

IC 16-42

ARTICLE 42. REGULATION OF FOOD, DRUGS, AND COSMETICS

IC 16-42-1

Chapter 1. Uniform Food, Drug, and Cosmetic Act: General Provisions

IC 16-42-1-1

Purpose of act

Sec. 1. (a) IC 16-42-1 through IC 16-42-4 are intended to safeguard the public health and promote the public welfare by protecting the:

- (1) consuming public from injury by product use; and
- (2) purchasing public from injury by merchandising deceit; flowing from intrastate commerce in food, drugs, devices, and cosmetics.

(b) IC 16-42-1 through IC 16-42-4 are intended to be uniform with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and with the Federal Trade Commission Act (15 U.S.C. 41 et seq.) to the extent they expressly outlaw the false advertisement of food, drugs, devices, and cosmetics.

(c) IC 16-42-1 through IC 16-42-4 thus promote uniformity of such statutes and their administration and enforcement throughout the United States.

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

IC 16-42-1-1.1

Duties of state veterinarian and state board of animal health

Sec. 1.1. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

As added by P.L.137-1996, SEC.68. Amended by P.L.2-2008, SEC.41.

IC 16-42-1-2

Authority to adopt certain federal regulations

Sec. 2. The purpose of IC 16-42-1 through IC 16-42-4 being to promote uniformity with the Federal Act, in safeguarding the public health and in promoting public welfare, the state department may adopt, insofar as applicable, the regulations promulgated under the Federal Act and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

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

IC 16-42-1-3

Adoption of regulations; notice and hearing

Sec. 3. Except to the extent that the state department adopts the applicable regulations promulgated by the federal security administrator under the Federal Act (21 U.S.C. 301 et seq.), the state department, before adopting a rule contemplated by section 6 or 9 of this chapter, IC 16-42-2-1, IC 16-42-2-3(11), IC 16-42-3-4(4), IC 16-42-3-4(6), IC 16-42-3-4(7), or IC 16-42-3-4(8) shall give appropriate notice of the proposal and of the time and place for a public hearing to be held as provided by law.

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

IC 16-42-1-4

Construction of act and rules

Sec. 4. IC 16-42-1 through IC 16-42-4 and rules adopted under those provisions shall, insofar as applicable, be interpreted and construed to effectuate the general purpose to enact state legislation uniform with the Federal Act (21 U.S.C. 301 et seq.).

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

IC 16-42-1-5

Federal agency references; successor agency

Sec. 5. Whenever this chapter refers to a department or an agency of the federal government, the term includes a department or an agency of the federal government to which the duties, powers, or functions are transferred or given.

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

IC 16-42-1-6

Registration of manufacturer, processor, repackager, or wholesale distributor; maintaining place of business in state

Sec. 6. (a) A manufacturer, processor, repackager, or wholesale distributor of food, drugs, or cosmetics who maintains a place of business in Indiana shall file with the state department, upon forms to be furnished by the state department, a written statement of the name and address of the owner, the character of the business, and the business address of each place of business in Indiana.

(b) A new place of business for the manufacture, processing, repacking, or wholesale distribution of food, drugs, or cosmetics may not be established in Indiana until the place of business has been registered as provided in this chapter.

(c) If ownership of a registered place of business changes, the new owner shall reregister the place of business before operating the same.

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

IC 16-42-1-7

Misleading advertising or labeling; evaluation of representations

Sec. 7. If:

- (1) an article is alleged to be misbranded because the labeling is misleading; or
- (2) an advertisement is alleged to be false because the advertisement is misleading;

in determining whether the labeling or advertisement is misleading, there shall be taken into account among other items not only representations made or suggested by statement, word, design, device, sound, or any combination of those methods, but also the extent to which the labeling or advertisement fails to reveal facts that are material in the light of representations or that are material with respect to consequences that may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement or under conditions of use that are customary or usual.

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

IC 16-42-1-8

Labeling requirements; visibility

Sec. 8. A labeling requirement under IC 16-42-1 through IC 16-42-4 is not considered to be complied with unless:

- (1) the word, statement, or other information appearing on the label also appears on the outside container or wrapper, if any, of the retail package of the article; or
- (2) the word, statement, or other information appearing on the label is easily seen through the outside container or wrapper.

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

IC 16-42-1-9

Advertisements; curative or therapeutic effect for certain diseases

Sec. 9. (a) This section does not apply to an advertisement that:

- (1) is disseminated only to members of the medical, dental, pharmaceutical, and other legally recognized professions dealing with the healing arts;
- (2) appears only in the scientific periodicals of those professions; or
- (3) is disseminated only for the purpose of public health education by persons not commercially interested in the sale of such drugs or devices.

(b) The advertisement of a drug or device that represents that the drug or device has any effect in:

albuminuria
appendicitis
arteriosclerosis
blood poison
bone disease

Bright's disease
carbuncles
cancer
cholecystitis
diabetes
diphtheria
dropsy
erysipelas
gallstones
heart and vascular diseases
high blood pressure
mastoiditis
measles
mumps
nephritis
otitis media
paralysis
pneumonia
poliomyelitis (infantile paralysis)
prostate gland disorders
pyelitis
scarlet fever
sexual impotence
sinus infection
smallpox
tuberculosis
tumors
typhoid
uremia
venereal disease
meningitis

is considered false for purposes of IC 35-43-5-3.

(c) Whenever the state department determines that an advance in medical science has made a type of self medication safe as to any of the diseases listed in this section, the state department shall adopt rules to authorize the advertisement of drugs having curative or therapeutic effect for the disease, subject to conditions and restrictions the state department considers necessary in the interests of public health.

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

IC 16-42-1-10

Samples or specimen; investigation and examination

Sec. 10. The state department shall cause the investigation and examination of food, drugs, devices, and cosmetics subject to IC 16-42-1 through IC 16-42-4. The state health commissioner or the commissioner's authorized representative may do the following:

(1) Take a sample or specimen of any such merchandise, for

examination under IC 16-42-1 through IC 16-42-4, upon tendering the market price to the person having the merchandise in custody.

(2) Enter any place, establishment, or vehicle in Indiana at reasonable times for the purpose of taking a sample or specimen of merchandise for examination.

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

IC 16-42-1-11

Inspection of records

Sec. 11. For the purpose of enforcing IC 16-42-1 through IC 16-42-4, pertinent records of an administrative agency of the state are open to inspection by the state health commissioner or the commissioner's authorized representative.

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

IC 16-42-1-12

Access to and copying of records; use of evidence

Sec. 12. (a) For the purpose of enforcing IC 16-42-1 through IC 16-42-4, carriers engaged in commerce, and persons receiving food, drugs, devices, or cosmetics in commerce or holding such articles so received shall, upon the request of an officer or employee designated by the state department, permit the officer or employee, at reasonable times, to have access to and to copy all records showing the movement in commerce of any food, drug, device, or cosmetic, or the holding of a food, drug, device, or cosmetic during or after the movement, and the quantity, shipper, and consignee of the food, drug, device, or cosmetic.

(b) It is unlawful for a carrier or person described in subsection (a) to fail to permit access to and copying of such records upon request if the request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which the request relates.

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

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

IC 16-42-1-13

Inspection of factories, warehouses, and vehicles

Sec. 13. For the purpose of enforcing IC 16-42-1 through IC 16-42-4, the state health commissioner or the commissioner's authorized representative may do the following:

(1) Enter, at reasonable times any factory, warehouse, place of production, or establishment subject to IC 16-42-1 through IC 16-42-4 or enter any vehicle being used to transport or hold food, drugs, devices, or cosmetics.

(2) Inspect at reasonable times, the factory, warehouse, place of

production, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, and advertisements.

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

IC 16-42-1-14

Report of judgments, orders, and decrees

Sec. 14. The state health commissioner or the commissioner's legally authorized agent may periodically publish reports summarizing all judgments, decrees, and court orders given under IC 16-42-1 through IC 16-42-4, including the nature of the charge and the disposition of the charge.

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

IC 16-42-1-15

Dissemination of information

Sec. 15. (a) The state health commissioner or the commissioner's legally authorized agent may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the state health commissioner or the commissioner's legally authorized agent, imminent danger to health or gross deception of, or fraud upon, the consumer.

(b) This section does not prohibit the state health commissioner or the commissioner's legally authorized agent from collecting, reporting, and illustrating the results of the commissioner's examinations and investigations under IC 16-42-1 through IC 16-42-4.

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

IC 16-42-1-16

Prohibited acts; defenses; injunctions

Sec. 16. (a) A person may not engage in any of the following acts:

- (1) The sale in intrastate commerce of a food, drug, device, or cosmetic that is adulterated or misbranded.
- (2) The adulteration or misbranding of a food, drug, device, or cosmetic in intrastate commerce.
- (3) The receipt in intrastate commerce of a food, drug, device, or cosmetic that is adulterated or misbranded, and the sale of those items in intrastate commerce for pay or otherwise.
- (4) The sale of any article in violation of section 6 of this chapter, IC 16-42-3-7, IC 16-42-3-8, IC 16-42-3-9, or IC 16-42-3-10.
- (5) The refusal to permit access to or copying of any record as required by section 12 of this chapter.
- (6) The refusal to permit entry or inspection and collecting of samples as authorized by section 10 or 13 of this chapter.
- (7) The use, without proper authority, of any mark, stamp, tag, label, or other identification device authorized or required by

rules adopted under this chapter or IC 16-42-2 through IC 16-42-4.

(8) The use by any person to the person's own advantage, or the revelation, other than to the state health commissioner or the state health commissioner's authorized representative or to the courts when relevant in any judicial proceeding, any information acquired under authority of section 13 of this chapter or IC 16-42-3-7 through IC 16-42-3-10 concerning any method or process that as a trade secret is entitled to protection.

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic if the act is done while the article is held for sale and results in the article being misbranded.

(10) The use on the labeling of any drug or in any advertising relating to the drug of any representation or suggestion that an application with respect to the drug is effective under IC 16-42-3-7 and IC 16-42-3-8 unless the drug complies with those sections.

(11) The removal or disposal of a detained or embargoed article in violation of this chapter.

(12) The giving of a guaranty or undertaking in intrastate commerce referred to in subsection (c) that is false.

(b) A person who violates subsection (a) commits a Class A misdemeanor. However, the offense is a Level 6 felony if the offense is committed with intent to defraud or mislead.

(c) It is a defense for a person accused of violating subsection (a)(1) or subsection (a)(3) if the person establishes a guaranty or undertaking signed by and containing the name and address of the person residing in the United States from whom the accused person received in good faith the article to the effect that the article is not adulterated or misbranded within the meaning of this article or the Federal Act.

(d) In addition to the remedies provided in this article, the state health commissioner or the commissioner's legally authorized agent may apply to the circuit or superior court for a temporary or permanent injunction restraining any person from violating any provision of this section.

As added by P.L.2-1993, SEC.25. Amended by P.L.158-2013, SEC.247.

IC 16-42-1-17

Schedule of civil penalties; order of compliance; consolidation of proceedings

Sec. 17. (a) In addition to the other remedies provided in this article, the state department shall adopt a schedule of civil penalties that may be levied to enforce the following:

(1) This chapter, IC 16-42-2-6, IC 16-42-2-7, and IC 16-42-18.

(2) The rules adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, and IC 16-42-18 by the state department.

(b) A penalty included in the schedule of civil penalties adopted under subsection (a) may not exceed one thousand dollars (\$1,000) for each violation per day.

(c) The state department may issue an order of compliance, impose a civil penalty included in the schedule of civil penalties adopted under subsection (a), or both, against a person who does any of the following:

(1) Fails to comply with this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18 or a rule adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(2) Interferes with or obstructs the state department in the performance of duties under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(d) An order of compliance may be issued under IC 4-21.5-3-6, IC 4-21.5-3-8, or IC 4-21.5-4. A civil penalty may be imposed only in a proceeding under IC 4-21.5-3-8.

(e) A proceeding commenced to impose a civil penalty may be consolidated with any other proceeding commenced to enforce any of the following:

(1) This chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

(2) A rule adopted under this chapter, IC 16-42-2-6, IC 16-42-2-7, or IC 16-42-18.

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

IC 16-42-1-18

Embargo or detention of adulterated or misbranded merchandise; tagging or marking

Sec. 18. (a) Whenever a duly authorized agent of the state department finds or has probable cause to believe that any food, drug, device, or cosmetic is:

(1) adulterated; or

(2) so misbranded as to be dangerous or fraudulent;

within the meaning of IC 16-42-1 through IC 16-42-4, the state health commissioner or the commissioner's legally authorized agent shall affix to the merchandise a tag or other appropriate marking as described in subsection (b).

(b) The tag or marking required in subsection (a) must do the following:

(1) Give notice that the merchandise is or is suspected of being adulterated or misbranded.

(2) Give notice that the merchandise has been detained or embargoed as follows:

(A) Five (5) days in the case of food.

(B) Ten (10) days in the case of drugs and cosmetics.

(3) Contain a warning to all persons not to remove or dispose of the merchandise by sale or otherwise until permission for

removal or disposal is given by the state department or the court.

(c) A person may not remove or dispose of detained or embargoed merchandise by sale or otherwise without permission of the state department or the court.

(d) The claimant may, under the supervision of the state department, destroy the detained merchandise.

(e) If the state department finds that merchandise that has been detained or embargoed is not adulterated or misbranded, the state department shall remove the tag or marking.

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

IC 16-42-1-19

Condemnation of detained or embargoed merchandise; petition

Sec. 19. (a) When merchandise detained or embargoed under section 18 of this chapter has been found by the state department to be adulterated or misbranded, the state department shall within five (5) days cause to be filed a petition in any circuit or superior court in whose jurisdiction the merchandise is detained or embargoed for condemnation of the merchandise as provided in this chapter.

(b) The proceedings shall be brought in the name of the state by the prosecuting attorney of the county in which a violation occurs against the merchandise, and the petition shall be verified by the state department. The petition must do the following:

- (1) Describe the merchandise.
- (2) State the location of the merchandise.
- (3) State the name of the person, firm, limited liability company, or corporation in actual possession.
- (4) State the name of the owner, if known, to the state department.
- (5) Allege the particular violation that is claimed to exist.
- (6) Otherwise conform to the requirements of a petition for condemnation of an adulterated or misbranded food, drug, device, or cosmetic in the United States courts.

As added by P.L.2-1993, SEC.25. Amended by P.L.8-1993, SEC.252.

IC 16-42-1-20

Seizure and destruction of embargoed or detained merchandise

Sec. 20. (a) Upon the filing of a petition for condemnation of an adulterated or misbranded food, drug, device, or cosmetic, the court shall promptly cause process to issue to the appropriate law enforcement agency commanding the law enforcement agency to seize the merchandise described in the court order and to hold the goods for further order of the court.

(b) The appropriate law enforcement agency shall, at the time of seizure of goods under this section, serve a copy of the process upon the owner of the merchandise.

(c) At the expiration of thirty (30) days after the seizure of merchandise under this section, if no claimant has appeared to

defend against the petition, the court shall order the appropriate law enforcement agency to destroy the seized merchandise.

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

IC 16-42-1-21

Filing of answer or demurrer

Sec. 21. A person:

(1) having an interest in the alleged adulterated or misbranded foods, drugs, devices, or cosmetics; or

(2) against whom a civil or criminal liability would exist if the merchandise is adulterated or misbranded;

may, at any time before destruction of the merchandise, appear and file answer or demurrer to the petition. Such appearance and answer or demurrer shall be filed in open court, or if in vacation, with the clerk or judge of the court. The answer or demurrer must allege the interest or liability of the party filing it. In all other respects, the issues shall be raised as in other civil actions.

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

IC 16-42-1-22

Rights of litigants

Sec. 22. The right of change of venue from the county, the right of change of judge, and the right of trial by jury are the same as in civil cases.

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

IC 16-42-1-23

Election to divide libeled merchandise into lots; dismissal as to particular lots; consent to destruction of particular lots

Sec. 23. (a) At any time before trial, the defense may file with the court a written election to divide into lots the merchandise that is alleged to be adulterated or misbranded. Each of the lots must be described in the written election in such a way as to enable them to be distinguished.

(b) If different parties are defending as to separate lots, the court shall proceed to docket as many separate actions as there are separate defendants.

(c) The state department may dismiss as to any lot without prejudice to the proceeding against all other lots in the same seizure. Those defending may consent to the destruction of any lot without prejudice to their right to defend against the condemnation of all other lots in the same seizure.

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

IC 16-42-1-24

Judgment

Sec. 24. The court or jury trying the cause shall determine and the judgment shall specify whether the contents of each separate lot are

adulterated or misbranded. The court shall order the destruction by the appropriate law enforcement agency of all lots found to be adulterated or misbranded and the return by the appropriate law enforcement agency of all lots not found to be adulterated or misbranded.

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

IC 16-42-1-25

Judgment for costs

Sec. 25. (a) A personal judgment may not be given against a defendant, except as provided in subsection (b).

(b) When merchandise is ordered destroyed, the court may give judgment against the defendant for that part of the costs occasioned by the defendant.

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

IC 16-42-1-26

Return of libeled merchandise; liability for damages

Sec. 26. (a) Whenever the court orders the return of merchandise, the appropriate law enforcement agency shall immediately return the merchandise to the place of seizure. The appropriate law enforcement agency and the appropriate law enforcement agency's bondsmen are liable for any damage to the merchandise while in the custody of the appropriate law enforcement agency if the damage was due to negligence, willfulness, or carelessness upon the part of the appropriate law enforcement agency or the appropriate law enforcement agency's agents.

(b) No subsequent proceeding in the cause or new trial may in any way involve any returned merchandise.

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

IC 16-42-1-27

New trial; appeal; appeal bond

Sec. 27. (a) A defendant may move for a new trial and may appeal to the supreme court or the court of appeals in the manner provided by law for appeals in civil actions.

(b) An appeal bond shall be fixed in an amount that covers the reasonable costs of preserving the condemned merchandise for the probable time of appeal and the court costs.

(c) If an appeal is not prosecuted to determination or if the judgment of the trial court is affirmed, the defendant bringing the appeal is liable for the following:

(1) The costs adjudged against the defendant or defendants in the trial court.

(2) The costs of appeal.

(3) The actual reasonable cost of preserving the condemned merchandise during the appeal period.

(d) The court of appeals and the supreme court shall dispose of

appeals brought under this chapter as speedily as possible with due regard to the rights of the parties involved.

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

IC 16-42-1-28

Judgment as evidence

Sec. 28. A judgment in a condemnation proceeding under this chapter is not admissible as evidence in any other legal proceeding.

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

IC 16-42-1-29

Costs not adjudicated against defendants

Sec. 29. All costs not adjudicated against the defendants in accordance with this chapter are to be determined and collected in the manner provided by law for the determination and collection of costs in unsuccessful criminal prosecutions.

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

IC 16-42-1-30

Libel for condemnation; procedure

Sec. 30. Except as otherwise provided in this chapter, the procedure for condemnation proceedings under this chapter must conform, as nearly as possible, to the procedure for civil actions.

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

IC 16-42-1-31

Destruction of adulterated or misbranded products; expenses

Sec. 31. (a) If the court finds that detained or embargoed merchandise is adulterated or misbranded, the merchandise must, after entry of the judgment or decree, be destroyed at the expense of the claimant, under the supervision of the state department.

(b) All:

- (1) court costs and fees; and
- (2) storage and other proper expenses;

shall be taxed against the claimant of the merchandise or the claimant's agent.

(c) If the adulteration or misbranding of merchandise can be corrected by proper labeling or processing of the merchandise, the court may order the merchandise to be delivered to the claimant for labeling or processing under the supervision of the state department under the following conditions:

- (1) After entry of the decree or judgment.
- (2) After costs, fees, and expenses have been paid.
- (3) After sufficient bond, conditioned that the merchandise be so labeled or processed, is executed.

The expense of the supervision of labeling and processing shall be paid by the claimant. The bond shall be returned to the claimant of the merchandise on representation to the court by the state health

commissioner or the commissioner's legally authorized agent that the merchandise no longer violates IC 16-42-1 through IC 16-42-4 and that the expenses of supervision by the state department have been paid.

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

IC 16-42-1-32

Notice and opportunity for hearing preceding criminal prosecution

Sec. 32. Before any violation of IC 16-42-1 through IC 16-42-4 is reported by the state health commissioner or the commissioner's authorized agent to a prosecuting attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views to the state health commissioner or the commissioner's authorized agent, either orally or in writing, with regard to the contemplated proceeding.

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

IC 16-42-1-33

Minor violations

Sec. 33. IC 16-42-1 through IC 16-42-4 does not require the state health commissioner or the commissioner's authorized agent to report, for the institution of proceedings under those provisions, minor violations of those provisions whenever the state health commissioner or the commissioner's legally authorized agent believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

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

IC 16-42-1-34

Chapter violations; offenses

Sec. 34. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

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

IC 16-42-2

Chapter 2. Uniform Food, Drug, and Cosmetic Act: Adulteration or Misbranding of Foods

IC 16-42-2-1

Conformity to federal standards and definitions; promotion of honesty and fair dealing; optional ingredients

Sec. 1. (a) Whenever any definitions or standard of identity, quality, or fill of container for any food or class of food are promulgated under authority of the Federal Act or the Federal Meat Inspection Act of 1907, as amended, the state department shall adopt definitions and standards for Indiana.

(b) Whenever, with regard to any other food or class of food, the state department finds that such action will promote honesty and fair dealing in the interest of consumers, the state department shall adopt rules establishing for any food or class of food:

- (1) a reasonable definition and standard of identity; and
- (2) a reasonable standard of quality and fill of container.

(c) In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the state department shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients required to be named on the label.

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

IC 16-42-2-1.1

Duties of state veterinarian and state board of animal health

Sec. 1.1. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

As added by P.L.137-1996, SEC.69. Amended by P.L.2-2008, SEC.42.

IC 16-42-2-2

Adulterated foods

Sec. 2. (a) A food is considered adulterated under any of the following conditions:

- (1) If the food bears or contains any poisonous or deleterious substance that may make the food injurious to health. However, if the substance is not an added substance, the food is not to be considered adulterated under this subdivision if the quantity of the substance in the food does not ordinarily make the food injurious to health.

- (2) If:
- (A) the food bears or contains any added poison or added deleterious substance (other than a poison or a deleterious substance that is a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive) that is unsafe within the meaning of section 5 of this chapter;
 - (B) the food is a raw agricultural commodity and the food bears or contains a pesticide chemical that is unsafe under section 5 of this chapter; or
 - (C) the food is or contains a food additive that is unsafe under section 5 of this chapter.

However, when a pesticide chemical is used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 5 of this chapter and the raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of the pesticide chemical remaining in or on the processed food, notwithstanding section 5 of this chapter and clause (C) is not considered unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the residues in the processed food, when ready to eat, is not greater than the tolerance prescribed for the raw agricultural commodity.

- (3) If the food consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance or if the food is otherwise unfit for food.
- (4) If the food has been produced, transported, handled, prepared, packed, or held under unsanitary conditions or in unsanitary containers as the result of which the food may have become contaminated with filth or made diseased, unwholesome, or injurious to health.
- (5) If the food is, in whole or in part, the product of:
 - (A) a diseased animal;
 - (B) an animal that has died otherwise than by slaughter; or
 - (C) an animal that has been fed upon the uncooked offal from a slaughterhouse.
- (6) If the food's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.
- (7) If the food has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a rule or an exemption in effect under section 5 of this chapter.
- (8) If any valuable constituent has been in whole or in part omitted or abstracted from the food.
- (9) If any substance has been substituted wholly or in part.
- (10) If damage or inferiority has been concealed in any manner.
- (11) If any substance has been added to the food or mixed or

packed with the food to:

- (A) increase the food's bulk or weight;
- (B) reduce the food's quality or strength;
- (C) make the food appear better or of greater value than the food is; or
- (D) create a deceptive appearance.

(12) If the food bears or contains a coal-tar color other than one from a batch that has been certified by the federal Food and Drug Administrator, as provided by regulations promulgated under authority of the Federal Act.

(13) If the food is a confectionery and has partially or completely imbedded in the food any nonnutritive object. However, this subdivision does not apply in the case of any nonnutritive object if, in the judgment of the state department as provided by rules, the nonnutritive object is of practical, functional value to the confectionery product and would not make the product injurious or hazardous to health.

(14) If the food is a confectionery and bears or contains any alcohol other than alcohol not in excess of one-half of one percent (0.5%) by volume derived solely from the use of flavoring extracts.

(15) If the food is a confectionery and bears or contains any nonnutritive substance. However, this subdivision does not apply to a safe, nonnutritive substance if:

(A) the nonnutritive substance is in or on a confectionery for a practical, functional purpose in the manufacture, packaging, or storing of the confectionery; and

(B) the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of IC 16-42-1 through IC 16-42-4. In addition, the state department may, for the purpose of avoiding or resolving uncertainty as to the application of this subdivision, adopt rules allowing or prohibiting the use of particular nonnutritive substances.

(16) If the food falls below the standard of purity, quality, or strength that the food purports or is represented to possess.

(17) If the food is or bears or contains any color additive that is unsafe under section 5 of this chapter.

(b) Subsection (a)(8) and (a)(9) do not prohibit:

- (1) the removal of butterfat from; or
- (2) the addition of skim milk to;

dairy products that comply with the definitions and standards for dairy products adopted by the state department.

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

IC 16-42-2-3

Misbranded foods

Sec. 3. A food is considered to be misbranded under any of the

following conditions:

- (1) If the food's labeling is false or misleading in any way.
- (2) If the food's labeling or packaging fails to conform with the rules adopted under IC 16-42-1-2.
- (3) If the food is offered for sale under the name of another food.
- (4) If the food is an imitation of another food, unless the food's label bears, in type of uniform size and prominence, the word "imitation" and, immediately following that term, the name of the food imitated.
- (5) If the food's container is so made, formed, or filled as to be misleading.
- (6) If the food is in package form, unless the food bears a label containing the following:
 - (A) The name and place of business of the manufacturer, packer, or distributor.
 - (B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, reasonable variations shall be permitted under this clause and exemptions for small packages shall be established by rules adopted by the state department.
- (7) If any word, statement, or other information required under IC 16-42-1 through IC 16-42-4 to appear on the label or labeling is not prominently placed on the food with the conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (8) If the food purports to be or is represented as a food for which a definition and standard of identity has been prescribed by rules under section 1 of this chapter, unless:
 - (A) the food conforms to that definition and standard; and
 - (B) the food's label bears the name of the food specified in the definition and standard, and, insofar as may be required by those rules, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food.

This subdivision with respect to artificial coloring does not apply to butter, cheese, or ice cream.

- (9) If the food purports to be or is represented as:
 - (A) a food for which a standard of quality has been prescribed by rules as provided by section 1 of this chapter and the food's quality falls below that standard, unless the label bears, in the manner and form as the rules specify, a statement that the food falls below that standard; or
 - (B) a food for which a standard or standards of fill of container have been prescribed by rule under section 1 of this chapter and the food falls below the applicable standard

of fill of container unless the food's label bears, in such manner and form as the rules specify, a statement that the food falls below that standard.

(10) If the food is not subject to subdivision (8), unless the food's label bears:

- (A) the common or usual name of the food, if any; and
- (B) if the food is fabricated from at least two (2) ingredients, the common or usual name of each ingredient. However, spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each. In addition, to the extent that compliance with this clause is impracticable or results in deception or unfair competition, the state department shall establish exemptions by rule.

This subdivision with respect to artificial coloring does not apply to butter, cheese, or ice cream.

(11) If the food purports to be or is represented to be for special dietary uses, unless the food's label bears information concerning the food's vitamin, mineral, and other dietary properties that the state department determines to be, and by rules prescribes as necessary to fully inform purchasers as to the food's value for such uses.

(12) If the food bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless the food bears labeling stating that fact. However, to the extent that compliance with the requirements of this subdivision is impracticable, the state department shall establish exemptions by rule. This subdivision:

- (A) with respect to artificial coloring, does not apply to butter, cheese, or ice cream; and
- (B) with respect to chemical preservatives, does not apply to a pesticide chemical when used in or on a raw agricultural commodity that is the product of the soil.

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

IC 16-42-2-4

Food in transit for repackaging or relabeling

Sec. 4. Food that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the food was originally processed or packed, is exempt from the affirmative labeling requirements of IC 16-42-1 through IC 16-42-4 while the food is in transit in intrastate commerce from one (1) establishment to the other, if such transit is made in good faith for completion purposes only. However, the food is otherwise subject to all the applicable provisions of IC 16-42-1 through IC 16-42-4.

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

IC 16-42-2-5

Poisonous or deleterious substances; regulations

Sec. 5. (a) Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, with respect to any particular use or intended use, are considered unsafe for the purpose of application of:

- (1) section 2(a)(2) of this chapter with respect to any food;
- (2) IC 16-42-3-3(1) through IC 16-42-3-3(5) with respect to any drug or device; or
- (3) IC 16-42-4-2(1) with respect to any cosmetic;

unless there is in effect a rule under IC 16-42-1-2 or this section limiting the quantity of the substance and unless the use or intended use of the substance conforms to the terms prescribed by rule. While the rules regarding the substance are in effect, a food, drug, or cosmetic is not, by reason of bearing or containing the substance in accordance with the rules, to be considered adulterated within the meaning of section 2(a)(1) of this chapter, IC 16-42-3-3(1) through IC 16-42-3-3(5), or IC 16-42-4-2(1).

(b) The state department may, whenever public health or other considerations in Indiana require and upon the state department's own motion or upon the petition of an interested party, adopt, amend, or repeal rules (whether or not in accordance with regulations promulgated under the Federal Act) that do the following:

- (1) Prescribe tolerances for any of the following:
 - (A) Any added, poisonous, or deleterious substances.
 - (B) Food additives.
 - (C) Pesticide chemicals in or on raw agricultural commodities.
 - (D) Color additives.

This includes zero tolerances and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities.

- (2) Prescribe the conditions under which a food additive or a color additive may be safely used and exemptions where the food additive or color additive is to be used solely for investigational or experimental purposes.

(c) It is incumbent upon an interested party who petitions that a rule be adopted under subsection (b) to establish, by data submitted to the state health commissioner or the commissioner's legally authorized agent, that:

- (1) a necessity exists for the rule; and
- (2) the rule's effect will not be detrimental to the public health.

(d) If the data furnished by an interested party who petitions that a rule be adopted under subsection (b) is not sufficient to allow the state department to determine whether the rule should be adopted, the state department may require additional data to be submitted. Failure to comply with such a request is sufficient grounds to deny

the request.

(e) In adopting, amending, or repealing rules regarding such substances, the state department shall consider, among other relevant factors, the following items that are required to be furnished by the interested party who petitions for the adoption of a rule, if any:

(1) The name and all pertinent information concerning the substance, including if available the following:

(A) The chemical identity and composition of the substance.

(B) A statement of the conditions of the proposed use, including directions, recommendations, and suggestions, and specimens of proposed labeling.

(C) All relevant data bearing on the physical or other technical effect and the quantity required to produce that effect.

(2) The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of that substance.

(3) The probable consumption of the substance in the diet of man and animals, taking into account any chemically or pharmacologically related substance in the diet.

(4) Safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the substances for the use for which the substances are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data.

(5) The availability of any needed practicable methods of analysis for determining the identity and quantity of the following:

(A) The substance in or on an article.

(B) Any substance formed in or on such article because of the use of that substance.

(C) The pure substance and all intermediates and impurities.

(6) Facts supporting a contention that the proposed use of the substance will serve a useful purpose.

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

IC 16-42-2-6

Unfit perishable articles; condemnation or destruction

Sec. 6. (a) Any dairy product, meat, meat product, seafood, poultry, confectionery, bakery product, vegetable, fruit, or other perishable article:

(1) that is unsound;

(2) that contains any filthy, decomposed, or putrid substance; or

(3) that may be poisonous or deleterious to health or otherwise unsafe;

constitutes a nuisance.

(b) Whenever the state health commissioner or the commissioner's authorized agent finds:

(1) in any room, building, vehicle of transportation, or other structure; or

(2) on any premises;

perishable food or a food product which constitutes a nuisance under this section, the state health commissioner or the commissioner's authorized agent shall condemn or destroy the food or food product or in any other manner make the food or food product unsaleable as human food.

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

IC 16-42-2-7

PCB contaminated livestock and poultry; indemnification

Sec. 7. (a) The state department shall indemnify livestock and poultry producers who, as a result of the direction of a state agency, are required after January 1, 1976, to remove livestock, livestock products, poultry, or poultry products of the producers from commercial markets because of contamination by polychlorinated biphenyls (PCB's).

(b) Indemnity may not be paid for any contamination that is the result of an intentional act of the livestock or poultry producer or that results from the continuous use of a known contaminated feed or water supply.

(c) Indemnity compensation shall be paid for losses incurred in the preceding calendar year and may not exceed eighty percent (80%) of the average commercial market value of the livestock, livestock product, poultry, or poultry product, less any indemnity received from another state or federal agency, for the period the producer is unable to sell the products. However, the aggregate indemnity compensation paid may not exceed the appropriation for any fiscal year.

(d) For purposes of this section, the commercial market value of livestock subject to indemnity compensation shall be determined as of the time of condemnation.

(e) The state department may adopt rules under IC 4-22-2 for the administration of this section.

(f) The state has the power of subrogation against any third party for indemnity amounts paid.

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

IC 16-42-2-8

Recipe or teaching adulteration or imitation of foods; offense

Sec. 8. A person who:

(1) knowingly sells, offers for sale, trades, or gives away a recipe or formula for the adulteration or imitation of food; or

(2) knowingly teaches or offers to teach any method or means of adulterating any article of food or means of producing or manufacturing any imitation of any article of food;

commits a Class B misdemeanor.

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

IC 16-42-2-9

Chapter violations; offenses

Sec. 9. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

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

IC 16-42-3

Chapter 3. Uniform Food, Drug, and Cosmetic Act: Adulteration and Misbranding of Drugs or Devices

IC 16-42-3-1

Antibiotic drug defined

Sec. 1. As used in this chapter, "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance that is produced by microorganisms and that has the capacity to inhibit or destroy microorganisms in dilute solution, including the chemically synthesized equivalent of the substance.

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

IC 16-42-3-2

Established name defined

Sec. 2. As used in this chapter, "established name", with respect to a drug or ingredient of a drug, means:

- (1) the applicable official name designated under Section 508 of the Federal Act;
- (2) if there is no official name and the drug or the ingredient is an article recognized in an official compendium, the official title of the drug or ingredient in the compendium; or
- (3) if neither subdivision (1) nor (2) applies, the common or usual name, if any, of the drug or the ingredient.

However, when subdivision (2) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia applies unless the article is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia applies.

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

IC 16-42-3-2.5

Duties of state veterinarian and state board of animal health

Sec. 2.5. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

As added by P.L.137-1996, SEC.70. Amended by P.L.2-2008, SEC.43.

IC 16-42-3-3

Adulterated drug or device

Sec. 3. A drug or device is considered to be adulterated under the

following conditions:

- (1) If the drug or device consists in whole or in part of any filthy, putrid, or decomposed substance.
- (2) If the drug or device has been produced, prepared, packed, or held under unsanitary conditions under which the drug or device may have been contaminated with filth or made injurious to health.
- (3) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that:
 - (A) the drug meets the requirements of this article as to safety; and
 - (B) the drug:
 - (i) has the identity and strength; and
 - (ii) meets the quality and purity characteristics;that the drug purports or is represented to possess.
- (4) If a drug's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.
- (5) If:
 - (A) a drug bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of IC 16-42-2-5; or
 - (B) a color additive, the intended use of which in or on drugs is for purposes of coloring only, is unsafe under IC 16-42-2-5.
- (6) If:
 - (A) the drug or device purports to be or is represented as a drug, the name of which is recognized in an official compendium; and
 - (B) the strength of the drug differs from or the drug's quality or purity falls below the standard set forth in that compendium;

the determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence or inadequacy of such tests or methods of assay, those tests or methods prescribed by the federal security administrator in regulations promulgated under the Federal Act. A drug defined in an official compendium is not considered to be adulterated under this subdivision because the drug differs from the standard of strength, quality, or purity set forth in the compendium if the drug's difference in strength, quality, or purity from the standard is plainly stated on the drug's label. If a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia unless the drug is labeled and

offered for sale as a homeopathic drug. In the latter case, the drug is subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(7) If:

(A) the drug or device is not subject to the provisions of subdivision (6); and

(B) the drug's or device's strength differs from or the drug's or device's purity or quality falls below that which the drug or device purports or is represented to possess.

(8) If the drug or device is a drug and any substance has been:

(A) mixed or packed with the drug or device so as to reduce the drug's or device's quality or strength; or

(B) substituted wholly or in part for the drug.

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

IC 16-42-3-4

Misbranded drug or device

Sec. 4. A drug or device is considered to be misbranded under any of the following conditions:

(1) If the labeling of the drug or device is false or misleading in any way.

(2) If the drug or device is in package form unless the drug or device bears a label containing:

(A) the name and place of business of the manufacturer, packer, or distributor; and

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

However, under clause (B) reasonable variations shall be permitted and exemptions as to small packages shall be established by rules adopted by the state department.

(3) If any word, statement, or other information required to appear on the label or labeling, under this chapter or a rule adopted under IC 16-42-1-2 is not prominently placed on the drug or device with conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the label likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If the drug or device:

(A) is for use by humans; and

(B) contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, methamphetamine, or sulphonmethane, or any chemical derivative of such substance, which derivative after investigation has been found to be and is designated as habit

forming, by rules adopted by the state department under IC 16-42-1 through IC 16-42-4 or by regulations issued under 21 U.S.C. 352(d);

unless the label on the drug or device bears the name and quantity or proportion of that substance or derivative and the statement "Warning – May Be Habit Forming".

(5) If a drug, unless the following conditions are met:

(A) The label on the drug bears, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula, the following:

(i) The established name of the drug, if any.

(ii) If the drug is fabricated from at least two (2) ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of those substances contained in the drug. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, applies only to prescription drugs.

(B) If a prescription drug, the established name of the drug or ingredient on the label (and on any labeling on which a name for the drug or ingredient is used) is printed prominently and in type at least half as large as that used for any proprietary name or designation for the drug or ingredient.

However, to the extent that compliance with the requirements of clause (A)(ii) or clause (B) is impracticable, exemptions shall be allowed under rules adopted by the state department or by regulations promulgated under the Federal Act.

(6) Unless the drug's or device's labeling bears:

(A) adequate directions for use; and

(B) adequate warnings against use in those pathological conditions or by children where the drug's or device's use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in the manner and form that is necessary for the protection of users.

However, if any requirement of clause (A) as applied to any drug or device is not necessary for the protection of the public health, the state department shall adopt rules exempting the drug or device from that requirement.

(7) If a drug purports to be a drug the name of which is

recognized in an official compendium, unless the drug is packaged and labeled as prescribed in the compendium. However, the method of packing may be modified with the consent of the state department in accordance with regulations promulgated by the federal security administrator under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless the drug is labeled and offered for sale as a homeopathic drug. In that case the drug is subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia.

(8) If a drug or device has been found by the federal security administrator or the state department to be a drug liable to deterioration, unless the drug or device is packaged in a form and manner and the drug's or device's label bears a statement of such precautions as the federal security administrator or the state department requires by rule or regulation as necessary for the protection of the public health. A rule or regulation may not be established for any drug recognized in an official compendium until the federal security administrator or the state department informs the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body fails within a reasonable time to prescribe requirements.

(9) If a drug's container is made, formed, or filled as to be misleading.

(10) If a drug is an imitation of another drug.

(11) If a drug is offered for sale under the name of another drug.

(12) If a drug is or purports to be or is represented to be a drug composed wholly or partly of insulin, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 506 of the Federal Act; and

(B) the certificate or release is in effect with respect to the drug.

(13) If a drug is or purports to be or is represented to be a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative of those drugs, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 507 of the Federal Act; and

(B) the certificate or release is in effect with respect to that drug.

However, this subdivision does not apply to any drug or class

of drugs exempted by regulations promulgated under Section 507(c) or 507(d) of the Federal Act.

(14) If a drug or device is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug or device.

(15) Under the conditions described in section 6 of this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.17-2001, SEC.3.

IC 16-42-3-5

Exemption of drugs or devices in transit for further processing, labeling, or repackaging

Sec. 5. A drug or device that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the drug or device was originally processed or packed, is exempt from the labeling and packaging requirements of IC 16-42-1 through IC 16-42-4 while the drug or device is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only. However, the drug or device is otherwise subject to the applicable provisions of IC 16-42-1 through IC 16-42-4.

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

IC 16-42-3-6

Drugs dispensed on prescription

Sec. 6. (a) This section applies to a drug intended for use by humans that:

(1) is a habit forming drug to which section 4(4) of this chapter applies;

(2) because of:

(A) the drug's toxicity or other potential for harmful effect;

(B) the method of the drug's use; or

(C) the collateral measures necessary to the drug's use;

is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(3) is limited by an approved application under Section 505 of the Federal Act or section 7 or 8 of this chapter to use under the professional supervision of a practitioner licensed by law to administer the drug.

(b) A drug described in subsection (a) may be dispensed only:

(1) upon a written or an electronically transmitted prescription of a practitioner licensed by law to administer the drug;

(2) upon an oral prescription of the practitioner that is reduced promptly to writing and filed by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2); or

(3) by refilling a prescription if the refilling is authorized by the prescriber either in the original prescription, by an

electronically transmitted order that is recorded in an electronic format, or by oral order that is reduced promptly to writing or is entered into an electronic format and filed by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2).

(c) If a prescription for a drug described in subsection (a) does not indicate how many times the prescription may be refilled, if any, the prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

(d) The act of dispensing a drug contrary to subsection (a), (b), or (c) is considered to be an act that results in a drug being misbranded while held for sale.

(e) A drug dispensed by filling or refilling a prescription of a practitioner licensed by law to administer the drug is exempt from the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6), 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing the following:

- (1) The name and address of the dispenser.
- (2) The serial number and date of the prescription or of the prescription's filling.
- (3) The name of the drug's prescriber and, if stated in the prescription, the name of the patient.
- (4) The directions for use and cautionary statements, if any, contained in the prescription.

This exemption does not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of subsection (a), (b), (c), or (d).

(f) The state department may adopt rules to remove drugs subject to section 4(4) of this chapter, section 7 of this chapter, or section 8 of this chapter from the requirements of subsections (a) through (d) when the requirements are not necessary for the protection of public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued under the Federal Act may also, by rules adopted by the state department, be removed from the requirement of subsections (a) through (d).

(g) A drug that is subject to subsections (a) through (d) is considered to be misbranded if at any time before dispensing the drug's label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsections (a) through (d) do not apply is considered to be misbranded if, at any time before dispensing, the drug's label bears the caution statement described in this subsection.

(h) This section does not relieve a person from a requirement prescribed by or under authority of law with respect to drugs included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

(i) A drug may be dispensed under subsection (b) upon an

electronically transmitted prescription only to the extent permitted by federal law.

As added by P.L.2-1993, SEC.25. Amended by P.L.144-1996, SEC.12; P.L.204-2005, SEC.4.

IC 16-42-3-7

New drugs; federal qualification; testing; application to introduce drug

Sec. 7. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) A person may not sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce any new drug unless:

- (1) an application to sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce a new drug has been approved and the approval has not been withdrawn under Section 505 of the Federal Act; or
- (2) if not subject to the Federal Act the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling of the drug.

(c) Before selling or offering for sale the new drug, there must be filed with the state department an application setting forth the following:

- (1) Full reports of investigations that have been made to show whether or not the drug is safe for use and whether the drug is effective in use.
- (2) A full list of the articles used as components of the drug.
- (3) A full statement of the composition of the drug.
- (4) A full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drug.
- (5) Such samples of the drug and of the articles used as components of the drug that the state department requires.
- (6) Specimens of the labeling proposed to be used for the drug.

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

IC 16-42-3-8

New drugs; time for application to take effect

Sec. 8. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) An application provided for under section 7 of this chapter becomes effective on the one hundred eightieth day after the filing of the application. However, if the state department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing that:

- (1) the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the

proposed labeling of the drug;

(2) the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drugs are inadequate to preserve the drug's identity, strength, quality, and purity; or

(3) based on a fair evaluation of all material facts, that the labeling is false or misleading in any particular;

the state department shall, before the effective date of the application, issue an order refusing to permit the application to become effective.

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

IC 16-42-3-9

New drugs; exemption

Sec. 9. (a) Sections 7 and 8 of this chapter do not apply to the following:

(1) To a drug dispensed on a written or an electronically transmitted prescription signed by or with an electronic signature of a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail) if the physician, dentist, or veterinarian is licensed by law to administer the drug, and the drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, and the name of the physician, dentist, or veterinarian.

(2) To a drug exempted by rule of the state department and that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

(3) To a drug sold in Indiana or introduced into intrastate commerce at any time before the enactment of the Federal Act, if the drug's labeling contained the same representations concerning the conditions of the drug's use.

(4) To any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.).

(5) To a drug subject to section 4(10) of this chapter.

(b) Rules exempting drugs intended for investigational use under subsection (a)(2) may, within the discretion of the state department among other conditions relating to the protection of the public health, provide for conditioning the exemption upon the following:

(1) The submission to the state department, before any clinical testing of a new drug is undertaken, of reports by the manufacturer or the sponsor of the investigation of the drug or preclinical tests, including tests on animals, of the drug adequate to justify the proposed clinical testing.

(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of the investigators that patients to whom the drug is administered will be under the manufacturer's or sponsor's personal supervision or under the supervision of investigators responsible to the manufacturer or sponsor and that the manufacturer or sponsor will not supply the drug to any other investigator or to clinics for administration to human beings.

(3) The establishment and maintenance of the records and the making of the reports to the state department by the manufacturer or the sponsor of the investigation of the drug of data (including analytical reports by investigators) obtained as the result of the investigational use of the drug that the state department finds will enable the state department to evaluate the safety and effectiveness of the drug if an application is filed under section 8 of this chapter.

(c) Rules exempting drugs intended for investigational use under subsection (a)(2) must provide that the exemption is conditioned upon the manufacturer or the sponsor of the investigation requiring that experts using the drugs for investigational purposes certify to the manufacturer or sponsor that the experts will inform any human beings to whom the drugs or any controls used in connection with the drugs are being administered that the drugs are being used for investigational purposes and will obtain the consent of the human beings or their representatives, except where they consider it not feasible or, in their professional judgment, contrary to the best interests of the human beings.

(d) This section does not require a clinical investigator to submit directly to the state department reports on the investigational use of drugs. The regulations adopted under Section 505(i) of the Federal Act are the rules in Indiana. The state may adopt rules, whether or not in accordance with regulations promulgated under the Federal Act.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.5.

IC 16-42-3-10

New drugs; revocation of order refusing application to take effect; revocation of approved application

Sec. 10. (a) An order refusing to permit an application under section 7 or 8 of this chapter to become effective may be revoked by the state department.

(b) The state department may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved under section 7 or 8 of this chapter if the state department finds any of the following:

(1) That the drug, based on evidence acquired after approval, may not be safe or effective for the intended use.

(2) That the facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.

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

IC 16-42-3-11

Representation of antiseptic

Sec. 11. The representation of a drug in the labeling or advertisement as an antiseptic is considered to be a representation that the drug is a germicide, except if a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involves prolonged contact with the body.

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

IC 16-42-3-12

Violation of chapter; offenses

Sec. 12. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

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

IC 16-42-4

Chapter 4. Uniform Food, Drug, and Cosmetic Act: Adulteration or Misbranding of Cosmetics

IC 16-42-4-1

Hair dye defined

Sec. 1. As used in this chapter, "hair dye" does not include eyelash dyes or eyebrow dyes.

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

IC 16-42-4-1.1

Duties of state veterinarian and state board of animal health

Sec. 1.1. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

As added by P.L.137-1996, SEC.71. Amended by P.L.2-2008, SEC.44.

IC 16-42-4-2

Adulterated cosmetics

Sec. 2. A cosmetic is considered to be adulterated under the following conditions:

(1) If the cosmetic bears or contains a poisonous or deleterious substance that may make the cosmetic injurious to users under the conditions of use prescribed in the labeling of the cosmetic or under the conditions of use that are customary or usual. However this subdivision does not apply to coal-tar hair dye if the following conditions are met:

(A) The label on the dye conspicuously displays the following message:

"Caution – This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

(B) The labeling contains adequate directions for preliminary testing.

(2) If the cosmetic consists in whole or in part of a filthy, putrid, or decomposed substance.

(3) If the cosmetic has been prepared, packed, or held under unsanitary conditions as the result of which the cosmetic may have become contaminated with filth or as the result of which the cosmetic may have been made injurious to health.

(4) If the container of the cosmetic is composed in whole or in part of a poisonous or deleterious substance that may make the contents injurious to health.

(5) If the cosmetic is not a hair dye and the cosmetic is, bears, or contains a color additive that is unsafe under IC 16-42-2-5.

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

IC 16-42-4-3

Misbranded cosmetics

Sec. 3. A cosmetic is considered to be misbranded under the following conditions:

(1) If the cosmetic's labeling is false or misleading in any way.

(2) If the cosmetic is in package form unless the cosmetic bears a label containing the following:

(A) The name and place of business of the manufacturer, packer, or distributor.

(B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

However, reasonable variations are permitted under clause (B) and exemptions for small packages shall be established by rules adopted by the state department.

(3) If a word, statement, or other information required by this chapter or a rule adopted under IC 16-42-1-2 to appear on the label or labeling is not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to make the label or labeling likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If the container of the cosmetic is so made, formed, or filled as to be misleading.

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

IC 16-42-4-4

Cosmetics in transit for processing, labeling, or repacking; exemption

Sec. 4. A cosmetic that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the cosmetic was originally processed or packed is exempt from the affirmative labeling requirements of IC 16-42-1 through IC 16-42-4 while the cosmetic is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only, but the cosmetic is otherwise subject to all the applicable provisions of IC 16-42-1 through IC 16-42-4.

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

IC 16-42-4-5

Chapter violations; offenses

Sec. 5. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.
As added by P.L.2-1993, SEC.25.

IC 16-42-5

Chapter 5. Food: Sanitary Requirements for Food Establishments

IC 16-42-5-0.1

Application of certain amendments to chapter

Sec. 0.1. The amendments made to section 28 of this chapter by P.L.266-2001 apply to violations that occur after June 30, 2001.

As added by P.L.220-2011, SEC.322.

IC 16-42-5-0.3

Initial schedule of civil penalties; rules; enforcement of previously adopted local penalties

Sec. 0.3. (a) The state department of health may adopt rules establishing the initial schedule of civil penalties required under section 28 of this chapter, as added by P.L.266-2001, at any time after May 11, 2001, in the manner provided for the adoption of emergency rules under IC 4-22-2-37.1. An emergency rule adopted under this section expires on the later of:

- (1) the date permanent rules are adopted to replace the emergency rules; or
- (2) July 1, 2003.

(b) A corporation or local health department that, before January 1, 2001, adopted monetary penalties for the violation of any state or local law or rule concerning food handling or food establishments may continue to enforce those locally prescribed monetary penalties (including the issuance of tickets or citations authorized by local law) and deposit the amounts collected as prescribed by local law until the later of:

- (1) the date permanent rules are adopted establishing the schedule of civil penalties required under section 28 of this chapter, as added by P.L.266-2001; or
- (2) July 1, 2003.

As added by P.L.220-2011, SEC.323.

IC 16-42-5-0.4

Enforcement of local standards for food handling or food establishments

Sec. 0.4. A corporation or local health department that, before January 1, 2001, adopted sanitary standards for food handling or food establishments that are different from the state rules concerning sanitary standards for food handling or food establishments may continue to enforce those locally prescribed sanitary standards until the later of:

- (1) the date that the state department adopts rules to modify or replace the state department's rules that were in effect on January 1, 2001, concerning sanitary standards for food handling or food establishments; or

(2) July 1, 2003.
As added by P.L.220-2011, SEC.324.

IC 16-42-5-0.5

Local standards or penalties regarding food handling or food establishments precluded

Sec. 0.5. Except as provided in this chapter, a corporation or local health department may not impose any:

- (1) sanitary standards on; or
- (2) locally prescribed monetary penalties for the violation of any state law or rule concerning; food handling or food establishments.

As added by P.L.266-2001, SEC.9.

IC 16-42-5-0.7

Local standards regarding food handling machinery precluded

Sec. 0.7. (a) Except as provided in this chapter, a corporation or local health department may not impose any requirements or standards on the installation of food handling machinery in a food establishment regulated by this chapter.

(b) The installation of food handling machinery includes all activities associated with the machinery's installation, including the wiring, plumbing, air handling, and all other processes.

(c) This section does not limit the authority of the state fire marshal or other state agencies to regulate food establishments.

(d) This section does not limit the authority of a corporation or local health department to enforce requirements or standards established by state law or the state department for the installation of food handling machinery.

As added by P.L.266-2001, SEC.10. Amended by P.L.1-2006, SEC.306.

IC 16-42-5-0.9

Petitions for changes in rules

Sec. 0.9. (a) A corporation or local health department may petition the state department requesting one (1) or more modifications or changes in the state department's rules concerning:

- (1) food handling machinery;
 - (2) sanitary standards for food handling or food establishments;
- or
- (3) civil penalties authorized under IC 16-42-5-28.

(b) Following the receipt of a petition described in subsection (a), the state department shall hold a public hearing concerning the corporation or local health department's requested modifications or changes and shall determine in writing whether to adopt rules under IC 4-22-2 to modify or change the state department's rules.

As added by P.L.266-2001, SEC.11.

IC 16-42-5-1

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.266-2001, SEC.17.)

IC 16-42-5-2

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.266-2001, SEC.17.)

IC 16-42-5-2.3

Food handling machinery defined

Sec. 2.3. As used in this chapter, "food handling machinery" means any of the following used for and in food handling:

- (1) Equipment.
- (2) Appliances.
- (3) Tools.
- (4) Plumbing and related fixtures.
- (5) Refrigeration devices.
- (6) Heating, ventilation, and cooling equipment.
- (7) Any other piece of equipment used for and in food handling.

As added by P.L.266-2001, SEC.12.

IC 16-42-5-3

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.266-2001, SEC.17.)

IC 16-42-5-4

Repealed

(As added by P.L.2-1993, SEC.25. Amended by P.L.192-2002(ss), SEC.159; P.L.138-2006, SEC.11. Repealed by P.L.100-2007, SEC.2.)

IC 16-42-5-5

Rules

Sec. 5. The state department may adopt rules under IC 4-22-2 for the efficient enforcement of this chapter and to establish minimum sanitary standards for the operation of all food establishments.

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

IC 16-42-5-5.2

Variances from rules

Sec. 5.2. The state department may grant a variance from one (1) or more of the state rules concerning:

- (1) food handling machinery; or
- (2) sanitary standards for the operation of food establishments;

in accordance with IC 16-19-3-4.3.

As added by P.L.266-2001, SEC.13.

IC 16-42-5-6**Conditions of health and comfort**

Sec. 6. A food establishment must meet the following conditions:

- (1) Be adequately lighted, heated, drained, and ventilated.
- (2) Be supplied with uncontaminated running water.
- (3) Have adequate sanitary facilities.

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

IC 16-42-5-7**Construction to facilitate cleanliness**

Sec. 7. Each food establishment and the machinery used in each food establishment must be constructed so as to be easily and thoroughly cleaned.

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

IC 16-42-5-8**Cleanliness and sanitation of premises and vehicles**

Sec. 8. The floors, sidewalls, ceiling, furniture, receptacles, implements, and machinery of a food establishment and a vehicle used to transport food products must at all times be clean and sanitary.

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

IC 16-42-5-9**Walls and ceilings; construction; washing**

Sec. 9. (a) The sidewalls, woodwork, and ceiling of a food establishment must be made of an impervious material with a finish that is washable.

(b) The sidewalls, woodwork, and ceiling must be kept washed clean with detergent and water.

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

IC 16-42-5-10**Floors; construction; washing**

Sec. 10. (a) The floor of a food establishment must be made of nonabsorbent material that can be flushed with water.

(b) The floor of a food establishment must be kept washed clean with detergent and water.

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

IC 16-42-5-11**Domestic animals; rodents; insects**

Sec. 11. A food establishment must be protected by all reasonable means against the presence of and entrance of domestic animals, rodents, flies, and other insects.

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

IC 16-42-5-12

Garbage removal

Sec. 12. Refuse, dirt, and waste products subject to decomposition and fermentation incident to food handling shall be removed daily from food establishments.

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

IC 16-42-5-13**Toilet room**

Sec. 13. (a) A food establishment must have a convenient toilet room separate and apart from and not opening directly into a room that is used for food handling.

(b) The floor of the toilet room must be made of a nonabsorbent material.

(c) The floor of the toilet room shall be washed and scoured daily.

(d) Each toilet fixture and each toilet room must be adequately ventilated.

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

IC 16-42-5-14**Washrooms**

Sec. 14. (a) A food establishment must have a washroom adjacent to each toilet room.

(b) The washroom shall be supplied with adequate lavatories, soap, hot and cold running water, and clean individual towels.

(c) The washroom shall be kept clean by washing with detergent and water.

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

IC 16-42-5-15**Food handling rooms; exclusive use**

Sec. 15. A room that is used for food handling or that is equipped for use for food handling may not be used for any other purpose.

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

IC 16-42-5-16**Dressing rooms**

Sec. 16. (a) Rooms separate and apart from rooms used for food handling must be provided for the changing and hanging of wearing apparel.

(b) The rooms for changing and hanging wearing apparel must be kept clean.

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

IC 16-42-5-17**Expectorating**

Sec. 17. A person may not expectorate in or on the machinery, equipment, floor, sidewalls, or other structure of a food establishment.

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

IC 16-42-5-18

Sleeping in food handling rooms

Sec. 18. A person may not live or sleep in a room used for food handling or in a room opening directly into a food establishment.

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

IC 16-42-5-19

Diseases; employees

Sec. 19. A person who has a communicable or infectious disease may not work in a food establishment in any capacity in which epidemiological evidence indicates the person may spread the disease.

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

IC 16-42-5-20

Wearing apparel; employees

Sec. 20. A person shall wear clean outer garments while working in a food establishment.

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

IC 16-42-5-21

Washing; employees

Sec. 21. A person who works in a food establishment shall wash the person's hands and arms thoroughly with soap and clean water before beginning work, before resuming work after a rest period, and before resuming work after visiting a toilet room.

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

IC 16-42-5-22

Sitting or lying on food handling equipment

Sec. 22. A person may not sit or lie upon equipment used or installed for use in handling food.

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

IC 16-42-5-23

Inspections

Sec. 23. The state department may do the following:

(1) Enter at any time a food establishment or place suspected of being a food establishment.

(2) Inspect the premises, utensils, fixtures, equipment, furniture, and machinery used in food handling.

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

IC 16-42-5-24

Local health officers

Sec. 24. (a) For the purpose of enforcing IC 16-41-20,

IC 16-41-23, IC 16-41-24, IC 16-41-34, or IC 16-42-5, the local health officers are food environmental health specialists subordinate to the state department.

(b) The state department shall provide to the local health officers who are food environmental health specialists guidelines concerning the interpretation of the state department's rules concerning food handling and food establishments so that enforcement of the state laws and rules is uniform throughout the state.

As added by P.L.2-1993, SEC.25. Amended by P.L.137-1996, SEC.72; P.L.144-1996, SEC.13; P.L.266-2001, SEC.14; P.L.104-2003, SEC.7; P.L.86-2015, SEC.2.

IC 16-42-5-25

Prosecution of violators; orders to abate condition or violation

Sec. 25. If, upon inspection of a food establishment, a local health officer or food environmental health specialist finds an employer, operator, or other employee to be violating IC 16-41-20, IC 16-41-23, IC 16-41-24, IC 16-41-34, or this chapter, the local health officer or food environmental health specialist shall do at least one (1) of the following:

(1) Furnish evidence of the violation to the prosecuting attorney of the county or circuit in which the violation occurs. The prosecuting attorney shall prosecute all persons violating IC 16-41-20, IC 16-41-23, IC 16-41-24, IC 16-41-34, or this chapter, or rules adopted under those provisions.

(2) Report the condition and violation to the state health commissioner or the commissioner's legally authorized agent. The state health commissioner may issue an order to the person in authority at the offending establishment to abate the condition or violation within five (5) days or within another reasonable time required to abate the condition or violation. The proceedings to abate must be in accordance with IC 4-21.5.

As added by P.L.2-1993, SEC.25. Amended by P.L.137-1996, SEC.73; P.L.144-1996, SEC.14; P.L.104-2003, SEC.8; P.L.1-2009, SEC.118; P.L.86-2015, SEC.3.

IC 16-42-5-26

Noncompliance with order or requirement; offenses

Sec. 26. (a) A person who refuses to comply with a lawful order or requirement of the state health commissioner made in writing as provided in this chapter commits a Class B misdemeanor.

(b) Each day after the expiration of the time limit for abating unsanitary conditions and completing improvements to abate the conditions as ordered by the state health commissioner constitutes a separate offense.

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

IC 16-42-5-27

Violations of chapter; offenses

Sec. 27. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.
As added by P.L.2-1993, SEC.25.

IC 16-42-5-28

Civil penalties

Sec. 28. (a) The state department shall adopt rules under IC 4-22-2 establishing a schedule of civil penalties that may be imposed by the state department to enforce either of the following:

(1) This chapter.

(2) Rules adopted to implement this chapter.

(b) A penalty included in the schedule of civil penalties established under this section may not exceed one thousand dollars (\$1,000) for each violation per day.

(c) The civil penalties collected under this section shall be deposited in the state general fund.

(d) The state department may issue an order of compliance or impose a civil penalty included in the schedule of civil penalties established under this section, or both, against a person who does any of the following:

(1) Fails to comply with this chapter or a rule adopted to implement this chapter.

(2) Interferes with or obstructs the state department or the state department's designated agent in the performance of duties under this chapter.

(e) The state department may issue an order of compliance against a person described in subsection (d) under IC 4-21.5-3-6, IC 4-21.5-3-8, or IC 4-21.5-4. The state department may impose a civil penalty against a person described in subsection (d) only in a proceeding under IC 4-21.5-3-8.

(f) A proceeding commenced to impose a civil penalty under the schedule of civil penalties established under this section may be consolidated with any other proceeding commenced to enforce either of the following:

(1) This chapter.

(2) A rule adopted by the state department to implement this chapter.

(g) A corporation or a local health department:

(1) may bring an administrative action to enforce this chapter, rules adopted to implement this chapter, or the schedule of civil penalties established by the state department under this section;

(2) may use tickets or citations to enforce this chapter, rules adopted under this chapter, or the schedule of civil penalties established by the state department under this section; and

(3) shall deposit in the general fund of the corporation or the

local health department the civil penalties collected under this section.

(h) For each violation of the state law or rules concerning food handling or food establishments, the state or either:

- (1) a corporation; or
- (2) a local health department;

may bring an enforcement action against a food establishment.

As added by P.L.266-2001, SEC.15. Amended by P.L.97-2004, SEC.70.

IC 16-42-5-29

Exemption from food establishment requirements; standards for farmers markets and roadside stands; samples; health hazards; distribution of poultry products and rabbit meat

Sec. 29. (a) Except as provided in subsection (h), this section applies to an individual vendor of a farmers market or roadside stand.

(b) As used in this section, "end consumer" means a person who is the last person to purchase any food product and who does not resell the food product.

(c) An individual vendor of a farmers market or roadside stand is not considered to be a food establishment and is exempt from the requirements of this title that apply to food establishments if the individual vendor's food product:

- (1) is made, grown, or raised by an individual at the individual's primary residence, property owned by the individual, or property leased by the individual;
- (2) is not a potentially hazardous food product;
- (3) is prepared by an individual who practices proper sanitary procedures, including:
 - (A) proper hand washing;
 - (B) sanitation of the container or other packaging in which the food product is contained; and
 - (C) safe storage of the food product;
- (4) is not resold; and
- (5) includes a label that contains the following information:
 - (A) The name and address of the producer of the food product.
 - (B) The common or usual name of the food product.
 - (C) The ingredients of the food product, in descending order by predominance by weight.
 - (D) The net weight and volume of the food product by standard measure or numerical count.
 - (E) The date on which the food product was processed.
 - (F) The following statement in at least 10 point type: "This product is home produced and processed and the production area has not been inspected by the state department of health."

(d) An individual vendor who meets the requirements in

subsection (c) is subject to food sampling and inspection if:

(1) the state department determines that the individual vendor's food product is:

(A) misbranded under IC 16-42-2-3; or

(B) adulterated; or

(2) a consumer complaint has been received by the state department.

(e) If the state department has reason to believe that an imminent health hazard exists with respect to an individual vendor's food product, the state department may order cessation of production and sale of the food product until the state department determines that the hazardous situation has been addressed.

(f) For purposes of this section, the state health commissioner or the commissioner's authorized representatives may take samples for analysis and conduct examinations and investigations through any officers or employees under the state health commissioner's supervision. Those officers and employees may enter, at reasonable times, the facilities of an individual vendor and inspect any food products in those places and all pertinent equipment, materials, containers, and labeling.

(g) The state health commissioner may develop guidelines for an individual vendor who seeks an exemption from regulation as a food establishment as described in subsection (c). The guidelines may include:

(1) standards for best safe food handling practices;

(2) disease control measures; and

(3) standards for potable water sources.

(h) The department shall exclude from the definition of food establishment the sale of products described in subsection (i):

(1) by an individual vendor of a farmers market or roadside stand; and

(2) by a farmer selling directly to the end consumer on the farm where the product is produced and through delivery to the end consumer.

(i) Subsection (h) applies to the distribution of the following products:

(1) Poultry products produced under IC 15-17-5-11. Poultry products sold at a farmers market or roadside stand must be frozen at the point of sale. Poultry products sold on the farm where the product is produced must be refrigerated at the point of sale and through delivery.

(2) Rabbits that are slaughtered and processed on a farm for the purpose of conducting limited sales on the farm, at a farmers market, and at a roadside stand. Rabbit meat sold at a farmers market or roadside stand must be frozen at the point of sale. Rabbit meat sold on the farm where the product is produced must be refrigerated at the point of sale and through delivery.

Subsection (h) does not apply to the distribution of meat from a game

animal.

(j) An individual vendor of a farmers market or roadside stand that sells eggs that meet the requirements under IC 16-42-11 is not considered to be a food establishment and is exempt from the requirements of this title that apply to a food establishment relating to the sale of eggs.

(k) Notwithstanding any other law, a local unit of government (as defined in IC 14-22-31.5-1) may not by ordinance or resolution require any licensure, certification, or inspection of foods or food products of an individual vendor who meets the requirements in subsection (c), including an individual vendor who delivers the individual's food or food product directly to an end consumer.

As added by P.L.86-2009, SEC.3. Amended by P.L.86-2012, SEC.1; P.L.128-2013, SEC.1; P.L.154-2014, SEC.1; P.L.202-2015, SEC.7; P.L.80-2016, SEC.3.

IC 16-42-5-30

Exemption from food establishment requirements; standards for farm winery and small brewery permit holders at festivals, fairs, and other temporary locations; licensure, registration, and certification requirements by local units prohibited

Sec. 30. (a) As used in this section, "permit holder" means the holder of:

(1) a farm winery permit under IC 7.1-3-12-5; or

(2) a brewer's permit under IC 7.1-3-2-7(5).

(b) A permit holder that sells or furnishes alcoholic beverages by the glass at a festival, fair, or other temporary location authorized by the permit holder's permit under IC 7.1, is not considered to be a food establishment and is exempt from the requirements of this title that apply to food establishments, if the following requirements are met:

(1) The holder of a farm winery permit furnishes only the following for consumption on the premises, regardless of whether there is a charge:

(A) Wine samples.

(B) Wine by the glass.

The holder may not serve or furnish any food, including any fruit, condiment, flavoring, or garnish added to the wine after the wine is poured from its original container.

(2) The holder of a brewer's permit furnishes only the following for consumption on the premises, regardless of whether there is a charge:

(A) Beer samples.

(B) Beer by the glass.

The holder may not serve or furnish any food, including any fruit, condiment, flavoring, or garnish added to the beer after the beer is poured from its original container.

(c) A local unit of government (as defined in IC 14-22-31.5-1) may not require any licensure, registration, or certification of a

permit holder as a condition of providing alcoholic beverages at a festival, fair, or other temporary location authorized by the permit holder's permit under IC 7.1, if the permit holder meets the requirements of this section.

As added by P.L.144-2015, SEC.6.

IC 16-42-5-31

Sale of poultry products produced under a limited permit

Sec. 31. A food establishment may sell or serve poultry products produced by an establishment operating under a limited permit issued under IC 15-17-5-11(f) only if the poultry products are produced and labeled in accordance with the requirements of IC 15-17-5-11(f).

