SENATE

KENTUCKY GENERAL ASSEMBLY AMENDMENT FORM

2016 REGULAR SESSION

Amend printed copy of HB 398/SCS 1

On page 1, after line 2, by inserting the following sections and renumbering subsequent sections accordingly:

"➔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

Amendment No.	SFA 1	Sponsor:	Sen. Ralph Alvarado
Committee Amendment:		Signed:	
Floor Amendment:		LRC Drafter:	Scott, Jonathan
Adopted:		Date:	
Rejected:		Doc. ID:	XXXXX

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;

(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) ***"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;

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

(17) ~~[(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;

(18) ~~[(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;

(19) ~~[(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;

(20) ~~[(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;

(21) ~~[(20)]~~ "Practitioner" has the same meaning given in KRS 217.015(35);

(22) ~~[(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;

(23) ~~[(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;

(24) ~~[(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;

(25) ~~[(24)]~~ "Society" means the Kentucky Society of Health-Systems Pharmacists;

(26) ~~[(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

(27) ~~[(26)]~~ "Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.

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

(1) (a) A person shall not operate an outsourcing facility within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without first obtaining a permit from the board.

(b) An application for a permit to operate an outsourcing facility shall be made to the board upon forms provided by the board and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with such reasonable standards and regulations as may be prescribed by the board.

(c) Each application shall be accompanied by a permit fee to be set by administrative regulation promulgated by the board, not to exceed two hundred fifty dollars ($250).

(2) As a prerequisite to obtaining or renewing a permit from the board, the outsourcing facility shall:

(a) Register as an outsourcing facility with the United States Secretary of Health and Human Services in accordance with 21 U.S.C. sec. 353b;

(b) Submit a copy of a current inspection report resulting from an inspection conducted by the United States Food and Drug Administration;

(c) 1. The inspection report required pursuant to paragraph (b) of this subsection shall be deemed current for the purposes of this section if the inspection was

conducted:

a. No more than one (1) year prior to the date of submission of an application for a permit to the board; or

b. No more than two (2) years prior to the date of submission of an application for renewal of a permit to the board.

2. If the outsourcing facility has not been inspected by the United States Food and Drug Administration within the period required under subparagraph 1. of this paragraph, the board may:

a. Accept an inspection report or other documentation from another entity that is satisfactory to the board; or

b. Cause an inspection to be conducted by its duly authorized agent and charge an inspection fee in an amount sufficient to cover the costs of the inspection.

(3) (a) Upon receipt of an application of a permit to operate an outsourcing facility accompanied by the permit fee prescribed by administrative regulation, the board shall:

1. Issue a permit if the outsourcing facility meets the standards and requirements of KRS Chapter 315 and administrative regulations promulgated by the board; or

2. Refuse to issue or renew any permit to operate if the outsourcing facility fails to meet the standards and requirements of KRS Chapter 315 and administrative regulations promulgated by the board.

(b) The board shall act upon an application for a permit to operate within thirty (30) days after the receipt of the application. The board may issue a temporary permit to operate in any instance where it considers additional time necessary for

investigation and consideration before taking final action upon the application, and the temporary permit shall be valid for a period of thirty (30) days, unless extended.

(4) A separate permit to operate shall be required for each outsourcing facility.

(5) (a) Each permit to operate an outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the renewal fee as established by administrative regulation of the board. The renewal fee shall not:

1. Exceed two hundred fifty dollars ($250); or

2. Increase more than twenty-five dollars ($25) per year.

(b) 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 June 30 of each year.

(6) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable, except that a buyer may operate the outsourcing facility under the permit of the seller pending a decision by the board on an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(7) The board may promulgate administrative regulations to ensure:

(a) That proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular outsourcing facility: and

(b) Reasonable health and sanitation standards for areas within outsourcing facilities that are not subject to health and sanitation standards enforced by the Cabinet for Health and Family Services or a local health department.

(8) Each outsourcing facility shall comply with KRS 218A.202.

(9) Each outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

(10) A pharmacist may temporarily operate an outsourcing facility in an area not designated on the permit as authorized in KRS 315.500.

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

(1) (a) Each out-of-state outsourcing facility that does business, physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth shall hold a current outsourcing facility permit issued by the board.

(b) An application for a permit to operate an out-of-state outsourcing facility shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with reasonable standards and regulations as may be prescribed by the board.

