GENERAL ASSEMBLY
COMMONWEALTH OF KENTUCKY

2016 REGULAR SESSION

HOUSE BILL NO. 527

AS ENACTED

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ALISON LUNDERGAN GRIMES
SECRETARY OF STATE
COMMONWEALTH OF KENTUCKY
BY K. Adler

1 AN ACT relating to administrative duties in pharmacies.

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***

8 ***performed by a pharmacy adhering to all local, state, and federal patient privacy***

9 ***laws:***

10 ***(a) Investigating and researching a patient's insurance benefits and updating***

11 ***the patient profile regarding insurance coverage;***

12 ***(b) Billing and collections activities, including:***

13 ***1. Contacting patients for copayments and coinsurance payments; and***

14 ***2. Communicating with insurance companies;***

15 ***(c) Performing patient financial assistance activities and updating patient***

16 ***records accordingly;***

17 ***(d) Opening faxes and accessing electronic prescriptions for the purposes of***

18 ***setting up patient demographic and insurance profiles, excluding height,***

19 ***weight, and allergy information, so long as the activity does not involve the***

20 ***entering of a prescription order into the dispensing or medication***

21 ***management system;***

22 ***(e) Initiating insurance prior authorizations for submission to the licensed***

23 ***pharmacy, including communications with the prescribing physician to***

24 ***collect, record, and transmit information to insurance companies, so long***

25 ***as the activity does not include the authorization or receipt of new or refill***

26 ***prescription orders;***

27 ***(f) Answering and transferring telephone calls, whether or not such calls***

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

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

(12)[~~(11)~~] "Immediate supervision" means under the physical and visual supervision of a pharmacist;

(13)[~~(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;

(14)[~~(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;

(15)[~~(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;

1 *(16)*[~~(15)~~] "Pharmacist" means a natural person licensed by this state to engage in the
2 practice of the profession of pharmacy;
3 *(17)*[~~(16)~~] "Pharmacist intern" means a natural person who is:
4 (a) Currently certified by the board to engage in the practice of pharmacy under
5 the direction of a licensed pharmacist and who satisfactorily progresses
6 toward meeting the requirements for licensure as a pharmacist;
7 (b) A graduate of an approved college or school of pharmacy or a graduate who
8 has established educational equivalency by obtaining a Foreign Pharmacy
9 Graduate Examination Committee (FPGEC) certificate, who is currently
10 licensed by the board for the purpose of obtaining practical experience as a
11 requirement for licensure as a pharmacist;
12 (c) A qualified applicant awaiting examination for licensure as a pharmacist or
13 the results of an examination for licensure as a pharmacist; or
14 (d) An individual participating in a residency or fellowship program approved by
15 the board for internship credit;
16 *(18)*[~~(17)~~] "Pharmacy" means every place where:
17 (a) Drugs are dispensed under the direction of a pharmacist;
18 (b) Prescription drug orders are compounded under the direction of a pharmacist;
19 or
20 (c) A registered pharmacist maintains patient records and other information for
21 the purpose of engaging in the practice of pharmacy, whether or not
22 prescription drug orders are being dispensed;
23 ***(19) "Pharmacy-related primary care" means the pharmacists' activities in patient***
24 ***education, health promotion, and assistance in the selection and use of over-the-***
25 ***counter drugs and appliances for the treatment of common diseases and injuries,***
26 ***as well as those other activities falling within their statutory scope of practice;***
27 *(20)*[~~(18)~~] "Pharmacy technician" means a natural person who works under the

1 immediate supervision, or general supervision if otherwise provided for by statute
2 or administrative regulation, of a pharmacist for the purpose of assisting a
3 pharmacist with the practice of pharmacy;
4 *(21)*[~~(19)~~] "Practice of pharmacy" means interpretation, evaluation, and implementation
5 of medical orders and prescription drug orders; responsibility for dispensing
6 prescription drug orders, including radioactive substances; participation in drug and
7 drug-related device selection; administration of medications or biologics in the
8 course of dispensing or maintaining a prescription drug order; the administration of
9 adult immunizations pursuant to prescriber-approved protocols; the administration
10 of influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to
11 prescriber-approved protocols with the consent of a parent or guardian; the
12 administration of immunizations to individuals fourteen (14) to seventeen (17) years
13 of age pursuant to prescriber-approved protocols with the consent of a parent or
14 guardian; the administration of immunizations to a child as defined in KRS
15 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation,
16 utilization, or regimen review; maintenance of patient pharmacy records; and
17 provision of patient counseling and those professional acts, professional decisions,
18 or professional services necessary to maintain and manage all areas of a patient's
19 pharmacy-related care, including pharmacy-related primary care as defined in this
20 section;
21 *(22)*[~~(20)~~] "Practitioner" has the same meaning given in KRS 217.015(35);
22 *(23)*[~~(21)~~] "Prescription drug" means a drug which:
23 (a) Under federal law is required to be labeled with either of the following
24 statements:
25 1. "Caution: Federal law prohibits dispensing without prescription";
26 2. "Caution: Federal law restricts this drug to use by, or on the order of, a
27 licensed veterinarian";

1 3. "Rx Only"; or
2 4. "Rx"; or
3 (b) Is required by any applicable federal or state law or administrative regulation
4 to be dispensed only pursuant to a prescription drug order or is restricted to
5 use by practitioners;
6 ***(24)***[~~(22)~~] "Prescription drug order" means an original or new order from a practitioner
7 for drugs, drug-related devices or treatment for a human or animal, including orders
8 issued through collaborative care agreements ***or protocols authorized by the board***.
9 Lawful prescriptions result from a valid practitioner-patient relationship, are
10 intended to address a legitimate medical need, and fall within the prescribing
11 practitioner's scope of professional practice;
12 ~~[(23) "Pharmacy-related primary care" means the pharmacists' activities in patient~~
13 ~~education, health promotion, assistance in the selection and use of over-the-counter~~
14 ~~drugs and appliances for the treatment of common diseases and injuries as well as~~
15 ~~those other activities falling within their statutory scope of practice;]~~
16 ***(25)***[~~(24)~~] "Society" means the Kentucky Society of Health-Systems Pharmacists;
17 ***(26)***[~~(25)~~] "Supervision" means the presence of a pharmacist on the premises to which a
18 pharmacy permit is issued, who is responsible, in whole or in part, for the
19 professional activities occurring in the pharmacy; and
20 ***(27)***[~~(26)~~] "Wholesaler" means any person who legally buys drugs for resale or
21 distribution to persons other than patients or consumers.
22 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
23 READ AS FOLLOWS:
24 ***Administrative activities of a pharmacy do not constitute the practice of pharmacy and***
25 ***shall be performed in the United States in a pharmacy or in a location other than a***
26 ***pharmacy.***
27 ➔Section 3. KRS 315.205 is amended to read as follows:

1 Upon the request of an individual or his or her parent or guardian, a pharmacist who
2 administers an immunization to an individual who is fourteen (14) to seventeen (17) years
3 of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of
4 age, as authorized in KRS 315.010*(21)*[~~(19)~~], shall provide notification of the
5 immunization to the individual's primary care provider.

Speaker-House of Representatives

President of Senate

Attest: Chief Clerk of House of Representatives

Approved Governor

Date 13 APRIL 2016