

CHAPTER 73

(HB 282)

AN ACT relating to home medical equipment and services providers and making an appropriation therefor.

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:

Sections 1 to 8 of this Act shall be known and may be cited as the Home Medical Equipment and Services Provider Licensure Act.

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

As used in Sections 1 to 8 of this Act unless the context requires otherwise:

- (1) *"Applicant" means a person who applies for licensure by the board as a home medical equipment and services provider;*
- (2) *"Board" means the Kentucky Board of Pharmacy, established in KRS 315.150;*
- (3) *"Home medical equipment" means durable medical equipment which:*
 - (a) *Withstands repeated use;*
 - (b) *Is primarily and customarily used to serve a medical purpose;*
 - (c) *Is generally not useful to a person in the absence of illness or injury; and*
 - (d) *Is appropriate for use in the home;*
- (4) *"Providing home medical equipment and services" means the sale, lease, rental, delivery, installation, maintenance, replacement, or instruction in the use of home medical equipment, related equipment and supplies, and mobility enhancing equipment used by a sick or disabled person to allow the person to be maintained in his or her residence and which is funded through a third party payor;*
- (5) *"Home medical equipment and services provider" or "provider" means a person engaged in the business of providing home medical equipment and services, either directly or through a contractual arrangement, to an unrelated sick or disabled person in the residence of that person; and*
- (6) *"Person" has the same meaning as in KRS 446.010.*

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

- (1) *No person shall provide home medical equipment and services, or use the title "home medical equipment and services provider" in connection with his or her profession or business, without a license issued by the board.*
- (2) *Unless home medical equipment and services are provided through a separate legal entity, nothing in Sections 1 to 8 of this Act or any administrative regulations promulgated thereunder shall be construed as preventing or restricting the practices, services, or activities of the following:*
 - (a) *A person licensed or registered in this state under any other law who is engaging in the profession or occupation for which he or she is licensed or registered;*
 - (b) *Health care practitioners who lawfully prescribe or order home medical equipment and services, or who use home medical equipment and services to treat their patients;*
 - (c) *Home health agencies that do not engage in the provision of home medical equipment and services;*
 - (d) *Hospitals that provide home medical equipment and services only as an integral part of patient care;*
 - (e) *Manufacturers and wholesale distributors of home medical equipment who do not sell, lease, or rent home medical equipment directly to a patient;*
 - (f) *Pharmacies that are engaged in the sale, lease, or rental of home medical equipment and services;*
 - (g) *An employee of a person licensed under Sections 1 to 8 of this Act;*

- (h) *Hospice programs that do not involve the sale, lease, or rental of home medical equipment and services;*
- (i) *Skilled nursing facilities that do not involve the sale, lease, or rental of home medical equipment and services; and*
- (j) *Government agencies, including fire districts which provide emergency medical services.*

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

A person licensed under Sections 1 to 8 of this Act shall provide home medical equipment and services that carry a legend or require an order from a licensed health care practitioner.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *A home medical equipment and services provider shall be licensed by the board under Sections 1 to 8 of this Act prior to engaging in providing home medical equipment and services in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred dollars (\$200) initially per year or increase more than twenty-five dollars (\$25) per year up to a maximum of four hundred dollars (\$400). Upon receipt of an application for a license to operate as a home medical equipment and services provider, the board shall issue a license if the provider meets the standards and requirements of this chapter and the administrative regulations of the board.*
- (2) *Home medical equipment and services providers shall be required to maintain adequate records of all home medical equipment and services provided as established by administrative regulation by the board. Records shall be made available to agents of the board for inspection at reasonable times. The board may require by administrative regulation that home medical equipment and services providers periodically report to the board all home medical equipment and services provided.*
- (3) *Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of Section 11 of this Act.*
- (4) *The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure.*
- (5) *Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.*