As added by P.L.80-2016, SEC.4.

IC 16-42-5.2

Chapter 5.2. Food Handlers

IC 16-42-5.2-1

Local regulation precluded

Sec. 1. Except as provided in this chapter, a corporation or local health department may not impose any registration, certification, or licensing requirements on food handling or food handlers.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-2

Exempt food establishments

Sec. 2. (a) Except as provided in subsection (b), this chapter does not apply to a food establishment when the food establishment's food handling activities are limited solely to one (1) or more of the following:

- (1) Heating or serving precooked foods.
- (2) Preparing or serving a continental breakfast such as rolls, coffee, juice, milk, and cold cereal.
- (3) Preparing or serving nonalcoholic or alcoholic beverages that are not potentially hazardous beverages or ice.
- (4) Preparing or serving packaged or unpackaged foods that are not potentially hazardous foods, including elephant ears, funnel cakes, cotton candy, confectionaries, baked goods, popcorn, and chips and grinding coffee beans.
- (5) Providing prepackaged food in its original package.

(b) This subsection does not apply to a pharmacy that is a food establishment that provides only prepackaged food products for sale. A food establishment that has more than ten thousand (10,000) square feet in total retail sales space at the food establishment location must comply with this chapter.

As added by P.L.266-2001, SEC.16. Amended by P.L.139-2005, SEC.1.

IC 16-42-5.2-3

Exempt entities

Sec. 3. This chapter does not apply to the following:

- (1) Hospitals licensed under IC 16-21.
- (2) Health facilities licensed under IC 16-28.
- (3) Housing with services establishments that are required to file disclosure statements under IC 12-10-15.
- (4) Continuing care retirement communities required to file disclosure statements under IC 23-2-4.
- (5) Community mental health centers (as defined in IC 12-7-2-38).
- (6) Private mental health institutions licensed under IC 12-25.
- (7) An area agency on aging designated under IC 12-10-1 that provides food under a nutrition service program. However, the

premises where the food is prepared is not exempt from the requirements under this chapter.

(8) A food pantry that:

(A) is operated or affiliated with a nonprofit organization that is exempt from federal income taxation under Section 501(c)(3) of the Internal Revenue Code; and

(B) distributes food, which may include food from the United States Department of Agriculture, to needy persons.

However, a food bank or other facility that distributes donated food to other organizations is not exempt from the requirements of this chapter.

As added by P.L.266-2001, SEC.16. Amended by P.L.104-2003, SEC.9; P.L.97-2004, SEC.71; P.L.139-2005, SEC.2.

IC 16-42-5.2-3.5

Exempt organizations

Sec. 3.5. (a) An organization that is exempt from the state gross retail tax under IC 6-2.5-5-21(b)(1)(B), IC 6-2.5-5-21(b)(1)(C), or IC 6-2.5-5-21(b)(1)(D) is exempt from complying with the requirements of this chapter.

(b) This section does not prohibit an exempted organization from waiving the exemption and using a certified food handler.

As added by P.L.139-2005, SEC.3.

IC 16-42-5.2-4

"Certified food handler" defined

Sec. 4. As used in this chapter, "certified food handler" means a food handler who holds a certificate described in section 7 of this chapter.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-5

"Food handler" defined

Sec. 5. As used in this chapter, "food handler" means an individual who:

(1) is an owner, an operator, a manager, or an employee of a food establishment; and

(2) is responsible for or oversees the storage, preparation, display, or serving of food to the public.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-6

Certified food handler requirement

Sec. 6. After December 31, 2004, at least one (1) food handler at a food establishment must be a certified food handler.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-7

Food borne illness prevention training requirement

Sec. 7. A food handler who holds a certificate recognized by the Conference for Food Protection or an equivalent nationally recognized certification program as determined by the state department of health meets the food borne illness prevention training requirements established by the state department of health.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-8

Presence of certified food handler

Sec. 8. After December 31, 2004, a food establishment must have at least one (1) certified food handler responsible for all periods of the food establishment's operation. However, a certified food handler need not be present at the food establishment during all hours of operation.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-9

Time requirements; food establishment beginning operation or changing ownership

Sec. 9. After December 31, 2004, a food establishment that begins operation or changes ownership shall comply with section 6 of this chapter not later than six (6) months after beginning operation or changing ownership.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-10

Time requirements; certified food handler terminating employment

Sec. 10. After December 31, 2004, if a food establishment does not have a certified food handler because a certified food handler terminates employment with the food establishment, the owner or operator of the food establishment shall comply with section 6 of this chapter not later than three (3) months after the termination date of the previous certified food handler.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-11

Multiple food establishments on same property

Sec. 11. After December 31, 2004, if more than one (1) food establishment operated by the same individual is located on the same property or on contiguous properties, only one (1) certified food handler is required for the food establishments.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-12

Penalties

Sec. 12. After December 31, 2004, an individual who violates any

of the provisions of this chapter is subject to the penalties prescribed by the executive board under section 13 of this chapter.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-13

Adoption of rules

Sec. 13. Not later than December 31, 2003, the executive board shall adopt rules under IC 4-22-2 establishing standards for:

- (1) the administration of this chapter; and
- (2) the imposition of penalties for violations of this chapter.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-14

Local licensing authority not limited

Sec. 14. This chapter does not limit the authority of a corporation or local health department to license retail food establishments.

As added by P.L.266-2001, SEC.16.

IC 16-42-5.2-15

Local enforcement

Sec. 15. A corporation or local health department may, upon application to and approval of the state department, enforce the provisions of this chapter.

As added by P.L.266-2001, SEC.16.

IC 16-42-6

Repealed

(Repealed by P.L.144-1996, SEC.15.)

IC 16-42-7

Repealed

(Repealed by P.L.104-2003, SEC.10.)

IC 16-42-8

Repealed

(Repealed by P.L.144-1996, SEC.15.)

IC 16-42-9

Repealed

(Repealed by P.L.87-1994, SEC.16.)

IC 16-42-10

Chapter 10. Food: Manufacture and Sale of Flour, White Bread, and Rolls

IC 16-42-10-1

"Enriched" defined

Sec. 1. As used in this chapter, "enriched" as applied to flour, means the addition to flour of the vitamins and other nutritional ingredients necessary to make the flour conform to the definition and standard of identity of enriched flour, enriched bromated flour, or enriched self-rising flour, as established or modified by order of the state department.

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

IC 16-42-10-2

"Flour" defined

Sec. 2. (a) As used in this chapter, "flour" means the following foods as defined in the definitions and standards of identity adopted by the state department:

- (1) Flour, white flour, wheat flour, plain flour.
- (2) Bromated flour.
- (3) Self-rising flour, self-rising white flour, self-rising wheat flour.
- (4) Phosphated flour, phosphated white flour, and phosphated wheat flour.

(b) The term does not include special flours not used for bread, roll, bun, or biscuit baking, such as specialty cake, pancake, and pastry flours.

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

IC 16-42-10-3

"Person" defined

Sec. 3. As used in this chapter, "person" means an individual, a corporation, a partnership, a limited liability company, an association, a joint stock company, a trust, or an unincorporated organization to the extent the person is engaged in the commercial manufacture or sale of flour, white bread, or rolls.

As added by P.L.2-1993, SEC.25. Amended by P.L.8-1993, SEC.253.

IC 16-42-10-4

"Rolls" defined

Sec. 4. (a) As used in this chapter, "rolls" includes the following:

- (1) Plain white rolls and buns of the semibread dough type, such as soft rolls, hamburger, hot dog, and Parker House.
- (2) Hard rolls, such as Vienna and Kaiser.
- (3) All rolls or buns made without fillings or icing.

(b) The term does not include yeast-raised sweet rolls or sweet buns, cinnamon rolls or buns, butterfly rolls, and other items of the

same class.

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

IC 16-42-10-5

"White bread" defined

Sec. 5. As used in this chapter, "white bread" means any bread, whether baked in a pan or on a hearth or screen, that is commonly known or usually represented and sold as white bread, including Vienna bread, French bread, and Italian bread.

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

IC 16-42-10-6

Enforcement; rules and orders

Sec. 6. The state health commissioner shall enforce the provisions of this chapter and shall adopt, amend, or rescind rules and orders for the efficient enforcement of this chapter.

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

IC 16-42-10-7

Enriched flour; exceptions; certificate of intent

Sec. 7. (a) This section does not apply to flour sold to bakers or other commercial secondary processors if, before or simultaneously with delivery, the purchaser furnishes to the seller a certificate of intent in the form the state health commissioner prescribes by rule certifying that the flour may be used only in the manufacture, mixing, or compounding of flour or white bread or rolls enriched to meet the requirements of this chapter or of products other than flour or white bread or rolls.

(b) A person may only manufacture, mix, compound, sell, or offer for sale in Indiana for human consumption in Indiana flour that is enriched.

(c) A purchaser described in subsection (a) who furnishes a certificate of intent may not use the flour so purchased in a manner other than as stated in the certificate.

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

IC 16-42-10-8

White bread or rolls; standards

Sec. 8. (a) Except as provided in subsection (b), a person may not manufacture, bake, sell, or offer for sale in Indiana for human consumption white bread or rolls unless the white bread or rolls conform to the definition and standard of identity then in effect for enriched bread and enriched rolls or enriched buns, as established by order of the state department under the pure food statutes or rules of Indiana.

(b) If no order of a federal agency or officer fixing and establishing a definition and standard of identity for enriched bread and enriched rolls or enriched buns is in effect, a person may not

manufacture, bake, sell, or offer for sale in Indiana for human consumption any white bread or rolls unless the white bread or rolls conform to the proposed definition and standard of identity for enriched bread and enriched rolls or enriched buns under the pure food statutes or rules of Indiana.

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

IC 16-42-10-9

Labeling requirements; interstate commerce

Sec. 9. (a) This section does not apply to white bread or rolls that bear no labeling of any kind and that are sold directly to the consumer by the manufacturer.

(b) A person may not sell or offer for sale in Indiana for human consumption in Indiana any flour, wrapped white bread, or rolls meeting the requirements of sections 7 and 8 of this chapter that fail to conform to the labeling requirements of the state department and the rules adopted by the state department concerning those products when introduced in interstate commerce.

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

IC 16-42-10-10

Shortages of ingredients; exempting orders; hearings; rescinding orders

Sec. 10. (a) If the state health commissioner finds that:

- (1) there is an existing or imminent shortage of any ingredient required by section 7 or 8 of this chapter; and
- (2) because of the existing or imminent shortage the sale and distribution of flour or white bread or rolls may be impeded by the enforcement of this chapter;

the state health commissioner shall issue an order, effective immediately upon issuance, permitting the omission of that ingredient from flour or white bread or rolls, and if the state health commissioner finds it necessary or appropriate, excepting those foods from the labeling requirements of this chapter until further order of the state health commissioner.

(b) Findings of the state health commissioner under subsection (a) may be made without a hearing on the basis of an order or of factual information supplied by the appropriate officer. In the absence of an order of the appropriate federal agency or factual information supplied by the federal agency, the state health commissioner:

- (1) may, upon the commissioner's own motion; or
- (2) shall, within twenty (20) days after receiving the sworn statements of at least ten (10) persons subject to this chapter that a shortage exists or is imminent;

hold a public hearing on that topic at which any interested person may present evidence. At the conclusion of the hearing, the state health commissioner shall make findings based upon the evidence presented.

(c) The state health commissioner shall publish notice of a hearing under subsection (b) at least ten (10) days before the hearing.

(d) Whenever the state health commissioner has reason to believe that a shortage no longer exists, the state health commissioner shall hold a public hearing, after giving at least ten (10) days notice at which any interested person may present evidence. At the conclusion of the hearing, the state health commissioner shall make findings based upon the evidence presented at the hearing.

(e) If the state health commissioner finds that a shortage no longer exists, the state health commissioner shall issue an order revoking the previous order. An order revoking the previous order becomes effective not less than thirty (30) days after publication of the revocation order. However, undisposed flour stocks on hand at the effective date of the revocation order or flour manufactured before the effective date of the revocation order for sale in Indiana may subsequently be lawfully sold or disposed of.

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

IC 16-42-10-11

Publication of orders, rules, or notices

Sec. 11. (a) All orders and rules adopted by the state health commissioner under this chapter shall be published in the manner prescribed in this chapter and, within the limits specified by this chapter, take effect on the date the state health commissioner determines.

(b) Whenever publication of any notice, order, or rule is required under this chapter, publication must be made at least one (1) time in at least one (1) daily newspaper of general circulation printed and published in Indiana.

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

IC 16-42-10-12

Examinations, investigations, and inspections

Sec. 12. For the purposes of this chapter, the state health commissioner or the commissioner's authorized representatives may take samples for analysis and conduct examinations and investigations through any officers or employees under the state health commissioner's supervision. Those officers and employees may enter, at reasonable times:

(1) a factory, mill, warehouse, shop, or establishment where flour, white bread, or rolls are manufactured, processed, packed, sold, or held; or

(2) a vehicle being used for the transportation of those items; and may inspect those places and any flour, white bread, or rolls in those places and all pertinent equipment, materials, containers, and labeling.

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

IC 16-42-10-13

Violations

Sec. 13. A person who recklessly violates this chapter commits a Class B misdemeanor.

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

IC 16-42-11

Chapter 11. Food: Eggs Offered for Sale and State Egg Board

IC 16-42-11-1

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.28-2009, SEC.16.)

IC 16-42-11-1.1

Definitions

Sec. 1.1. The following definitions apply throughout this chapter:

- (1) "Case" means thirty (30) dozen.
- (2) "Eggs" means shell eggs represented as fresh or treated.
- (3) "Farmers market" means a common facility where two (2) or more farmers or growers gather on a regular basis to sell farm products, which they produce, directly to the consumer.
- (4) "Fresh eggs" means consumer grades of eggs as defined by the standards of quality and weights as set forth by the state egg board.
- (5) "Person" means any individual, partnership, association, business trust, corporation, or any organized group of persons, regardless of whether the group is incorporated.
- (6) "Retailer" means any person who sells eggs for human consumption and not for resale.
- (7) "Treated eggs" means eggs that have been treated by a process such as pasteurization, irradiation, or other method of treatment that changes the interior quality of an egg in such a manner that United States Department of Agriculture quality standards do not apply.
- (8) "Wholesaler" means any person engaged in buying eggs for human consumption for resale to retailers, hotels, restaurants, hospitals, nursing homes, schools, state or federal institutions, operators of multiple unit retail outlets engaged in the distribution of eggs to their own retail units, or producers who sell or deliver eggs to retailers, hotels, restaurants, hospitals, nursing homes, schools, or state or federal institutions.

As added by P.L.28-2009, SEC.4.

IC 16-42-11-2

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.28-2009, SEC.16.)

IC 16-42-11-3

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.28-2009, SEC.16.)

IC 16-42-11-4

Establishment of board; membership; term; oath; officers; compensation; business office

Sec. 4. (a) The state egg board is established. The board consists of nine (9) members appointed by the governor as follows:

- (1) One (1) member from recommendations submitted by the Indiana State Poultry Association, Inc.
- (2) One (1) member from recommendations submitted by the Indiana Farm Bureau, Inc.
- (3) One (1) member from recommendations submitted by the Indiana Retail Grocery and Convenience Store Association, Inc.
- (4) One (1) member from recommendations submitted by the Indiana Retail Council, Inc.
- (5) One (1) member from recommendations submitted by the Egg Council of the Indiana State Poultry Association, Inc.
- (6) One (1) member from recommendations submitted by the dean of the college of agriculture of Purdue University.
- (7) One (1) member at large to represent the interests of the consumer.
- (8) One (1) member to represent those engaged in the wholesaling of eggs through the Federal-State Egg Grading Program in Indiana.
- (9) One (1) member to represent the interests of the food service industry.

(b) All appointments are for terms of three (3) years. However, an appointment to fill an unexpired term shall be made by the governor for the remainder of that term only.

(c) The recommendations provided for in this section shall be submitted to the governor within ten (10) days before an appointment is to be made to the state egg board. All appointments by the governor under this chapter shall be made within twenty (20) days after submission to the governor of the recommendations for appointments. If the recommendations are not submitted to the governor within the specified time, the governor shall make the appointment without the recommendations. If the governor does not make an appointment to fill an expired term for a member described in subsection (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), or (a)(6) within twenty (20) days after receiving the recommendation, the current members of the state egg board may select an individual from the names submitted by an organization under subsection (a) to fill the position represented by that organization on the state egg board. The individual shall serve a three (3) year term beginning with the next official board meeting following the twenty (20) day deadline.

(d) The members of the state egg board shall, before entering upon their duties, take and subscribe to the oath of office provided for other state officers. The oath of office shall be filed in the office of the secretary of state. The secretary of state shall administer the oath as a part of the duties of the office of secretary of state.

(e) The state egg board shall elect from its own membership the following officers:

- (1) President.
- (2) A vice president who serves in the president's absence or disability.
- (3) Recording secretary.

The officers serve for one (1) year or until their successors are elected and qualified.

(f) Each member of the state egg board who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(g) The state egg board shall provide a suitable office, equipment, supplies, and facilities for the conduct of the board's business.

As added by P.L.2-1993, SEC.25. Amended by P.L.40-1993, SEC.55; P.L.28-2009, SEC.5.

IC 16-42-11-5

Powers and duties

Sec. 5. (a) The state egg board shall administer, enforce, and carry out this chapter.

(b) The state egg board shall do the following:

- (1) Formulate and determine standards of quality and weights of eggs sold or offered for sale.
- (2) Regulate the sale of and commerce in eggs sold or offered for sale at retail or wholesale and regulate the sale of eggs by wholesalers and retailers.
- (3) Formulate and publish definitions, names, and grades of eggs and specifications for the care and handling of eggs that may be offered for sale at retail and wholesale under the terms of this chapter and for the care and handling of eggs that may be offered for sale by wholesalers and retailers as eggs fit for human consumption.
- (4) Provide for and issue permits to wholesalers or retailers of eggs and provide for the registration of wholesalers and retailers of eggs.
- (5) Adopt rules necessary for or incident to carrying out this chapter.
- (6) Investigate and report violations of this chapter and violations of the rules of the state egg board to the proper authorities for prosecution.
- (7) Revoke any registration or permit for a violation of this chapter or of the rules adopted by the state egg board.
- (8) Hold four (4) regular meetings at quarterly intervals at the time and place the state egg board designates. The president of

the state egg board may call special meetings of the state egg board whenever in the president's judgment it becomes necessary. The president shall call a special meeting of the state egg board upon written request of a majority of the members of the state egg board.

(9) The state egg board shall publish or cause to be published an annual report of the board's work. In addition, the state egg board may periodically publish or cause to be published and distributed other information concerning eggs.

As added by P.L.2-1993, SEC.25. Amended by P.L.28-2009, SEC.6.

IC 16-42-11-6

Substandard eggs; prohibited sale

Sec. 6. A person may not sell, offer for sale, or advertise for sale at retail or wholesale eggs that do not meet the standards of quality and weight set forth by the state egg board.

As added by P.L.2-1993, SEC.25. Amended by P.L.28-2009, SEC.7.

IC 16-42-11-7

Proof of delivery

Sec. 7. (a) Every person selling eggs to a retailer shall furnish proof of delivery at the time of delivery showing:

- (1) the date;
- (2) the grades; and
- (3) the quantity of the eggs;

according to the standards prescribed by the state egg board.

(b) A copy of the proof of delivery shall be kept on file by retailers at their respective places of business for thirty (30) days and at all reasonable times shall be available and open for inspection by accredited inspectors or representatives of the state egg board.

As added by P.L.2-1993, SEC.25. Amended by P.L.28-2009, SEC.8.

IC 16-42-11-8

Farmers' and egg producers' exemption

Sec. 8. Farmers and other bona fide egg producers who sell and deliver, on the premises where produced, eggs produced by their own flocks on their own premises are exempt from this chapter.

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

IC 16-42-11-9

Farmer's or egg producer's wholesaler or retailer registration

Sec. 9. A farmer or bona fide egg producer may apply for registration as a wholesaler or retailer under this chapter and may, upon application, after being registered receive a permit to sell eggs.

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

IC 16-42-11-9.5

Farmers market retail permit

Sec. 9.5. (a) A farmer or bona fide egg producer who markets directly to the consumer at a location that is not the farmer's or producer's own premises and is recognized as a farmers market may be required to have a farmers market retail permit issued by the state egg board. The state egg board shall establish requirements and procedures for obtaining a farmers market retail permit by rule under IC 4-22-2.

(b) Notwithstanding any other law, a local unit of government (as defined in IC 14-22-31.5-1) may not by ordinance or resolution require any licensure, certification, or inspection of foods or food products of a farmer or bona fide egg producer acting under this section.

As added by P.L.28-2009, SEC.9. Amended by P.L.154-2014, SEC.2.

IC 16-42-11-10

Application of section; registration statement; fees; wholesaler report permit

Sec. 10. (a) Except as provided in section 10.2(d) of this chapter, this section applies to:

- (1) registrations and permits issued by; and
- (2) fees due and payable to;

the state egg board before July 1, 2010.

(b) Every wholesaler or retailer selling eggs shall, before July 1 of each year, file with the state egg board a statement setting forth the fact that the wholesaler or retailer desires to sell eggs. The statement shall designate the name of the wholesaler or retailer desiring to register the location of the wholesaler's or retailer's principal office and any location where eggs are stored or distributed if that location is different from the principal office. The state egg board shall furnish blank forms for registration. The state egg board shall register the facts set forth in the statement in a permanent record. The state egg board shall furnish to each registered wholesaler a registration number upon payment of the registration fee and deposit.

(c) The state egg board shall require and collect from each wholesaler at the time of registration a fee based upon the average number of cases of eggs sold to retailers, hotels, restaurants, hospitals, nursing homes, schools, or to state or federal institutions each week during the preceding calendar year, as follows:

Average Number of Cases Sold	Registration Fee
0 - 100	\$ 30
101 - 250	\$ 60
251 - 500	\$ 90
501 - 1,000	\$ 120
1,001 and over	\$ 150

(d) The state egg board shall require and collect from each wholesaler at the time of registration a deposit equal to the product

obtained by using a multiplier of six cents (\$0.06) and a multiplicand that is the number of cases of eggs sold in that quarter of the immediately preceding five (5) calendar quarters in which the highest number of cases of eggs were sold by the wholesaler to retailers, hotels, restaurants, hospitals, nursing homes, schools, or to state or federal institutions. However, if the wholesaler does not have a five (5) quarter history, the state egg board shall fix the deposit at a reasonable amount.

(e) The state egg board shall require and collect from each retail store or unit of retailing a fee based upon the average number of cases of eggs sold each week during the preceding calendar year, as follows:

Average Number of Cases Sold	Registration Fee
1-5	\$20
more than 5	\$25

(f) All registered wholesalers must make application to the state egg board for a permit to report the case volume of eggs sold in Indiana and submit a fee of six cents (\$0.06) for each thirty (30) dozen eggs or a fraction of that number of the volume reported. In applying for a permit, the applicant must agree to do the following:

- (1) Keep records the state egg board considers necessary to indicate accurately the case volume of eggs sold in Indiana.
- (2) Grant the state egg board permission to examine those records and verify the statement of the number and grade of eggs reported.
- (3) Report under oath to the state egg board, on forms furnished by the state egg board, the number of eggs reported during the period covered.

As added by P.L.2-1993, SEC.25. Amended by P.L.183-1993, SEC.1; P.L.28-2009, SEC.10.

IC 16-42-11-10.2

Application of section; permit and registration requirements; fees

Sec. 10.2. (a) Except as provided in subsection (d), this section applies to:

- (1) registrations and permits issued by; and
- (2) fees due and payable to;

the state egg board after June 30, 2010.

(b) The state egg board may establish requirements for issuing a permit or registration under this chapter by rule under IC 4-22-2.

(c) The state egg board may establish fees necessary to carry out this chapter by rule under IC 4-22-2.

(d) If a rule is not in effect by July 1, 2010, the fees and requirements for obtaining a registration or permit under section 10 of this chapter apply until the date the rule takes effect.

As added by P.L.28-2009, SEC.11.

IC 16-42-11-10.4

Permits; issuance; revocation; fees

Sec. 10.4. The state egg board may grant a permit if the board determines that the action will lead to efficient enforcement of this chapter. The state egg board may revoke a permit at any time if it appears to the state egg board that a wholesaler is not complying with the terms of the agreement entered into at the time of the issuance. The report of eggs is due and the fees are payable quarterly on the last day of the month following the end of the quarter. If:

- (1) the report is not filed and the fee paid by the tenth day following the due date;
- (2) the report is false; or
- (3) the requirements of this chapter have not been complied with;

the state egg board may revoke the permit. If the fee is unpaid after the ten (10) day grace period, a penalty of the greater of twenty dollars (\$20) or ten percent (10%) of the amount due in addition to the amount due shall be assessed. If the state egg board determines that an account review is necessary, out-of-state permit holders shall reimburse the state egg board for expenses incurred to conduct the account review.

As added by P.L.28-2009, SEC.12.

IC 16-42-11-11

Prohibited sales or distribution

Sec. 11. (a) A person may not sell as a wholesaler to a retailer, hotel, restaurant, hospital, nursing home, school, or state or federal institution eggs for human consumption that are not subject to being reported as provided in this chapter.

(b) A person operating multiple retail outlets may not distribute or deliver to retail units eggs for human consumption that are not subject to being reported as provided for in this chapter. A retail store or retail unit may not receive from a wholesaler eggs for human consumption that are not subject to being reported as provided for in this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.28-2009, SEC.13.

IC 16-42-11-12

Purdue University; inspections

Sec. 12. The dean of the college of agriculture of Purdue University may, subject to the approval of the state egg board, employ an executive administrator, inspectors, clerks, and other assistants necessary to carry out this chapter under the direction and supervision of the state egg board. The inspectors shall inspect and examine eggs sold, offered for sale, or exposed for sale and shall also inspect and examine eggs sold by wholesalers and retailers as fit for human consumption under this chapter at times and places and in the manner the state egg board directs.

As added by P.L.2-1993, SEC.25. Amended by P.L.40-1993, SEC.56; P.L.28-2009, SEC.14.

IC 16-42-11-13

Fiscal management

Sec. 13. All money received by the state egg board shall be paid to the treasurer of Purdue University who shall, under the direction of the state egg board, expend the money on proper vouchers to meet all necessary expenditures for carrying out this chapter and for any other expenses of Purdue University agricultural programs authorized by law and in support of the purposes of this chapter. The dean of agriculture shall submit to the state egg board an annual report showing the receipts and expenditures of all money received and expended by the director under this chapter. The report shall be made a part of the annual report of the state egg board.

As added by P.L.2-1993, SEC.25. Amended by P.L.40-1993, SEC.57.

IC 16-42-11-14

Violations

Sec. 14. A person who violates this chapter commits a Class C infraction.

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

IC 16-42-11-15

Immunity from liability

Sec. 15. The:

- (1) members of the state egg board;
- (2) dean of the college of agriculture of Purdue University; and
- (3) employees of the state egg board;

are not liable in their individual capacity, except to the state, for an act done or omitted in connection with the performance of their respective duties under this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.40-1993, SEC.58; P.L.28-2009, SEC.15.

IC 16-42-12

Repealed

(Repealed by P.L.137-1996, SEC.75.)

IC 16-42-13

Repealed

(Repealed by P.L.137-1996, SEC.75.)

IC 16-42-14

Repealed

(Repealed by P.L.144-1996, SEC.15.)

IC 16-42-15

Repealed

(Repealed by P.L.87-1994, SEC.16.)

IC 16-42-16

Repealed

(Repealed by P.L.137-1996, SEC.75.)

IC 16-42-17

Chapter 17. Food: Regulation of Sodium Saccharin, N.F.

IC 16-42-17-1

Permitted activities

Sec. 1. Notwithstanding any rule or regulation adopted by the federal Food and Drug Administration concerning sodium saccharin, N.F., the chemical substance sodium saccharin, N.F. may be manufactured, distributed, sold, and used within Indiana.

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

IC 16-42-17-2

Powers of board of pharmacy and department of health

Sec. 2. (a) The Indiana board of pharmacy and the state department may not prohibit the manufacture, distribution, sale, or use of sodium saccharin, N.F. within Indiana, either as a component of any other substance produced within Indiana or as a separate product.

(b) The state department may regulate the manufacture, distribution, sale, or use of sodium saccharin, N.F. only to ensure that the substance is not adulterated or misbranded within the meaning of IC 16-42-2 and IC 16-42-3.

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

IC 16-42-17-3

Manufacture, distribution, sale, or use not prohibited

Sec. 3. A person who is engaged in the manufacture, sale, distribution, or use of sodium saccharin, N.F. may not be prohibited from the manufacture, sale, distribution, or use of sodium saccharin, N.F. within Indiana.

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

IC 16-42-18

Chapter 18. Food: Transportation of Food in Trucks Used to Transport Solid Waste

IC 16-42-18-1

"Solid waste" defined

Sec. 1. (a) As used in this chapter and except as provided in subsection (b), "solid waste" has the meaning set forth in IC 13-11-2-205(a).

(b) The term does not include waste that is regulated under the following:

(1) IC 13-22-1 through IC 13-22-8.

(2) IC 13-22-11.5.

(3) IC 13-22-13 through IC 13-22-14.

As added by P.L.2-1993, SEC.25. Amended by P.L.1-1996, SEC.77; P.L.45-1997, SEC.22; P.L.128-1997, SEC.10.

IC 16-42-18-2

"Truck" defined

Sec. 2. As used in this chapter, "truck" has the meaning set forth in IC 9-13-2-188(a).

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

IC 16-42-18-3

Trucks transporting both solid waste and food; time limitations

Sec. 3. Except as provided in section 4 of this chapter, a truck that is used to transport a quantity of more than four thousand (4,000) pounds of solid waste to a landfill, an incinerator, or a transfer station may not be used to transport food until at least fifteen (15) days after transporting the solid waste.

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

IC 16-42-18-4

Sanitizing trucks transporting both solid waste and food

Sec. 4. A truck that is used to transport a quantity of more than four thousand (4,000) pounds of solid waste to a landfill, an incinerator, or a transfer station may be used to transport food less than fifteen (15) days after transporting the solid waste if the truck, after transporting the solid waste, has been properly sanitized according to rules adopted under section 5 of this chapter.

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

IC 16-42-18-5

Rules

Sec. 5. The state department may adopt rules under IC 4-22-2 to implement this chapter. The rules adopted under this section may do the following:

(1) Require documentation on the transportation of food in

Indiana that would disclose violations of section 3 of this chapter.

(2) Establish procedures for the proper sanitizing of trucks for the purposes of this chapter.

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

IC 16-42-18-6

Civil penalties

Sec. 6. A person who violates section 3 of this chapter is subject to civil penalties under IC 16-42-1-17.

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

IC 16-42-18-7

Violations

Sec. 7. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

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

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

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.59-2016, SEC.3.)

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 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 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.

(c) 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; P.L.59-2016, SEC.4.

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.

IC 16-42-20

Chapter 20. Drugs: Enforcement of Pharmacy Laws and Rules

IC 16-42-20-1

Powers of enforcement officers

Sec. 1. (a) Each member of the Indiana board of pharmacy, designated employees of the Indiana board of pharmacy, and all law enforcement officers of Indiana are primarily responsible for the enforcement of all statutes and rules of Indiana relating to controlled substances. However, the Indiana board of pharmacy is primarily responsible for making accountability audits of the supply and inventory of controlled substances.

(b) An officer or employee of the Indiana board of pharmacy designated by the board may do any of the following:

- (1) Carry firearms in the performance of the officer's or employee's official duties.
- (2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state.
- (3) Make arrests without warrant for any offense relating to controlled substances committed in the officer's or employee's presence or if the officer or employee has probable cause to believe that the person to be arrested has committed or is committing a felony relating to controlled substances.
- (4) Make seizures of property under this chapter.
- (5) Perform other law enforcement duties that the Indiana board of pharmacy designates.

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

IC 16-42-20-2

"Controlled premises" defined; administrative inspections and warrants

Sec. 2. (a) As used in this section, "controlled premises" means the following:

- (1) Places where persons registered or exempted from registration requirements under IC 35-48-3 are required to keep records.
- (2) Places, including factories, warehouses, establishments, and conveyances, in which persons registered or exempted from registration requirements under IC 35-48-3 are permitted to possess, manufacture, compound, process, sell, deliver, or otherwise dispose of a controlled substance.

(b) Issuance and execution of administrative inspection warrants must be as follows:

- (1) A judge of a court of record within the judge's jurisdiction may, upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative

inspections authorized by this chapter and seizures of property appropriate to the inspections.

(2) For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this chapter sufficient to justify administrative inspection of the area, premises, building, or conveyance in the circumstances specified in the application for the warrant.

(3) A warrant shall be issued only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge, and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe the grounds exist, the judge shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected.

(4) The warrant must do the following:

(A) State the grounds for the warrant's issuance and the name of each person whose affidavit has been taken in support of the warrant.

(B) Be directed to a person authorized by section 1 of this chapter to execute the warrant.

(C) Command the person to whom the warrant is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified.

(D) Identify the item or types of property to be seized, if any.

(E) Direct that the warrant may be served during normal business hours and designate the judge to whom the warrant shall be returned.

(5) A warrant issued under this section must be executed and returned within ten (10) days of the warrant's date unless, upon a showing of a need for additional time, the court orders otherwise.

(6) If property is seized under a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one (1) credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

(7) The judge who issues a warrant shall attach to the warrant

a copy of the return and all papers returnable in connection with the issuance of the warrant and file them with the clerk of the circuit or superior court for the judicial circuit in which the inspection was made.

(c) The Indiana board of pharmacy may make administrative inspections of controlled premises in accordance with the following provisions:

(1) When authorized by an administrative inspection warrant issued under subsection (b), an officer or employee designated by the Indiana board of pharmacy, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.

(2) When authorized by an administrative inspection warrant, an officer or employee designated by the Indiana board of pharmacy may do the following:

(A) Inspect and copy records required by IC 35-48-3 to be kept.

(B) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers, and labeling found on the premises, and, except as provided in subdivision (4), all other things on the premises, including records, files, papers, processes, controls, and facilities bearing on violation of laws relating to controlled substances.

(C) Inventory any stock of any controlled substance on the premises and obtain samples of the controlled substance.

