

CHAPTER 22

(HB 300)

AN ACT relating to emergency authority for pharmacists.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *When the Governor declares a state of emergency pursuant to Section 3 of this Act, the Governor may issue an executive order for a period of up to thirty (30) days giving pharmacists emergency authority. The executive order shall designate the geographical area to which it applies. In the executive order, the Governor may vest pharmacists with the authority to:*
- (a) *Dispense up to a thirty (30) day emergency supply of medication;*
 - (b) *Administer immunizations to children pursuant to protocols established by the Centers for Disease Control and Prevention, the National Institutes of Health, or the National Advisory Committee on Immunization Practices or determined to be appropriate by the commissioner of public health or his designee;*
 - (c) *Operate temporarily, a pharmacy in an area not designated on the pharmacy permit; and*
 - (d) *Dispense drugs as needed to prevent or treat the disease or ailment responsible for the emergency pursuant to protocols established by the Centers for Disease Control and Prevention or the National Institutes of Health or determined to be appropriate by the commissioner of public health or his designee to respond to the circumstances causing the emergency.*
- (2) *The provisions of this section may be extended, in writing, by the Governor if necessary to protect the lives or welfare of the citizens.*

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

The Kentucky Board of Pharmacy may promulgate administrative regulations in accordance with KRS Chapter 13A to allow pharmacists to effectuate the authority granted in subsection (1) of Section 1 of this Act.

➔Section 3. KRS 39A.100 is amended to read as follows:

- (1) In the event of the occurrence or threatened or impending occurrence of any of the situations or events contemplated by KRS 39A.010, 39A.020, or 39A.030, the Governor may declare, in writing, that a state of emergency exists. The Governor shall have and may exercise the following emergency powers during the period in which the state of emergency exists:
- (a) To enforce all laws, and administrative regulations relating to disaster and emergency response and to assume direct operational control of all disaster and emergency response forces and activities in the Commonwealth;
 - (b) To require state agencies and to request local governments, local agencies, and special districts to respond to the emergency or disaster in the manner directed;
 - (c) To seize, take, or condemn property, excluding firearms and ammunition, components of firearms and ammunition, or a combination thereof, for the protection of the public or at the request of the President, the Armed Forces, or the Federal Emergency Management Agency of the United States, including:
 - 1. All means of transportation and communication;
 - 2. All stocks of fuel of whatever nature;
 - 3. Food, clothing, equipment, materials, medicines, and all supplies; and
 - 4. Facilities, including buildings and plants;
 - (d) To sell, lend, give, or distribute any of the property under paragraph (c) of this subsection among the inhabitants of the Commonwealth and to account to the State Treasurer for any funds received for the property;