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *The board shall refuse to renew any license to operate unless the home medical equipment and services provider meets the standards and requirements of Sections 1 to 8 of this Act and the administrative regulations of the board. The board shall act upon an application for a license within thirty (30) days after the receipt thereof.*
- (2) *A separate license shall be required for each location of a home medical equipment and services provider.*
- (3) *A home medical equipment and services provider shall display its license at its place of business.*
- (4) *Each license as a home medical equipment and services provider, unless sooner suspended or revoked, shall expire on September 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 dollars (\$200) initially per year nor to increase more than twenty-five dollars (\$25) per year up to a maximum of four hundred dollars (\$400). 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 September 30 of each year.*
- (5) *Licenses to operate shall be issued only for the premises and persons named in the application and shall not be transferable.*

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *The board may permit an out-of-state home medical equipment and services provider to obtain a license on the basis of reciprocity if:*
 - (a) *The out-of-state provider physically located in one (1) of the bordering states possesses a valid license from another jurisdiction that grants the same privileges to persons licensed by the Commonwealth as the Commonwealth grants to persons licensed by the other jurisdiction;*

- (b) *The requirements for licensure in the bordering state are substantially similar to the requirements under Sections 1 to 8 of this Act; and*
 - (c) *The out-of-state provider seeking licensure states that he or she has studied, is familiar with, and shall abide by Sections 1 to 8 of this Act and the administrative regulations promulgated thereunder.*
- (2) *If the requirements for licensure under Sections 1 to 8 of this Act and the administrative regulations promulgated thereunder are more restrictive than the standards of the other jurisdiction, then the out-of-state provider shall comply with the additional requirements of Sections 1 to 8 of this Act to obtain a reciprocal license.*

➔SECTION 8. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *A person who engages in the business of providing home medical equipment and services and who is required to be licensed under Sections 1 to 8 of this Act and who knowingly provides home medical equipment and services without a license issued under this chapter commits a Class A misdemeanor.*
- (2) *Each day a violation of this section continues constitutes a separate offense.*

➔Section 9. KRS 304.17A-005 is amended to read as follows:

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

- (1) "Association" means an entity, other than an employer-organized association, that has been organized and is maintained in good faith for purposes other than that of obtaining insurance for its members and that has a constitution and bylaws;
- (2) "At the time of enrollment" means:
 - (a) At the time of application for an individual, an association that actively markets to individual members, and an employer-organized association that actively markets to individual members; and
 - (b) During the time of open enrollment or during an insured's initial or special enrollment periods for group health insurance;
- (3) "Base premium rate" means, for each class of business as to a rating period, the lowest premium rate charged or that could have been charged under the rating system for that class of business by the insurer to the individual or small group, or employer as defined in KRS 304.17A-0954, with similar case characteristics for health benefit plans with the same or similar coverage;
- (4) "Basic health benefit plan" means any plan offered to an individual, a small group, or employer-organized association that limits coverage to physician, pharmacy, home health, preventive, emergency, and inpatient and outpatient hospital services in accordance with the requirements of this subtitle. If vision or eye services are offered, these services may be provided by an ophthalmologist or optometrist. Chiropractic benefits may be offered by providers licensed pursuant to KRS Chapter 312;
- (5) "Bona fide association" means an entity as defined in 42 U.S.C. sec. 300gg-91(d)(3);
- (6) "Church plan" means a church plan as defined in 29 U.S.C. sec. 1002(33);
- (7) "COBRA" means any of the following:
 - (a) 26 U.S.C. sec. 4980B other than subsection (f)(1) as it relates to pediatric vaccines;
 - (b) The Employee Retirement Income Security Act of 1974 (29 U.S.C. sec. 1161 et seq. other than sec. 1169); or
 - (c) 42 U.S.C. sec. 300bb;
- (8) (a) "Creditable coverage" means, with respect to an individual, coverage of the individual under any of the following:
 - 1. A group health plan;
 - 2. Health insurance coverage;
 - 3. Part A or Part B of Title XVIII of the Social Security Act;
 - 4. Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928;