(3) This section does not prevent an inspection without a warrant of books and records under an administrative subpoena issued in accordance with IC 4-21.5-3 or prevent entries and administrative inspections, including seizures of property, without a warrant if any of the following conditions exist:

(A) The owner, operator, or agent in charge of the controlled premises consents.

(B) A situation presents imminent danger to health or safety.

(C) A situation involves the inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant.

(D) An exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking.

(E) A situation in which a warrant is not constitutionally required.

(4) An inspection authorized by this section may not extend to financial data, sales data (other than shipment data), or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

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

IC 16-42-20-3

Injunctions

Sec. 3. Any court of record has jurisdiction to restrain or enjoin violations of laws relating to controlled substances.

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

IC 16-42-20-4

Cooperative arrangements and confidentiality

Sec. 4. (a) The Indiana board of pharmacy shall cooperate with federal and other state agencies in discharging the board's responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, the board may do the following:

(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances.

(2) Coordinate and cooperate in training programs concerning controlled substance law enforcement at local, state, and federal levels.

(3) Cooperate with the Drug Enforcement Administration by establishing a centralized unit to accept, catalog, file, and collect statistics, including records of drug dependent persons and other controlled substance law offenders within Indiana, and make the information available for federal, state, and local law enforcement purposes. The board may not furnish the name or identity of a patient or research subject whose identity cannot be obtained under subsection (c).

(4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

(b) Results, information, and evidence received from the Drug Enforcement Administration relating to the regulatory functions of this chapter, including the results of inspections conducted by the Drug Enforcement Administration, may be relied on and acted upon by the Indiana board of pharmacy in the exercise of the board's regulatory functions.

(c) A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the Indiana board of pharmacy. A practitioner may not be compelled in any state or local civil, criminal, administrative, legislative, or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.

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

IC 16-42-20-5

Forfeitures

Sec. 5. (a) The following are subject to forfeiture:

(1) All controlled substances that are or have been unlawfully manufactured, distributed, dispensed, acquired, or possessed, or with respect to which there has been an act by a person in violation of laws relating to controlled substances.

(2) All raw materials, instruments, devices, and other objects that are used or intended for use by the person in possession of them in unlawfully planting, growing, manufacturing, compounding, processing, delivering, importing, or exporting a controlled substance.

(3) All property that is used or intended for use by the person in possession of the property as a container for property described in subdivision (1) or (2).

(4) All books, records, and research products and materials, including formulas, microfilm, tapes, and data that are used or intended for use by the person in possession in violation of a law relating to controlled substances.

(b) Property subject to forfeiture under this chapter may be seized by an enforcement officer upon process issued by any state court of record having jurisdiction over the property. Seizure without process may be made if any of the following conditions exist:

(1) The seizure is incident to an arrest, a search under a search warrant, or an inspection under an administrative inspection warrant.

(2) The property subject to seizure has been the subject of a prior judgment in favor of the state in a criminal injunction or forfeiture proceeding.

(3) The Indiana board of pharmacy has probable cause to believe that the property is directly or indirectly dangerous to health or safety.

(4) The Indiana board of pharmacy has probable cause to believe that the property was used by the person in possession of the property or is intended to be used in violation of a law relating to controlled substances.

(c) In a seizure under subsection (b), proceedings under subsection (d) shall be instituted promptly.

(d) Property taken or detained under this section is not subject to replevin, but is considered to be in the custody of the Indiana board of pharmacy subject only to the orders and decrees of the court having jurisdiction over the forfeiture proceedings. When property is seized under this chapter, the Indiana board of pharmacy may do any of the following:

(1) Place the property under seal.

(2) Remove the property to a place designated by the board.

(3) Take custody of the property and remove the property to an appropriate location for disposition in accordance with law.

All property seized under this chapter shall be retained by the Indiana board of pharmacy until all proceedings in which the property may be involved have concluded.

(e) When property is forfeited under this chapter, the Indiana board of pharmacy shall do the following:

(1) Sell property that by law is not required to be transferred or destroyed, that has a monetary value, and that is not harmful to the public. The proceeds shall be used for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody, advertising, and court costs. All proceeds in excess of expenses shall be paid into the common school fund of the state.

(2) Take custody of property that has no monetary value or cannot lawfully be sold and remove the property for disposition in accordance with administrative rule or forward the property to the Drug Enforcement Administration for disposition.

(f) Controlled substances listed in schedule I that are unlawfully possessed, transferred, sold, or offered for sale are contraband and shall be seized and summarily forfeited to the state. Controlled substances listed in schedule I that are seized or come into the possession of the state, the owners of which are unknown, are contraband and shall be summarily forfeited to the state.

(g) Species of plants from which controlled substances in schedules I and II may be derived that:

(1) have been unlawfully planted or cultivated and the owners or cultivators are unknown; or

(2) are wild growths;

may be seized and summarily forfeited to the state.

(h) The failure, upon demand by the Indiana board of pharmacy or the board's authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored to produce an appropriate registration or proof that the person is the holder of the plants constitutes authority for the seizure and forfeiture of the plants.

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

IC 16-42-20-6

Burden of proof; liabilities

Sec. 6. (a) It is not necessary for the state to negate any exemption or exception in this chapter or in IC 35-48 in a complaint, an information, an indictment, or other pleading or in a trial, hearing, or other proceeding under this chapter or under IC 35-48. The burden of proof of an exemption or exception is on the person claiming the exemption or exception.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under IC 35-48-3, a person is presumed not to be the holder of the registration or form.

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

IC 16-42-20-7

Judicial review

Sec. 7. All final determinations, findings, and conclusions of the Indiana board of pharmacy under this chapter are conclusive decisions of the matters involved. A person aggrieved by the decision may obtain review of the decision in accordance with IC 4-21.5-5. Findings of fact by the Indiana board of pharmacy, if supported by substantial evidence, are conclusive.

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

IC 16-42-20-8**Education programs**

Sec. 8. The addiction services bureau of the division of mental health and addiction shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs, the bureau may do the following:

- (1) Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations.
- (2) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances.
- (3) Consult with interested groups and organizations to aid the groups and organizations in solving administrative and organizational problems.
- (4) Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances.
- (5) Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat the problems.
- (6) Assist in the education and training of state and local law enforcement officials in efforts to control misuse and abuse of controlled substances.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.86.

IC 16-42-20-9**Research**

Sec. 9. The addiction services bureau of the division of mental health and addiction shall encourage research on misuse and abuse of controlled substances. In connection with the research and in furtherance of the enforcement of laws relating to controlled substances, the bureau may do the following:

- (1) Establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse.
- (2) Make studies and undertake programs of research to do the

following:

(A) Develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of laws relating to controlled substances.

(B) Determine patterns of misuse and abuse of controlled substances and the social effects of such behavior.

(C) Improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of controlled substances.

(3) Enter into contracts with public agencies, postsecondary educational institutions, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects that bear directly on misuse and abuse of controlled substances.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.87; P.L.2-2007, SEC.195.

IC 16-42-20-10

Contracts for educational and research activities

Sec. 10. The addiction services bureau of the division of mental health and addiction may enter into contracts for educational and research activities without performance bonds.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.88.

IC 16-42-20-11

Anonymity of research subjects

Sec. 11. The Indiana board of pharmacy may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization may not be compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

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

IC 16-42-20-12

Possession and distribution of controlled substances for research purposes

Sec. 12. The Indiana board of pharmacy may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

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

IC 16-42-21

Chapter 21. Drugs: Drug Samples

IC 16-42-21-1

"Controlled substance" defined

Sec. 1. As used in this chapter, "controlled substance" has the meaning set forth in IC 35-48-1.

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

IC 16-42-21-2

"Drug sample" defined

Sec. 2. As used in this chapter, "drug sample" means a legend drug or a controlled substance that is manufactured, packaged, labeled, or otherwise marketed to be distributed and dispensed without consideration.

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

IC 16-42-21-3

"Practitioner" defined

Sec. 3. As used in this chapter, "practitioner" means any of the following:

- (1) A licensed physician.
- (2) A dentist licensed to practice dentistry in Indiana.
- (3) A podiatrist licensed to practice podiatry in Indiana.
- (4) A veterinarian licensed to practice veterinary 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 licensed and granted the authority to prescribe legend drugs under IC 25-23.

As added by P.L.2-1993, SEC.25. Amended by P.L.157-2006, SEC.7; P.L.105-2008, SEC.1.

IC 16-42-21-4

Delivery of drug samples to ultimate user after removal from original packaging or after expiration date; offense

Sec. 4. A person who:

- (1) is a manufacturer, wholesaler, practitioner, or pharmacist, or is an employee or agent of a manufacturer, wholesaler, practitioner, or pharmacist; and
- (2) either:
 - (A) knowingly or intentionally removes a drug sample from its original packaging, repackages the drug sample, and delivers the drug sample to an ultimate user in exchange for money or other property; or
 - (B) knowingly or intentionally delivers a drug sample to an ultimate user when the expiration date listed by the

manufacturer on the drug sample has passed;
commits a Class B misdemeanor.
As added by P.L.2-1993, SEC.25.

IC 16-42-22

Chapter 22. Drugs: Generic Drugs

IC 16-42-22-1

"Brand name" defined

Sec. 1. As used in this chapter, "brand name" means the proprietary or trade name selected by the drug manufacturer and placed upon a drug or the drug's container, label, or wrappings at the time of packaging.

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

IC 16-42-22-2

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.239-1999, SEC.9.)

IC 16-42-22-3

"Customer" defined

Sec. 3. As used in this chapter, "customer" means the individual for whom a prescription is written or electronically transmitted or the individual's representative.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.8.

IC 16-42-22-4

"Generically equivalent drug product" defined

Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a multiple source drug product:

- (1) that contains an identical quantity of identical active ingredients in the identical dosage forms (but not necessarily containing the same inactive ingredients) that meet the identical physical and chemical standards in The United States Pharmacopeia (USP) described in IC 16-42-19-2, or its supplements, as the prescribed brand name drug; and
- (2) if applicable, for which the manufacturer or distributor holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.

(b) A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on or after July 1, 1987, as having actual or potential bioequivalence problems.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.4.

IC 16-42-22-4.5

"Practitioner" defined

Sec. 4.5. As used in this chapter, "practitioner" means any of the following:

- (1) A licensed physician.

- (2) A dentist licensed to practice dentistry in Indiana.
- (3) A podiatrist licensed to practice podiatric medicine in Indiana.
- (4) An optometrist who is:
 - (A) licensed to practice optometry in Indiana; and
 - (B) certified under IC 25-24-3.
- (5) An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-23.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.5; P.L.157-2006, SEC.8.

IC 16-42-22-5

"Substitute" defined

Sec. 5. As used in this chapter, "substitute" means to dispense a generically equivalent drug product in place of the brand name drug product prescribed by the practitioner.

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

IC 16-42-22-5.5

Limitation of effect of chapter

Sec. 5.5. Nothing in this chapter authorizes any substitution other than substitution of a generically equivalent drug product.

As added by P.L.239-1999, SEC.6.

IC 16-42-22-6

Prescription forms

Sec. 6. (a) Each written prescription issued by a practitioner must have two (2) signature lines printed at the bottom of the prescription form, one (1) of which must be signed by the practitioner for the prescription to be valid. Under the blank line on the left side of the form must be printed the words "Dispense as written.". Under the blank line on the right side of the form must be printed the words "May substitute.".

(b) Each electronically transmitted prescription issued by a practitioner must:

- (1) have an electronic signature; and
- (2) include the electronically transmitted instructions "Dispense as written." or "May substitute.".

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.9.

IC 16-42-22-7

Repealed

(As added by P.L.2-1993, SEC.25. Repealed by P.L.239-1999, SEC.9.)

IC 16-42-22-8

Requirements for substitution

Sec. 8. (a) For substitution to occur for a prescription other than

a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, the biosimilar biological products requirements under IC 16-42-25, or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must:

(A) sign on the line under which the words "May substitute" appear; or

(B) for an electronically transmitted prescription, electronically transmit the instruction "May substitute."; and

(2) the pharmacist must inform the customer of the substitution.

(b) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.7; P.L.291-2001, SEC.233; P.L.204-2005, SEC.10; P.L.96-2014, SEC.5.

IC 16-42-22-9

Transmission of practitioner's instructions to pharmacist

Sec. 9. If the practitioner communicates instructions to the pharmacist orally or electronically, the pharmacist shall:

(1) indicate the instructions in the pharmacist's own handwriting on the written copy of the prescription order; or

(2) record the electronically transmitted instructions in an electronic format.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.11.

IC 16-42-22-10

Substitution prohibited

Sec. 10. (a) If a prescription is filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, or the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall substitute a generically equivalent drug product and inform the customer of the substitution if the substitution would result in a lower price unless:

(1) the words "Brand Medically Necessary" or words of similar meaning are:

(A) written in the practitioner's own writing on the form; or

(B) electronically transmitted with an electronically transmitted prescription; or

(2) the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by:

(A) orally stating that a substitution is not permitted; or

(B) for an electronically transmitted prescription, indicating with the electronic prescription that a substitution is not permitted.

(b) If a practitioner orally states that a generically equivalent drug product may not be substituted, the practitioner must subsequently

forward to the pharmacist a written or electronically transmitted prescription with the "Brand Medically Necessary" instruction appropriately indicated in the physician's own handwriting.

(c) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.8; P.L.291-2001, SEC.234; P.L.204-2005, SEC.12; P.L.32-2013, SEC.1.

IC 16-42-22-11

Substitution of generic drugs; identification of brand name drug

Sec. 11. If under this section a pharmacist substitutes a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the brand name drug for which the substitution is made and the generic drug. The identification required under this subsection must take the form of the following statement on the drug container label, with the generic name and the brand name inserted on the blank lines:

"_____ Generic for _____".

As added by P.L.2-1993, SEC.25. Amended by P.L.186-1993, SEC.1.

IC 16-42-22-12

Identification of manufacturer or distributor of dispensed drug product on prescription

Sec. 12. The pharmacist shall record on the prescription in writing or in an electronic format for an electronically transmitted prescription the name of the manufacturer or distributor, or both, of the actual drug product dispensed under this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.13.

IC 16-42-23

Chapter 23. Drugs: Use of Amygdalin (Laetrile)

IC 16-42-23-1

Health care facilities; restrictions on use

Sec. 1. Except as provided in section 8 of this chapter, a hospital or other health care facility may not interfere with the physician-patient relationship by restricting or forbidding the use of amygdalin (laetrile) as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of any malignancy, disease, illness, or physical condition if the following conditions exist:

- (1) Amygdalin (laetrile) is prescribed or administered by a physician holding an unlimited license for the practice of medicine in Indiana.
- (2) The patient has signed the "written informed request" as set forth in section 5 of this chapter.

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

IC 16-42-23-2

Disciplinary action against attending physician

Sec. 2. A physician may not be subjected to disciplinary action by the medical licensing board of Indiana for prescribing or administering amygdalin (laetrile) to a patient under the physician's care as an adjunct to recognized, customary, or accepted modes of therapy in the treatment of a malignancy, a disease, an illness, or a physical condition if the patient has signed the written informed request as set forth in section 5 of this chapter.

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

IC 16-42-23-3

Prescription or administration permitted with written informed request

Sec. 3. A physician may prescribe or administer amygdalin (laetrile) instead of or in addition to customary or accepted modes of therapy in the treatment of a malignancy, a disease, an illness, or a physical condition of a patient who has signed the written informed request as set forth in section 5 of this chapter.

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

IC 16-42-23-4

Construction of chapter

Sec. 4. (a) This chapter does not constitute an endorsement of amygdalin (laetrile) for the treatment of a malignancy, a disease, an illness, or a physical condition.

(b) This chapter does not prevent a physician from prescribing amygdalin (laetrile) as a dietary supplement to a patient not suffering from a known malignancy, disease, illness, or physical condition

upon execution of the written informed request.
As added by P.L.2-1993, SEC.25.

IC 16-42-23-5

Written informed request form

Sec. 5. (a) The written informed request must be on a form prepared by and obtained from the medical licensing board of Indiana and must be in substance as follows:

WRITTEN INFORMED REQUEST
FOR PRESCRIPTION OF AMYGDALIN
(LAETRILE) FOR MEDICAL
TREATMENT

Patient's name _____

Address _____

Age _____ Sex _____

Name and address of prescribing physician

Malignancy, disease, illness, or physical condition diagnosed for medical treatment by amygdalin (laetrile) or the use of amygdalin as a dietary supplement:

My physician has explained the following to me:

(1) That the manufacture and distribution of amygdalin (laetrile) has been banned by the Federal Food and Drug Administration.

(2) That neither the American Cancer Society, the American Medical Association, nor the Indiana State Medical Association recommend use of amygdalin (laetrile) in the treatment of a malignancy, a disease, an illness, or a physical condition.

(3) That there are alternative recognized treatments for the malignancy, disease, illness, or physical condition from which I suffer that my physician has offered to provide for me, including the following:

(Here describe)

Notwithstanding this explanation, I request prescription and use of amygdalin (laetrile):

(1) in the medical treatment of the malignancy, disease, illness, or physical condition from which I suffer (); or

(2) as a dietary supplement ().

(Check (1) or (2))

Patient or person signing for patient

ATTEST:

Prescribing physician

(b) A copy of the written informed request shall be forwarded after execution to the medical licensing board of Indiana for appropriate filing.

