AN ACT relating to voluntary non-opioid directives.

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) As used in this section:

(a) "Opioid drug" means a controlled substance that contains any salt, compound, derivative, or preparation of an opioid;

(b) "State licensing board" has the same meaning as in KRS 218A.205; and

(c) "Voluntary non-opioid directive" means a declaration by a patient to inform practitioners that an opioid drug shall not be prescribed, ordered, or administered to that patient.

(2) The cabinet shall:

(a) Establish a voluntary non-opioid directive form. The form shall:

1. Inform practitioners that an opioid drug shall not be prescribed, ordered, or administered to a patient who has executed and filed the form with the cabinet;

2. Permit an individual to appoint and list a duly authorized guardian or health care proxy who may revoke the directive by written or verbal means at any time and for any reason; and

3. Be posted on the cabinet's Web site as a downloadable document that can be completed and submitted electronically or printed and submitted by mail;

(b) Document receipt of a completed voluntary non-opioid directive form, within ten (10) business days of receiving the completed form, in the electronic monitoring system established in KRS 218A.202, including a list of any duly authorized guardian or health care proxy who may revoke the directive; and

(c) Promulgate administrative regulations necessary to carry out the provisions of this section, including but not limited to a process by which an individual may revoke or terminate a voluntary non-opioid directive.

(3) Before prescribing, ordering, or administering an opioid drug to a human patient for the treatment of acute pain or chronic nonmalignant pain, a practitioner shall provide a copy of the form created under subsection (2) of this section to the patient to whom an opioid drug may be prescribed, ordered, or administered in the course of treatment, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care proxy.

(4) (a) A person acting in good faith as a duly authorized guardian or health care proxy shall not be liable for damages in a civil action or subject to criminal prosecution for revoking a voluntary non-opioid directive.

(b) A practitioner who exercises reasonable care shall not be liable for damages in a civil action, subject to criminal prosecution, deemed to have violated the standard of care, or subject to disciplinary action by a professional licensing board for refusing to prescribe, order, or administer an opioid drug pursuant to a voluntary non-opioid directive.

(c) A practitioner employed by a hospital emergency department, acting either as a patient's health care provider or as the emergency medical services director, who exercises reasonable care shall not be liable for damages in a civil action, subject to criminal prosecution, deemed to have violated the standard of care, or subject to disciplinary action by a professional licensing board for prescribing, ordering, or administering an opioid drug to a patient who has executed and filed a voluntary non-opioid directive form if the practitioner has reasonable cause to believe that an opioid drug is necessary and the practitioner has no knowledge of the patient's voluntary non-opioid directive at the time of prescribing, ordering, or administering an opioid

drug.

(d) A practitioner who fails to comply with subsection (3) of this section, a patient's voluntary non-opioid directive, or the revocation of a voluntary non-opioid directive by a duly authorized guardian or health care proxy may be subject to disciplinary action by his or her professional licensing board.

(5) (a) For the purposes of this section, a pharmacist shall presume that an electronic, written, oral, or faxed prescription for an opioid drug is valid and is authorized to dispense an opioid drug in contradiction of a voluntary non-opioid directive.

(b) A pharmacist who exercises reasonable care shall not be liable for damages in a civil action, subject to criminal prosecution, deemed to have violated the standard of care, or subject to disciplinary action by a professional licensing board for dispensing an opioid drug in contradiction of a voluntary non-opioid directive.

(6) Each state licensing board shall promulgate administrative regulations necessary to carry out the provisions of this section.

➔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***:***

1. To determine if the patient has filed a voluntary non-opioid directive

form established in subsection (2) of Section 1 of this Act; and

2. 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***; and***

(f) Provide, in accordance with subsection (3) of Section 1 of this Act, the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care proxy with a copy of the voluntary non-opioid directive form established in subsection (2) of Section 1 of this Act.

(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***, including if the patient has filed a voluntary non-opioid directive form established in subsection (2) of Section 1 of this Act***; 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 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 218A.202 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall establish and maintain an electronic system for monitoring Schedules II, III, IV, and V controlled substances. 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.

(2) A practitioner or a pharmacist authorized to prescribe or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every 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 for Health and Family Services 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:

(a) A drug administered directly to a patient in a hospital, a resident of a health care facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility;

(b) A 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

(c) A drug administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National

Institutes of Health.

