

ARTICLE 3. WHOLESALE LEGEND DRUGS

Rule 1. Definitions

856 IAC 3-1-1 Definitions

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 1. All terms which are defined in IC 25-26-14 shall have the same meanings as they are so defined when used in this article. (*Indiana Board of Pharmacy; 856 IAC 3-1-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-1-2 "Chain drug warehouse" defined

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 2. As used in IC 25-26-14 and in this article, "chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:

- (1) is licensed as a wholesale distributor;
- (2) acts as a central warehouse; and
- (3) primarily performs intracompany sales and transfers of legend drugs or devices to chain pharmacies that are members of the same affiliated group under common ownership and control.

(*Indiana Board of Pharmacy; 856 IAC 3-1-2; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2195; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-1-3 "Statement" defined

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 3. "Statement" means the specific unit of the specific legend drug that was purchased directly from the manufacturer. (*Indiana Board of Pharmacy; 856 IAC 3-1-3; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

Rule 2. Licensing and Operational Requirements

856 IAC 3-2-1 Persons required to register (Repealed)

Sec. 1. (*Repealed by Indiana Board of Pharmacy; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2198*)

856 IAC 3-2-2 Fees

Authority: IC 25-26-14-13

Affected: IC 25-26-14-14

Sec. 2. (a) The fee for original licensure and biennial renewal shall be one hundred dollars (\$100) for in-state applicants. The fee for original licensure and biennial renewal shall be one hundred dollars (\$100) for out-of-state applicants.

(b) Licensure fees shall be paid at the time when the application for licensure or renewal of a license is filed. (*Indiana Board of Pharmacy; 856 IAC 3-2-2; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3107; readopted filed Oct 17, 2001, 3:30 p.m.: 25 IR 941; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-2-3 Application forms; renewal forms

Authority: IC 25-26-14-13

Affected: IC 25-26-14-14

Sec. 3. (a) Applications for licensure may be obtained by writing to the Indiana Board of Pharmacy, Indiana Professional Licensing Agency, 402 West Washington Street, Room W072, Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September 30 of each even-numbered year. Applications for renewal shall be mailed to the licensee. (*Indiana Board of Pharmacy; 856 IAC 3-2-3; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-2-4 Inspection and review of application

Authority: IC 25-26-14-13

Affected: IC 25-26-14-17; IC 25-26-14-19

Sec. 4. The board may inspect, or cause to be inspected, the establishment of an applicant or licensee pursuant to IC 25-26-14-19. The board shall review the application for licensure and other information regarding an applicant to determine whether the applicable standards of IC 25-26-14-17 have been met by the applicant. (*Indiana Board of Pharmacy; 856 IAC 3-2-4; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-2-5 Wholesale drug distributor license

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 5. (a) The board shall issue a wholesale drug distributor license to applicants that qualify under IC 25-26-14.

(b) The wholesale drug distributor license shall contain the name, address, and license number of the licensee, the amount of fee paid, and the expiration date of the license. The licensee shall maintain the wholesale drug distributor license in a readily retrievable manner and shall permit inspection of the license by any official, agent, or employee of the board. (*Indiana Board of Pharmacy; 856 IAC 3-2-5; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-2-6 Termination of licensure; transfer of license

Authority: IC 25-26-14-13

Affected: IC 25-26-14-14; IC 25-26-14-15

Sec. 6. (a) The license of any person shall terminate if and when such person dies or ceases legal existence. Any licensee who ceases legal existence or discontinues business shall notify the board within ten (10) days of such fact in writing.

(b) No license or any authority conferred thereby shall be assigned or otherwise transferred except to the extent allowed by IC 25-26-14-15, and then only pursuant to the written consent of the board. (*Indiana Board of Pharmacy; 856 IAC 3-2-6; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823; readopted filed Oct 4, 2007, 3:33 p.m.: 20071031-IR-856070060RFA; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-2-7 Reciprocity (Repealed)

Sec. 7. *(Repealed by Indiana Board of Pharmacy; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2198)*

856 IAC 3-2-8 Minimum conditions for licensure, renewal, and operations (Repealed)

Sec. 8. *(Repealed by Indiana Board of Pharmacy; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2198)*

Rule 3. Accreditation

856 IAC 3-3-1 Board-approved accreditation body

Authority: IC 25-26-14-13; IC 25-26-14-14

Affected: IC 25-26-14-14

Sec. 1. The National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program shall do the following:

(1) Evaluate a wholesale drug distributor's operations to determine compliance with the following:

(A) Industry standards.

(B) IC 25-26-14.

(C) This title.

(D) Any other applicable law.

(2) Perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

(3) Ensure that the information obtained during accreditation remains confidential and privileged.

(4) Adhere to other requirements set by the board or the Indiana professional licensing agency.

