State of Arkansas *As Engrossed: H3/12/09 H3/20/09*

87th General Assembly **A Bill**

Regular Session, 2009 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 Title 4, Chapter 86, Subchapter 1 is amended to add an additional section to read as follows:

4-86-108. Distribution of drug samples.

(a) As used in this section:

(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;

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

(3) "Distribute" does not include the providing of a drug sample to a patient by a:

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

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

(C) Pharmacy that has been granted approval from the

Arkansas State Board of Pharmacy to handle samples at the direction of a physician or practitioner and that received the sample under this subchapter;

(4) "Drug" includes 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 humans or other animals;

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

(6) "Licensed pharmacist" means a person holding a license under § 17-92, 101 et seq.;

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

(8) "Physician" means a practitioner of medicine licensed under the laws of this state or some other state.

(b) Except under subsections (c) and (d) 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 of record 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 *may* 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.

(k) A drug manufacturer that distributes drug samples in the State of Arkansas shall have a policy for drug screening of an employee that distributes drug samples in this state.

/s/ Hall

APPROVED: 4/6/2009