AN ACT relating to discussion with patients on the risks, benefits, and limitations of treatment with controlled substances.

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

➔Section 1. 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 reasons the prescription is necessary and possible alternative treatments;

2. The risks of tolerance and drug dependence;

3. The dangers of mixing opioid drugs with alcohol, benzodiazepines, and other central nervous system depressants;

4. The risks of taking more opioids than prescribed; and

5. The risks associated with the use of the drugs being prescribed, even when taken as prescribed;

~~[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.

(c) The administrative regulations shall require that the practitioner repeat the discussion of risks, benefits, and limitations under subsection (1)(d) of this section prior to prescribing or dispensing a third sequential controlled substance to a patient.

(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) ***Initial and any subsequent discussions***~~[discussion]~~ of ***risks***~~[risk]~~, benefits, and limitations of treatments ***as required under subsections (2) and (3) 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.