(Indiana Board of Pharmacy; 856 IAC 3-3-1; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA)

856 IAC 3-3-2 Accreditation for new applicants

Authority: IC 25-26-14-13

Affected: IC 25-26-14-14

Sec. 2. For licenses issued after December 31, 2005, applicants for licensure as wholesale drug distributors shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before issuance of licensure. *(Indiana Board of Pharmacy; 856 IAC 3-3-2; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA)*

856 IAC 3-3-3 Accreditation for existing license holders

Authority: IC 25-26-14-13

Affected: IC 25-26-14-14

Sec. 3. For licenses issued before January 1, 2006, license holders shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before renewal of licensure on September 30, 2006. *(Indiana Board of Pharmacy; 856 IAC 3-3-3; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA)*

Rule 4. Pedigrees

856 IAC 3-4-1 Pedigrees; contents

Authority: IC 25-26-14-8.7; IC 25-26-14-13

Affected: IC 25-26-14

Sec. 1. A pedigree for each legend drug shall contain the following information:

- (1) The legend drug proprietary and established name.
- (2) The container size of the legend drug.
- (3) The number of containers.
- (4) The dosage form.
- (5) The dosage strength.
- (6) Lot/control numbers with expiration dates.
- (7) The name of the manufacturer and repackager, if applicable, of the finished legend drug product.
- (8) The name, address, and telephone number of each entity involved in the chain of the legend drug's custody.
- (9) The name and address of each person certifying delivery or receipt of the legend drug.
- (10) The sales invoice number or other number, unique to the shipping document.
- (11) The dates of each transaction, including manufacturer, delivery, and receipt.
- (12) A certification that each recipient has authenticated the pedigree, back to the manufacturer.
- (13) A certification from the licensed entity that the information contained on the pedigree is true.

(Indiana Board of Pharmacy; 856 IAC 3-4-1; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2196; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA)

856 IAC 3-4-2 Pedigrees; approved formats

Authority: IC 25-26-14-8.7; IC 25-26-14-13

Affected: IC 25-26-14

Sec. 2. The pedigree format:

- (1) shall include the contents described in section 1 of this rule; and
- (2) may be subject to the approval of the board.

(Indiana Board of Pharmacy; 856 IAC 3-4-2; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA)

Rule 5. Normal Distribution Chain of Custody

856 IAC 3-5-1 Authorized distributor to authorized distributor transaction; pedigree requirement

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 1. For purposes of IC 25-26-14 and this article, within the normal distribution chain of custody, an authorized distributor that receives a legend drug directly from the manufacturer, or from the manufacturer's third party logistics provider, may sell the legend drug to a pharmacy, chain drug warehouse, or practitioner or one (1) other authorized distributor of the manufacturer that sells the legend drug directly to a pharmacy, chain drug warehouse, or practitioner without passing a pedigree if the invoice or accompanying document for the transaction includes a statement that the product was purchased directly from:

- (1) the manufacturer; or
- (2) an authorized distributor of the manufacturer who purchased the product direct from the manufacturer.

(Indiana Board of Pharmacy; 856 IAC 3-5-1; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA)

856 IAC 3-5-2 Chain drug warehouses in the normal distribution chain of custody

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-1.8; IC 25-26-14-17

Sec. 2. As used in IC 25-26-14 and in this article, chain drug warehouses that are distributing to their affiliated pharmacies or warehouses are not required to:

(1) be recognized as an authorized distributor, as defined in IC 25-26-14-1.8, for the normal distribution chain of custody to apply; or

(2) within the normal distribution chain of custody, pass a pedigree to or between their affiliated pharmacies or warehouses. (*Indiana Board of Pharmacy; 856 IAC 3-5-2; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA*)

856 IAC 3-5-3 Entities within the normal distribution chain custody

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 3. All entities, other than manufacturers approved by the Food and Drug Administration, within the normal distribution chain of custody shall be located and licensed within the United States or its territories. (*Indiana Board of Pharmacy; 856 IAC 3-5-3; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

856 IAC 3-5-4 Applicability of normal distribution chain of custody

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 4. Normal distribution chain of custody applies to the following:

(1) Physical movement of the legend drug.

(2) Its passage of title.

(*Indiana Board of Pharmacy; 856 IAC 3-5-4; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA*)

Rule 6. Drug Returns

856 IAC 3-6-1 Drug returns; pedigree requirement

Authority: IC 25-26-14-11; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 1. The returns or exchanges of saleable legend drugs, received by the wholesale distributor as provided by this article, are not subject to the pedigree requirements under IC 25-26-14 and 856 IAC 3-4. Wholesale distributors are responsible for the following:

(1) Policing the returns process.

(2) Maintaining operations that are designed against the entry of an adulterated or counterfeit product into distribution.

(*Indiana Board of Pharmacy; 856 IAC 3-6-1; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA*)

Rule 7. Authentications

856 IAC 3-7-1 Authentication

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 1. Manufacturers shall cooperate in the process of authentication, as defined in IC 25-26-14. (*Indiana Board of Pharmacy; 856 IAC 3-7-1; filed Mar 10, 2006, 8:37 a.m.: 29 IR 2197; readopted filed Nov 9, 2012, 11:23 a.m.: 20121205-IR-856120389RFA; readopted filed Nov 21, 2018, 8:35 a.m.: 20181219-IR-856180407RFA*)

*