- (e) To make compensation for the property seized, taken, or condemned under paragraph (c) of this subsection;
 - (f) To exclude all nonessential, unauthorized, disruptive, or otherwise uncooperative personnel from the scene of the emergency, and to command those persons or groups assembled at the scene to disperse. A person who refuses to leave an area in which a written order of evacuation has been issued in accordance with a written declaration of emergency or a disaster may be forcibly removed to a place of safety or shelter, or may, if this is resisted, be arrested by a peace officer. Forcible removal or arrest shall not be exercised as options until all reasonable efforts for voluntary compliance have been exhausted;
 - (g) To declare curfews and establish their limits;
 - (h) To prohibit or limit the sale or consumption of goods, excluding firearms and ammunition, components of firearms and ammunition, or a combination thereof, or commodities for the duration of the emergency;
 - (i) ***To grant emergency authority to pharmacists pursuant to Section 1 of this Act, for the duration of the emergency;***
 - (j) Except as prohibited by this section or other law, to perform and exercise other functions, powers, and duties deemed necessary to promote and secure the safety and protection of the civilian population;
 - ~~(k)~~~~(j)~~ To request any assistance from agencies of the United States as necessary and appropriate to meet the needs of the people of the Commonwealth; and
 - ~~(l)~~~~(k)~~ Upon the recommendation of the Secretary of State, to declare by executive order a different time or place for holding elections in an election area for which a state of emergency has been declared for part or all of the election area. The election shall be held within thirty-five (35) days from the date of the suspended or delayed election. The State Board of Elections shall establish procedures for election officials to follow.
- (2) In the event of the occurrence or threatened or impending occurrence of any of the situations or events contemplated by KRS 39A.010, 39A.020, or 39A.030, which in the judgment of a local chief executive officer is of such severity or complexity as to require the exercise of extraordinary emergency measures, the county judge/executive of a county other than an urban-county government, or mayor of a city or urban-county government, or chief executive of other local governments or their designees as provided by ordinance of the affected county, city, or urban-county may declare in writing that a state of emergency exists, and thereafter, subject to any orders of the Governor, shall have and may exercise for the period as the state of emergency exists or continues, the following emergency powers:
- (a) To enforce all laws and administrative regulations relating to disaster and emergency response and to direct all local disaster and emergency response forces and operations in the affected county, city, urban-county, or charter county;
 - (b) To exclude all nonessential, unauthorized, disruptive, or uncooperative personnel from the scene of the emergency, and to command persons or groups of persons at the scene to disperse. A person who refuses to leave an area in which a written order of evacuation has been issued in accordance with a written declaration of emergency or a disaster may be forcibly removed to a place of safety or shelter, or may, if this is resisted, be arrested by a peace officer. Forcible removal or arrest shall not be exercised as options until all reasonable efforts for voluntary compliance have been exhausted;
 - (c) To declare curfews and establish their limits;
 - (d) To order immediate purchase or rental of, contract for, or otherwise procure, without regard to procurement codes or budget requirements, the goods and services essential for protection of public health and safety or to maintain or to restore essential public services; and
 - (e) To request emergency assistance from any local government or special district and, through the Governor, to request emergency assistance from any state agency and to initiate requests for federal assistance as are necessary for protection of public health and safety or for continuation of essential public services.

- (3) Nothing in this section shall be construed to allow any governmental entity to impose additional restrictions on the lawful possession, transfer, sale, transport, carrying, storage, display, or use of firearms and ammunition or components of firearms and ammunition.

➔Section 4. KRS 217.215 is amended to read as follows:

- (1) The State Board of Pharmacy, its agents and inspectors shall have the same powers of inspection and enforcement as the cabinet under KRS 217.005 to 217.215, insofar as it relates to drugs in licensed pharmacies.
- (2) The board of pharmacy may establish regulations relating to the storage and retrieval of prescription records in licensed pharmacies, including regulations regarding computerized recordkeeping systems.
- (3) No prescription for any drug may be refilled by a pharmacist unless authorized by the prescribing practitioner, except that the board of pharmacy may promulgate rules and regulations to permit a pharmacist to:
- (a) Dispense up to a seventy-two (72) hour supply of maintenance medication in emergency situations in which such authorization may not be readily or easily obtained from the practitioner; **and**
- (b) ***Dispense up to a thirty (30) day supply of maintenance medication in emergency situations as authorized by Section 1 of this Act.***
- (4) Such emergency refills shall not be authorized for any controlled substance or for any drug which is not essential to maintenance of life or continuation of therapy in chronic disease conditions.

➔Section 5. KRS 315.010 is amended to read as follows:

As used in this chapter, unless the context requires otherwise:

- (1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, or ingestion, whether topically or by any other means;
- (2) "Association" means the Kentucky Pharmacists Association;
- (3) "Board" means the Kentucky Board of Pharmacy;
- (4) "Collaborative care agreement" means a written agreement between a specifically identified individual practitioner and a pharmacist who is specifically identified, whereby the practitioner outlines a plan of cooperative management of a specifically identified individual patient's drug-related health care needs that fall within the practitioner's statutory scope of practice. The agreement shall be limited to specification of the drug-related regimen to be provided and any tests which may be necessarily incident to its provisions; stipulated conditions for initiating, continuing, or discontinuing drug therapy; directions concerning the monitoring of drug therapy and stipulated conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;
- (5) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients. "Compounding," as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists;
- (6) "Confidential information" means information which is accessed or maintained by a pharmacist in a patient's record, or communicated to a patient as part of patient counseling, whether it is preserved on paper, microfilm, magnetic media, electronic media, or any other form;
- (7) "Continuing education unit" means ten (10) contact hours of board approved continuing pharmacy education. A "contact hour" means fifty (50) continuous minutes without a break period;
- (8) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription drug in a suitable container, appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;
- (9) "Drug" means any of the following:
- (a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

- (b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;
 - (c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
 - (d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;
- (10) "Drug regimen review" means retrospective, concurrent, and prospective review by a pharmacist of a patient's drug-related history, including but not limited to the following areas:
- (a) Evaluation of prescription drug orders and patient records for:
 - 1. Known allergies;
 - 2. Rational therapy contraindications;
 - 3. Appropriate dose and route of administration;
 - 4. Appropriate directions for use; or
 - 5. Duplicative therapies.
 - (b) Evaluation of prescription drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions;
 - (c) Evaluation of prescription drug orders and patient records for adverse drug reactions; or
 - (d) Evaluation of prescription drug orders and patient records for proper utilization and optimal therapeutic outcomes;
- (11) "Immediate supervision" means under the physical and visual supervision of a pharmacist;
- (12) "Manufacturer" means any person, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, compounding, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container;
- (13) "Medical order" means a lawful order of a specifically identified practitioner for a specifically identified patient for the patient's health care needs. "Medical order" may or may not include a prescription drug order;
- (14) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government;
- (15) "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy;
- (16) "Pharmacist intern" means a natural person who is:
- (a) Currently certified by the board to engage in the practice of pharmacy under the direction of a licensed pharmacist and who satisfactorily progresses toward meeting the requirements for licensure as a pharmacist;
 - (b) A graduate of an approved college or school of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;
 - (c) A qualified applicant awaiting examination for licensure as a pharmacist or the results of an examination for licensure as a pharmacist; or
 - (d) An individual participating in a residency or fellowship program approved by the board for internship credit;
- (17) "Pharmacy" means every place where:
- (a) Drugs are dispensed under the direction of a pharmacist;

- (b) Prescription drug orders are compounded under the direction of a pharmacist; or
 - (c) A registered pharmacist maintains patient records and other information for the purpose of engaging in the practice of pharmacy, whether or not prescription drug orders are being dispensed;
- (18) "Pharmacy technician" means a natural person who works under the immediate supervision, or general supervision if otherwise provided for by statute or administrative regulation, of a pharmacist for the purpose of assisting a pharmacist with the practice of pharmacy;
- (19) "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; *the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by Section 1 of this Act*; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;
- (20) "Practitioner" has the same meaning given in KRS 217.015(35);
- (21) "Prescription drug" means a drug which:
- (a) Under federal law is required to be labeled with either of the following statements:
 1. "Caution: Federal law prohibits dispensing without prescription";
 2. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian";
 3. "Rx Only"; or
 4. "Rx"; or
 - (b) Is required by any applicable federal or state law or administrative regulation to be dispensed only pursuant to a prescription drug order or is restricted to use by practitioners;
- (22) "Prescription drug order" means an original or new order from a practitioner for drugs, drug-related devices or treatment for a human or animal, including orders issued through collaborative care agreements. Lawful prescriptions result from a valid practitioner-patient relationship, are intended to address a legitimate medical need, and fall within the prescribing practitioner's scope of professional practice;
- (23) "Pharmacy-related primary care" means the pharmacists' activities in patient education, health promotion, assistance in the selection and use of over-the-counter drugs and appliances for the treatment of common diseases and injuries as well as those other activities falling within their statutory scope of practice;
- (24) "Society" means the Kentucky Society of Health-Systems Pharmacists;
- (25) "Supervision" means the presence of a pharmacist on the premises to which a pharmacy permit is issued, who is responsible, in whole or in part, for the professional activities occurring in the pharmacy; and
- (26) "Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.