5. Chapter 55 of Title 10, United States Code, including medical and dental care for members and certain former members of the uniformed services, and for their dependents; for purposes of Chapter 55 of Title 10, United States Code, "uniformed services" means the Armed Forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service;
 6. A medical care program of the Indian Health Service or of a tribal organization;
 7. A state health benefits risk pool;
 8. A health plan offered under Chapter 89 of Title 5, United States Code, such as the Federal Employees Health Benefit Program;
 9. A public health plan as established or maintained by a state, the United States government, a foreign country, or any political subdivision of a state, the United States government, or a foreign country that provides health coverage to individuals who are enrolled in the plan;
 10. A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. sec. 2504(e)); or
 11. Title XXI of the Social Security Act, such as the State Children's Health Insurance Program.
- (b) This term does not include coverage consisting solely of coverage of excepted benefits as defined in subsection (14) of this section;
- (9) "Dependent" means any individual who is or may become eligible for coverage under the terms of an individual or group health benefit plan because of a relationship to a participant;
- (10) "Employee benefit plan" means an employee welfare benefit plan or an employee pension benefit plan or a plan which is both an employee welfare benefit plan and an employee pension benefit plan as defined by ERISA;
- (11) "Eligible individual" means an individual:
- (a) For whom, as of the date on which the individual seeks coverage, the aggregate of the periods of creditable coverage is eighteen (18) or more months and whose most recent prior creditable coverage was under a group health plan, governmental plan, or church plan. A period of creditable coverage under this paragraph shall not be counted if, after that period, there was a sixty-three (63) day period of time, excluding any waiting or affiliation period, during all of which the individual was not covered under any creditable coverage;
 - (b) Who is not eligible for coverage under a group health plan, Part A or Part B of Title XVIII of the Social Security Act (42 U.S.C. secs. 1395j et seq.), or a state plan under Title XIX of the Social Security Act (42 U.S.C. secs. 1396 et seq.) and does not have other health insurance coverage;
 - (c) With respect to whom the most recent coverage within the coverage period described in paragraph (a) of this subsection was not terminated based on a factor described in KRS 304.17A-240(2)(a), (b), and (c);
 - (d) If the individual had been offered the option of continuation coverage under a COBRA continuation provision or under KRS 304.18-110, who elected the coverage; and
 - (e) Who, if the individual elected the continuation coverage, has exhausted the continuation coverage under the provision or program;
- (12) "Employer-organized association" means any of the following:
- (a) Any entity that was qualified by the commissioner as an eligible association prior to April 10, 1998, and that has actively marketed a health insurance program to its members since September 8, 1996, and which is not insurer-controlled;
 - (b) Any entity organized under KRS 247.240 to 247.370 that has actively marketed health insurance to its members and that is not insurer-controlled;
 - (c) Any entity that is a bona fide association as defined in 42 U.S.C. sec. 300gg-91(d)(3), whose members consist principally of employers, and for which the entity's health insurance decisions are made by a board or committee, the majority of which are representatives of employer members of the entity who obtain group health insurance coverage through the entity or through a trust or other mechanism

established by the entity, and whose health insurance decisions are reflected in written minutes or other written documentation.

Except as provided in KRS 304.17A-200, 304.17A.210, and 304.17A-220, no employer-organized association shall be treated as an association, small group, or large group under this subtitle;

