

IC 16-42-19

Chapter 19. Drugs: Indiana Legend Drug Act

IC 16-42-19-1

Intent of chapter

Sec. 1. This chapter is intended to supplement IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-2

"Drug"

Sec. 2. As used in this chapter, "drug" means the following:

- (1) Articles or substances recognized in United States Pharmacopeial Convention, Inc.; The United States Pharmacopeia, Twenty-Second Edition (1990) or United States Pharmacopeial Convention, Inc.; The National Formulary, Seventeenth Edition (1990) as revised by United States Pharmacopeial Convention, Inc.; Supplement 1 to The United States Pharmacopeia, Twenty-Second Edition and The National Formulary, Seventeenth Edition (1990); and any supplements printed after 1990.
- (2) Articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
- (3) Articles other than food intended to affect the structure or any function of the body of human beings or other animals.
- (4) Articles intended for use as a component of any article specified in subdivision (1), (2), or (3).
- (5) Devices.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.1.

IC 16-42-19-3

"Drug order"

Sec. 3. As used in this chapter, "drug order" means an order that meets the following conditions:

- (1) Is:
 - (A) a written order in a hospital or other health care institution for an ultimate user for a drug or device, issued and signed by a practitioner; or
 - (B) an order transmitted by other means of communication from a practitioner that is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution.
- (2) Contains the following:
 - (A) The name and bed number of the patient.
 - (B) The name and strength or size of the drug or device.
 - (C) Unless specified by individual institutional policy or guidelines, the amount to be dispensed either in quantity or

days.

(D) Adequate directions for the proper use of the drug or device when administered to the patient.

(E) The name of the prescriber.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-4

"Investigational or new drug"

Sec. 4. As used in this chapter, "investigational or new drug" means a drug that is limited by state law to use under professional supervision of a practitioner authorized by law to prescribe or administer the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-5

"Practitioner"

Sec. 5. As used in this chapter, "practitioner" means any of the following:

- (1) A physician licensed under IC 25-22.5.
- (2) A veterinarian licensed to practice veterinary medicine in Indiana.
- (3) A dentist licensed to practice dentistry in Indiana.
- (4) A podiatrist licensed to practice podiatric medicine in Indiana.
- (5) An optometrist who is:
 - (A) licensed to practice optometry in Indiana; and
 - (B) certified under IC 25-24-3.
- (6) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.
- (7) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.

As added by P.L.2-1993, SEC.25. Amended by P.L.185-1993, SEC.1; P.L.157-2006, SEC.6; P.L.90-2007, SEC.2; P.L.177-2009, SEC.8.

IC 16-42-19-6

"Precursor"

Sec. 6. As used in this chapter, "precursor" means a substance, other than a legend drug, that:

- (1) is an immediate chemical intermediate that can be processed or synthesized into a legend drug; and
- (2) is used or produced primarily for use in the manufacture of a legend drug by persons other than persons:
 - (A) licensed to manufacture the legend drug by the Indiana board of pharmacy;
 - (B) registered by the state department; or
 - (C) licensed to practice pharmacy by the Indiana board of pharmacy.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-7**"Prescription"**

Sec. 7. As used in this chapter, "prescription" means:

- (1) a written order to or for an ultimate user for a drug or device containing the name and address of the patient, the name and strength or size of the drug or device, the amount to be dispensed, adequate directions for the proper use of the drug or device by the patient, and the name of the practitioner, issued and signed by a practitioner; or
- (2) an order transmitted by other means of communication from a practitioner that is:
 - (A) immediately reduced to writing by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2); or
 - (B) for an electronically transmitted prescription:
 - (i) has the electronic signature of the practitioner; and
 - (ii) is recorded by the pharmacist in an electronic format.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.6.

IC 16-42-19-8**"Sale"**

Sec. 8. As used in this chapter, "sale" means every sale and includes the following:

- (1) Manufacturing, processing, transporting, handling, packing, or any other production, preparation, or repackaging.
- (2) Exposure, offer, or any other proffer.
- (3) Holding, storing, or any other possession.
- (4) Dispensing, giving, delivering, or any other supplying.
- (5) Applying, administering, or any other using.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-9**"Warehouseman"**

Sec. 9. As used in this chapter, "warehouseman" means a person who stores legend drugs for others and who has no control over the disposition of legend drugs except for the purpose of storage.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-10**"Wholesaler"**

Sec. 10. As used in this chapter, "wholesaler" means a person engaged in the business of distributing legend drugs that the person has not produced or prepared to persons included in any of the classes named in section 21 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-11**Sale of legend drug unlawful; exceptions**

Sec. 11. (a) Except as provided in section 21 of this chapter, a person may not sell a legend drug unless either of the following

conditions exist:

(1) Except as provided in subsection (b), the legend drug is dispensed by a pharmacist upon an original prescription or drug order with the drug product specified on the prescription or drug order or by the authorization of the practitioner and there is affixed to the immediate container in which the drug is delivered a label bearing the following:

(A) The name, address, and phone number of the establishment from which the drug was dispensed.

(B) The date on which the prescription for the drug was filled.

(C) The number of the prescription as filed in the prescription files of the pharmacist who filled the prescription.

(D) The name of the practitioner who prescribed the drug.

(E) The name of the patient, or if the drug was prescribed for an animal, a statement of the species of the animal.

(F) The directions for the use of the drug as contained in the prescription.

(2) The legend drug is delivered by the practitioner in good faith in the course of practice and the immediate container in which the drug is delivered bears a label on which appears the following:

(A) The directions for use of the drug.

(B) The name and address of the practitioner.

(C) The name of the patient.

(D) If the drug is prescribed for an animal, a statement of the species of the animal.

This section does not prohibit a practitioner from delivering professional samples of legend drugs in their original containers in the course of the practitioner's practice when oral directions for use are given at the time of delivery.

(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.2.

IC 16-42-19-12

Refilling prescription or drug order

Sec. 12. Except as authorized under IC 25-26-13-25(d), a person may not refill a prescription or drug order for a legend drug except in the manner designated on the prescription or drug order or by the authorization of the practitioner.

As added by P.L.2-1993, SEC.25. Amended by P.L.270-2001, SEC.1; P.L.204-2005, SEC.7.

IC 16-42-19-13**Possession or use of legend drug or precursor**

Sec. 13. A person may not possess or use a legend drug or a precursor unless the person obtains the drug:

- (1) on the prescription or drug order of a practitioner;
- (2) in accordance with section 11(2) or 21 of this chapter; or
- (3) in accordance with rules adopted by the board of pharmacy under IC 25-26-23.

As added by P.L.2-1993, SEC.25. Amended by P.L.119-2011, SEC.3.

IC 16-42-19-14**Records**

Sec. 14. A person may not fail to keep records as required by section 22 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-15**Inspection of records**

Sec. 15. A person may not refuse to make available and to accord full opportunity to check a record, as required by section 22 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-16**Unlawful acts**

Sec. 16. Except as provided in section 30 of this chapter, a person may not do any of the following:

- (1) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by any of the following:
 - (A) Fraud, deceit, misrepresentation, or subterfuge.
 - (B) The forgery or alteration of a prescription, drug order, or written order.
 - (C) The concealment of a material fact.
 - (D) The use of a false name or the giving of a false address.
- (2) Communicate information to a physician in an effort unlawfully to procure a legend drug or unlawfully to procure the administration of a legend drug. Such a communication is not considered a privileged communication.
- (3) Intentionally make a false statement in a prescription, drug order, order, report, or record required by this chapter.
- (4) For the purpose of obtaining a legend drug, falsely assume the title of or represent oneself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or other person.
- (5) Make or utter a false or forged prescription or false drug order or forged written order.
- (6) Affix a false or forged label to a package or receptacle containing legend drugs. This subdivision does not apply to law enforcement agencies or their representatives while engaged in

enforcing this chapter.

(7) Dispense a legend drug except as provided in this chapter.
As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.3; P.L.48-2015, SEC.1.

IC 16-42-19-17

Legend drug smoking devices

Sec. 17. A person may not possess or have under the person's control with intent to violate this chapter an instrument or contrivance designed or generally used in smoking a legend drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-18

Legend drug injection devices; violation

Sec. 18. (a) A person may not possess with intent to:

(1) violate this chapter; or

(2) commit an offense described in IC 35-48-4;

a hypodermic syringe or needle or an instrument adapted for the use of a controlled substance or legend drug by injection in a human being.

(b) A person who violates subsection (a) commits a Level 6 felony.

As added by P.L.2-1993, SEC.25. Amended by P.L.187-2015, SEC.23.

IC 16-42-19-19

Anabolic steroids

Sec. 19. Except as provided in section 21 of this chapter, a person may not possess or use an anabolic steroid without a valid prescription or drug order issued by a practitioner acting in the usual course of the practitioner's professional practice.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-20

Validity of prescriptions or drug orders

Sec. 20. (a) Except as provided in section 30 of this chapter, a prescription or drug order for a legend drug is not valid unless the prescription or drug order is issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's business.

(b) A practitioner may not knowingly issue an invalid prescription or drug order for a legend drug.

(c) A pharmacist may not knowingly fill an invalid prescription or drug order for a legend drug.

As added by P.L.2-1993, SEC.25. Amended by P.L.48-2015, SEC.2.

IC 16-42-19-21

Authorized sale or possession

Sec. 21. Sections 11, 13, 19, and 25(b) of this chapter are not

applicable to the following:

- (1) The sale of legend drugs to persons included in any of the classes named in subdivision (2), or to the agents or employees of such persons for use in the usual course of their business or practice or in the performance of their official duties.
- (2) Possession of legend drugs by the following persons or their agents or employees for such use:
 - (A) Pharmacists.
 - (B) Practitioners.
 - (C) Persons who procure legend drugs for handling by or under the supervision of pharmacists or practitioners employed by them or for the purpose of lawful research, teaching, or testing and not for resale.
 - (D) Hospitals and other institutions that procure legend drugs for lawful administration by practitioners.
 - (E) Manufacturers and wholesalers.
 - (F) Carriers and warehousemen.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-22

Manufacturers and wholesalers; records

Sec. 22. (a) Manufacturers and wholesalers shall maintain records of the movement in commerce of legend drugs for two (2) years immediately following the date of the last entry on those records and shall make those records available, at reasonable times, to law enforcement agencies and their representatives in the enforcement of this chapter.

(b) Evidence obtained under this section may not be used in a criminal prosecution of the person from whom obtained.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-23

Mechanical device for storage or dispensing of drugs; restrictions; inspection of premises

Sec. 23. (a) As used in this section, "mechanical device" means a machine for storage and dispensing of drugs. The term does not include devices or instruments used by practitioners in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(b) A person may not maintain, operate, or use any type of mechanical device in which any legend drug or narcotic drug is stored or held for the purpose of dispensing the drug from the mechanical device. However, the mechanical device may be used for the storage and dispensing of legend drugs if:

- (1) the mechanical device is used in a:
 - (A) pharmacy that holds a permit issued by the Indiana board of pharmacy;
 - (B) remote location under the jurisdiction of the board of pharmacy; or

(C) health care facility that is licensed under IC 16-28 or IC 16-21-2; and
(2) the mechanical device is operated under the direct supervision and control of a:
(A) registered pharmacist; or
(B) practitioner;
who is directly responsible for dispensing the drug from the mechanical device.
(c) Inspectors of the Indiana board of pharmacy may inspect the premises of any person suspected of violating this section.
As added by P.L.2-1993, SEC.25. Amended by P.L.98-2006, SEC.1.

IC 16-42-19-24

Nuisance; place of illegal use or storage; prohibited acts

Sec. 24. (a) A store, shop, warehouse, dwelling house, apartment, building, vehicle, boat, aircraft, or any other place that is used:
(1) by a person for the purpose of unlawfully using a legend drug; or
(2) for the unlawful keeping or selling of the legend drug;
is a common nuisance.
(b) A person may not:
(1) keep or maintain a common nuisance; or
(2) frequent or visit a place knowing the place to be used for a purpose;
as described in subsection (a).
As added by P.L.2-1993, SEC.25.

IC 16-42-19-25

Anabolic steroids; unlawful acts

Sec. 25. (a) A practitioner may not prescribe, order, distribute, supply, or sell an anabolic steroid for any of the following:
(1) Enhancing performance in an exercise, sport, or game.
(2) Hormonal manipulation intended to increase muscle mass, strength, or weight without a medical necessity.
(b) Except as provided in section 21 of this chapter, a person who is not a practitioner or lawful manufacturer of anabolic steroids may not do any of the following:
(1) Knowingly or intentionally manufacture or deliver an anabolic steroid, pure or adulterated.
(2) Possess, with intent to manufacture or deliver, an anabolic steroid.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-26

Pleading

Sec. 26. In:
(1) any complaint, information, affidavit, or indictment; and
(2) any action or proceeding brought for the enforcement of any provision of this chapter;

it is not necessary to negate an exception, excuse, proviso, or exemption contained in this chapter. The burden of proof of such an exception, excuse, proviso, or exemption is upon the defendant.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-27

Violations; prior offenders; anabolic steroids

Sec. 27. (a) Unless otherwise specified, a person who knowingly violates this chapter, except sections 24, 25(b), and 30(c) of this chapter, commits a Level 6 felony. However, the offense is a Level 5 felony if the person has a prior conviction under this subsection or IC 16-6-8-10(a) before its repeal.

(b) A person who violates section 24 of this chapter commits a Class B misdemeanor.

(c) A person who violates section 25(b) of this chapter commits dealing in an anabolic steroid, a Level 5 felony. However, the offense is a Level 4 felony if the person delivered the anabolic steroid to a person who is:

- (1) less than eighteen (18) years of age; and
- (2) at least three (3) years younger than the delivering person.

(d) A person who violates section 30(c) of this chapter commits a Class A infraction.

As added by P.L.2-1993, SEC.25. Amended by P.L.2-2005, SEC.58; P.L.158-2013, SEC.248; P.L.48-2015, SEC.3; P.L.187-2015, SEC.24.

IC 16-42-19-28

Immunity of law enforcement officers from prosecution

Sec. 28. Law enforcement officers in the performance of their official duties are exempt from prosecution for and may not be convicted of violations of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-29

Requirement of prescription for retail sale of insulin

Sec. 29. A legend drug that is composed wholly or partly of insulin may be sold for retail sale by a pharmacy only to an individual who possesses a prescription from one (1) of the following:

- (1) A physician licensed under IC 25-22.5.
- (2) A veterinarian licensed to practice veterinary medicine in Indiana.
- (3) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.
- (4) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.

As added by P.L.131-2014, SEC.8.

IC 16-42-19-30

Investigation of suspected legend drugs; records

Sec. 30. (a) Sections 16 and 20 of this chapter do not apply to the actions of a:

- (1) person who is employed or retained as an investigator by a pharmaceutical manufacturer described in subdivision (3);
- (2) practitioner; or
- (3) pharmaceutical manufacturer that is approved by the federal Food and Drug Administration;

performed in an investigation of a pharmaceutical manufacturer's legend drug that is suspected of being counterfeited, adulterated, or misbranded.

(b) A drug sample collected during an investigation described in subsection (a) may only be used for testing or a civil or criminal action. A drug sample collected during an investigation may not be resold or provided for human consumption.

(c) A pharmaceutical manufacturer that collects drug samples during an investigation described in subsection (a) shall:

- (1) maintain records of the drug samples; and
- (2) make these records available, at a reasonable time, to law enforcement agencies or the agencies' representatives in the enforcement of this chapter.

As added by P.L.48-2015, SEC.4.