

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.

1 State of Arkansas
2 85th General Assembly
3 Regular Session, 2005

As Engrossed: H3/29/05

A Bill

HOUSE BILL 2446

4
5 By: Representative Mahony
6
7

For An Act To Be Entitled

8 THE WHOLESALE LICENSURE AND PRESCRIPTION
9 MEDICATION INTEGRITY ACT.
10

Subtitle

11 THE WHOLESALE LICENSURE AND PRESCRIPTION
12 MEDICATION INTEGRITY ACT.
13
14
15
16

17 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
18

19 *SECTION 1. Arkansas Code Title 17, Chapter 92, Subchapter 1 is amended*
20 *to add an additional section to read as follows:*

21 *17-92-113. Wholesale licensure and prescription drug integrity.*

22 *(a)(1) The Arkansas State Board of Pharmacy shall promulgate rules*
23 *regarding the issuance and renewal of licenses and permits for both in-state*
24 *and out-of-state wholesale distributors of drugs, manufacturers of drugs,*
25 *sellers of drugs, manufacturer-sellers of drugs, chain pharmacy warehouses,*
26 *and drug repackagers shipping into or within the State of Arkansas.*

27 *(2) The board shall seek input from both in-state and out-of-*
28 *state wholesale distributors of drugs, manufacturers of drugs, sellers of*
29 *drugs, manufacturer-sellers of drugs, chain pharmacy warehouses, and drug*
30 *repackagers in making rules under this section.*

31 *(b) The requirements for new and renewal applications shall include,*
32 *but not be limited to:*

33 *(1) The type of ownership, whether individual, partnership, or*
34 *corporation;*

35 *(2) Names of principal owners or officers and their social*
36 *security numbers;*



1 (3) Names of designated representatives and their social
2 security numbers;

3 (4) Fingerprints of applicants and designated representatives;

4 (5) Criminal background checks of applicants and designated
5 representatives;

6 (6) A copy of the entity's license in the entity's home state;

7 (7) Information regarding any criminal conviction of principals
8 or designated representatives;

9 (8) Bond requirements;

10 (9)(A) Rules for the establishment of a pedigree or electronic
11 file to be used by wholesale distributors of drugs, manufacturers of drugs,
12 sellers of drugs, manufacturer-sellers of drugs, chain pharmacy warehouses,
13 and drug repackagers for the purpose of ensuring the integrity of drugs
14 owned, purchased, distributed, returned, transferred, and sold when the
15 products leave the normal distribution channel.

16 (B) The board may exempt a United States Food and Drug
17 Administration-licensed drug manufacturer, including its affiliates,
18 subsidiaries, agents, and other entities under common ownership and control
19 with the manufacturer, from the wholesale distributor requirements of this
20 section, if the manufacturer, its affiliates, subsidiaries, agents, or other
21 entities under common ownership and control with the manufacturer ship or
22 invoice only the manufacturer's products into this state.

23 (10) Rules regarding the authentication, contents,
24 implementation, maintenance, and recordkeeping for a drug pedigree or
25 electronic file;

26 (11) Rules determining enforcement of drug pedigree or
27 electronic file requirements;

28 (12) Rules determining prohibited acts under drug pedigree or
29 electronic file requirements; and

30 (13) Rules establishing penalties for committing prohibited acts
31 in violation of drug pedigree or electronic file requirements.

32 (c) The board may use an outside agency to accredit wholesale
33 distributors and repackagers, including, but not limited to the National
34 Association of Boards of Pharmacy's Verified-Accredited Wholesale
35 Distributors program.

36 (d) The board may establish exemptions for noncommercial and other

1 distribution channels that the board determines to have legitimate business
2 reasons for an exemption.

3 (e) The board may exempt drug wholesalers accredited by the National
4 Association of Boards of Pharmacy's Verified-Accredited Wholesale
5 Distributors program from some of the requirements under this section.

6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36

/s/ Mahony