1 AN ACT relating to controlled substances.

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

- 3 → Section 1. KRS 205.529 is amended to read as follows:
- 4 (1) The Department for Medicaid Services or a managed care organization contracted
- 5 to provide services pursuant to this chapter shall provide a program for
- 6 synchronization of medications when it is agreed among the member, a provider,
- 7 and a pharmacist that synchronization of multiple prescriptions for the treatment of
- 8 a chronic illness is in the best interest of the patient for the management or
- 9 treatment of a chronic illness provided that the medications:
- 10 (a) Are covered by the Department for Medicaid Services or a managed care
- organization contracted to provide services pursuant to this chapter;
- 12 (b) Are used for treatment and management of chronic conditions that are subject
- to refills;
- 14 (c) Are not a Schedule II controlled substance or a Schedule III controlled
- 15 <u>substance containing hydrocodone</u>];
- 16 (d) Meet all prior authorization criteria specific to the medications at the time of
- 17 the synchronization request;
- 18 (e) Are of a formulation that can be effectively split over required short fill
- 19 periods to achieve synchronization; and
- 20 (f) Do not have quantity limits or dose optimization criteria or requirements that
- would be violated in fulfilling synchronization.
- 22 (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.
- 26 (3) Any dispensing fee shall not be prorated and shall be based on an individual
- 27 prescription filled or refilled.

1		→ S	ection 2. KRS 218A.172 is amended to read as follows:
2	(1)	Adn	ninistrative regulations promulgated under KRS 218A.205(3) shall require that,
3		prio	r to the initial prescribing or dispensing of any Schedule II controlled substance
4		[or ε	Schedule III controlled substance containing hydrocodone]to a human patient,
5		a pra	actitioner shall:
6		(a)	Obtain a medical history and conduct a physical or mental health examination
7			of the patient, as appropriate to the patient's medical complaint, and document
8			the information in the patient's medical record;
9		(b)	Query the electronic monitoring system established in KRS 218A.202 for all
10			available data on the patient for the twelve (12) month period immediately
11			preceding the patient encounter and appropriately utilize that data in the
12			evaluation and treatment of the patient;
13		(c)	Make a written plan stating the objectives of the treatment and further
14			diagnostic examinations required;
15		(d)	Discuss the risks and benefits of the use of controlled substances with the
16			patient, the patient's parent if the patient is an unemancipated minor child, or
17			the patient's legal guardian or health care surrogate, including the risk of
18			tolerance and drug dependence; and
19		(e)	Obtain written consent for the treatment.
20	(2)	(a)	Administrative regulations promulgated under KRS 218A.205(3) shall require
21			that a practitioner prescribing or dispensing additional amounts of Schedule II
22			controlled substances [or Schedule III controlled substances containing
23			hydrocodone] for the same medical complaint and related symptoms shall:
24			1. Review, at reasonable intervals based on the patient's individual
25			circumstances and course of treatment, the plan of care;
26			2. Provide to the patient any new information about the treatment: and

Modify or terminate the treatment as appropriate.

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1		(b)	If the course of treatment extends beyond three (3) months, the administrative
2			regulations shall also require that the practitioner:
3			1. Query the electronic monitoring system established in KRS 218A.202
4			no less than once every three (3) months for all available data on the
5			patient for the twelve (12) month period immediately preceding the
6			query; and
7			2. Review that data before issuing any new prescription or refills for the
8			patient for any Schedule II controlled substance[or a Schedule III
9			controlled substance containing hydrocodone].
10	(3)	Adn	ninistrative regulations promulgated under KRS 218A.205(3) shall require that,
11		for	each patient for whom a practitioner prescribes any Schedule II controlled
12		subs	tance[or a Schedule III controlled substance containing hydrocodone], the
13		prac	titioner shall keep accurate, readily accessible, and complete medical records
14		whic	ch include, as appropriate:
15		(a)	Medical history and physical or mental health examination;
16		(b)	Diagnostic, therapeutic, and laboratory results;
17		(c)	Evaluations and consultations;
18		(d)	Treatment objectives;
19		(e)	Discussion of risk, benefits, and limitations of treatments;
20		(f)	Treatments;
21		(g)	Medications, including date, type, dosage, and quantity prescribed or
22			dispensed;
23		(h)	Instructions and agreements; and
24		(i)	Periodic reviews of the patient's file.
25	(4)	Adn	ninistrative regulations promulgated under KRS 218A.205(3) may exempt, in
26		who	le or in part, compliance with the mandatory diagnostic, treatment, review, and
27		othe	r protocols and standards established in this section for:

1	(a)	A licensee prescribing or administering a controlled substance immediately
2		prior to, during, or within the fourteen (14) days following an operative or
3		invasive procedure or a delivery if the prescribing or administering is
4		medically related to the operative or invasive procedure or the delivery and
5		the medication usage does not extend beyond the fourteen (14) days;
6	(b)	A licensee prescribing or administering a controlled substance necessary to
7		treat a patient in an emergency situation;
8	(c)	A licensed pharmacist or other person licensed by the Kentucky Board of
9		Pharmacy to dispense drugs or a licensed pharmacy;
10	(d)	A licensee prescribing or dispensing a controlled substance:
11		1. For administration in a hospital or long-term [-]care facility if the
12		hospital or long-term [-]care facility with an institutional account, or a
13		practitioner in those hospitals or facilities where no institutional account
14		exists, queries the electronic monitoring system established in KRS
15		218A.202 for all available data on the patient or resident for the twelve
16		(12) month period immediately preceding the query within twelve (12)
17		hours of the patient's or resident's admission and places a copy of the
18		query in the patient's or resident's medical records during the duration of

2. As part of the patient's hospice or end-of-life treatment;

the patient's stay at the facility;

- 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;

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1			b. Cancels any refills for the initial prescription; and
2			c. Requires the patient to dispose of any remaining unconsumed
3			medication;
4			6. Within ninety (90) days of an initial prescribing or dispensing under
5			subsection (1) of this section if the prescribing or dispensing is done by
6			another practitioner in the same practice or in an existing coverage
7			arrangement, if done for the same patient for the same medical
8			condition; or
9			7. To a research subject enrolled in a research protocol approved by an
10			institutional review board that has an active federalwide assurance
11			number from the United States Department of Health and Human
12			Services, Office for Human Research Protections, where the research
13			involves single, double, or triple blind drug administration or is
14			additionally covered by a certificate of confidentiality from the National
15			Institutes of Health;
16		(e)	The prescribing of a Schedule III, IV, or V controlled substance by a licensed
17			optometrist to a patient in accordance with the provisions of KRS 320.240; or
18		(f)	The prescribing of a three (3) day supply of a Schedule III controlled
19			substance following the performance of oral surgery by a dentist licensed
20			pursuant to KRS Chapter 313.
21	(5)	(a)	A state licensing board promulgating administrative regulations under KRS
22			218A.205(3) may promulgate an administrative regulation authorizing
23			exemptions supplemental or in addition to those specified in subsection (4) of
24			this section. Prior to exercising this authority, the board shall:
25			1. Notify the Kentucky Office of Drug Control Policy that it is considering
26			a proposal to promulgate an administrative regulation authorizing
27			exemptions supplemental or in addition to those specified in subsection

1				(4) of this section and invite the office to participate in the board
2				meeting at which the proposal will be considered;
3			2.	Make a factual finding based on expert testimony as well as evidence or
4				research submitted to the board that the exemption demonstrates a low
5				risk of diversion or abuse and is supported by the dictates of good
6				medical practice; and
7			3.	Submit a report to the Governor and the Legislative Research
8				Commission of its actions, including a detailed explanation of the
9				factual and policy basis underlying the board's action. A copy of this
10				report shall be provided to the regulations compiler.
11		(b)	With	nin one (1) working day of promulgating an administrative regulation
12			auth	orizing an exemption under this section, the promulgating board shall e-
13			mail	to the Kentucky Office of Drug Control Policy:
14			1.	A copy of the administrative regulation as filed, and all attachments
15				required by KRS 13A.230(1); and
16			2.	A request from the board that the office review the administrative
17				regulation in the same manner as would the Commission on Small
18				Business Innovation and Advocacy under KRS 11.202(1)(e), and submit
19				its report or comments in accordance with the deadline established in
20				KRS 13A.270(1)(c). A copy of the report or comments shall be filed
21				with the regulations compiler.
22		→ Se	ection	3. KRS 218A.182 is amended to read as follows:
23	(1)	Noty	withst	anding KRS 218A.180 or any other state law to the contrary, beginning
24		Janu	ary 1	, 2021, no practitioner shall issue any prescription for a controlled
25		subs	tance	unless the prescription is made by electronic prescription from the
26		prac	titione	er issuing the prescription to a pharmacy, except for prescriptions issued:

(a)

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By veterinarians;

1 (b) In circumstances where electronic prescribing is not available due to temporary technological or electrical failure; 2 3

- (c) By a practitioner to be dispensed by a pharmacy located outside the state;
- (d) When the prescriber and dispenser are the same entity;

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- (e) That include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;
 - (f) By a practitioner for a drug that contains certain elements that cannot be incorporated as required by the United States Food and Drug Administration with electronic prescribing, including extemporaneous compounding;
 - (g) By a practitioner allowing for the dispensing of a nonpatient specific prescription under a standing order, approved protocol for drug therapy, or collaborative drug management or comprehensive medication management, in response to a public health emergency;
 - By a practitioner prescribing a drug under a research protocol; (h)
 - (i) By practitioners who have received a waiver or a renewal thereof, from the requirement to use electronic prescribing due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. The initial waiver and each subsequent waiver renewal shall not exceed one (1) year per waiver or waiver renewal;
 - (j) By a practitioner under circumstances where, notwithstanding practitioner's present ability to make an electronic prescription as required by this subsection, the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and delay would adversely impact the patient's medical condition;

I		(k) By a practitioner for an individual who receives hospice care; [or]
2		(l) By a practitioner for an individual who is a resident of a nursing facility; or
3		(m) By a practitioner who is issuing a prescription as part of providing
4		charitable health care services pursuant to the Kentucky Charitable Health
5		Care Services Act, KRS 216.940 to 216.945.
6	(2)	A pharmacist who receives a written, oral, or faxed prescription for a controlled
7		substance shall not be required to verify that the prescription properly falls under
8		one (1) of the exceptions from the requirement to electronically prescribe.
9		Pharmacists may continue to dispense medications from otherwise valid written,
10		oral, or fax prescriptions that are consistent with current laws and administrative
11		regulations.
12	(3)	The cabinet shall promulgate administrative regulations to implement this section
13		including enforcement mechanisms, waivers of requirements, and appropriate
14		penalties for violations.
15		→ Section 4. KRS 218A.202 is amended to read as follows:
16	(1)	The Cabinet for Health and Family Services shall establish and maintain an
17		electronic system for monitoring Schedules II, III, IV, and V controlled substances.
18		The cabinet may contract for the design, upgrade, or operation of this system if the
19		contract preserves all of the rights, privileges, and protections guaranteed to
20		Kentucky citizens under this chapter and the contract requires that all other aspects
21		of the system be operated in conformity with the requirements of this or any other
22		applicable state or federal law.
23	(2)	A practitioner or a pharmacist authorized to prescribe or dispense controlled
24		substances to humans shall register with the cabinet to use the system provided for
25		in this section and shall maintain an active account with the electronic monitoring
26		<u>system</u> [such registration] continuously during the practitioner's or pharmacist's term
27		of licensure and shall not have to pay a fee or tax specifically dedicated to the

1 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.

1 (5) Data for each controlled substance that is reported shall include but not be limited

- 2 to the following:
- 3 (a) Patient identifier;
- 4 (b) National drug code of the drug dispensed;
- 5 (c) Date of dispensing;
- 6 (d) Quantity dispensed;
- 7 (e) Prescriber; and
- 8 (f) Dispenser.
- 9 (6) The data shall be provided in the electronic format specified by the Cabinet for 10 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.
- 15 (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
- 19 prohibited unless specifically authorized by this section. The Cabinet for Health and
- 20 Family Services shall be authorized to provide data to:
- 21 (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;
- 25 (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