- (13) "Employer-organized association health insurance plan" means any health insurance plan, policy, or contract issued to an employer-organized association, or to a trust established by one (1) or more employer-organized associations, or providing coverage solely for the employees, retired employees, directors and their spouses and dependents of the members of one (1) or more employer-organized associations;
- (14) "Excepted benefits" means benefits under one (1) or more, or any combination thereof, of the following:
 - (a) Coverage only for accident, including accidental death and dismemberment, or disability income insurance, or any combination thereof;
 - (b) Coverage issued as a supplement to liability insurance;
 - (c) Liability insurance, including general liability insurance and automobile liability insurance;
 - (d) Workers' compensation or similar insurance;
 - (e) Automobile medical payment insurance;
 - (f) Credit-only insurance;
 - (g) Coverage for on-site medical clinics;
 - (h) Other similar insurance coverage, specified in administrative regulations, under which benefits for medical care are secondary or incidental to other insurance benefits;
 - (i) Limited scope dental or vision benefits;
 - (j) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof;
 - (k) Such other similar, limited benefits as are specified in administrative regulations;
 - (l) Coverage only for a specified disease or illness;
 - (m) Hospital indemnity or other fixed indemnity insurance;
 - (n) Benefits offered as Medicare supplemental health insurance, as defined under section 1882(g)(1) of the Social Security Act;
 - (o) Coverage supplemental to the coverage provided under Chapter 55 of Title 10, United States Code;
 - (p) Coverage similar to that in paragraphs (n) and (o) of this subsection that is supplemental to coverage under a group health plan; and
 - (q) Health flexible spending arrangements;
- (15) "Governmental plan" means a governmental plan as defined in 29 U.S.C. sec. 1002(32);
- (16) "Group health plan" means a plan, including a self-insured plan, of or contributed to by an employer, including a self-employed person, or employee organization, to provide health care directly or otherwise to the employees, former employees, the employer, or others associated or formerly associated with the employer in a business relationship, or their families;
- (17) "Guaranteed acceptance program participating insurer" means an insurer that is required to or has agreed to offer health benefit plans in the individual market to guaranteed acceptance program qualified individuals under KRS 304.17A-400 to 304.17A-480;
- (18) "Guaranteed acceptance program plan" means a health benefit plan in the individual market issued by an insurer that provides health benefits to a guaranteed acceptance program qualified individual and is eligible for assessment and refunds under the guaranteed acceptance program under KRS 304.17A-400 to 304.17A-480;
- (19) "Guaranteed acceptance program" means the Kentucky Guaranteed Acceptance Program established and operated under KRS 304.17A-400 to 304.17A-480;
- (20) "Guaranteed acceptance program qualified individual" means an individual who, on or before December 31, 2000:

- (a) Is not an eligible individual;
 - (b) Is not eligible for or covered by other health benefit plan coverage or who is a spouse or a dependent of an individual who:
 - 1. Waived coverage under KRS 304.17A-210(2); or
 - 2. Did not elect family coverage that was available through the association or group market;
 - (c) Within the previous three (3) years has been diagnosed with or treated for a high-cost condition or has had benefits paid under a health benefit plan for a high-cost condition, or is a high risk individual as defined by the underwriting criteria applied by an insurer under the alternative underwriting mechanism established in KRS 304.17A-430(3);
 - (d) Has been a resident of Kentucky for at least twelve (12) months immediately preceding the effective date of the policy; and
 - (e) Has not had his or her most recent coverage under any health benefit plan terminated or nonrenewed because of any of the following:
 - 1. The individual failed to pay premiums or contributions in accordance with the terms of the plan or the insurer had not received timely premium payments;
 - 2. The individual performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage; or
 - 3. The individual engaged in intentional and abusive noncompliance with health benefit plan provisions;
- (21) "Guaranteed acceptance plan supporting insurer" means either an insurer, on or before December 31, 2000, that is not a guaranteed acceptance plan participating insurer or is a stop loss carrier, on or before December 31, 2000, provided that a guaranteed acceptance plan supporting insurer shall not include an employer-sponsored self-insured health benefit plan exempted by ERISA;
- (22) "Health benefit plan" means any hospital or medical expense policy or certificate; nonprofit hospital, medical-surgical, and health service corporation contract or certificate; provider sponsored integrated health delivery network; a self-insured plan or a plan provided by a multiple employer welfare arrangement, to the extent permitted by ERISA; health maintenance organization contract; or any health benefit plan that affects the rights of a Kentucky insured and bears a reasonable relation to Kentucky, whether delivered or issued for delivery in Kentucky, and does not include policies covering only accident, credit, dental, disability income, fixed indemnity medical expense reimbursement policy, long-term care, Medicare supplement, specified disease, vision care, coverage issued as a supplement to liability insurance, insurance arising out of a workers' compensation or similar law, automobile medical-payment insurance, insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance, short-term coverage, student health insurance offered by a Kentucky-licensed insurer under written contract with a university or college whose students it proposes to insure, medical expense reimbursement policies specifically designed to fill gaps in primary coverage, coinsurance, or deductibles and provided under a separate policy, certificate, or contract, or coverage supplemental to the coverage provided under Chapter 55 of Title 10, United States Code, or limited health service benefit plans;
- (23) "Health care provider" or "provider" means any facility or service required to be licensed pursuant to KRS Chapter 216B, pharmacist, *or home medical equipment and services provider* as defined pursuant to KRS Chapter 315, and any of the following independent practicing practitioners:
- (a) Physicians, osteopaths, and podiatrists licensed under KRS Chapter 311;
 - (b) Chiropractors licensed under KRS Chapter 312;
 - (c) Dentists licensed under KRS Chapter 313;
 - (d) Optometrists licensed under KRS Chapter 320;
 - (e) Physician assistants regulated under KRS Chapter 311;
 - (f) Advanced practice registered nurses licensed under KRS Chapter 314; and
 - (g) Other health care practitioners as determined by the department by administrative regulations promulgated under KRS Chapter 13A;

