharmacist Interface SCRIPT Standard;
- 22 (f) By a practitioner for a drug that contains certain elements that cannot be
- 23 incorporated as required by the United States Food and Drug Administration
- 24 with electronic prescribing, including extemporaneous compounding;
- 25 (g) By a practitioner allowing for the dispensing of a nonpatient specific
- 26 prescription under a standing order, approved protocol for drug therapy, or
- 27 collaborative drug management or comprehensive medication management, in

1 response to a public health emergency;

2 (h) By a practitioner prescribing a drug under a research protocol;

3 (i) By practitioners who have received a waiver or a renewal thereof, from the
4 requirement to use electronic prescribing due to economic hardship,
5 technological limitations that are not reasonably within the control of the
6 practitioner, or other exceptional circumstance demonstrated by the
7 practitioner. The initial waiver and each subsequent waiver renewal shall not
8 exceed one (1) year per waiver or waiver renewal;

9 (j) By a practitioner under circumstances where, notwithstanding the
10 practitioner's present ability to make an electronic prescription as required by
11 this subsection, the practitioner reasonably determines that it would be
12 impractical for the patient to obtain substances prescribed by electronic
13 prescription in a timely manner, and delay would adversely impact the
14 patient's medical condition;

15 (k) By a practitioner for an individual who receives hospice care;~~or~~

16 (l) By a practitioner for an individual who is a resident of a nursing facility;or

17 (m) By a practitioner who is issuing a prescription as part of providing
18 charitable health care services pursuant to the Kentucky Charitable Health
19 Care Services Act, KRS 216.940 to 216.945.

20 (2) A pharmacist who receives a written, oral, or faxed prescription for a controlled
21 substance shall not be required to verify that the prescription properly falls under
22 one (1) of the exceptions from the requirement to electronically prescribe.
23 Pharmacists may continue to dispense medications from otherwise valid written,
24 oral, or fax prescriptions that are consistent with current laws and administrative
25 regulations.

26 (3) The cabinet shall promulgate administrative regulations to implement this section
27 including enforcement mechanisms, waivers of requirements, and appropriate

1 penalties for violations.

2 ➔Section 5. KRS 218A.202 is amended to read as follows:

3 (1) As used in this section:

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

5 (b) "Cannabis business" has the same meaning as in KRS 218B.010;

6 (c) "Controlled substance" means any Schedule II, III, IV, or V controlled
7 substance and does not include medicinal cannabis;

8 (d) "Dispensary" has the same meaning as in KRS 218B.010;

9 (e) "Dispensary agent" has the same meaning as in KRS 218B.010;

10 (f) "Disqualifying felony offense" has the same meaning as in KRS 218B.010;

11 (g) "Medicinal cannabis" has the same meaning as in KRS 218B.010;

12 (h) "Medicinal cannabis practitioner" has the same meaning as in KRS 218B.010;

13 (i) "Registry identification card" has the same meaning as in KRS 218B.010;

14 (j) "State licensing board" has the same meaning as in KRS 218B.010;

15 (k) "Use of medicinal cannabis" has the same meaning as in KRS 218B.010; and

16 (l) "Written certification" has the same meaning as in KRS 218B.010.

17 (2) The cabinet shall establish and maintain an electronic system for monitoring
18 Schedules II, III, IV, and V controlled substances and medicinal cannabis. The
19 cabinet may contract for the design, upgrade, or operation of this system if the
20 contract preserves all of the rights, privileges, and protections guaranteed to
21 Kentucky citizens under this chapter and the contract requires that all other aspects
22 of the system be operated in conformity with the requirements of this or any other
23 applicable state or federal law.

24 (3) For the purpose of monitoring the prescribing and dispensing of Schedule II, III, IV,
25 or V controlled substances:

26 (a) A practitioner or a pharmacist authorized to prescribe or dispense controlled
27 substances to humans shall register with the cabinet to use the system

1 provided for in this section and shall maintain *an active account with the*
2 *electronic monitoring system*~~[such registration]~~ continuously during the
3 practitioner's or pharmacist's term of licensure and shall not have to pay a fee
4 or tax specifically dedicated to the operation of the system;

5 (b) Every practitioner or pharmacy which dispenses a controlled substance to a
6 person in Kentucky, or to a person at an address in Kentucky, shall report to
7 the cabinet the data required by this section, which includes the reporting of
8 any Schedule II controlled substance dispensed at a facility licensed by the
9 cabinet and a Schedule II through Schedule V controlled substance regardless
10 of dosage when dispensed by the emergency department of a hospital to an
11 emergency department patient. Reporting shall not be required for:

- 12 1. A drug administered directly to a patient in a hospital, a resident of a
13 health care facility licensed under KRS Chapter 216B, a resident of a
14 child-caring facility as defined by KRS 199.011, or an individual in a
15 jail, correctional facility, or juvenile detention facility;
- 16 2. A Schedule III through Schedule V controlled substance dispensed by a
17 facility licensed by the cabinet provided that the quantity dispensed is
18 limited to an amount adequate to treat the patient for a maximum of
19 forty-eight (48) hours and is not dispensed by the emergency department
20 of a hospital; or
- 21 3. A drug administered or dispensed to a research subject enrolled in a
22 research protocol approved by an institutional review board that has an
23 active federalwide assurance number from the United States Department
24 of Health and Human Services, Office for Human Research Protections,
25 where the research involves single, double, or triple blind drug
26 administration or is additionally covered by a certificate of
27 confidentiality from the National Institutes of Health;

- 1 (c) In addition to the data required by paragraph (d) of this subsection, a
2 Kentucky-licensed acute care hospital or critical access hospital shall report to
3 the cabinet all positive toxicology screens that were performed by the
4 hospital's emergency department to evaluate the patient's suspected drug
5 overdose;
- 6 (d) Data for each controlled substance that is reported shall include but not be
7 limited to the following:
- 8 1. Patient identifier;
 - 9 2. National drug code of the drug dispensed;
 - 10 3. Date of dispensing;
 - 11 4. Quantity dispensed;
 - 12 5. Prescriber; and
 - 13 6. Dispenser;
- 14 (e) The data shall be provided in the electronic format specified by the cabinet
15 unless a waiver has been granted by the cabinet to an individual dispenser.
16 The cabinet shall establish acceptable error tolerance rates for data.
17 Dispensers shall ensure that reports fall within these tolerances. Incomplete or
18 inaccurate data shall be corrected upon notification by the cabinet if the
19 dispenser exceeds these error tolerance rates;
- 20 (f) The cabinet shall only disclose data to persons and entities authorized to
21 receive that data under this subsection. Disclosure to any other person or
22 entity, including disclosure in the context of a civil action where the
23 disclosure is sought either for the purpose of discovery or for evidence, is
24 prohibited unless specifically authorized by this section. The cabinet shall be
25 authorized to provide data to:
- 26 1. A designated representative of a board responsible for the licensure,
27 regulation, or discipline of practitioners, pharmacists, or other person

- 1 who is authorized to prescribe, administer, or dispense controlled
2 substances and who is involved in a bona fide specific investigation
3 involving a designated person;
- 4 2. Employees of the Office of the Inspector General of the cabinet who
5 have successfully completed training for the electronic system and who
6 have been approved to use the system, federal prosecutors, Kentucky
7 Commonwealth's attorneys and assistant Commonwealth's attorneys,
8 county attorneys and assistant county attorneys, a peace officer certified
9 pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer
10 of another state, or a federal agent whose duty is to enforce the laws of
11 this Commonwealth, of another state, or of the United States relating to
12 drugs and who is engaged in a bona fide specific investigation involving
13 a designated person;
- 14 3. A state-operated Medicaid program in conformity with paragraph (g) of
15 this subsection;
- 16 4. A properly convened grand jury pursuant to a subpoena properly issued
17 for the records;
- 18 5. A practitioner or pharmacist, or employee of the practitioner's or
19 pharmacist's practice acting under the specific direction of the
20 practitioner or pharmacist, who certifies that the requested information
21 is for the purpose of:
- 22 a. Providing medical or pharmaceutical treatment to a bona fide
23 current or prospective patient;
- 24 b. Reviewing data on controlled substances that have been reported
25 for the birth mother of an infant who is currently being treated by
26 the practitioner for neonatal abstinence syndrome, or has
27 symptoms that suggest prenatal drug exposure; or

- 1 c. Reviewing and assessing the individual prescribing or dispensing
2 patterns of the practitioner or pharmacist or to determine the
3 accuracy and completeness of information contained in the
4 monitoring system;
- 5 6. The chief medical officer of a hospital or long-term-care facility, an
6 employee of the hospital or long-term-care facility as designated by the
7 chief medical officer and who is working under his or her specific
8 direction, or a physician designee if the hospital or facility has no chief
9 medical officer, if the officer, employee, or designee certifies that the
10 requested information is for the purpose of providing medical or
11 pharmaceutical treatment to a bona fide current or prospective patient or
12 resident in the hospital or facility;
- 13 7. In addition to the purposes authorized under subparagraph 1. of this
14 paragraph, the Kentucky Board of Medical Licensure, for any physician
15 who is:
- 16 a. Associated in a partnership or other business entity with a
17 physician who is already under investigation by the Board of
18 Medical Licensure for improper prescribing or dispensing
19 practices;
- 20 b. In a designated geographic area for which a trend report indicates
21 a substantial likelihood that inappropriate prescribing or
22 dispensing may be occurring; or
- 23 c. In a designated geographic area for which a report on another
24 physician in that area indicates a substantial likelihood that
25 inappropriate prescribing or dispensing may be occurring in that
26 area;
- 27 8. In addition to the purposes authorized under subparagraph 1. of this

