

# EXHIBIT E

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.

## Act 943 of the Regular Session

1 State of Arkansas  
2 87th General Assembly  
3 Regular Session, 2009

*As Engrossed: H3/12/09 H3/20/09*

## A Bill

HOUSE BILL 1997

4  
5 By: Representative Hall  
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### For An Act To Be Entitled

9 AN ACT TO ESTABLISH PROVISIONS OF LAW REGARDING  
10 THE DISTRIBUTION OF DRUG SAMPLES; AND FOR OTHER  
11 PURPOSES.  
12

### Subtitle

14 AN ACT TO ESTABLISH PROVISIONS OF LAW  
15 REGARDING THE DISTRIBUTION OF DRUG  
16 SAMPLES.  
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19 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:  
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21 *SECTION 1. Arkansas Code Title 4, Chapter 86, Subchapter 1 is amended to*  
22 *add an additional section to read as follows:*

23 *4-86-108. Distribution of drug samples.*

24 *(a) As used in this section:*

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

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

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

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

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

35 *(C) Pharmacy that has been granted approval from the*



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

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

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

9 (6) "Licensed pharmacist" means a person holding a license under §  
10 17-92, 101 et seq.;

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

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

16 (b) Except under subsections (c) and (d) of this section, a person  
17 shall not distribute a drug sample.

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

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

25 (B) The written request shall contain:

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

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

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

32 (iv) The date of the request.

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

36 (B) A drug sample that is distributed by common carrier

1 shall be shipped in a manner which requires the signature of the recipient  
2 before delivery.

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

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

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

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

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

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

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

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

26 (B) Each site where drug samples are stored.

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

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

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

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

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

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/s/ Hall

**APPROVED: 4/6/2009**