- (24) (a) "High-cost condition," pursuant to the Kentucky Guaranteed Acceptance Program, means a covered condition in an individual policy as listed in paragraph (c) of this subsection or as added by the commissioner in accordance with KRS 304.17A-280, but only to the extent that the condition exceeds the numerical score or rating established pursuant to uniform underwriting standards prescribed by the commissioner under paragraph (b) of this subsection that account for the severity of the condition and the cost associated with treating that condition.
- (b) The commissioner by administrative regulation shall establish uniform underwriting standards and a score or rating above which a condition is considered to be high-cost by using:
1. Codes in the most recent version of the "International Classification of Diseases" that correspond to the medical conditions in paragraph (c) of this subsection and the costs for administering treatment for the conditions represented by those codes; and
 2. The most recent version of the questionnaire incorporated in a national underwriting guide generally accepted in the insurance industry as designated by the commissioner, the scoring scale for which shall be established by the commissioner.
- (c) The diagnosed medical conditions are: acquired immune deficiency syndrome (AIDS), angina pectoris, ascites, chemical dependency cirrhosis of the liver, coronary insufficiency, coronary occlusion, cystic fibrosis, Friedreich's ataxia, hemophilia, Hodgkin's disease, Huntington chorea, juvenile diabetes, leukemia, metastatic cancer, motor or sensory aphasia, multiple sclerosis, muscular dystrophy, myasthenia gravis, myotonia, open heart surgery, Parkinson's disease, polycystic kidney, psychotic disorders, quadriplegia, stroke, syringomyelia, and Wilson's disease;
- (25) "Index rate" means, for each class of business as to a rating period, the arithmetic average of the applicable base premium rate and the corresponding highest premium rate;
- (26) "Individual market" means the market for the health insurance coverage offered to individuals other than in connection with a group health plan. The individual market includes an association plan that is not employer related, issued to individuals on an individually underwritten basis, other than an employer-organized association or a bona fide association, that has been organized and is maintained in good faith for purposes other than obtaining insurance for its members and that has a constitution and bylaws;
- (27) "Insurer" means any insurance company; health maintenance organization; self-insurer or multiple employer welfare arrangement not exempt from state regulation by ERISA; provider-sponsored integrated health delivery network; self-insured employer-organized association, or nonprofit hospital, medical-surgical, dental, or health service corporation authorized to transact health insurance business in Kentucky;
- (28) "Insurer-controlled" means that the commissioner has found, in an administrative hearing called specifically for that purpose, that an insurer has or had a substantial involvement in the organization or day-to-day operation of the entity for the principal purpose of creating a device, arrangement, or scheme by which the insurer segments employer groups according to their actual or anticipated health status or actual or projected health insurance premiums;
- (29) "Kentucky Access" has the meaning provided in KRS 304.17B-001(17);
- (30) "Large group" means:
- (a) An employer with fifty-one (51) or more employees; or
 - (b) An affiliated group with fifty-one (51) or more eligible members;
- (31) "Managed care" means systems or techniques generally used by third-party payors or their agents to affect access to and control payment for health care services and that integrate the financing and delivery of appropriate health care services to covered persons by arrangements with participating providers who are selected to participate on the basis of explicit standards for furnishing a comprehensive set of health care services and financial incentives for covered persons using the participating providers and procedures provided for in the plan;
- (32) "Market segment" means the portion of the market covering one (1) of the following:
- (a) Individual;
 - (b) Small group;
 - (c) Large group; or

