

**CHAPTER 148****(HB 328)**

AN ACT relating to the practice of pharmacy.

*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) *Effective April 1, 2009, a person shall not assist in the practice of pharmacy unless he or she is duly registered as a pharmacy technician under the provisions of this chapter or is exempt under subsection (2) of this section.*
- (2) *A person may assist in the practice of pharmacy without obtaining the registration required by this section if the person:*
  - (a) *Has filed an application with the board in accordance with Section 2 of this Act and no more than thirty (30) days has elapsed since the date the applicant was first employed by the pharmacy. The exemption shall not apply if:*
    1. *The application has been denied;*
    2. *The person is less than sixteen (16) years of age; or*
    3. *The person has previously been denied a registration or has had a registration revoked or suspended in any jurisdiction and the registration has not yet been issued or reinstated;*
  - (b) *Is in the employ of a son, daughter, spouse, parent, or legal guardian; or*
  - (c) *Is participating in a work-study program through an accredited secondary or postsecondary educational institution.*

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

- (1) *Every applicant for registration as a pharmacy technician shall be sixteen (16) years of age and of good mental health and moral character and shall file with the board an application in such form and containing such data as the board may reasonably require.*
- (2) *The application fee shall be twenty-five dollars (\$25).*
- (3) *The board shall issue a certificate of registration and a pocket registration card to an applicant who meets the requirements for registration.*

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *The board may deny an application for registration filed under Section 2 of this Act if the applicant:*
  - (a) *Submits an incomplete application;*
  - (b) *Fails to submit the application fee; or*
  - (c) *Violates or is deemed to be in violation of any of the provisions of Section 8 of this Act.*
- (2) *After denying an application for registration, the board shall set the matter for a hearing in accordance with KRS Chapter 13B, upon the written request of the applicant. The applicant's request shall be submitted to the board no later than thirty (30) days immediately following the date the letter of denial is postmarked.*

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *Every pharmacy technician who wishes to renew his or her registration shall pay to the executive director of the board an annual renewal fee of twenty-five dollars (\$25) and shall file with the board an application in such form and containing such information that the board reasonably determines necessary to renew the registration. Each pharmacy technician's registration shall expire on March 31 of each year. A delinquent renewal penalty fee not to exceed twenty-five dollars (\$25) may be assessed for each renewal period the registrant fails to remove his or her registration after the expiration of the registration.*
- (2) *Every pharmacy technician shall keep his or her current certificate of registration conspicuously displayed in the technician's primary place of employment.*

- (3) *In addition to a current certificate of registration, each pharmacy technician shall be issued, upon renewal, a pocket registration card which shall be in the registrant's possession when the registrant is assisting in the practice of pharmacy. The pocket registration card shall be exhibited upon the request of any member, inspector, or agent of the board.*

➔Section 5. KRS 315.125 is amended to read as follows:

- (1) When the board has probable cause to believe a pharmacist, *pharmacy technician*, certificate holder, or permit holder is suffering from a mental or physical condition that might impede that person's ability to practice competently, the board may order the individual to undergo a mental or physical examination by an appropriately-trained professional designated by the board.
- (2) Failure of a pharmacist, *pharmacy technician*, or permit holder to submit to such an examination when directed, unless the failure was due to circumstances beyond his *or her* control, shall constitute an admission that he *or she* has developed such a mental or physical disability, or other condition, that continued practice is dangerous to patients or to the public. Failure to attend the examination shall constitute a default, and a final order suspending, limiting, restricting, or revoking the license or permit may be entered without the taking of testimony or presentation of evidence.
- (3) A pharmacist, *pharmacy technician*, or permit holder whose license has been suspended, limited, restricted, or revoked pursuant to this section shall at reasonable intervals be afforded an opportunity, pursuant to KRS 315.121(4), to demonstrate that he can resume the competent practice of pharmacy with reasonable skill and safety to patients.

➔Section 6. KRS 315.005 is amended to read as follows:

The purpose of this chapter is to promote, preserve, and protect public health, safety, and welfare by and through effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, control, and regulation of all sites or persons who are required to obtain a license, *certificate*, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth.

➔Section 7. KRS 315.020 is amended to read as follows:

- (1) No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his place of business except in the presence and under the immediate supervision of a pharmacist.
- (2) No manufacturer of pharmaceuticals who is not a pharmacist shall fail to place a pharmacist in charge of his place of business or shall permit any person to compound prescription drugs, medicines, or pharmaceuticals in his place of business, except as provided by the board through the promulgation of administrative regulations pursuant to KRS Chapter 13A.
- (3) Except as provided in subsection (4) of this section, no person shall engage in the practice of pharmacy unless licensed to practice under the provisions of KRS Chapter 315.
- (4) The provisions of subsection (3) of this section shall not apply to:
  - (a) Pharmacist interns performing professional practice activities under the immediate supervision of a licensed pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
  - (b) Pharmacist interns and pharmacy technicians performing specifically identified pharmacy practice activities while under the supervision of a pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
  - (c) Other licensed health care professionals practicing within the statutory scope of their professional practices; or
  - (d) Volunteer health practitioners providing services under KRS 39A.350 to 39A.366.
- (5) *Effective April 1, 2009, an owner of a pharmacy shall not employ a person to assist in the practice of pharmacy unless the person is registered as a pharmacy technician by the board or exempt under Section 1 of this Act.*

➔Section 8. 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, ~~or~~ 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; ~~or~~
  - (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*
  - (l) *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, ~~or~~ 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, ~~or~~ 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) 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.