(c) Each application shall be accompanied by a permit fee to be set by administrative regulation promulgated by the board. The fee shall not:

1. Exceed two hundred fifty dollars ($250);

2. Be increased by more than twenty-five dollars ($25) per year; or

3. Exceed the current in-state outsourcing facility permit.

(2) As a prerequisite to obtaining or renewing a permit from the board, the out-of-state outsourcing facility shall:

(a) Register as an outsourcing facility with the United States Secretary of Health and Human Services in accordance with 21 U.S.C. sec. 353b; and

(b) Submit a copy of a current inspection report resulting from an inspection conducted by the United States Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

(c) 1. The inspection report required pursuant to paragraph (b) of this subsection shall be deemed current for the purposes of this section if the inspection was conducted:

a. No more than one (1) year prior to the date of submission of an application for a permit to the board; or

b. No more than two (2) years prior to the date of submission of an application for renewal of a permit to the board.

2. If the out-of-state outsourcing facility has not been inspected by the United States Food and Drug Administration within the period required under subparagraph 1. of this paragraph, the board may:

a. Accept an inspection report or other documentation from another entity that is satisfactory to the board; or

b. Cause an inspection to be conducted by its duly authorized agent and charge an inspection fee in an amount sufficient to cover the costs of the inspection.

(3) (a) Upon receipt of an application of a permit fee to operate an out-of-state outsourcing facility, accompanied by the permit fee required by subsection (1) of this section, the board shall:

1. Issue a permit if the out-of-state outsourcing facility meets the standards and requirements of KRS Chapter 315 and administrative regulations

promulgated by the board; or

2. Refuse to renew any permit to operate unless the out-of-state outsourcing facility meets the standards and requirements of KRS Chapter 315 and administrative regulations promulgated by the board.

(b) The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof. The board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application, and the temporary permit shall be valid for a period of thirty (30) days, unless extended.

(4) A separate permit to operate shall be required for each out-of-state outsourcing facility.

(5) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office or corporate officer.

(6) (a) An out-of-state outsourcing facility granted an out-of-state outsourcing facility permit shall comply with all statutorily authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with this section.

(b) An out-of-state outsourcing facility shall maintain at all times a valid unexpired permit, license, or registration to conduct the outsourcing facility in compliance with the laws of the jurisdiction in which it is a resident.

(c) As a prerequisite to seeking a permit from the board, the out-of-state outsourcing facility shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in

which it is located. Thereafter, the out-of-state outsourcing facility granted a permit shall submit to the board a copy of any subsequent inspection report of the outsourcing facility conducted by the regulatory or licensing body of the jurisdiction in which it is located.

(7) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall maintain records of any controlled substances or dangerous drugs or devices.

(8) Each out-of-state outsourcing facility shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state outsourcing facility and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container.

(9) An out-of-state outsourcing facility shall have a pharmacist in charge that is licensed to engage in the practice of pharmacy by the board that shall be responsible for compliance by the out-of-state outsourcing facility.

(10) An out-of-state outsourcing facility shall comply with KRS 218A.202.

(11) An out-of-state outsourcing facility doing business within the Commonwealth of Kentucky shall use the address on file with the board as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner.

(12) (a) A permit to operate an out-of-state outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the renewal fee

established by subsection (1) of this section.

(b) 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 June 30 of each year.

(13) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable, except that a buyer may operate the out-of-state outsourcing facility under the permit of the seller pending a decision by the board on an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(14) The board may promulgate administrative regulations to ensure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular out-of-state outsourcing facility.

(15) Each out-of-state outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, to include all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

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

(1) A medical gas wholesaler shall be licensed by the board. Each license application shall include a fee which shall:

(a) Be prescribed by administrative regulation promulgated by the board in an amount not to exceed two hundred fifty dollars ($250); and

(b) Not be increased by more than twenty-five dollars ($25) per year.

(2) A medical gas wholesaler shall be required to maintain accurate records of all drugs handled. Records shall be made available to agents of the board for inspection upon

request.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under KRS 315.131.

(4) The board shall promulgate administrative regulations to specify the criteria for licensure and discipline of a medical gas wholesaler."; and

On page 2, after line 13, by inserting the following:"

➔Section 7. KRS 315.205 is amended to read as follows:

Upon the request of an individual or his or her parent or guardian, a pharmacist who administers an immunization to an individual who is fourteen (14) to seventeen (17) years of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of age, as authorized in KRS 315.010***(20)*** ~~[(19)]~~, shall provide notification of the immunization to the individual's primary care provider.".