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TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule LSA Document #05-138

DIGEST

Adds 856 IAC 1-38 to implement rules based on House Enrolled Act 1098 (P.L.212-2005) to establish standards and procedures to ensure that a pharmacist has entered into a contract that accepts the return of expired drugs with or is subject to a policy that accepts the return of expired drugs of a wholesaler, manufacturer, or agent of a wholesaler or manufacturer. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

Estimated Number of Small Businesses Subject to This Rule:

NAICS 446110 Pharmacies and Drug Stores

NAICS 424210 Drugs and Druggists' Sundries Merchant Wholesalers

The Indiana Board of Pharmacy (Board) estimates that some small businesses will be directly affected by this rule. The Indiana Board of Pharmacy has the authority to promulgate rules in accordance with the requirements of HEA 1098 (P.L.212-2005) to establish standards and procedures to ensure that a pharmacist has entered into a contract that accepts the return of expired drugs with or is subject to a policy that accepts the return of expired drugs of a wholesaler, manufacturer, or agent of a wholesaler or manufacturer. This proposed rule will not have any costs on small businesses. In fact, the proposed rule when implemented will make it easier for independent pharmacies to return expired drugs for credit or replacement.

Estimated Average Annual Administrative Costs That Small Businesses Will Incur:

The Board estimates that there will be minimal annual reporting, record keeping, or administrative costs incurred by small businesses to comply with this rule. The drug manufacturers will have to maintain records for credits and replacements of expired drugs.

Estimated Total Annual Economic Impact on Small Businesses:

The Board estimates that there will be no impact on small businesses as a result of compliance with this rule.

- Justification of Requirements or Costs on Small Businesses Where Rule Is Not Expressly Required by Law: There will be no compliance costs on small businesses.
- Supporting Data, Studies, or Analyses: The Board has not relied on any studies in reaching these estimates.

Regulatory Flexibility Analysis of Alternative Methods:

The new proposed rule was mandated by P.L.212-2005 (HEA 1098-2005); therefore, the Board has not analyzed alternatives to this proposed rule.

- Explanation of Preliminary Determination: The General Assembly required the Board to enact and establish these rules, and thus the Board did not explore alternative measures.
- Supporting Data, Studies, or Analyses: The Board did not rely on any studies in its decision not to employ alternatives to rulemaking.

856 IAC 1-38

SECTION 1. 856 IAC 1-38 IS ADDED TO READ AS FOLLOWS:

Rule 38. Credit for Returned Expired Drugs

856 IAC 1-38-1 Applicability

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 1. (a) This rule establishes the standards and procedures concerning the return of expired legend drugs by an individual or entity licensed to receive legend drugs to either of the following:

- (1) A drug manufacturer.
- (2) A designated agent of a drug manufacturer.

(b) This rule does not apply to the following:

- (1) Vaccines that prevent influenza.
- (2) Medicine used for the treatment of malignant hyperthermia.
- (3) Other legend drugs as determined by the board.

(Indiana Board of Pharmacy; 856 IAC 1-38-1)

856 IAC 1-38-2 “Board” defined

Authority: IC 25-26-13-4

Affected: IC 25-26-13-2

Sec. 2. As used in this rule, “board” has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-38-2)*

856 IAC 1-38-3 “Designated agent” defined

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 3. As used in this rule, “designated agent” means an individual or entity that contracts with a drug manufacturer to administer the manufacturer’s drug return policy for expired legend drugs. *(Indiana Board of Pharmacy; 856 IAC 1-38-3)*

856 IAC 1-38-4 Application of return of expired drugs

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 4. Effective with all drug orders placed after December 31, 2005, all drug manufacturers or their designated agents shall make adequate provisions for the return of expired legend drugs. *(Indiana Board of Pharmacy; 856 IAC 1-38-4)*

856 IAC 1-38-5 Record keeping

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 5. Drug manufacturers or their designated agents shall do the following:

- (1) Maintain records of all credits made under this rule for a period of two (2) years.
- (2) Make the records available to the board or its agent upon request.

(Indiana Board of Pharmacy; 856 IAC 1-38-5)

856 IAC 1-38-6 Compliance with other relevant law

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 6. The return of expired legend drugs under this rule shall also be consistent with all other applicable federal, state, and local laws and regulations. *(Indiana Board of Pharmacy; 856 IAC 1-38-6)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on December 12, 2005 at 10:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Room W064, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on a proposed new rule to implement rules based on House Enrolled Act 1098 (P.L.212-2005) to establish standards and procedures to ensure that a pharmacist has entered into a contract that accepts the return of expired drugs with or is subject to a policy that accepts the return of expired drugs of a wholesaler, manufacturer, or agent of a wholesaler or manufacturer.

The Indiana Board of Pharmacy has the authority to promulgate rules establishing the standards and procedures for the return of expired drugs by an individual or entity to a wholesaler, manufacturer, or agent of a wholesaler or manufacturer. This proposed rule establishes those standards and policies. This proposed rule will have no costs to regulated entities. In fact, this proposed rule

when implemented will make it easier for independent pharmacies to return expired drugs for credit or replacement.

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W072 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency