Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

State of Arkansas
87th General Assembly
Regular Session, 2009

A Bill

HOUSE BILL 1997

By: Representative Hall

For An Act To Be Entitled

AN ACT TO ESTABLISH PROVISIONS OF LAW REGARDING THE DISTRIBUTION OF DRUG SAMPLES; AND FOR OTHER PURPOSES.

Subtitle

AN ACT TO ESTABLISH PROVISIONS OF LAW REGARDING THE DISTRIBUTION OF DRUG SAMPLES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 17-92-101 is amended to read as follows:

17-92-101. Definitions.

As used in this chapter:

(1) "Authorized distributors of record" means those distributors with whom a drug manufacturer has established an ongoing relationship to distribute the drug manufacturer's products;

~~(1)~~(2) "Board" means the Arkansas State Board of Pharmacy;

~~(2)~~(3) "Credentialing" means the issuance of or approval by the Arkansas State Board of Pharmacy of a credential issued to a pharmacist by an agency approved by the board certifying that the pharmacist has met the standards of competency established by the board for disease state management or other pharmacy services necessitating a credential;

~~(3)~~(4) "Dentist" means a practitioner of dentistry ~~duly~~ licensed under the laws of this or some other state;

~~(4)(A)~~(5)(A) "Disease state management" means a strategy that utilizes a team-oriented, multidisciplinary approach to improve health care

outcomes and quality of care, and when possible, to control health care cost through management of targeted chronic disease states.

(B) Disease state management focuses on improving health care from prevention to diagnosis and treatment to ongoing follow-up.

(C) Disease state management will involve, ~~but not be limited to,~~ without limitation patient education, self-care techniques, and outpatient drug therapy management ~~pursuant to~~ under a patient care plan;

~~(5)~~(6) "Drug" shall include all medicines and preparations recognized in the United States Pharmacopoeia or the National Formulary as substances intended to be used for the care, mitigation, or prevention of disease of either ~~man~~ humans or other animals;

(7) "Drug sample" means a unit of a drug that is not intended to be sold and is intended to promote the sale of the drug;

~~(6)~~(8) "Generically equivalent" means a drug that is pharmaceutically and therapeutically equivalent to the drug prescribed;

~~(7)~~(9) "Licensed pharmacist" means a person holding a license under ~~the provisions of~~ this chapter;

~~(8)~~(10) "Medicine" means a drug or preparation of drugs in suitable form for use as a curative or remedial substance;

~~(9)~~(11) "Optometrist" means a practitioner of optometry ~~duly~~ licensed under the laws of this state;

~~(10)~~(12) "Patient care plan" means a written course of action that is patient- or physician- or pharmacist-specific and disease-specific for helping a patient to achieve outcomes that improve a patient's quality of life;

~~(11)~~(13) "Pharmaceutically equivalent" means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical, compendious, or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium;

~~(12)~~(14) "Pharmacy" means the place licensed by the board in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail;

~~(13)~~(15) "Pharmacy care" means the process by which a pharmacist in consultation with the prescribing practitioner identifies, resolves, and prevents potential and actual drug-related problems and optimizes patient

therapy outcomes through the responsible provision of drug therapy or disease state management for the purpose of achieving any of the following definite outcomes that improve a patient's quality of life:

(A) Cure of disease;

(B) Elimination or reduction of a patient's symptomology;

(C) Arresting or slowing a disease process; or

(D) Preventing a disease or symptomology;

~~(14)~~(16) "Physician" means a practitioner of medicine ~~duly~~ licensed under the laws of this or some other state;

~~(15)~~(17) "Poisons" means any drug, chemical, medicine, or preparation liable to be destructive to adult human life in quantities of sixty (60) grains or less;

~~(16)(A)~~(18)(A) "Practice of pharmacy" means the learned profession of:

(i)(a) Dispensing, selling, distributing, transferring possession of, vending, bartering, or, in accordance with ~~regulations~~ rules adopted by the board, administering drugs, medicines, poisons, or chemicals that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription and order of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Except in accordance with ~~regulations~~ rules adopted by the board as recommended by the Medications Administration Advisory Committee, the administration of medications ~~shall be~~ is limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications.

(c) The administration of medications shall not include the administration of medications to any person under the age of eighteen (18);

(ii) Placing, packing, pouring, or putting into a container for dispensing, sale, distribution, transfer of, possession of, vending, or bartering any drug, medicine, poison, or chemical that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals;

(iii) Placing in or affixing upon any container described in subdivision ~~(16)(A)(ii)~~(18)(A)(ii) of this section a label required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(iv) Preparing, typing, or writing labels to be placed in or affixed on any container described in subdivision ~~(16)(A)(ii)~~(18)(A)(ii) of this section, which label ~~is required to~~ shall be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(v) Interpreting prescriptions for drugs, medicines, poisons, or chemicals issued by practitioners authorized by law to prescribe drugs, medicines, poisons, or chemicals that may be sold or dispensed only on prescription;

(vi) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons that are required by the laws of the United States or the State of Arkansas to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them;

(vii) Compounding, mixing, preparing, or combining drugs, medicines, chemicals, or poisons that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe them;

(viii) Advising and providing information concerning utilization of drugs and devices and participation in drug utilization reviews;

(ix)(a) Performing a specific act of drug therapy management or disease state management delegated to a pharmacist for an individual patient based upon a written protocol or a patient care plan approved by the patient's physician, who shall be licensed in this state under the Arkansas Medical Practices Act, §§ 17-95-201 et seq., 17-95-301 et seq., and 17-95-401 et seq.

(b) Drug therapy management shall not include the selection of drug products not prescribed by the physician unless the drug products are either named in the physician-initiated protocol or the

physician-approved patient care plan;

(x) Providing pharmacy care; and

(xi) Providing pharmacokinetic services.