1		prosecutors, Kentucky Commonwealth's attorneys and assistant
2		Commonwealth's attorneys, county attorneys and assistant county attorneys, a
3		peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-
4		time peace officer of another state, or a federal agent whose duty is to enforce
5		the laws of this Commonwealth, of another state, or of the United States
6		relating to drugs and who is engaged in a bona fide specific investigation
7		involving a designated person;
8	(c)	A state-operated Medicaid program in conformity with subsection (8) of this
9		section;
10	(d)	A properly convened grand jury pursuant to a subpoena properly issued for
11		the records;
12	(e)	A practitioner or pharmacist, or employee of the practitioner's or pharmacist's
13		practice acting under the specific direction of the practitioner or pharmacist,
14		who certifies that the requested information is for the purpose of:
15		1. Providing medical or pharmaceutical treatment to a bona fide current or
16		prospective patient;
17		2. Reviewing data on controlled substances that have been reported for the
18		birth mother of an infant who is currently being treated by the
19		practitioner for neonatal abstinence syndrome, or has symptoms that
20		suggest prenatal drug exposure; or
21		3. Reviewing and assessing the individual prescribing or dispensing
22		patterns of the practitioner or pharmacist or to determine the accuracy
23		and completeness of information contained in the monitoring system;
24	(f)	The chief medical officer of a hospital or long-term [-]care facility, an
25		employee of the hospital or long-term [-]care facility as designated by the
26		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,

1		if the officer, employee, or designee certifies that the requested information is
2		for the purpose of providing medical or pharmaceutical treatment to a bona
3		fide current or prospective patient or resident in the hospital or facility;
4	(g)	In addition to the purposes authorized under paragraph (a) of this subsection,
5		the Kentucky Board of Medical Licensure, for any physician who is:
6		1. Associated in a partnership or other business entity with a physician
7		who is already under investigation by the Board of Medical Licensure
8		for improper prescribing or dispensing practices;
9		2. In a designated geographic area for which a trend report indicates a
10		substantial likelihood that inappropriate prescribing or dispensing may
11		be occurring; or
12		3. In a designated geographic area for which a report on another physician
13		in that area indicates a substantial likelihood that inappropriate
14		prescribing or dispensing may be occurring in that area;
15	(h)	In addition to the purposes authorized under paragraph (a) of this subsection,
16		the Kentucky Board of Nursing, for any advanced practice registered nurse
17		who is:
18		1. Associated in a partnership or other business entity with a physician
19		who is already under investigation by the Kentucky Board of Medical
20		Licensure for improper prescribing or dispensing practices;
21		2. Associated in a partnership or other business entity with an advanced
22		practice registered nurse who is already under investigation by the
23		Board of Nursing for improper prescribing practices;
24		3. In a designated geographic area for which a trend report indicates a
25		substantial likelihood that inappropriate prescribing or dispensing may
26		be occurring; or

In a designated geographic area for which a report on a physician or

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1			another advanced practice registered nurse in that area indicates a
2			substantial likelihood that inappropriate prescribing or dispensing may
3			be occurring in that area;
4		(i)	A judge or a probation or parole officer administering a diversion or probation
5			program of a criminal defendant arising out of a violation of this chapter or of
6			a criminal defendant who is documented by the court as a substance abuser
7			who is eligible to participate in a court-ordered drug diversion or probation
8			program; or
9		(j)	A medical examiner engaged in a death investigation pursuant to KRS 72.026.
10	(8)	The	Department for Medicaid Services shall use any data or reports from the
11		syste	em for the purpose of identifying Medicaid providers or recipients whose
12		pres	cribing, dispensing, or usage of controlled substances may be:
13		(a)	Appropriately managed by a single outpatient pharmacy or primary care
14			physician; or
15		(b)	Indicative of improper, inappropriate, or illegal prescribing or dispensing
16			practices by a practitioner or drug seeking by a Medicaid recipient.
17	(9)	A pe	erson who receives data or any report of the system from the cabinet shall not
18		prov	vide it to any other person or entity except as provided in this section, in another
19		statu	ate, or by order of a court of competent jurisdiction and only to a person or
20		entit	y authorized to receive the data or the report under this section, except that:
21		(a)	A person specified in subsection (7)(b) of this section who is authorized to
22			receive data or a report may share that information with any other persons
23			specified in subsection (7)(b) of this section authorized to receive data or a
24			report if the persons specified in subsection (7)(b) of this section are working
25			on a bona fide specific investigation involving a designated person. Both the
26			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

