AN ACT relating to prescription drugs.

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

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

(1) The Department for Medicaid Services or a managed care organization contracted to provide services pursuant to this chapter shall provide a program for synchronization of medications when it is agreed among the member, a provider, and a pharmacist that synchronization of multiple prescriptions for the treatment of a chronic illness is in the best interest of the patient for the management or treatment of a chronic illness provided that the medications:

(a) Are covered by the Department for Medicaid Services or a managed care organization contracted to provide services pursuant to this chapter;

(b) Are used for treatment and management of chronic conditions that are subject to refills;

(c) Are not a Schedule II controlled substance~~[or a Schedule III controlled substance containing hydrocodone]~~;

(d) Meet all prior authorization criteria specific to the medications at the time of the synchronization request;

(e) Are of a formulation that can be effectively split over required short fill periods to achieve synchronization; and

(f) Do not have quantity limits or dose optimization criteria or requirements that would be violated in fulfilling synchronization.

(2) When applicable to permit synchronization, the Department for Medicaid Services or a managed care organization contracted to provide services pursuant to this chapter shall apply a prorated daily cost-sharing rate to any medication dispensed by a network pharmacy pursuant to this section.

(3) Any dispensing fee shall not be prorated and shall be based on an individual prescription filled or refilled.

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

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

(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 classified as Schedule III controlled substances pursuant to KRS 218A.020 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) "Certified community based palliative care program" means a palliative care program which has received certification from the Joint Commission;

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

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

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

(9) (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;

(10) "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;

(11) "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;

(12) "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;

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

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

(15) "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;

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

(17) "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) piperadine:

(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;

(18) "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;

(19) "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;

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

(21) "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;

(22) "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;

(23) "Industrial hemp" has the same meaning as in KRS 260.850;

(24) "Industrial hemp products" has the same meaning as in KRS 260.850;

(25) "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;

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

(27) "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 ***or her*** 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;

(28) "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 a license issued by the Department of Agriculture permitting that person to cultivate, handle, or process industrial hemp;

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

(c) 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;

(d) 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;

(f) For the purpose of conducting scientific research, a cannabinoid product derived from industrial hemp, as defined in KRS 260.850;

(g) A cannabinoid product approved as a prescription medication by the United States Food and Drug Administration; or

(h) Medicinal cannabis as defined in KRS 218B.010;

(29) "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;

(30) "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;

(31) "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;

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

(33) "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;

(34) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under KRS 218A.020, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms;

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

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

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

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

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

(40) "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, physician assistant as authorized under KRS 311.858, 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, ***optometrist, physician assistant,*** 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;

(41) "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;

(42) "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;

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

(44) "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;

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

(46) "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;

(47) "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;

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

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

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

(51) "Synthetic cannabinoids or piperazines" means any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not dispensed or possessed in accordance with state and federal law, that contains Benzylpiperazine (BZP); Trifluoromethylphenylpiperazine (TFMPP); 1,1-Dimethylheptyl-11-hydroxytetrahydrocannabinol (HU-210); 1-Butyl-3-(1-naphthoyl)indole; 1-Pentyl-3-(1-naphthoyl)indole; dexanabinol (HU-211); or any compound in the following structural classes:

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

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

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl,

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

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

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

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

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

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

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

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

(52) "Synthetic cathinones" means any chemical compound which is not approved by the United States Food and Drug Administration or, if approved, which is not

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

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

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

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

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

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

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

(55) "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;

(56) "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;

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

(58) "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 3. KRS 218A.172 is amended to read as follows:

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

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query the electronic monitoring system established in KRS 218A.202 for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2) (a) Administrative regulations promulgated under KRS 218A.205(3) shall require that a practitioner prescribing or dispensing additional amounts of Schedule II controlled substances ~~[or Schedule III controlled substances containing hydrocodone]~~for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;
2. Provide to the patient any new information about the treatment; and
3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the administrative regulations shall also require that the practitioner:

1. Query the electronic monitoring system established in KRS 218A.202 no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and
2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance~~[or a Schedule III controlled substance containing hydrocodone]~~.

