AN ACT relating to controlled substances.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) When prescribing a controlled substance that contains any salt, compound, derivative, or preparation of an opioid to a human patient, a practitioner shall:

(a) Offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient if any of the following conditions are present:

1. The prescription dosage for the patient is ninety (90) or more morphine milligram equivalents of an opioid medication per day;

2. The opioid medication is prescribed concurrently with a benzodiazepine; or

3. The patient presents with an increased risk for overdose, including but not limited to a history of overdose, a history of substance use disorder, or a risk of returning to a high dose of opioid medication to which the patient is no longer tolerant; and

(b) Consistent with the existing standard of care, provide education on overdose prevention and on the use of the opioid depression reversal drug prescribed under paragraph (a) of this subsection to:

1. The patient receiving the prescription; and

2. One (1) or more persons designated by the patient or, for a patient who is an unemancipated minor child, to the unemancipated minor child's parent, legal guardian, or health care surrogate.

(2) This section shall not apply to a practitioner prescribing a controlled substance that contains any salt, compound, derivative, or preparation of an opioid to a

patient solely for administration in a hospital or long-term-care facility.

➔Section 2. 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***, benefits, and limitations*** ~~[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***:*** ~~[ ]~~

1. The risk of tolerance and ***addiction associated with the prescribed drug, including any risk of developing a physical or psychological*** ~~[drug]~~ dependence ***on the drug***;

2. The risk of overdose associated with the prescribed drug; and

3. The danger of taking the prescribed drug with benzodiazepines, alcohol, or other central nervous system depressants;

(e) Offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or

partial reversal of opioid depression as required by Section 1 of this Act; and

(f) ~~[(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;
3. ***Offer, at reasonable intervals, a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression as required by Section 1 of this Act;*** and
4. ~~[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]~~***; and***
3. ***Repeat the discussion of risks, benefits, and limitations required under subsection (1)(d) of this section no less than once every three (3) months***.

(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 ***as required under subsections (1) and (2) of this section***;

(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 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 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 3. 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 4. 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 5. 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.