AN ACT relating to medical service providers.

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

➔Section 1. 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 pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:***

(a) Patients' drug-related health care needs fall within the practitioner's or practitioners' statutory scope of practice;

(b) Patients are referred by the practitioner or practitioners to the pharmacist or pharmacists; and

(c) The agreement:

1. Identifies the practitioner or practitioners and the pharmacist or pharmacists who are parties to the agreement;

2. Specifies the drug-related regimen to be provided, and how drug therapy is to be monitored; and

3. Stipulates the conditions for initiating, continuing, or discontinuing drug therapy and conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration~~[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 influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to individuals fourteen (14) to seventeen (17) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by KRS 315.500; 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.