HOUSE OF REPRESENTATIVES

KENTUCKY GENERAL ASSEMBLY AMENDMENT FORM

2022 REGULAR SESSION

Amend printed copy of **HB 354/HCS 1**

On page 1, line 3, to page 13, line 12, delete Sections 1 and 2 in their entirety and insert the following in lieu thereof:

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

(1) There is hereby established the Controlled Substance Prescribing Review and Enforcement Advisory Council to provide advice, guidance, and recommendations to state licensing boards charged with enforcing and reviewing prescribing practices.

(2) The council shall consist of the following members to be appointed by the Governor:

(a) Five (5) physicians who are licensed in Kentucky, one (1) who is a family physician or internist, one (1) who is a surgeon, one (1) who is a specialist in pain medicine, one (1) who is an oncologist, and one (1) who is a psychiatrist, to be appointed from lists provided by the Kentucky Board of Medical Licensure containing the names of three (3) physicians for each of the five (5) areas of practice;

(b) Two (2) advanced practice registered nurses who are licensed in Kentucky to be appointed from lists provided by the Kentucky Board of Nursing containing the names of three (3) advanced practice registered nurses for each board appointment;

(c) One (1) substance abuse and mental health professional who is licensed in

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Amendment No. HFA 1 Rep. Rep. Kimberly Poore Moser

Committee Amendment Signed:

Floor Amendment LRC Drafter:

Adopted: Date:

Rejected: Doc. ID: XXXX

Kentucky to be appointed from a list of three (3) professionals provided by the Cabinet for Health and Family Services;

(d) One (1) community mental health center representative to be appointed from a list of three (3) individuals provided by the Cabinet for Health and Family Services;

(e) Two (2) pharmacists who are licensed in Kentucky, each of whom shall be appointed from one (1) of two (2) separate lists provided by the Kentucky Board of Pharmacy containing the names of three (3) pharmacists from each the following general geographic areas in Kentucky:

1. The area west of Interstate 75; and

2. The area east of Interstate 75;

(f) Two (2) dentists who are licensed in Kentucky to be appointed from a list of three (3) dentists provided by the Kentucky Board of Dentistry for each board appointment;

(g) One (1) representative of the Office of Drug Control Policy; and

(h) One (1) representative from the Office of Inspector General, who shall also serve as chair of the council.

The lists of recommendations for initial appointments to the council shall be delivered to the Governor no later than August 1, 2022.

(3) Initial appointments to the council shall be for staggered terms, and thereafter members shall serve four (4) year terms.

(4) The duties of the council shall include but not be limited to:

(a) Providing advice, guidance, and recommendations to assist state licensing boards in expanding their enforcement activities of identifying and eliminating drug abuse, misuse, diversion, and illegal prescription and sale of prescription drugs by

their respective licensees; and

(b) Developing guidelines for utilizing the electronic system for monitoring Schedules II, III, IV, and V controlled substances established under KRS 218A.202 to identify potential problem areas and proactively generate information useful to the particular prescriber and dispenser licensing boards.

(5) The council shall work in cooperation with the affected professional licensing boards of practitioners and pharmacists, law enforcement, substance abuse and mental health treatment professionals, and other stakeholders.

(6) The council shall meet at regular intervals, and no less than quarterly and at the call of the chair.

(7) Support staff, facilities, and resources for the meetings of the council shall be provided as directed by the secretary of the Cabinet for Health and Family Services.

(8) Members of the council shall serve at the pleasure of the Governor and without compensation, but shall be reimbursed for actual expenses incurred in the connection with the discharge of their official duties.

(9) All cabinets, departments, commissions, boards, agencies, and officers of the state, or any political subdivision thereof, are hereby authorized and directed to cooperate with the council in implementing this section.

(10) The council shall provide an annual report to the Governor and to the co-chairs of the Interim Joint Committee on Health, Welfare, and Family Services by December 1, 2022, and by December 1 of each year thereafter.

➔Section 2. 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 ***consult with a licensed physician and*** employ or obtain the services of a specialist in ***prescribing controlled substances***~~[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.

(9) Every state licensing board shall promulgate administrative regulations that require the board to:

(a) Review, investigate, and enforce violations of prescribing practices;

(b) Request that the Office of Inspector General conduct a review using the electronic system for monitoring Schedules II, III, IV, and V controlled substances established under KRS 218A.202, in order to generate a broad sampling of at least fifteen (15) patient charts to be reviewed when a prescribing case is referred to the licensing board by a source other than the Office of Inspector General within the Cabinet for Health and Family Services;

(c) Employ investigators with law enforcement or drug task force backgrounds for any prescribing investigation;

(d) Require a review of a prescriber be performed by physicians practicing within or similar to the prescriber's self-defined or practice-defined specialty;

(e) Form specific or separate disciplinary panels made up of clinicians who are authorized to prescribe controlled substances to review cases involving controlled substances;

(f) Focus reviews of prescribers on whether the prescriber's clinical judgment and reasoning supported the necessity for the prescription, for that treatment purpose, at that strength, and for that period of time; and

(g) Require each reviewer of a prescriber to submit the reviewer's opinion on whether the prescribing practices of a prescriber increase the risk for dependence, abuse, or diversion, or present a harm to patients or the public. If the opinion is affirmative, the board shall take immediate action to restrict the prescriber's prescribing authority.

(10) Nothing in this section shall prohibit an employer from instituting or implementing stricter standards for medical practice or prescribing than those required by state law.".