(B) The provisions of subdivisions ~~(16)(A)~~(18)(A) and (C) of this section shall not apply to employees of wholesale drug companies or other drug distributors who do not fill prescriptions or sell or dispense drugs to the consumer.

(C)(i)(a) The board may permit pharmacy technicians other than pharmacists or interns to perform some or all of those functions described in board ~~regulations~~ rules under the direct, personal supervision of a licensed pharmacist ~~pursuant to regulations~~ under rules defining the minimum qualifications of ~~such~~ the employees, the ratio of pharmacy technicians to supervising pharmacists, and the scope of the duties, practices, and procedures that the board determines will promote the delivery of competent, professional pharmaceutical services and promote the public health and welfare.

(b) ~~Nothing in this chapter shall be construed as allowing~~ This chapter does not allow pharmacy technicians to administer medications.

(ii) The conduct of a pharmacy technician is the responsibility of the pharmacist-in-charge and supervising pharmacist of the pharmacy who shall not permit the employee to perform any act, task, or function that involves the exercise of independent judgment by the employee.

(iii) Pharmacy products prepared by pharmacy technicians shall be verified for accuracy by the supervising pharmacist ~~prior to~~ before release for patient use, and the verification shall be documented.

(iv) The use of pharmacy technicians in a manner not authorized by this chapter or ~~regulations promulgated hereunder shall be~~ rules adopted under this chapter are unprofessional conduct by the pharmacist-in-charge and the supervising pharmacist.

(v) It is recognized that hospital pharmacy technicians as defined in § 17-92-602(5) are governed by the Hospital Pharmacies Act, § 17-92-601 et seq., and related board regulations developed ~~pursuant to~~ under that act;

~~(17)~~(19) "Prescription" means an order for medicine or medicines

usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner. It contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time;

~~(18)~~(20) "Proprietary medicines", when not otherwise limited, means remedies that a certain individual or individuals have the exclusive right to manufacture or sell;

~~(19)~~(21) "Supervision" means under the direct charge or direction of and does not contemplate any continued absence of ~~such~~ the supervision;

~~(20)~~(22) "Therapeutically equivalent" means pharmaceutically equivalent drug products that if administered in the same amounts will provide the same therapeutic effect, identical in duration and intensity;

~~(21)~~(23) "Veterinarian" means a practitioner of veterinary medicine ~~duly~~ licensed under the laws of this or some other state; and

~~(22)(A)~~(24)(A) "Written protocol" means a physician's order, standing medical order, standing delegation order, or other order or protocol as defined by regulation of the Arkansas State Medical Board under the Arkansas Medical Practices Act, §§ 17-95-201 et seq., 17-95-301 et seq., and 17-95-401 et seq.

(B) Except for immunizations and vaccinations, which may be general protocols, protocols shall be patient- or physician- or pharmacist-specific for prescriptions or orders given by the physician authorizing the protocol.

SECTION 2 Arkansas Code Title 17, Chapter 92, subchapter 1 is amended to add an additional section to read as follows:

17-92-113. Distribution of drug samples.

(a) As used in this subsection, "distribute" does not include the providing of a drug sample to a patient by a:

(1) Physician or practitioner licensed to prescribe the drug;

(2) Health care professional acting at the direction and under the supervision of a physician or practitioner; or

(3) Pharmacy of a hospital or of another health care entity that is acting at the direction of a physician or practitioner and that received

the sample under this subchapter.

(b) Except under subsection (b) and (c) of this section, a person shall not distribute a drug sample.

(c)(1) A drug manufacturer or authorized distributor of record of a drug may distribute a drug sample by mail, common carrier, or by direct distribution by an authorized company representative to physicians or practitioners licensed to prescribe the drugs.

(2)(A) A distribution of a drug sample under subdivision (c)(1) of this section shall be made only upon the written request of the licensed physician or practitioner.

(B) The written request shall contain:

(i) The name, address, professional designation, and signature of the physician or practitioner making the request;

(ii) The identity of the drug sample requested and the quantity requested;

(iii) The name of the drug manufacturer of the drug sample requested; and

(iv) The date of the request.

(d)(1)(A) A drug manufacturer or authorized distributor of record may distribute drug samples to its authorized company representatives by common carrier.

(B) A drug sample that is distributed by common carrier shall be shipped in a manner which requires the signature of the recipient before delivery.

(C) The authorized company representative shall personally sign for this delivery.

(2) The drug manufacturer or authorized distributor does not violate this subsection if the common carrier fails to obtain the authorized company representative's signature.

(e)(1) The authorized company representative shall store the drug samples under conditions that will maintain the stability, integrity, and effectiveness of the drug samples and ensure that the drug samples will be free of contamination, deterioration, and adulteration as required under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

(2) All compendial and labeling requirements for storage and handling of a particular prescription drug shall be followed.

(f)(1) The name and address of the individual responsible for responding to requests by the Federal Food and Drug Administration regarding samples on behalf of a drug manufacturer or distributor shall be provided by the manufacturer to the Arkansas State Board of Pharmacy.

(2) The individual identified under subdivision (f)(1) of this section shall further serve as the initial contact person to the board concerning any alleged violations of this section.

(g)(1) A drug manufacturer or an authorized distributor of record shall maintain a list of:

(A) The name and address of each representative of the manufacturer or authorized distributor who distributes drug samples; and

(B) Each site where drug samples are stored.

(2) A record and a list maintained under this subsection shall be made available by the drug manufacturer or authorized distributor to the board upon request.

(h) A drug manufacturer or an authorized distributor shall notify the board of any significant loss of drug samples and any known theft of drug samples.

(i) The board shall report to the Federal Food and Drug Administration any violation of this section.

(j) This section shall apply only to the distribution of drug samples within the State of Arkansas.