- 1 paragraph, the Kentucky Board of Nursing, for any advanced practice
2 registered nurse who is:
- 3 a. Associated in a partnership or other business entity with a
4 physician who is already under investigation by the Kentucky
5 Board of Medical Licensure for improper prescribing or
6 dispensing practices;
 - 7 b. Associated in a partnership or other business entity with an
8 advanced practice registered nurse who is already under
9 investigation by the Board of Nursing for improper prescribing
10 practices;
 - 11 c. In a designated geographic area for which a trend report indicates
12 a substantial likelihood that inappropriate prescribing or
13 dispensing may be occurring; or
 - 14 d. In a designated geographic area for which a report on a physician
15 or another advanced practice registered nurse in that area indicates
16 a substantial likelihood that inappropriate prescribing or
17 dispensing may be occurring in that area;
- 18 9. A judge or a probation or parole officer administering a diversion or
19 probation program of a criminal defendant arising out of a violation of
20 this chapter or of a criminal defendant who is documented by the court
21 as a substance abuser who is eligible to participate in a court-ordered
22 drug diversion or probation program; or
- 23 10. A medical examiner engaged in a death investigation pursuant to KRS
24 72.026;
- 25 (g) The Department for Medicaid Services shall use any data or reports from the
26 system for the purpose of identifying Medicaid providers or recipients whose
27 prescribing, dispensing, or usage of controlled substances may be:

- 1 1. Appropriately managed by a single outpatient pharmacy or primary care
- 2 physician; or
- 3 2. Indicative of improper, inappropriate, or illegal prescribing or
- 4 dispensing practices by a practitioner or drug seeking by a Medicaid
- 5 recipient;
- 6 (h) A person who receives data or any report of the system from the cabinet shall
- 7 not provide it to any other person or entity except as provided in this
- 8 subsection, in another statute, or by order of a court of competent jurisdiction
- 9 and only to a person or entity authorized to receive the data or the report
- 10 under this section, except that:
- 11 1. A person specified in paragraph (f)2. of this subsection who is
- 12 authorized to receive data or a report may share that information with
- 13 any other persons specified in paragraph (f)2. of this subsection
- 14 authorized to receive data or a report if the persons specified in
- 15 paragraph (f)2. of this subsection are working on a bona fide specific
- 16 investigation involving a designated person. Both the person providing
- 17 and the person receiving the data or report under this subparagraph shall
- 18 document in writing each person to whom the data or report has been
- 19 given or received and the day, month, and year that the data or report
- 20 has been given or received. This document shall be maintained in a file
- 21 by each agency engaged in the investigation;
- 22 2. A representative of the Department for Medicaid Services may share
- 23 data or reports regarding overutilization by Medicaid recipients with a
- 24 board designated in paragraph (f)1. of this subsection, or with a law
- 25 enforcement officer designated in paragraph (f)2. of this subsection;
- 26 3. The Department for Medicaid Services may submit the data as evidence
- 27 in an administrative hearing held in accordance with KRS Chapter 13B;

- 1 4. If a state licensing board as defined in KRS 218A.205 initiates formal
2 disciplinary proceedings against a licensee, and data obtained by the
3 board is relevant to the charges, the board may provide the data to the
4 licensee and his or her counsel, as part of the notice process required by
5 KRS 13B.050, and admit the data as evidence in an administrative
6 hearing conducted pursuant to KRS Chapter 13B, with the board and
7 licensee taking all necessary steps to prevent further disclosure of the
8 data; and
- 9 5. A practitioner, pharmacist, or employee who obtains data under
10 paragraph (f)5. of this subsection may share the report with the patient
11 or person authorized to act on the patient's behalf. Any practitioner,
12 pharmacist, or employee who obtains data under paragraph (f)5. of this
13 subsection may place the report in the patient's medical record, in which
14 case the individual report shall then be deemed a medical record subject
15 to disclosure on the same terms and conditions as an ordinary medical
16 record in lieu of the disclosure restrictions otherwise imposed by this
17 section;
- 18 (i) The cabinet, all peace officers specified in paragraph (f)2. of this subsection,
19 all officers of the court, and all regulatory agencies and officers, in using the
20 data for investigative or prosecution purposes, shall consider the nature of the
21 prescriber's and dispenser's practice and the condition for which the patient is
22 being treated;
- 23 (j) Intentional failure to comply with the reporting requirements of this
24 subsection shall be a Class B misdemeanor for the first offense and a Class A
25 misdemeanor for each subsequent offense; and
- 26 (k) If the cabinet becomes aware of a prescriber's or dispenser's failure to comply
27 with this section, the cabinet shall notify the licensing board or agency

1 responsible for licensing the prescriber or dispenser. The licensing board shall
2 treat the notification as a complaint against the license.

