

Final Rule

LSA Document #05-138(F)

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.

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

[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](#); filed Jun 27, 2006, 10:50 a.m.: [20060726-IR-856050138FRA](#))

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Proposed Rule: November 1, 2005; 29 IR 658

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