(3) Administrative regulations promulgated under KRS 218A.205(3) shall require that~~[,]~~ for each patient for whom a practitioner prescribes any Schedule II controlled substance ~~[or a Schedule III controlled substance containing hydrocodone,]~~the practitioner shall keep accurate, readily accessible, and complete medical records which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

(4) Administrative regulations promulgated under KRS 218A.205(3) may exempt, in whole or in part, compliance with the mandatory diagnostic, treatment, review, and other protocols and standards established in this section for:

(a) A licensee prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;

(b) A licensee prescribing or administering a controlled substance necessary to treat a patient in an emergency situation;

(c) A licensed pharmacist or other person licensed by the Kentucky Board of Pharmacy to dispense drugs or a licensed pharmacy;

(d) A licensee prescribing or dispensing a controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a practitioner in those hospitals or facilities where no institutional account exists, queries the electronic monitoring system established in KRS 218A.202

for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

5. Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

   a. Is done as a substitute for the initial prescribing or dispensing;

   b. Cancels any refills for the initial prescription; and

   c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another practitioner in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or

7. 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;

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

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

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

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

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

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

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

1. A copy of the administrative regulation as filed, and all attachments

required by KRS 13A.230(1); and

2. A request from the board that the office review the administrative regulation in the same manner as would the Commission on Small Business Innovation and Advocacy under KRS 11.202(1)(e), and submit its report or comments in accordance with the deadline established in KRS 13A.270(1)(c). A copy of the report or comments shall be filed with the regulations compiler.

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

(1) Notwithstanding KRS 218A.180 or any other state law to the contrary, beginning January 1, 2021, no practitioner shall issue any prescription for a controlled substance unless the prescription is made by electronic prescription from the practitioner issuing the prescription to a pharmacy, except for prescriptions issued:

(a) By veterinarians;

(b) In circumstances where electronic prescribing is not available due to temporary technological or electrical failure;

(c) By a practitioner to be dispensed by a pharmacy located outside the state;

(d) When the prescriber and dispenser are the same entity;

(e) That include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;

(f) By a practitioner for a drug that contains certain elements that cannot be incorporated as required by the United States Food and Drug Administration with electronic prescribing, including extemporaneous compounding;

(g) By a practitioner allowing for the dispensing of a nonpatient specific prescription under a standing order, approved protocol for drug therapy, or collaborative drug management or comprehensive medication management, in response to a public health emergency;

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

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

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

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

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

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

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

(3) The cabinet shall promulgate administrative regulations to implement this section including enforcement mechanisms, waivers of requirements, and appropriate penalties for violations.

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

(1) As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

(2) The cabinet shall establish and maintain an electronic system for monitoring Schedules II, III, IV, and V controlled substances and medicinal cannabis. 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.

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

(a) 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 ***an active account with the***

electronic monitoring system~~[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;

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

1. 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;
2. A Schedule III through Schedule V controlled substance dispensed by 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 and is not dispensed by the emergency department of a hospital; or
3. 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;

(c) In addition to the data required by paragraph (d) of this subsection, a

Kentucky-licensed acute care hospital or critical access hospital shall report to the cabinet all positive toxicology screens that were performed by the hospital's emergency department to evaluate the patient's suspected drug overdose;

(d) Data for each controlled substance that is reported shall include but not be limited to the following:

1. Patient identifier;
2. National drug code of the drug dispensed;
3. Date of dispensing;
4. Quantity dispensed;
5. Prescriber; and
6. Dispenser;

(e) The data shall be provided in the electronic format specified by the cabinet 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;

(f) The cabinet shall only disclose data to persons and entities authorized to receive that data under this subsection. 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 shall be authorized to provide data to:

1. 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;

2. Employees of the Office of the Inspector General of the cabinet who have successfully completed training for the electronic system and who have been approved to use the system, federal prosecutors, Kentucky Commonwealth's attorneys and assistant Commonwealth's attorneys, county attorneys and assistant county attorneys, a peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal agent 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;

3. A state-operated Medicaid program in conformity with paragraph (g) of this subsection;

4. A properly convened grand jury pursuant to a subpoena properly issued for the records;

5. 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 certifies that the requested information is for the purpose of:

a. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient;

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

c. 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;

6. 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;

7. In addition to the purposes authorized under subparagraph 1. of this paragraph, the Kentucky Board of Medical Licensure, for any physician who is:

   a. 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;

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

   c. 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;

8. In addition to the purposes authorized under subparagraph 1. of this paragraph, the Kentucky Board of Nursing, for any advanced practice

registered nurse who is:

a. 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;

b. 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;

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

d. 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;

9. 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

10. A medical examiner engaged in a death investigation pursuant to KRS 72.026;

(g) 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:

1. Appropriately managed by a single outpatient pharmacy or primary care

physician; or

2. Indicative of improper, inappropriate, or illegal prescribing or dispensing practices by a practitioner or drug seeking by a Medicaid recipient;

(h) 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 subsection, 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:

1. A person specified in paragraph (f)2. of this subsection who is authorized to receive data or a report may share that information with any other persons specified in paragraph (f)2. of this subsection authorized to receive data or a report if the persons specified in paragraph (f)2. of this subsection 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 subparagraph 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;

2. A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (f)1. of this subsection, or with a law enforcement officer designated in paragraph (f)2. of this subsection;

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

4. 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

5. A practitioner, pharmacist, or employee who obtains data under paragraph (f)5. of this subsection may share the report with the patient or person authorized to act on the patient's behalf. Any practitioner, pharmacist, or employee who obtains data under paragraph (f)5. of this subsection may place the report in the patient's medical record, in which case the individual report shall then be 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;

(i) The cabinet, all peace officers specified in paragraph (f)2. of this subsection, 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;

(j) Intentional failure to comply with the reporting requirements of this subsection shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense; and

(k) 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 license.