3 (4) For the purpose of monitoring the cultivation, processing, production,
4 recommending, and dispensing of medicinal cannabis:

5 (a) Every medicinal cannabis practitioner who is authorized pursuant to KRS
6 218B.050 to provide written certifications for the use of medicinal cannabis
7 and every cannabis business licensed under KRS 218B.080, 218B.085, and
8 218B.090 shall register with the cabinet to use the system provided for in this
9 section and shall maintain such registration continuously during the medicinal
10 cannabis practitioner's authorization to provide written certifications or a
11 cannabis business's term of licensure and shall not have to pay a fee or tax
12 specifically dedicated to the operation of the system;

13 (b) No later than July 1, 2024, the cabinet shall ensure that the system provided
14 for in this section allows:

- 15 1. Medicinal cannabis practitioners to record the issuance of written
16 certifications to a patient as required by KRS 218B.050;
- 17 2. The cabinet, law enforcement personnel, and dispensary agents to verify
18 the validity of registry identification cards issued by the cabinet. When
19 verifying the validity of an identification card, the system shall only
20 disclose whether the identification card is valid and whether the
21 cardholder is a registered qualified patient, visiting qualified patient, or
22 designated caregiver;
- 23 3. Dispensary agents to record the amount of medicinal cannabis that is
24 dispensed to a cardholder during each transaction, as required by KRS
25 218B.110;
- 26 4. Law enforcement personnel and dispensary agents to access medicinal
27 cannabis sales data recorded by dispensary agents pursuant to KRS

- 1 218B.110;
- 2 5. The sharing of dispensing data recorded by dispensary agents, pursuant
- 3 to KRS 218B.110, with all licensed dispensaries in real time;
- 4 6. Licensed cannabis businesses to record data required by administrative
- 5 regulations promulgated pursuant to KRS 218B.140 to facilitate the
- 6 tracking of medicinal cannabis from the point of cultivation to the point
- 7 of sale to cardholders; and
- 8 7. The cabinet to track all medicinal cannabis in the state from the point of
- 9 cultivation to the point of sale to a cardholder;
- 10 (c) The cabinet shall only disclose data related to the cultivation, production,
- 11 recommending, and dispensing of medicinal cannabis to persons and entities
- 12 authorized to receive that data under this subsection. Disclosure to any other
- 13 person or entity, including disclosure in the context of a civil action where the
- 14 disclosure is sought either for the purpose of discovery or for evidence, is
- 15 prohibited unless specifically authorized by this subsection. The cabinet shall
- 16 be authorized to provide data to:
- 17 1. Any person or entity authorized to receive data pursuant to paragraph
- 18 (b) of this subsection;
- 19 2. A designated representative of a state licensing board responsible for the
- 20 licensure, regulation, or discipline of medicinal cannabis practitioners
- 21 and who is involved in a bona fide specific investigation involving a
- 22 designated person;
- 23 3. Employees of the Office of the Inspector General of the cabinet who
- 24 have successfully completed training for the electronic system and who
- 25 have been approved to use the system, Kentucky Commonwealth's
- 26 attorneys and assistant Commonwealth's attorneys, and county attorneys
- 27 and assistant county attorneys who are engaged in a bona fide specific

- 1 investigation involving a designated person;
- 2 4. A properly convened grand jury pursuant to a subpoena properly issued
- 3 for the records;
- 4 5. A medicinal cannabis practitioner or an employee of a medicinal
- 5 cannabis practitioner's practice acting under the specific direction of the
- 6 medicinal cannabis practitioner, who certifies that the request for
- 7 information is for the purpose of complying with KRS 218B.050(4)(c);
- 8 6. The chief medical officer of a hospital or long-term-care facility, an
- 9 employee of the hospital or long-term-care facility as designated by the
- 10 chief medical officer and who is working under his or her specific
- 11 direction, or a physician designee if the hospital or facility has no chief
- 12 medical officer, if the officer, employee, or designee certifies that the
- 13 requested information is for the purpose of providing medical or
- 14 pharmaceutical treatment to a bona fide current or prospective patient or
- 15 resident in the hospital or facility;
- 16 7. In addition to the purposes authorized under subparagraph 2. of this
- 17 paragraph, the Kentucky Board of Medical Licensure, for any physician
- 18 who is:
- 19 a. Associated in a partnership, other business entity, or supervision
- 20 agreement established pursuant to KRS 311.854 with a physician
- 21 who is already under investigation by the Board of Medical
- 22 Licensure for improper issuance of written certifications;
- 23 b. Associated in a partnership or other business entity with an
- 24 advanced practice registered nurse who is already under
- 25 investigation by the Board of Nursing for improper issuance of
- 26 written certifications;
- 27 c. In a designated geographic area for which a trend report indicates