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

IC 16-42-23-6

Regulation of use, sale, prescription, manufacture, or distribution within state

Sec. 6. (a) Amygdalin (laetrile) is not a drug or a controlled substance under Indiana statutes governing the use, manufacture, or distribution of drugs and controlled substances within Indiana.

(b) A physician may prescribe amygdalin (laetrile) under this chapter as a treatment that may be prescribed under IC 25-22.5-1-1.1(f).

(c) The state department and the Indiana board of pharmacy may regulate the manufacture, distribution, and sale of amygdalin (laetrile) for use within Indiana only to ensure that the substance is not adulterated or misbranded within the meaning of IC 16-42-3.

(d) The state department may not adopt a rule that prohibits the use of amygdalin (laetrile) in a hospital, an ambulatory outpatient surgical center, or a health care facility licensed by the state department.

(e) The Indiana board of pharmacy may not adopt a rule that prohibits the manufacture, distribution, or sale of amygdalin (laetrile) by a person or in any place licensed by the Indiana board of pharmacy.

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

IC 16-42-23-7

Required manufacture, sale, distribution, or prescription

Sec. 7. (a) This chapter does not require a:

- (1) physician;
- (2) pharmacist;
- (3) pharmacy;
- (4) manufacturer; or
- (5) distributor;

to manufacture, sell, or distribute amygdalin (laetrile).

(b) This chapter does not require a physician to prescribe amygdalin (laetrile) for a patient.

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

IC 16-42-23-8

Federal funding of health care facilities

Sec. 8. If:

- (1) the federal government indicates that the federal government will withdraw all federal funds from a health care facility for allowing amygdalin (laetrile) to be used within the facility; and
- (2) providing or allowing use of amygdalin (laetrile) within the

facility would jeopardize the receipt of:

(A) federal funds for reimbursement for Medicare or Medicaid for all persons within the facility; or

(B) construction funds provided by the federal government under the Hill-Burton Hospital Construction Program (42 U.S.C. 291 et seq.) or under Title XVI of the Public Health Services Act (42 U.S.C. 300q-300t);

the hospital or other health care facility may prohibit the use of amygdalin (laetrile) within the hospital or facility.

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

IC 16-42-24

Chapter 24. Drugs: Use of Chymopapain

IC 16-42-24-1

Record of use

Sec. 1. The state department shall establish a record keeping system concerning the use of chymopapain and its effectiveness. The state department may require neurosurgeons and orthopedic surgeons to supply information concerning the use of chymopapain.

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

IC 16-42-24-2

Administration restricted

Sec. 2. Only a neurosurgeon or an orthopedic surgeon may administer chymopapain. Chymopapain may only be administered in a hospital licensed under IC 16-21-2.

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

IC 16-42-24-3

Hospital's restricting or forbidding use prohibited; conditions

Sec. 3. Except as provided in section 10 of this chapter, a hospital may not interfere with the physician-patient relationship by restricting or forbidding the use of chymopapain for treatment of certain back ailments if the following conditions are met:

- (1) Chymopapain is administered by a neurosurgeon or an orthopedic surgeon holding an unlimited license to practice medicine in Indiana.
- (2) The patient has signed the request form described in section 7 of this chapter.

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

IC 16-42-24-4

Disciplinary action against attending physician prohibited if use requested by patient

Revisor's Note: The version of IC 16-42-24-4 appearing in the 1993 Edition of the Indiana Code was printed incorrectly. Use the following version of IC 16-42-24-4.

Sec. 4. A neurosurgeon or an orthopedic surgeon may not be subjected to disciplinary action by the medical licensing board of Indiana for administering chymopapain to a patient under the neurosurgeon's or orthopedic surgeon's care to treat certain back ailments if the patient has signed the request form described in section 7 of this chapter.

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

IC 16-42-24-5

Use permitted in place of other therapies if requested by patient

Sec. 5. A neurosurgeon or an orthopedic surgeon may administer

chymopapain instead of other modes of therapy for treatment of certain back ailments of a patient who has signed the request form described in section 7 of this chapter.

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

IC 16-42-24-6

Construction of chapter

Sec. 6. This chapter is not an endorsement of chymopapain for the treatment of back ailments.

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

IC 16-42-24-7

Use request form

Sec. 7. (a) The state department shall prepare a form for a patient to use to request administration of chymopapain. The form must be substantially in the following form:

REQUEST FOR ADMINISTRATION OF
CHYMOPAPAIN FOR MEDICAL
TREATMENT

Patient's name _____

Address _____

Age _____ Sex _____

Name and address of administering physician

Physical condition diagnosed for medical treatment by
chymopapain

My physician has explained the following to me:

(1) That the manufacture and distribution of chymopapain has been banned by the federal Food and Drug Administration.

(2) That there are alternative recognized treatments for the back ailment from which I suffer that my physician has offered to provide for me, including the following: (Here describe)

Notwithstanding this explanation, I request the administration of chymopapain in the medical treatment of the back ailment from which I suffer.

Patient or person signing for patient

ATTEST:

Prescribing physician

(b) A copy of the request form shall be sent immediately after execution to the state department.

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

IC 16-42-24-8

Regulation of manufacture, distribution, sale, or use

Sec. 8. (a) Chymopapain is not a drug or a controlled substance under Indiana statutes governing the use, manufacture, or distribution of drugs and controlled substances within Indiana.

(b) The state department and the Indiana board of pharmacy may regulate the manufacture, distribution, and sale of chymopapain for use within Indiana only to ensure that the substance is not adulterated or misbranded within the meaning of IC 16-42-3.

(c) The state department may not adopt a rule that prohibits the use of chymopapain in a hospital or health care facility licensed by the state department.

(d) The Indiana board of pharmacy may not adopt a rule that prohibits the manufacture, distribution, or sale of chymopapain by a person or in a place licensed by the Indiana board of pharmacy.

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

IC 16-42-24-9

Manufacture, sale, distribution, or prescription not required

Sec. 9. (a) This chapter does not require a:

- (1) physician;
- (2) pharmacist;
- (3) pharmacy;
- (4) manufacturer; or
- (5) distributor;

to manufacture, sell, or distribute chymopapain.

(b) This chapter does not require a physician to prescribe chymopapain for a patient.

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

IC 16-42-24-10

Use prohibition by health care facility facing loss of federal funding

Sec. 10. If:

- (1) the federal government indicates that the federal government will withdraw all federal funds from a health care facility for allowing chymopapain to be used within the facility; and
- (2) providing or allowing use of chymopapain within the facility would jeopardize the receipt of:
 - (A) federal funds for reimbursement for Medicare or Medicaid for all persons within the facility; or
 - (B) construction funds provided by the federal government under the Hill-Burton Hospital Construction Program (42 U.S.C. 291 et seq.) or under Title XVI of the Public Health Services Act (42 U.S.C. 300q-300t);

the hospital or other health care facility may prohibit the use of chymopapain within the hospital or facility.

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

IC 16-42-25

Chapter 25. Drugs: Biosimilar Biological Products

IC 16-42-25-1

"Biological product"

Sec. 1. As used in this chapter, "biological product" means:

- (1) a virus;
- (2) a therapeutic serum;
- (3) a toxin;
- (4) an antitoxin;
- (5) a vaccine;
- (6) blood;
- (7) a blood component;
- (8) a blood derivative;
- (9) an allergenic product;
- (10) a protein (except any chemically synthesized polypeptide);
- (11) a product analogous to a product described in subdivisions (1) through (10);
- (12) arsphenamine;
- (13) an arsphenamine derivative; or
- (14) any other trivalent organic arsenic compound;

applicable to the prevention, treatment, or cure of a disease or condition for human beings.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-2

"Biosimilar"

Sec. 2. As used in this chapter, "biosimilar" refers to a biological product that:

- (1) has been licensed as a biosimilar product under 41 U.S.C. 262(k) or has been approved based on an application filed under 21 U.S.C. 355(b)(2); and
- (2) is highly similar to the reference product, with:
 - (A) no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product; and
 - (B) only minor differences in clinically inactive components.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-3

"Interchangeable"

Sec. 3. As used in this chapter, "interchangeable" means:

- (1) a determination by the federal Food and Drug Administration that a biosimilar product may be substituted for a reference biological product without the intervention of the health care provider that prescribed the biological product; or
- (2) concerning a biological product filed under 21 U.S.C. 355(b)(2), a product that is designated as therapeutically

equivalent by the federal Food and Drug Administration in the Approved Drug Products with Therapeutic Equivalence Evaluations.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-4

Substitution; conditions

Sec. 4. A pharmacist may substitute for a prescribed biological product if the following conditions are met:

- (1) The substitute has been determined by the federal Food and Drug Administration to be interchangeable with the prescribed biological product.
- (2) The prescribing practitioner has:
 - (A) for a written prescription, signed on the line under which the words "May substitute." appear; or
 - (B) for an electronically transmitted prescription, electronically transmitted the instruction "May substitute."
- (3) The pharmacist has informed the customer of the substitution.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-5

Records of dispensing biologic product; time frame; exception

Sec. 5. (a) Except as provided in subsection (b), in order to ensure medical records are complete and accurate, a pharmacist shall, not later than ten (10) calendar days after dispensing a biologic product, record the name and manufacturer of the biologic product dispensed using:

- (1) an interoperable electronic health records system shared with the prescribing practitioner, to the extent a system is in place between the pharmacist and the practitioner; or
- (2) if an electronic health records system is not in place between the pharmacist and the prescribing practitioner, any prevailing means available to communicate to the prescribing practitioner the name and manufacturer of the biologic product dispensed.

(b) The pharmacist is not required to report to or communicate with the prescribing practitioner under subsection (a)(2) if:

- (1) there is no federal Food and Drug Administration approved interchangeable biological product for the prescribed biological product; or
- (2) the refill prescription is not changed from the product originally dispensed.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-6

Record retention; pharmacy; prescribing practitioner

Sec. 6. (a) The pharmacy shall retain a record in accordance with

IC 25-26-13-25(a) of the dispensed biological product.

(b) The prescribing practitioner shall retain a record in accordance with IC 16-39-7-1 of the dispensed biological product.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-7

Link to current list of interchangeable biological products; rules

Sec. 7. (a) The Indiana board of pharmacy shall maintain a link on the board's Internet web site to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific reference biological product.

(b) The Indiana board of pharmacy may adopt rules under IC 4-22-2 necessary to implement this chapter.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-8

Compliance with prescription requirements

Sec. 8. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6.

As added by P.L.96-2014, SEC.6.

IC 16-42-26

Chapter 26. Drugs: Investigational Drug, Biological Product, or Device

IC 16-42-26-1

Affect on clinical trial laws; availability

Sec. 1. (a) This chapter does not affect IC 5-10-8-15, IC 12-15-5-9.2, IC 27-8-25, or IC 27-13-7-20.2.

(b) This chapter does not require a manufacturer to make available any investigational drug, biological product, or device.

As added by P.L.2-2015, SEC.3.

IC 16-42-26-2

"Investigational drug, biological product, or device"

Sec. 2. As used in this chapter, "investigational drug, biological product, or device" means an investigational or experimental:

- (1) drug;
- (2) biological product; or
- (3) medical device;

that has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial, but has not been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial.

As added by P.L.2-2015, SEC.3.

IC 16-42-26-3

"Qualified patient"

Sec. 3. As used in this chapter, "qualified patient" means a patient who meets the requirements under IC 25-22.5-1-2.1(a).

As added by P.L.2-2015, SEC.3.

IC 16-42-26-4

Availability of investigational drug, biological product, or device

Sec. 4. (a) A manufacturer of an investigational drug, biological product, or device may make available the investigational drug, biological product, or device to a qualified patient.

(b) A manufacturer may do any of the following:

- (1) Provide an investigational drug, biological product, or device to a qualified patient without receiving compensation.
- (2) Require a qualified patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

As added by P.L.2-2015, SEC.3.

IC 16-42-26-5

Causes of action

Sec. 5. This chapter does not create a cause of action against a manufacturer of an investigational drug, biological product, or device

for any harm to a qualified patient resulting from use of an
investigational drug, biological product, or device.
As added by P.L.2-2015, SEC.3.

IC 16-42-27

Chapter 27. Drugs: Overdose Intervention Drugs

IC 16-42-27-1

"Prescriber"

Sec. 1. As used in this chapter, "prescriber" means any of the following:

- (1) A physician licensed under IC 25-22.5.
- (2) A physician assistant licensed under IC 25-27.5 and granted the authority to prescribe by the physician assistant's supervisory physician and in accordance with IC 25-27.5-5-4.
- (3) An advanced practice nurse licensed and granted the authority to prescribe drugs under IC 25-23.
- (4) The state health commissioner, if the state health commissioner holds an active license under IC 25-22.5.
- (5) A public health authority.

As added by P.L.32-2015, SEC.7. Amended by P.L.6-2016, SEC.5.

IC 16-42-27-2

Prescribing or dispensing of overdose intervention drug without examination; requirements; administration of drug; exemption from practice of medicine; entities acting under standing order; statewide standing order; immunity from prosecution

Sec. 2. (a) A prescriber may, directly or by standing order, prescribe or dispense an overdose intervention drug without examining the individual to whom it may be administered if all of the following conditions are met:

- (1) The overdose intervention drug is dispensed or prescribed to:
 - (A) a person at risk of experiencing an opioid-related overdose; or
 - (B) a family member, a friend, or any other individual or entity in a position to assist an individual who, there is reason to believe, is at risk of experiencing an opioid-related overdose.
- (2) The prescriber instructs the individual receiving the overdose intervention drug or prescription to summon emergency services either immediately before or immediately after administering the overdose intervention drug to an individual experiencing an opioid-related overdose.
- (3) The prescriber provides education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.
- (4) The prescriber provides drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication

for the treatment of opioid or alcohol dependence.

(b) A prescriber may provide a prescription of an overdose intervention drug to an individual as a part of the individual's addiction treatment plan.

(c) An individual described in subsection (a)(1) may administer an overdose intervention drug to an individual who is suffering from an overdose.

(d) An individual described in subsection (a)(1) may not be considered to be practicing medicine without a license in violation of IC 25-22.5-8-2, if the individual, acting in good faith, does the following:

(1) Obtains the overdose intervention drug from a prescriber or entity acting under a standing order issued by a prescriber.

(2) Administers the overdose intervention drug to an individual who is experiencing an apparent opioid-related overdose.

(3) Attempts to summon emergency services either immediately before or immediately after administering the overdose intervention drug.

(e) An entity acting under a standing order issued by a prescriber must do the following:

(1) Annually register with either the:

(A) state department; or

(B) local health department in the county where services will be provided by the entity;

in a manner prescribed by the state department.

(2) Provide education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.

(3) Provide drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence.

(4) Submit an annual report to the state department containing:

(A) the number of sales of the overdose intervention drug dispensed;

(B) the dates of sale of the overdose intervention drug dispensed; and

(C) any additional information requested by the state department.

(f) The state department shall ensure that a statewide standing order for the dispensing of an overdose intervention drug in Indiana is issued under this section. The state health commissioner or a designated public health authority who is a licensed prescriber may, as part of the individual's official capacity, issue a statewide standing order that may be used for the dispensing of an overdose intervention drug under this section. The immunity provided in IC 34-13-3-3

applies to an individual described in this subsection.

(g) A law enforcement officer may not take an individual into custody based solely on the commission of an offense described in subsection (h), if the law enforcement officer, after making a reasonable determination and considering the facts and surrounding circumstances, reasonably believes that the individual:

- (1) obtained the overdose intervention drug as described in subsection (a)(1);
- (2) complied with the provisions in subsection (d);
- (3) administered an overdose intervention drug to an individual who appeared to be experiencing an opioid-related overdose;
- (4) provided:
 - (A) the individual's full name; and
 - (B) any other relevant information requested by the law enforcement officer;
- (5) remained at the scene with the individual who reasonably appeared to be in need of medical assistance until emergency medical assistance arrived;
- (6) cooperated with emergency medical assistance personnel and law enforcement officers at the scene; and
- (7) came into contact with law enforcement because the individual requested emergency medical assistance for another individual who appeared to be experiencing an opioid-related overdose.

(h) An individual who meets the criteria in subsection (g) is immune from criminal prosecution for the following:

- (1) IC 35-48-4-6 (possession of cocaine).
- (2) IC 35-48-4-6.1 (possession of methamphetamine).
- (3) IC 35-48-4-7 (possession of a controlled substance).
- (4) IC 35-48-4-8.3 (possession of paraphernalia).
- (5) IC 35-48-4-11 (possession of marijuana).
- (6) IC 35-48-4-11.5 (possession of a synthetic drug or synthetic drug lookalike substance).

As added by P.L.32-2015, SEC.7. Amended by P.L.6-2016, SEC.6.

IC 16-42-27-3

Immunity of provider, pharmacist, individual, entity

Sec. 3. (a) Except for an act of gross negligence or willful misconduct, a prescriber who dispenses or prescribes an overdose intervention drug in compliance with this chapter is immune from civil liability arising from those actions.

(b) Except for an act of gross negligence or willful misconduct, a pharmacist who dispenses an overdose intervention drug in compliance with this chapter is immune from civil liability arising from those actions.

(c) Except for an act of gross negligence or willful misconduct, an individual or entity described in section 2(a)(1) of this chapter is immune from civil liability for the following actions:

- (1) Obtaining an overdose intervention drug under this chapter.
- (2) Administering an overdose intervention drug in good faith.
- (3) Acting under a standing order under this chapter.

As added by P.L.32-2015, SEC.7.