➔Section 6. KRS 315.035 is amended to read as follows:

- (1) No person shall operate a pharmacy within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without having first obtained a permit as provided for in KRS Chapter 315. An application for a permit to operate a pharmacy shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with such reasonable standards and rules and regulations as may be prescribed by the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation promulgated by the board pursuant to KRS Chapter 13A, not to exceed two hundred fifty dollars (\$250).
- (2) Upon receipt of an application of a permit to operate a pharmacy, accompanied by the permit fee not to exceed two hundred fifty dollars (\$250), the board shall issue a permit if the pharmacy meets the standards and

requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall refuse to renew any permit to operate unless the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof; provided, however, that the board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. In such event, the temporary permit shall be valid for a period of thirty (30) days, unless extended.

- (3) A separate permit to operate shall be required for each pharmacy.
- (4) Each permit to operate a pharmacy, unless sooner suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by such reasonable renewal fee as may be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) nor to increase more than twenty-five dollars (\$25) per year. An additional fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.
- (5) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable; provided however, that a buyer may operate the pharmacy under the permit of the seller pending a decision by the board of an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.
- (6) The board may promulgate rules and regulations to assure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular pharmacy and to assure reasonable health and sanitation standards for areas within pharmacies which are not subject to health and sanitation standards promulgated by the Kentucky Cabinet for Health and Family Services or a local health department.
- (7) Each pharmacy shall comply with KRS 218A.202.
- (8) Any pharmacy within the Commonwealth that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall, prior to obtaining a permit, receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar program approved by the Kentucky Board of Pharmacy, accreditation shall be maintained and remain current.
- (9) Any pharmacy within the Commonwealth doing business by use of the Internet shall certify the percentage of its annual business conducted via the Internet and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.
- (10) ***A pharmacist may temporarily operate a pharmacy in an area not designated on the permit as authorized in Section 1 of this Act.***

➔Section 7. KRS 315.121 is amended to read as follows:

- (1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
 - (a) Unprofessional or unethical conduct;
 - (b) Mental or physical incapacity that prevents the licensee, permit holder, or certificate holder from engaging or assisting in the practice of pharmacy or the wholesale distribution or manufacturing of drugs with reasonable skill, competence, and safety to the public;
 - (c) Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea, one (1) or more of the following:
 1. A felony;
 2. An act involving moral turpitude or gross immorality; or

3. A violation of the pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government;
 - (d) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician is incapable of engaging or assisting in the practice of pharmacy with reasonable skill, competence, and safety to the public and failing to report any relevant information to the board;
 - (e) Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate;
 - (f) Engaging in fraud in connection with the practice of pharmacy or the wholesale distribution or manufacturing of drugs;
 - (g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," or other term which might imply that the individual is a pharmacist, pharmacist intern, or pharmacy technician;
 - (h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;
 - (i) Violation of any order issued by the board to comply with any applicable law or administrative regulation;
 - (j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the board; or
 - (k) Failure to notify the board within fourteen (14) days of a change in one's home address.
- (2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician:
 - (a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;
 - (b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:
 1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
 2. Certified or licensed health-care personnel who are responsible for care of the patient;
 3. Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A;
 4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
 5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;
 - (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of their intended use in illegal activities;
 - (d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;
 - (e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;

- (f) *Except as provided in Section 1 of this Act*, selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;
 - (g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;
 - (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
 - (i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care; or
 - (j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.
- (3) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.
- (4) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.
- (5) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.
- (6) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.
- (a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.
 - (b) No person may have his or her record expunged under this section more than once.

The board shall promulgate administrative regulations under KRS Chapter 13A to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; assist in the practice of pharmacy; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person, or create a significant threat of such harm.

Signed by the Governor March 24, 2010.