1 a substantial likelihood that inappropriate issuance of written
2 certifications may be occurring; or

3 d. In a designated geographic area for which a report on another
4 physician in that area indicates a substantial likelihood that
5 inappropriate issuance of written certifications may be occurring in
6 that area;

7 8. In addition to the purposes authorized under subparagraph 2. of this
8 paragraph, the Kentucky Board of Nursing, for any advanced practice
9 registered nurse who is:

10 a. Associated in a partnership or other business entity with a
11 physician who is already under investigation by the Kentucky
12 Board of Medical Licensure for improper issuance of written
13 certifications;

14 b. Associated in a partnership or other business entity with an
15 advanced practice registered nurse who is already under
16 investigation by the Board of Nursing for improper issuance of
17 written certifications;

18 c. In a designated geographic area for which a trend report indicates
19 a substantial likelihood that inappropriate issuance of written
20 certifications may be occurring; or

21 d. In a designated geographic area for which a report on another
22 advanced practice registered nurse in that area indicates a
23 substantial likelihood that inappropriate issuance of written
24 certifications may be occurring in that area;

25 9. A judge or a probation or parole officer administering a diversion or
26 probation program of a criminal defendant arising out of a violation of
27 this chapter or of a criminal defendant who is documented by the court

- 1 as a substance abuser who is eligible to participate in a court-ordered
2 drug diversion or probation program;
- 3 10. A medical examiner engaged in a death investigation pursuant to KRS
4 72.026; or
- 5 11. The Legislative Research Commission, the University of Kentucky
6 College of Medicine, or the Kentucky Center for Cannabis established
7 in KRS 164.983 if the cabinet determines that disclosing data related to
8 the cultivation, production, recommending, and dispensing of medicinal
9 cannabis to the Legislative Research Commission, the University of
10 Kentucky College of Medicine, or the Kentucky Center for Cannabis is
11 necessary to comply with the reporting requirements established in KRS
12 218B.020(8); and
- 13 (d) A person who receives data or any report of the system from the cabinet shall
14 not provide it to any other person or entity except as provided in this section,
15 in another statute, or by order of a court of competent jurisdiction and only to
16 a person or entity authorized to receive the data or the report under this
17 section, except that:
- 18 1. A person specified in paragraph (c)3. of this subsection who is
19 authorized to receive data or a report may share that information with
20 any other persons specified in paragraph (c)3. of this subsection
21 authorized to receive data or a report if the persons specified in
22 paragraph (c)3. of this subsection are working on a bona fide specific
23 investigation involving a designated person. Both the person providing
24 and the person receiving the data or report under this subparagraph shall
25 document in writing each person to whom the data or report has been
26 given or received and the day, month, and year that the data or report
27 has been given or received. This document shall be maintained in a file

- 1 by each agency engaged in the investigation;
- 2 2. If a state licensing board initiates formal disciplinary proceedings
3 against a licensee, and data obtained by the board is relevant to the
4 charges, the board may provide the data to the licensee and his or her
5 counsel, as part of the notice process required by KRS 13B.050, and
6 admit the data as evidence in an administrative hearing conducted
7 pursuant to KRS Chapter 13B, with the board and licensee taking all
8 necessary steps to prevent further disclosure of the data; and
- 9 3. A medicinal cannabis practitioner or an employee of a medicinal
10 cannabis practitioner's practice acting under the specific direction of the
11 medicinal cannabis practitioner who obtains data under paragraph (c)5.
12 of this subsection may share the report with the patient or person
13 authorized to act on the patient's behalf. Any medicinal cannabis
14 practitioner or employee who obtains data under paragraph (c)5. of this
15 subsection may place the report in the patient's medical record, in which
16 case the individual report shall then be deemed a medical record subject
17 to disclosure on the same terms and conditions as an ordinary medical
18 record in lieu of the disclosure restrictions otherwise imposed by this
19 section.
- 20 (5) The data contained in, and any report obtained from, the electronic system for
21 monitoring established pursuant to this section shall not be a public record, except
22 that the Department for Medicaid Services may submit the data as evidence in an
23 administrative hearing held in accordance with KRS Chapter 13B.
- 24 (6) Intentional disclosure of transmitted data to a person not authorized by subsection
25 (3)(f) to (h) or (4)(c) and (d) of this section or authorized by KRS 315.121, or
26 obtaining information under this section not relating to a bona fide current or
27 prospective patient or a bona fide specific investigation, shall be a Class B

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

3 (7) The cabinet may, by promulgating an administrative regulation, limit the length of
4 time that data remain in the electronic system. Any data removed from the system
5 shall be archived and subject to retrieval within a reasonable time after a request
6 from a person authorized to review data under this section.

7 (8) (a) The Cabinet for Health and Family Services shall work with each board
8 responsible for the licensure, regulation, or discipline of practitioners,
9 pharmacists, or other persons who are authorized to prescribe, administer, or
10 dispense controlled substances for the development of a continuing education
11 program about the purposes and uses of the electronic system for monitoring
12 established in this section.

