

1 AN ACT relating to pharmacy.

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

3 ➔Section 1. KRS 315.010 is amended to read as follows:

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

- 5 (1) "Administer" means the direct application of a drug to a patient or research subject  
6 by injection, inhalation, or ingestion, whether topically or by any other means;
- 7 (2) "Administrative activities of a pharmacy" means the following functions performed  
8 by a pharmacy adhering to all local, state, and federal patient privacy laws:
- 9 (a) Investigating and researching a patient's insurance benefits and updating the  
10 patient profile regarding insurance coverage;
- 11 (b) Billing and collections activities, including:
- 12 1. Contacting patients for copayments and coinsurance payments; and  
13 2. Communicating with insurance companies;
- 14 (c) Performing patient financial assistance activities and updating patient records  
15 accordingly;
- 16 (d) Opening faxes and accessing electronic prescriptions for the purposes of  
17 setting up patient demographic and insurance profiles, excluding height,  
18 weight, and allergy information, so long as the activity does not involve the  
19 entering of a prescription order into the dispensing or medication management  
20 system;
- 21 (e) Initiating insurance prior authorizations for submission to the licensed  
22 pharmacy, including communications with the prescribing physician to  
23 collect, record, and transmit information to insurance companies, so long as  
24 the activity does not include the authorization or receipt of new or refill  
25 prescription orders;
- 26 (f) Answering and transferring telephone calls, whether or not such calls require  
27 accessing a patient record, so long as the call does not involve the

- 1 interpretation, evaluation, or implementation of a drug order; and
- 2 (g) Communicating with patients via telephone or electronically regarding refill  
3 reminders, so long as the communication does not involve the interpretation,  
4 evaluation, or implementation of a drug order and a pharmacist is readily  
5 available for patient consultation;
- 6 (3) "Association" means the Kentucky Pharmacists Association;
- 7 (4) "Board" means the Kentucky Board of Pharmacy;
- 8 (5) "Collaborative care agreement" means a written agreement between a pharmacist or  
9 pharmacists and a practitioner or practitioners that outlines a plan of cooperative  
10 management of patients' drug-related health care needs where:
- 11 (a) Patients' drug-related health care needs fall within the practitioner's or  
12 practitioners' statutory scope of practice;
- 13 (b) Patients are referred by the practitioner or practitioners to the pharmacist or  
14 pharmacists; and
- 15 (c) The agreement:
- 16 1. Identifies the practitioner or practitioners and the pharmacist or  
17 pharmacists who are parties to the agreement;
- 18 2. Specifies the drug-related regimen to be provided, and how drug therapy  
19 is to be monitored; and
- 20 3. Stipulates the conditions for initiating, continuing, or discontinuing drug  
21 therapy and conditions which warrant modifications to dose, dosage  
22 regimen, dosage form, or route of administration;
- 23 (6) "Compound" or "compounding" means the preparation or labeling of a drug  
24 pursuant to or in anticipation of a valid prescription drug order, including but not  
25 limited to packaging, intravenous admixture or manual combination of drug  
26 ingredients. "Compounding," as used in this chapter, shall not preclude simple  
27 reconstitution, mixing, or modification of drug products prior to administration by

- 1 nonpharmacists;
- 2 (7) "Confidential information" means information which is accessed or maintained by a  
3 pharmacist in a patient's record, or communicated to a patient as part of patient  
4 counseling, whether it is preserved on paper, microfilm, magnetic media, electronic  
5 media, or any other form;
- 6 (8) "Continuing education unit" means ten (10) contact hours of board approved  
7 continuing pharmacy education. A "contact hour" means fifty (50) continuous  
8 minutes without a break period;
- 9 (9) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription  
10 drug in a suitable container, appropriately labeled for subsequent administration to  
11 or use by a patient or other individual entitled to receive the prescription drug;
- 12 (10) "Drug" means any of the following:
- 13 (a) Articles recognized as drugs or drug products in any official compendium or  
14 supplement thereto;
- 15 (b) Articles, other than food, intended to affect the structure or function of the  
16 body of man or other animals;
- 17 (c) Articles, including radioactive substances, intended for use in the diagnosis,  
18 cure, mitigation, treatment or prevention of disease in man or other animals;  
19 or
- 20 (d) Articles intended for use as a component of any articles specified in  
21 paragraphs (a) to (c) of this subsection;
- 22 (11) "Drug regimen review" means retrospective, concurrent, and prospective review by  
23 a pharmacist of a patient's drug-related history, including but not limited to the  
24 following areas:
- 25 (a) Evaluation of prescription drug orders and patient records for:
- 26 1. Known allergies;
- 27 2. Rational therapy contraindications;

- 1           3.   Appropriate dose and route of administration;
- 2           4.   Appropriate directions for use; or
- 3           5.   Duplicative therapies;
- 4       (b) Evaluation of prescription drug orders and patient records for drug-drug,
- 5           drug-food, drug-disease, and drug-clinical laboratory interactions;
- 6       (c) Evaluation of prescription drug orders and patient records for adverse drug
- 7           reactions; or
- 8       (d) Evaluation of prescription drug orders and patient records for proper
- 9           utilization and optimal therapeutic outcomes;
- 10   (12) "Immediate supervision" means under the physical and visual supervision of a
- 11       pharmacist;
- 12   (13) "Manufacturer" or "virtual manufacturer" of a product means:
- 13       (a) A person that holds an application approved under 21 U.S.C. sec. 355 or a
- 14           license issued under 42 U.S.C. sec. 262 for such product, or if such product is
- 15           not the subject of an approved application or license, the person who
- 16           manufactured the product;
- 17       (b) A co-licensed partner of the person described in paragraph (a) of this
- 18           subsection that obtains the product directly from a person described in this
- 19           paragraph or paragraph (a) of this subsection;
- 20       (c) An affiliate of a person described in paragraph (a) or (b) of this subsection
- 21           who receives the product directly from a person described in this paragraph or
- 22           in paragraph (a) or (b) of this subsection; or
- 23       (d) Any person, except a pharmacist compounding in the normal course of
- 24           professional practice;
- 25   (14) "Medical order" means a lawful order of a specifically identified practitioner for a
- 26       specifically identified patient for the patient's health care needs. "Medical order"
- 27       may or may not include a prescription drug order;