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

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

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

1. Medicinal cannabis practitioners to record the issuance of written certifications to a patient as required by KRS 218B.050;

2. The cabinet, law enforcement personnel, and dispensary agents to verify the validity of registry identification cards issued by the cabinet. When verifying the validity of an identification card, the system shall only disclose whether the identification card is valid and whether the cardholder is a registered qualified patient, visiting qualified patient, or designated caregiver;

3. Dispensary agents to record the amount of medicinal cannabis that is dispensed to a cardholder during each transaction, as required by KRS 218B.110;

4. Law enforcement personnel and dispensary agents to access medicinal cannabis sales data recorded by dispensary agents pursuant to KRS 218B.110;

5. The sharing of dispensing data recorded by dispensary agents, pursuant to KRS 218B.110, with all licensed dispensaries in real time;
6. Licensed cannabis businesses to record data required by administrative regulations promulgated pursuant to KRS 218B.140 to facilitate the tracking of medicinal cannabis from the point of cultivation to the point of sale to cardholders; and
7. The cabinet to track all medicinal cannabis in the state from the point of cultivation to the point of sale to a cardholder;

(c) The cabinet shall only disclose data related to the cultivation, production, recommending, and dispensing of medicinal cannabis to persons and entities authorized to receive that data under this subsection. 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 subsection. The cabinet shall be authorized to provide data to:

1. Any person or entity authorized to receive data pursuant to paragraph (b) of this subsection;
2. A designated representative of a state licensing board responsible for the licensure, regulation, or discipline of medicinal cannabis practitioners and who is involved in a bona fide specific investigation involving a designated person;
3. Employees of the Office of the Inspector General of the cabinet 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, and county attorneys and assistant county attorneys who are engaged in a bona fide specific investigation involving a designated person;

4. A properly convened grand jury pursuant to a subpoena properly issued for the records;
5. A medicinal cannabis practitioner or an employee of a medicinal cannabis practitioner's practice acting under the specific direction of the medicinal cannabis practitioner, who certifies that the request for information is for the purpose of complying with KRS 218B.050(4)(c);
6. 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;
7. In addition to the purposes authorized under subparagraph 2. of this paragraph, the Kentucky Board of Medical Licensure, for any physician who is:
    a. Associated in a partnership, other business entity, or supervision agreement established pursuant to KRS 311.854 with a physician who is already under investigation by the Board of Medical Licensure for improper issuance of written certifications;
    b. 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 issuance of written certifications;
    c. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate issuance of written

certifications may be occurring; or

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

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

a. 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 issuance of written certifications;

b. 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 issuance of written certifications;

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

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

9. 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;

10. A medical examiner engaged in a death investigation pursuant to KRS 72.026; or

11. The Legislative Research Commission, the University of Kentucky College of Medicine, or the Kentucky Center for Cannabis established in KRS 164.983 if the cabinet determines that disclosing data related to the cultivation, production, recommending, and dispensing of medicinal cannabis to the Legislative Research Commission, the University of Kentucky College of Medicine, or the Kentucky Center for Cannabis is necessary to comply with the reporting requirements established in KRS 218B.020(8); and

(d) 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:

1. A person specified in paragraph (c)3. of this subsection who is authorized to receive data or a report may share that information with any other persons specified in paragraph (c)3. of this subsection authorized to receive data or a report if the persons specified in paragraph (c)3. of this subsection 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 subparagraph 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;

2. If a state licensing board 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

3. A medicinal cannabis practitioner or an employee of a medicinal cannabis practitioner's practice acting under the specific direction of the medicinal cannabis practitioner who obtains data under paragraph (c)5. of this subsection may share the report with the patient or person authorized to act on the patient's behalf. Any medicinal cannabis practitioner or employee who obtains data under paragraph (c)5. of this subsection may place the report in the patient's medical record, in which case the individual report shall then be 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.

(5) The data contained in, and any report obtained from, the electronic system for monitoring established pursuant to this section 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.