➔Section 9. KRS 315.030 is amended to read as follows:

- (1) No person shall take, use or exhibit the title of drug, drug store, pharmacy or apothecary, or any combination of such names or titles, or any title, name or description of like import, or any form designed to take the place of such a title, or use any place with respect to which any of those terms are used in any advertisement or telephone directory listing, unless the facility has been issued a permit by the board.
- (2) No person shall call himself or hold himself out as or use the title of "pharmacist," "registered pharmacist," "licensed pharmacist," "druggist," or use the initials "R.Ph." or terms which would imply that he is a pharmacist, unless he is duly licensed under the provisions of KRS Chapter 315.
- (3) ***Effective April 1, 2009, a person shall not call himself or herself or hold himself or herself out as a or use the title of "pharmacy technician" unless the person is duly registered under Section 2 or 4 of this Act.***

➔Section 10. KRS 315.191 is amended to read as follows:

- (1) The board is authorized to:
  - (a) Promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters set forth in this chapter relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers, to the extent that regulation and control of same have not been delegated to some other agency of the Commonwealth, but administrative regulations relating to drugs shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order. However, nothing contained in this chapter shall be construed as authorizing the board to promulgate any administrative regulations relating to prices or fees or to advertising or the promotion of the sales or use of commodities or services;
  - (b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to schedule and conduct hearings on behalf of the board on any matter under the jurisdiction of the board;
  - (c) Prescribe the time, place, method, manner, scope, and subjects of examinations, with at least two (2) examinations to be held annually;
  - (d) Issue and renew all licenses, certificates, and permits for all pharmacists, pharmacist interns, pharmacies, ***pharmacy technicians***, wholesale distributors, and manufacturers engaged in the manufacture, distribution, or dispensation of drugs;
  - (e) Investigate all complaints or violations of the state pharmacy laws and the administrative regulations promulgated by the board, and bring all these cases to the notice of the proper law enforcement authorities;
  - (f) Promulgate administrative regulations, pursuant to KRS Chapter 13A, that are necessary and to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between pharmacists and pharmacies licensed or issued a permit by it;
  - (g) Perform all other functions necessary to carry out the provisions of law and the administrative regulations promulgated by the board relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers;
  - (h) Establish or approve programs for training, qualifications, and registration of pharmacist interns;
  - (i) Assess reasonable fees, in addition to the fees specifically provided for in this chapter and consistent with KRS 61.870 to 61.884, for services rendered to perform its duties and responsibilities, including, but not limited to, the following:
    1. Issuance of duplicate certificates;
    2. Mailing lists or reports of data maintained by the board;
    3. Copies of documents; or
    4. Notices of meetings;

- (j) Seize any drug or device found by the board to constitute an imminent danger to public health and welfare;
  - (k) Establish an advisory council to advise the board on administrative regulations and other matters, within the discretion of the board, pertinent to the regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug distribution, and drug manufacturing. The council shall consist of nine (9) members selected by the board for terms of up to four (4) years. No member shall serve on the council for more than eight (8) years. Membership of the council shall include nine (9) individuals broadly representative of the profession of pharmacy and the general public. Members shall be selected by the board from a list of qualified candidates submitted by the association, society, or other interested parties; and
- (1) Promulgate administrative regulations establishing the qualifications that pharmacy technicians are required to attain prior to engaging in pharmacy practice activities outside the immediate supervision of a pharmacist.
  - (2) The board shall have other authority as may be necessary to enforce pharmacy laws and administrative regulations of the board including, but not limited to:
    - (a) Joining or participating in professional organizations and associations organized exclusively to promote improvement of the standards of practice of pharmacy for the protection of public health and welfare or facilitate the activities of the board; and
    - (b) Receiving and expending funds, in addition to its biennial appropriation, received from parties other than the state, if:
      - 1. The funds are awarded for the pursuit of a specific objective which the board is authorized to enforce through this chapter, or which the board is qualified to pursue by reason of its jurisdiction or professional expertise;
      - 2. The funds are expended for the objective for which they were awarded;
      - 3. The activities connected with or occasioned by the expenditure of the funds do not interfere with the performance of the board's responsibilities and do not conflict with the exercise of its statutory powers;
      - 4. The funds are kept in a separate account and not commingled with funds received from the state; and
      - 5. Periodic accountings of the funds are maintained at the board office for inspection or review.
  - (3) In addition to the sanctions provided in KRS 315.121, the board or its hearing officer may direct any licensee, permit holder, or certificate holder found guilty of a charge involving pharmacy or drug laws, rules, or administrative regulations of the state, any other state, or federal government, to pay to the board a sum not to exceed the reasonable costs of investigation and prosecution of the case, not to exceed twenty-five thousand dollars (\$25,000).
  - (4) In an action for recovery of costs, proof of the board's order shall be conclusive proof of the validity of the order of payment and any terms for payment.

**Signed by Governor April 24, 2008.**