(4) In addition to the data required by subsection (5) of this section, 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.

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

(a) Patient identifier;

(b) National drug code of the drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(6) The data shall be provided in the electronic format specified by the Cabinet for Health and Family Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.

(7) The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is

authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) Employees of the Office of the Inspector General of the Cabinet for Health and Family Services who have successfully completed training for the electronic system and who have been approved to use the system, 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;

(c) A state-operated Medicaid program in conformity with subsection (8) of this section;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who certifies that the requested information is for the purpose of:

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

2. 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

3. Reviewing and assessing the individual prescribing or dispensing patterns of the practitioner or pharmacist or to determine the accuracy

and completeness of information contained in the monitoring system;

(f) The chief medical officer of a hospital or long-term-care facility, an employee of the hospital or long-term-care facility as designated by the chief medical officer and who is working under his or her specific direction, or a physician designee if the hospital or facility has no chief medical officer, if the officer, employee, or designee certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective patient or resident in the hospital or facility;

(g) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing or dispensing practices;
2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or
3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;

(h) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced practice registered nurse who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing or dispensing practices;
2. Associated in a partnership or other business entity with an advanced practice registered nurse who is already under investigation by the Board

of Nursing for improper prescribing practices;

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

4. In a designated geographic area for which a report on a physician or another advanced practice registered nurse in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;

(i) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program; or

(j) A medical examiner engaged in a death investigation pursuant to KRS 72.026.

(8) The Department for Medicaid Services shall use any data or reports from the system for the purpose of identifying Medicaid providers or recipients whose prescribing, dispensing, or usage of controlled substances may be:

(a) Appropriately managed by a single outpatient pharmacy or primary care physician; or

(b) Indicative of improper, inappropriate, or illegal prescribing or dispensing practices by a practitioner or drug seeking by a Medicaid recipient.

(9) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except as provided in this section, in another statute, or by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except that:

(a) A person specified in subsection (7)(b) of this section who is authorized to receive data or a report may share that information with any other persons

specified in subsection (7)(b) of this section authorized to receive data or a report if the persons specified in subsection (7)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each agency engaged in the investigation;

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection (7)(a) of this section, or with a law enforcement officer designated in subsection (7)(b) of this section;

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

(d) If a state licensing board as defined in KRS 218A.205 initiates formal disciplinary proceedings against a licensee, and data obtained by the board is relevant to the charges, the board may provide the data to the licensee and his or her counsel, as part of the notice process required by KRS 13B.050, and admit the data as evidence in an administrative hearing conducted pursuant to KRS Chapter 13B, with the board and licensee taking all necessary steps to prevent further disclosure of the data; and

(e) A practitioner, pharmacist, or employee who obtains data under subsection (7)(e) of this section 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 subsection (7)(e) of this section 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.

(10) The Cabinet for Health and Family Services, all peace officers specified in subsection (7)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(11) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

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

(13) Intentional disclosure of transmitted data to a person not authorized by subsections (7) to (9) 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.

(14) The Cabinet for Health and Family Services may, by promulgating an administrative regulation, limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

(15) (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 the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

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

(16) If the cabinet becomes aware of a prescriber's or dispenser's failure to comply with this section, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser. The licensing board shall treat the notification as a complaint against the licensee.

(17) The Cabinet for Health and Family Services, Office of Inspector General, shall conduct quarterly reviews to identify patterns of potential improper, inappropriate, or illegal prescribing or dispensing of a controlled substance. The Office of Inspector General may independently investigate and submit findings and recommendations to the appropriate boards of licensure or other reporting agencies.

(18) The cabinet shall promulgate administrative regulations to implement the provisions of this section. Included in these administrative regulations shall be:

(a) An error resolution process allowing a patient to whom a report had been disclosed under subsection (9) 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) of this section within one (1) day of dispensing.

(19) 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.

(20) The electronic monitoring system established in subsection (1) of this section shall permit:

(a) The cabinet to report and document receipt of a voluntary non-opioid directive form established in subsection (2) of Section 1 of this Act submitted by an individual and to list any duly authorized guardian or health care proxy who may revoke the directive; and

(b) A practitioner to determine if a patient has filed a voluntary non-opioid directive and to identify any duly authorized guardian or health care proxy who may revoke the directive.