AN ACT relating to pharmaceutical drug price discrimination.

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) As used in this section:

(a) "340B covered entity":

1. Means a health care facility that is registered as a covered entity under 42 U.S.C. sec. 256b, as amended; and

2. Includes any pharmacy owned or contracted by a covered health care facility to dispense covered drugs on behalf of the health care facility;

(b) "340B price" or "340B pricing" means the amount required to be paid to the manufacturer of a covered drug as established pursuant to 42 U.S.C. sec. 256b, as amended; and

(c) "Covered drug" has the same meaning as in 42 U.S.C. sec. 256b, as amended.

(2) A manufacturer shall not discriminate, or cause others to discriminate, against a 340B covered entity by refusing or withholding 340B pricing for a covered drug if the manufacturer offers the same drug at a 340B price in any other state. Discrimination prohibited under this section also includes but is not limited to any manufacturer-imposed condition, limitation, or delay on the sale of or purchase of a covered drug at a 340B price, unless the condition, limitation, or delay:

(a) Is expressly required under federal or state law; or

(b) Can be proven to be beyond the control of the manufacturer.

(3) Any person who believes that a manufacturer is in violation of subsection (2) of this section may make a complaint to the Attorney General who may, pursuant to KRS 315.235, investigate the complaint.

(4) Nothing in this section shall be construed or interpreted to be less restrictive than, or in conflict with, any other federal or state law.

➔Section 2. 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) "Administrative activities of a pharmacy" means the following functions performed by a pharmacy adhering to all local, state, and federal patient privacy laws:

(a) Investigating and researching a patient's insurance benefits and updating the patient profile regarding insurance coverage;

(b) Billing and collections activities, including:

1. Contacting patients for copayments and coinsurance payments; and

2. Communicating with insurance companies;

(c) Performing patient financial assistance activities and updating patient records accordingly;

(d) Opening faxes and accessing electronic prescriptions for the purposes of setting up patient demographic and insurance profiles, excluding height, weight, and allergy information, so long as the activity does not involve the entering of a prescription order into the dispensing or medication management system;

(e) Initiating insurance prior authorizations for submission to the licensed pharmacy, including communications with the prescribing physician to collect, record, and transmit information to insurance companies, so long as the activity does not include the authorization or receipt of new or refill prescription orders;

(f) Answering and transferring telephone calls, whether or not such calls require accessing a patient record, so long as the call does not involve the

interpretation, evaluation, or implementation of a drug order; and

(g) Communicating with patients via telephone or electronically regarding refill reminders, so long as the communication does not involve the interpretation, evaluation, or implementation of a drug order and a pharmacist is readily available for patient consultation;

(3) "Association" means the Kentucky Pharmacists Association;

(4) "Board" means the Kentucky Board of Pharmacy;

(5) "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;

(6) "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;

(7) "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;

(8) "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;

(9) "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;

(10) "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;

(11) "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;

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

(13) "Manufacturer" or "virtual manufacturer" of a product means:

(a) A person that holds an application approved under 21 U.S.C. sec. 355 or a license issued under 42 U.S.C. sec. 262 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(b) A co-licensed partner of the person described in paragraph (a) of this subsection that obtains the product directly from a person described in this paragraph or paragraph (a) of this subsection;

(c) An affiliate of a person described in paragraph (a) or (b) of this subsection who receives the product directly from a person described in this paragraph or in paragraph (a) or (b) of this subsection; or

(d) ***A pharmacist compounding drugs intended for human use without a valid prescription drug order***~~[Any person, except a pharmacist compounding in the normal course of professional practice]~~;

(14) "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) "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;

(16) "Outsourcing facility" means a facility at one (1) geographic location or address that:

(a) Is engaged in the compounding of human sterile drugs without a patient-specific prescription;

(b) Has registered as an outsourcing facility with the secretary of the United States Department of Health and Human Services, Food and Drug Administration; and

(c) Complies with all applicable state and federal requirements;

(17) "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy;

(18) "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;

(19) "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;

(20) "Pharmacy-related primary care" means the pharmacists' activities in patient education, health promotion, and 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;

(21) "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;

(22) "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 immunizations to individuals nine (9) 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;

(23) "Practitioner" has the same meaning given in KRS 217.015(35);

(24) "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;

(25) "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 or protocols authorized by the board. 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;

(26) "Society" means the Kentucky Society of Health-Systems Pharmacists;

(27) "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

(28) "Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.