13 (b) The cabinet shall work with each board responsible for the licensure,
14 regulation, or discipline of medicinal cannabis practitioners for the
15 development of a continuing education program about the purposes and uses
16 of the electronic system for monitoring established in this section.

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

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

25 (e) The cabinet shall develop a training program for cannabis business agents
26 about the purposes and uses of the electronic system for monitoring
27 established in this section.

- 1 (9) The cabinet, Office of Inspector General, shall conduct quarterly reviews to identify
2 patterns of potential improper, inappropriate, or illegal prescribing or dispensing of
3 a controlled substance, issuance of written certifications, or cultivation, processing,
4 or dispensing of medicinal cannabis. The Office of Inspector General may
5 independently investigate and submit findings and recommendations to the
6 appropriate boards of licensure or other reporting agencies.
- 7 (10) The cabinet shall promulgate administrative regulations *in accordance with KRS*
8 *Chapter 13 A* to implement the provisions of this section. Included in these
9 administrative regulations shall be:
- 10 (a) An error resolution process allowing a patient to whom a report had been
11 disclosed under subsections (3) and (4) of this section to request the correction
12 of inaccurate information contained in the system relating to that patient; and
- 13 (b) A requirement that data be reported to the system under subsection (3)(b) of
14 this section within one (1) day of dispensing.
- 15 (11) (a) Before July 1, 2018, the Administrative Office of the Courts shall forward
16 data regarding any felony or Class A misdemeanor conviction that involves
17 the trafficking or possession of a controlled substance or other prohibited acts
18 under KRS Chapter 218A for the previous five (5) calendar years to the
19 cabinet for inclusion in the electronic monitoring system established under
20 this section. On or after July 1, 2018, such data shall be forwarded by the
21 Administrative Office of the Courts to the cabinet on a continuing basis. The
22 cabinet shall incorporate the data received into the system so that a query by
23 patient name indicates any prior drug conviction.
- 24 (b) Before July 1, 2024, the Administrative Office of the Courts shall forward all
25 available data regarding any disqualifying felony offense for the previous five
26 (5) calendar years to the cabinet for inclusion in the electronic monitoring
27 system established under this section. On or after July 1, 2024, such data shall

1 be forwarded by the Administrative Office of the Courts to the cabinet on a
2 continuing basis. The cabinet shall incorporate the data received into the
3 system so that a query by patient name indicates any prior disqualifying
4 felony conviction.

5 ➔Section 6. KRS 218A.205 is amended to read as follows:

6 (1) As used in this section:

7 (a) "Reporting agency" includes:

- 8 1. The Department of Kentucky State Police;
- 9 2. The Office of the Attorney General;
- 10 3. The Cabinet for Health and Family Services; and
- 11 4. The applicable state licensing board; and

12 (b) "State licensing board" means:

- 13 1. The Kentucky Board of Medical Licensure;
- 14 2. The Kentucky Board of Nursing;
- 15 3. The Kentucky Board of Dentistry;
- 16 4. The Kentucky Board of Optometric Examiners;
- 17 5. The State Board of Podiatry; and
- 18 6. Any other board that licenses or regulates a person who is entitled to
19 prescribe or dispense controlled substances to humans.

20 (2) (a) When a reporting agency or a law enforcement agency receives a report of
21 improper, inappropriate, or illegal prescribing or dispensing of a controlled
22 substance it may, to the extent otherwise allowed by law, send a copy of the
23 report within three (3) business days to every other reporting agency.

24 (b) A county attorney or Commonwealth's attorney shall notify the Office of the
25 Attorney General and the appropriate state licensing board within three (3)
26 business days of an indictment or a waiver of indictment becoming public in
27 his or her jurisdiction charging a licensed person with a felony offense

1 relating to the manufacture of, trafficking in, prescribing, dispensing, or
2 possession of a controlled substance.

3 (3) Each state licensing board shall, in consultation with the Kentucky Office of Drug
4 Control Policy, establish the following by administrative regulation for those
5 licensees authorized to prescribe or dispense controlled substances:

6 (a) Mandatory prescribing and dispensing standards related to controlled
7 substances, the requirements of which shall include the diagnostic, treatment,
8 review, and other protocols and standards established for Schedule II
9 controlled substances ~~and Schedule III controlled substances containing~~
10 ~~hydrocodone~~ under KRS 218A.172 and which may include the exemptions
11 authorized by KRS 218A.172(4);

12 (b) In accord with the CDC Guideline for Prescribing Opioids for Chronic Pain
13 published in 2016, a prohibition on a practitioner issuing a prescription for a
14 Schedule II controlled substance for more than a three (3) day supply of a
15 Schedule II controlled substance if the prescription is intended to treat pain as
16 an acute medical condition, with the following exceptions:

- 17 1. The practitioner, in his or her professional judgment, believes that more
18 than a three (3) day supply of a Schedule II controlled substance is
19 medically necessary to treat the patient's pain as an acute medical
20 condition and the practitioner adequately documents the acute medical
21 condition and lack of alternative treatment options which justifies
22 deviation from the three (3) day supply limit established in this
23 subsection in the patient's medical records;
- 24 2. The prescription for a Schedule II controlled substance is prescribed to
25 treat chronic pain;
- 26 3. The prescription for a Schedule II controlled substance is prescribed to
27 treat pain associated with a valid cancer diagnosis;

- 1 4. The prescription for a Schedule II controlled substance is prescribed to
- 2 treat pain while the patient is receiving hospice or end-of-life treatment
- 3 or is receiving care from a certified community based palliative care
- 4 program;
- 5 5. The prescription for a Schedule II controlled substance is prescribed as
- 6 part of a narcotic treatment program licensed by the Cabinet for Health
- 7 and Family Services;
- 8 6. The prescription for a Schedule II controlled substance is prescribed to
- 9 treat pain following a major surgery or the treatment of significant
- 10 trauma, as defined by the state licensing board in consultation with the
- 11 Kentucky Office of Drug Control Policy;
- 12 7. The Schedule II controlled substance is dispensed or administered
- 13 directly to an ultimate user in an inpatient setting; or
- 14 8. Any additional treatment scenario deemed medically necessary by the
- 15 state licensing board in consultation with the Kentucky Office of Drug
- 16 Control Policy.

17 Nothing in this paragraph shall authorize a state licensing board to promulgate
18 regulations which expand any practitioner's prescriptive authority beyond that
19 which existed prior to June 29, 2017;

- 20 (c) A prohibition on a practitioner dispensing greater than a forty-eight (48) hour
21 supply of any Schedule II controlled substance ~~for a Schedule III controlled~~
22 ~~substance containing hydrocodone~~ unless the dispensing is done as part of a
23 narcotic treatment program licensed by the Cabinet for Health and Family
24 Services;
- 25 (d) A procedure for temporarily suspending, limiting, or restricting a license held
26 by a named licensee where a substantial likelihood exists to believe that the
27 continued unrestricted practice by the named licensee would constitute a

1 danger to the health, welfare, or safety of the licensee's patients or of the
2 general public;

3 (e) A procedure for the expedited review of complaints filed against their
4 licensees pertaining to the improper, inappropriate, or illegal prescribing or
5 dispensing of controlled substances that is designed to commence an
6 investigation within seven (7) days of a complaint being filed and produce a
7 charging decision by the board on the complaint within one hundred twenty
8 (120) days of the receipt of the complaint, unless an extension for a definite
9 period of time is requested by a law enforcement agency due to an ongoing
10 criminal investigation;

11 (f) The establishment and enforcement of licensure standards that conform to the
12 following:

- 13 1. A permanent ban on licensees and applicants convicted after July 20,
14 2012, in this state or any other state of any felony offense relating to
15 controlled substances from prescribing or dispensing a controlled
16 substance;
- 17 2. Restrictions short of a permanent ban on licensees and applicants
18 convicted in this state or any other state of any misdemeanor offense
19 relating to prescribing or dispensing a controlled substance;
- 20 3. Restrictions mirroring in time and scope any disciplinary limitation
21 placed on a licensee or applicant by a licensing board of another state if
22 the disciplinary action results from improper, inappropriate, or illegal
23 prescribing or dispensing of controlled substances; and
- 24 4. A requirement that licensees and applicants report to the board any
25 conviction or disciplinary action covered by this subsection with
26 appropriate sanctions for any failure to make this required report;

27 (g) A procedure for the continuous submission of all disciplinary and other

- 1 reportable information to the National Practitioner Data Bank of the United
2 States Department of Health and Human Services;
- 3 (h) If not otherwise required by other law, a process for submitting a query on
4 each applicant for licensure to the National Practitioner Data Bank of the
5 United States Department of Health and Human Services to retrieve any
6 relevant data on the applicant; and
- 7 (i) Continuing education requirements beginning with the first full educational
8 year occurring after July 1, 2012, that specify that at least seven and one-half
9 percent (7.5%) of the continuing education required of the licensed
10 practitioner relate to the use of the electronic monitoring system established in
11 KRS 218A.202, pain management, or addiction disorders.
- 12 (4) For the purposes of pharmacy dispensing, the medical necessity for a Schedule II
13 controlled substance as documented by the practitioner in the patient's medical
14 record and the prescription for more than a three (3) day supply of that controlled
15 substance are presumed to be valid.
- 16 (5) A state licensing board shall employ or obtain the services of a specialist in the
17 treatment of pain and a specialist in drug addiction to evaluate information received
18 regarding a licensee's prescribing or dispensing practices related to controlled
19 substances if the board or its staff does not possess such expertise, to ascertain if the
20 licensee under investigation is engaging in improper, inappropriate, or illegal
21 practices.
- 22 (6) Any statute to the contrary notwithstanding, no state licensing board shall require
23 that a grievance or complaint against a licensee relating to controlled substances be
24 sworn to or notarized, but the grievance or complaint shall identify the name and
25 address of the grievant or complainant, unless the board by administrative
26 regulation authorizes the filing of anonymous complaints. Any such authorizing
27 administrative regulation shall require that an anonymous complaint or grievance be