- (d) Association;
- (33) "Participant" means any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of the employer or members of the organization, or whose beneficiaries may be eligible to receive any benefit as established in Section 3(7) of ERISA;
- (34) "Preventive services" means medical services for the early detection of disease that are associated with substantial reduction in morbidity and mortality;
- (35) "Provider network" means an affiliated group of varied health care providers that is established to provide a continuum of health care services to individuals;
- (36) "Provider-sponsored integrated health delivery network" means any provider-sponsored integrated health delivery network created and qualified under KRS 304.17A-300 and KRS 304.17A-310;
- (37) "Purchaser" means an individual, organization, employer, association, or the Commonwealth that makes health benefit purchasing decisions on behalf of a group of individuals;
- (38) "Rating period" means the calendar period for which premium rates are in effect. A rating period shall not be required to be a calendar year;
- (39) "Restricted provider network" means a health benefit plan that conditions the payment of benefits, in whole or in part, on the use of the providers that have entered into a contractual arrangement with the insurer to provide health care services to covered individuals;
- (40) "Self-insured plan" means a group health insurance plan in which the sponsoring organization assumes the financial risk of paying for covered services provided to its enrollees;
- (41) "Small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two (2) but not more than fifty (50) employees on business days during the preceding calendar year and who employs at least two (2) employees on the first day of the plan year;
- (42) "Small group" means:
- (a) A small employer with two (2) to fifty (50) employees; or
 - (b) An affiliated group or association with two (2) to fifty (50) eligible members;
- (43) "Standard benefit plan" means the plan identified in KRS 304.17A-250; and
- (44) "Telehealth" has the meaning provided in KRS 311.550.

➔Section 10. 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, **or provide home medical equipment and services** within the Commonwealth.

➔Section 11. 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, **or of providing home medical equipment and services** 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, **or home medical equipment** 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, **or home medical equipment and services provider** is incapable of engaging or assisting in the practice of pharmacy **or of providing home medical equipment and services** 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, **or of providing home medical equipment and services**;
 - (g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy **or of providing home medical equipment and services** without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," **"home medical equipment and services provider," "provider,"** or other term which might imply that the individual is a pharmacist, pharmacist intern, **pharmacy technician, or home medical equipment and services provider**~~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 KRS 315.500, 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) ***Unprofessional or unethical conduct includes but is not limited to the following acts of a home medical equipment and services provider:***
- (a) ***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 sick or disabled person, or engaging in conduct which substantially departs from accepted standards of providing home medical equipment and services ordinarily exercised by a home medical equipment and services provider, with or without established proof of actual injury;***
 - (b) ***Engaging in grossly negligent professional conduct, with or without established proof of actual injury;***
 - (c) ***Obtaining any remuneration by fraud, misrepresentation, or deception;***
 - (d) ***Providing home medical equipment and services that carry a legend or require a prescription without a medical order from a licensed health care practitioner; or***
 - (e) ***Willfully or knowingly failing to maintain complete and accurate records of home medical equipment and services provided in compliance with federal and state laws, rules, or administrative regulations.***
- (4) 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.
- ~~(5)~~(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 ***or providing home medical equipment and services*** 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.
- ~~(6)~~(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.
- ~~(7)~~(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 *or of providing home medical equipment and services*; 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 12. KRS 315.125 is amended to read as follows:

- (1) When the board has probable cause to believe a pharmacist, pharmacy technician, *licensee*, 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, *licensee*, 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, *licensee*, 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(5)~~(4)~~, to demonstrate that he can resume the competent practice of pharmacy *or of providing home medical equipment or services* with reasonable skill and safety to patients.

➔Section 13. 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, *and home medical equipment and services providers* 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 *and home medical equipment and services* shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order *or home medical equipment sold pursuant to a medical 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 *for*:
 1. *Home medical equipment and services providers engaged in providing home medical equipment and services; and*
 2. *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 *and home medical equipment* 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, **manufacturers, and home medical equipment and services providers**~~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, **drug manufacturing, and home medical equipment and services**~~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, **the profession of providing home medical equipment and services**, 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~~
 - (l) 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; **and**
 - (m) **Oversee and administer the licensure of home medical equipment and services providers pursuant to Sections 1 to 8 of this Act.**
- (2) The board shall have other authority as may be necessary to enforce pharmacy **and home medical equipment** 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 **and of providing home medical equipment and services** 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 **home medical equipment**, 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.

➔Section 14. KRS 315.195 is amended to read as follows:

- (1) All license, permit, and certificate fees, ~~and~~ charges, **and fines**, and other moneys collected by the board under the provisions of this chapter, and the administrative regulations of the board ~~[adopted hereunder]~~, shall be **deposited** ~~paid~~ into the State Treasury and credited to a trust and agency fund to be used by the board in carrying out the provisions of this chapter, **and are hereby appropriated for those purposes**.
- (2) **Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the fiscal year shall not lapse but shall be carried forward into the succeeding fiscal year** ~~[No part of this fund shall revert to the general fund of the Commonwealth. All fines shall be deposited to the credit of the board to be used by the board in carrying out the provisions of this chapter].~~

➔Section 15. KRS 315.220 is amended to read as follows:

- (1) For the purpose of enforcing the provisions of this chapter, officers, agents, and inspectors of the board shall have the power and authority to:
- (a) Administer oaths;
 - (b) Enter upon premises of all facilities issued a permit **or license** by the board, at all reasonable times for the purpose of:
 1. Making inspections and carrying out the provisions of this chapter;
 2. Conducting investigations;
 3. Requiring production of books, papers, documents, records, or other evidence for inspection or copying;
 4. Seizing evidence; or
 5. Securing oral or written statements;
 - (c) Employ special investigators;
 - (d) Expend funds for the purpose of obtaining evidence; and
 - (e) Issue subpoenas.
- (2) As used in subsection (1) of this section, "records" includes, but is not limited to, patient records.
- (3) Any decision to inspect, copy, or seize books, papers, documents, records, or other evidence shall be at the discretion of the officer, agent, or inspector of the board.
- (4) Inspection, copying, or seizure of books, papers, documents, records, or other evidence does not affect the confidential nature of those records, and the board shall maintain the records so as to protect the confidentiality of the records.

➔Section 16. The General Assembly finds and declares that home medical equipment and services providers in the Commonwealth affect the public health, welfare, and safety and, therefore, finds regulation and control of providers by a board to be in the public interest. As a matter of public policy, providers shall merit the confidence of the public, and only qualified persons shall be permitted to hold themselves out to the public as licensed home medical equipment and services providers.

Signed by Governor April 11, 2012.