(6) Intentional disclosure of transmitted data to a person not authorized by subsection (3)(f) to (h) or (4)(c) and (d) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide current or prospective patient or a bona fide specific investigation, shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent

offense.

(7) The cabinet 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.

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

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

(c) 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.

(d) 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.

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

(9) The cabinet, Office of Inspector General, shall conduct quarterly reviews to identify

patterns of potential improper, inappropriate, or illegal prescribing or dispensing of a controlled substance, issuance of written certifications, or cultivation, processing, or dispensing of medicinal cannabis. The Office of Inspector General may independently investigate and submit findings and recommendations to the appropriate boards of licensure or other reporting agencies.

(10) 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 subsections (3) and (4) of this section to request the correction of inaccurate information contained in the system relating to that patient; and

(b) A requirement that data be reported to the system under subsection (3)(b) of this section within one (1) day of dispensing.

(11) (a) Before July 1, 2018, the Administrative Office of the Courts shall forward data regarding any felony or Class A misdemeanor conviction that involves the trafficking or possession of a controlled substance or other prohibited acts under KRS Chapter 218A for the previous five (5) calendar years to the cabinet for inclusion in the electronic monitoring system established under this section. On or after July 1, 2018, such data shall be forwarded by the Administrative Office of the Courts to the cabinet on a continuing basis. The cabinet shall incorporate the data received into the system so that a query by patient name indicates any prior drug conviction.

(b) Before July 1, 2024, the Administrative Office of the Courts shall forward all available data regarding any disqualifying felony offense for the previous five (5) calendar years to the cabinet for inclusion in the electronic monitoring system established under this section. On or after July 1, 2024, such data shall be forwarded by the Administrative Office of the Courts to the cabinet on a continuing basis. The cabinet shall incorporate the data received into the

system so that a query by patient name indicates any prior disqualifying felony conviction.

➔Section 6. 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 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

or is receiving care from a certified community based palliative care program;

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 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 June 29, 2017;

(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) 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) 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) 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;
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) 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) 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) 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 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) 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) 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) 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 7. KRS 218A.245 is amended to read as follows:

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

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

(a) The essential purposes of the program and the success of the program in fulfilling those purposes;

(b) The safeguards for privacy of patient records and its success in protecting patient privacy;

(c) The persons authorized to view the data collected by the program;

(d) The schedules of controlled substances monitored;

(e) The data required to be submitted on each prescription or dispensing;

(f) Any implementation criteria deemed essential for a thorough comparison; and

(g) The costs and benefits to the Commonwealth in mutually sharing particular information available in the Commonwealth's database with the program under consideration.

(3) The secretary shall review any agreement on an annual basis to determine its continued compatibility with the Kentucky prescription drug monitoring program.

(4) Any agreement between the cabinet and another state, jurisdiction, or organization shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber or dispenser for any purpose not otherwise authorized by this section or KRS 218A.202.

➔Section 8. KRS 304.17A-165 is amended to read as follows:

(1) Any health benefit plan that provides benefits for prescription drugs shall include an exceptions policy or an override policy that provides coverage for the refill of a covered drug dispensed prior to the expiration of the insured's supply of the drug. The insurer shall provide notice in existing written or electronic communications to pharmacies doing business with the insurer, the pharmacy benefit manager if applicable, and to the insured regarding the exceptions policy or override policy. This subsection shall not apply to controlled substances as classified by KRS Chapter 218A.

(2) Nothing in this section shall prohibit an insurer from limiting payment to no more than three (3) refills of a covered drug in a ninety (90) day period.

(3) Any individual or group health benefit plan that provides benefits for prescription

drugs shall provide a program for synchronization of medications when it is agreed among the insured, a provider, and a pharmacist that synchronization of multiple prescriptions for the treatment of a chronic illness is in the best interest of the patient for the management or treatment of a chronic illness provided that the medications:

(a) Are covered by the individual or group health benefit plan:

(b) Are used for treatment and management of chronic conditions that are subject to refills;

(c) Are not a Schedule II controlled substance~~[or a Schedule III controlled substance containing hydrocodone]~~;

(d) Meet all prior authorization criteria specific to the medications at the time of the synchronization request;

(e) Are of a formulation that can be effectively split over required short fill periods to achieve synchronization; and

(f) Do not have quantity limits or dose optimization criteria or requirements that would be violated in fulfilling synchronization.

(4) To permit synchronization, an individual or group health benefit plan shall apply a prorated daily cost-sharing rate to any medication dispensed by a network pharmacy pursuant to this section.

(5) Any dispensing fee shall not be prorated and shall be based on an individual prescription filled or refilled.