- 1 (15) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold  
2 without a prescription and are prepackaged and labeled for use by the consumer in  
3 accordance with the requirements of the statutes and regulations of this state and the  
4 federal government;
- 5 (16) "Outsourcing facility" means a facility at one (1) geographic location or address  
6 that:
- 7 (a) Is engaged in the compounding of human sterile drugs without a patient-  
8 specific prescription;
  - 9 (b) Has registered as an outsourcing facility with the secretary of the United  
10 States Department of Health and Human Services, Food and Drug  
11 Administration; and
  - 12 (c) Complies with all applicable state and federal requirements;
- 13 (17) "Pharmacist" means a natural person licensed by this state to engage in the practice  
14 of the profession of pharmacy;
- 15 (18) "Pharmacist intern" means a natural person who is:
- 16 (a) Currently certified by the board to engage in the practice of pharmacy under  
17 the direction of a licensed pharmacist and who satisfactorily progresses  
18 toward meeting the requirements for licensure as a pharmacist;
  - 19 (b) A graduate of an approved college or school of pharmacy or a graduate who  
20 has established educational equivalency by obtaining a Foreign Pharmacy  
21 Graduate Examination Committee (FPGEC) certificate, who is currently  
22 licensed by the board for the purpose of obtaining practical experience as a  
23 requirement for licensure as a pharmacist;
  - 24 (c) A qualified applicant awaiting examination for licensure as a pharmacist or  
25 the results of an examination for licensure as a pharmacist; or
  - 26 (d) An individual participating in a residency or fellowship program approved by  
27 the board for internship credit;

- 1 (19) "Pharmacy" means every place where:
- 2 (a) Drugs are dispensed under the direction of a pharmacist;
- 3 (b) Prescription drug orders are compounded under the direction of a pharmacist;
- 4 or
- 5 (c) A registered pharmacist maintains patient records and other information for
- 6 the purpose of engaging in the practice of pharmacy, whether or not
- 7 prescription drug orders are being dispensed;
- 8 (20) "Pharmacy-related primary care" means the pharmacists' activities in patient
- 9 education, health promotion, and assistance in the selection and use of over-the-
- 10 counter drugs and appliances for the treatment of common diseases and injuries, as
- 11 well as those other activities falling within their statutory scope of practice;
- 12 (21) "Pharmacy technician" means a natural person who works under the immediate
- 13 supervision, or general supervision if otherwise provided for by statute or
- 14 administrative regulation, of a pharmacist for the purpose of assisting a pharmacist
- 15 with the practice of pharmacy;
- 16 (22) "Practice of pharmacy" means interpretation, evaluation, and implementation of
- 17 medical orders and prescription drug orders; responsibility for dispensing
- 18 prescription drug orders, including radioactive substances; participation in drug and
- 19 drug-related device selection; administration of medications or biologics in the
- 20 course of dispensing or maintaining a prescription drug order; the administration of
- 21 adult immunizations pursuant to prescriber-approved protocols; the administration
- 22 of immunizations to individuals nine (9) to seventeen (17) years of age pursuant to
- 23 prescriber-approved protocols with the consent of a parent or guardian; the
- 24 administration of immunizations to a child as defined in KRS 214.032, pursuant to
- 25 protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen
- 26 review; maintenance of patient pharmacy records; and provision of patient
- 27 counseling and those professional acts, professional decisions, or professional

- 1 services necessary to maintain and manage all areas of a patient's pharmacy-related  
2 care, including pharmacy-related primary care as defined in this section;
- 3 (23) "Practitioner" has the same meaning given in KRS 217.015(35);
- 4 (24) "Prescription drug" means a drug which:
- 5 (a) Under federal law is required to be labeled with either of the following  
6 statements:
- 7 1. "Caution: Federal law prohibits dispensing without prescription";  
8 2. "Caution: Federal law restricts this drug to use by, or on the order of, a  
9 licensed veterinarian";
- 10 3. "Rx Only"; or  
11 4. "Rx"; or
- 12 (b) Is required by any applicable federal or state law or administrative regulation  
13 to be dispensed only pursuant to a prescription drug order or is restricted to  
14 use by practitioners;
- 15 (25) "Prescription drug order" means an original or new order from a practitioner for  
16 drugs, drug-related devices or treatment for a human or animal, including orders  
17 issued through collaborative care agreements~~[or protocols authorized by the~~  
18 ~~board]~~. Lawful prescriptions result from a valid practitioner-patient relationship, are  
19 intended to address a legitimate medical need, and fall within the prescribing  
20 practitioner's scope of professional practice;
- 21 (26) "Society" means the Kentucky Society of Health-Systems Pharmacists;
- 22 (27) "Supervision" means the presence of a pharmacist on the premises to which a  
23 pharmacy permit is issued, who is responsible, in whole or in part, for the  
24 professional activities occurring in the pharmacy; and
- 25 (28) "Wholesaler" means any person who legally buys drugs for resale or distribution to  
26 persons other than patients or consumers.