1 accompanied by sufficient corroborating evidence as would allow the board to
2 believe, based upon a totality of the circumstances, that a reasonable probability
3 exists that the complaint or grievance is meritorious.

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

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

13 ➔Section 7. KRS 218A.245 is amended to read as follows:

14 (1) The secretary of the Cabinet for Health and Family Services may enter into
15 reciprocal agreements or a contract, either directly with any federal agency of the
16 United States or its territories, any other state or states of the United States or any
17 jurisdiction, county, or political subdivision thereof, or with an organization
18 administering the exchange of interstate data on behalf of the prescription
19 monitoring program of one (1) or more states or jurisdictions, to share prescription
20 drug monitoring information if the other prescription drug monitoring program or
21 data exchange program is compatible with the program in Kentucky. If the
22 secretary elects to evaluate the prescription drug monitoring program of another
23 state, jurisdiction, or organization as authorized by this section, priority shall be
24 given to a state or jurisdiction that is contiguous with the borders of the
25 Commonwealth or an organization that offers connectivity with a contiguous state
26 or jurisdiction.

27 (2) In determining compatibility, the secretary shall consider:

- 1 (a) The essential purposes of the program and the success of the program in
2 fulfilling those purposes;
- 3 (b) The safeguards for privacy of patient records and its success in protecting
4 patient privacy;
- 5 (c) The persons authorized to view the data collected by the program;
- 6 (d) The schedules of controlled substances monitored;
- 7 (e) The data required to be submitted on each prescription or dispensing;
- 8 (f) Any implementation criteria deemed essential for a thorough comparison; and
- 9 (g) The costs and benefits to the Commonwealth in mutually sharing particular
10 information available in the Commonwealth's database with the program
11 under consideration.
- 12 (3) The secretary shall review any agreement on an annual basis to determine its
13 continued compatibility with the Kentucky prescription drug monitoring program.
- 14 (4) Any agreement between the cabinet and another state, jurisdiction, or organization
15 shall prohibit the sharing of information about a Kentucky resident, practitioner,
16 pharmacist, or other prescriber or dispenser for any purpose not otherwise
17 authorized by this section or KRS 218A.202.
- 18 ➔Section 8. KRS 304.17A-165 is amended to read as follows:
- 19 (1) Any health benefit plan that provides benefits for prescription drugs shall include an
20 exceptions policy or an override policy that provides coverage for the refill of a
21 covered drug dispensed prior to the expiration of the insured's supply of the drug.
22 The insurer shall provide notice in existing written or electronic communications to
23 pharmacies doing business with the insurer, the pharmacy benefit manager if
24 applicable, and to the insured regarding the exceptions policy or override policy.
25 This subsection shall not apply to controlled substances as classified by KRS
26 Chapter 218A.
- 27 (2) Nothing in this section shall prohibit an insurer from limiting payment to no more

- 1 than three (3) refills of a covered drug in a ninety (90) day period.
- 2 (3) Any individual or group health benefit plan that provides benefits for prescription
3 drugs shall provide a program for synchronization of medications when it is agreed
4 among the insured, a provider, and a pharmacist that synchronization of multiple
5 prescriptions for the treatment of a chronic illness is in the best interest of the
6 patient for the management or treatment of a chronic illness provided that the
7 medications:
- 8 (a) Are covered by the individual or group health benefit plan:
- 9 (b) Are used for treatment and management of chronic conditions that are subject
10 to refills;
- 11 (c) Are not a Schedule II controlled substance~~[or a Schedule III controlled~~
12 ~~substance containing hydrocodone]~~;
- 13 (d) Meet all prior authorization criteria specific to the medications at the time of
14 the synchronization request;
- 15 (e) Are of a formulation that can be effectively split over required short fill
16 periods to achieve synchronization; and
- 17 (f) Do not have quantity limits or dose optimization criteria or requirements that
18 would be violated in fulfilling synchronization.
- 19 (4) To permit synchronization, an individual or group health benefit plan shall apply a
20 prorated daily cost-sharing rate to any medication dispensed by a network
21 pharmacy pursuant to this section.
- 22 (5) Any dispensing fee shall not be prorated and shall be based on an individual
23 prescription filled or refilled.