AN ACT relating to the electronic system for monitoring scheduled drug prescriptions.

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

➔Section 1. 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**;** ***or***

(k) An employer of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances if the

employer is conducting a bona fide specific investigation of the prescribing or dispensing practices of a designated employee who is authorized to prescribe, administer, or dispense controlled substances.

(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.