1		consider the nature of the prescriber's and dispenser's practice and the condition for
2		which the patient is being treated.
3	(11)	The data and any report obtained therefrom shall not be a public record, except that
4		the Department for Medicaid Services may submit the data as evidence in an
5		administrative hearing held in accordance with KRS Chapter 13B.
6	(12)	Intentional failure to comply with the reporting requirements of this section shall be
7		a Class B misdemeanor for the first offense and a Class A misdemeanor for each
8		subsequent offense.
9	(13)	Intentional disclosure of transmitted data to a person not authorized by subsections
10		(7) to (9) of this section or authorized by KRS 315.121, or obtaining information
11		under this section not relating to a bona fide current or prospective patient or a bona
12		fide specific investigation, shall be a Class B misdemeanor for the first offense and
13		a Class A misdemeanor for each subsequent offense.
14	(14)	The Cabinet for Health and Family Services may, by promulgating an
15		administrative regulation, limit the length of time that data remain in the electronic
16		system. Any data removed from the system shall be archived and subject to
17		retrieval within a reasonable time after a request from a person authorized to review
18		data under this section.
19	(15)	(a) The Cabinet for Health and Family Services shall work with each board
20		responsible for the licensure, regulation, or discipline of practitioners,
21		pharmacists, or other persons who are authorized to prescribe, administer, or
22		dispense controlled substances for the development of a continuing education
23		program about the purposes and uses of the electronic system for monitoring
24		established in this section.
25		(b) The cabinet shall work with the Kentucky Bar Association for the
26		development of a continuing education program for attorneys about the

purposes and uses of the electronic system for monitoring established in this

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1	section.
1	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

1		Cou	rts to the cabinet on a continuing basis. The cabinet shall incorporate the data		
2		rece	received into the system so that a query by patient name indicates any prior drug		
3		conv	conviction.		
4		→ S	ection 5. KRS 218A.205 is amended to read as follows:		
5	(1)	As u	sed in this section:		
6		(a)	"Reporting agency" includes:		
7			1. The Department of Kentucky State Police;		
8			2. The Office of the Attorney General;		
9			3. The Cabinet for Health and Family Services; and		
10			4. The applicable state licensing board; and		
11		(b)	"State licensing board" means:		
12			1. The Kentucky Board of Medical Licensure;		
13			2. The Kentucky Board of Nursing;		
14			3. The Kentucky Board of Dentistry;		
15			4. The Kentucky Board of Optometric Examiners;		
16			5. The State Board of Podiatry; and		
17			6. Any other board that licenses or regulates a person who is entitled to		
18			prescribe or dispense controlled substances to humans.		
19	(2)	(a)	When a reporting agency or a law enforcement agency receives a report of		
20			improper, inappropriate, or illegal prescribing or dispensing of a controlled		
21			substance it may, to the extent otherwise allowed by law, send a copy of the		
22			report within three (3) business days to every other reporting agency.		
23		(b)	A county attorney or Commonwealth's attorney shall notify the Office of the		
24			Attorney General and the appropriate state licensing board within three (3)		
25			business days of an indictment or a waiver of indictment becoming public in		
26			his or her jurisdiction charging a licensed person with a felony offense		
27			relating to the manufacture of, trafficking in, prescribing, dispensing, or		

1 possession of a controlled substance.

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2 (3) Each state licensing board shall, in consultation with the Kentucky Office of Drug
3 Control Policy, establish the following by administrative regulation for those
4 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[<u>and Schedule III controlled substances containing</u> <u>hydrocodone</u>] 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

1		treat pain while the patient is receiving hospice or end-of-life treatment
2		or is receiving care from a certified community based palliative care
3		program;
4		5. The prescription for a Schedule II controlled substance is prescribed as
5		part of a narcotic treatment program licensed by the Cabinet for Health
6		and Family Services;
7		6. The prescription for a Schedule II controlled substance is prescribed to
8		treat pain following a major surgery or the treatment of significant
9		trauma, as defined by the state licensing board in consultation with the
10		Kentucky Office of Drug Control Policy;
11		7. The Schedule II controlled substance is dispensed or administered
12		directly to an ultimate user in an inpatient setting; or
13		8. Any additional treatment scenario deemed medically necessary by the
14		state licensing board in consultation with the Kentucky Office of Drug
15		Control Policy.
16		Nothing in this paragraph shall authorize a state licensing board to promulgate
17		regulations which expand any practitioner's prescriptive authority beyond that
18		which existed prior to June 29, 2017;
19	(c)	A prohibition on a practitioner dispensing greater than a forty-eight (48) hour
20		supply of any Schedule II controlled substance[or a Schedule III controlled
21		substance containing hydrocodone] unless the dispensing is done as part of a
22		narcotic treatment program licensed by the Cabinet for Health and Family
23		Services;
24	(d)	A procedure for temporarily suspending, limiting, or restricting a license held
25		by a named licensee where a substantial likelihood exists to believe that the
26		continued unrestricted practice by the named licensee would constitute a
27		danger to the health, welfare, or safety of the licensee's patients or of the

