Hall of the House of Representatives

85th General Assembly - Regular Session, 2005

Amendment Form

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Subtitle of House Bill No. 2446

"THE WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY ACT."

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Amendment No. 1 to House Bill No. 2446.

Amend House Bill No. 2446 as originally introduced:

Delete everything after the ENACTING CLAUSE and substitute the following:

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

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

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

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

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

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

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

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

(4) Fingerprints of applicants and designated representatives;

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

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

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

(8) Bond requirements;

(9)(A) Rules for the establishment of a pedigree or electronic file to be used by wholesale distributors of drugs, manufacturers of drugs, sellers of drugs, manufacturer-sellers of drugs, chain pharmacy warehouses, and drug repackagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred, and sold when the

products leave the normal distribution channel.

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

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

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

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

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

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

(d) The board may establish exemptions for noncommercial and other distribution channels that the board determines to have legitimate business reasons for an exemption.

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

The Amendment was read _____

By: Representative Mahony

MGF/JGH - 03-28-2005 12:30 _____

MGF518 **Chief Clerk**