1 general public;

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(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:
 - 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;
 - 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;
 - 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
 - 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

1 States Department of Health and Human Services;

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(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.

- 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 (8) Each state licensing board shall require a fingerprint-supported criminal record
 9 check by the Department of Kentucky State Police and the Federal Bureau of
 10 Investigation of any applicant for initial licensure to practice any profession
 11 authorized to prescribe or dispense controlled substances.
- → Section 6. KRS 218A.245 is amended to read as follows:
 - (1) The secretary of the Cabinet for Health and Family Services may enter into reciprocal agreements or a contract, either directly with any federal agency of the United States or its territories, any other state or states of the United States or any jurisdiction, county, or political subdivision thereof, or with an organization administering the exchange of interstate data on behalf of the prescription monitoring program of one (1) or more states or jurisdictions, to share prescription drug monitoring information if the other prescription drug monitoring program or data exchange program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state, jurisdiction, or organization as authorized by this section, priority shall be given to a state or jurisdiction that is contiguous with the borders of the Commonwealth or an organization that offers connectivity with a contiguous state or jurisdiction.
- 26 (2) In determining compatibility, the secretary shall consider:
- 27 (a) The essential purposes of the program and the success of the program in

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1 fulfilling those purposes; 2 (b) The safeguards for privacy of patient records and its success in protecting 3 patient privacy; (c) The persons authorized to view the data collected by the program; 4 The schedules of controlled substances monitored; 5 (d) 6 (e) The data required to be submitted on each prescription or dispensing; 7 (f) Any implementation criteria deemed essential for a thorough comparison; and The costs and benefits to the Commonwealth in mutually sharing particular 8 (g) 9 information available in the Commonwealth's database with the program 10 under consideration. 11 (3)The secretary shall review any agreement on an annual basis to determine its 12 continued compatibility with the Kentucky prescription drug monitoring program. 13 Any agreement between the cabinet and another state, jurisdiction, or organization (4) 14 shall prohibit the sharing of information about a Kentucky resident, practitioner, 15 pharmacist, or other prescriber or dispenser for any purpose not otherwise 16 authorized by this section or KRS 218A.202. → Section 7. KRS 304.17A-165 is amended to read as follows: 17 18 Any health benefit plan that provides benefits for prescription drugs shall include an (1)19 exceptions policy or an override policy that provides coverage for the refill of a

- 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.
- 26 (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.

1	(3)	Any individual or group health benefit plan that provides benefits for prescription
2		drugs shall provide a program for synchronization of medications when it is agreed
3		among the insured, a provider, and a pharmacist that synchronization of multiple
4		prescriptions for the treatment of a chronic illness is in the best interest of the
5		patient for the management or treatment of a chronic illness provided that the
6		medications:

- 7 (a) Are covered by the individual or group health benefit plan:
- 8 (b) Are used for treatment and management of chronic conditions that are subject to refills;
- 10 (c) Are not a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone;
- 12 (d) Meet all prior authorization criteria specific to the medications at the time of 13 the synchronization request;
- 14 (e) Are of a formulation that can be effectively split over required short fill 15 periods to achieve synchronization; and
- 16 (f) Do not have quantity limits or dose optimization criteria or requirements that would be violated in fulfilling synchronization.
- 18 (4) To permit synchronization, an individual or group health benefit plan shall apply a 19 prorated daily cost-sharing rate to any medication dispensed by a network 20 pharmacy pursuant to this section.
- 21 (5) Any dispensing fee shall not be prorated and shall be based on an individual prescription filled or refilled.