

HOUSE BILL No. 1185

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-28; IC 34-30-2-83.9.

Synopsis: Prescription drug donation repositories. Establishes the prescription drug donation repository program (program) to allow a person to donate prescription drugs and supplies to a central repository or local repository for use by an individual who is an eligible recipient or qualified individual. Provides that controlled substances are not allowed in the program. Allows a health care facility or pharmacy to elect to participate as a local repository in the program. Establishes criteria for the acceptance and distribution of donated prescription drugs and supplies. Establishes immunity for certain persons who act reasonably and in good faith under the program.

Effective: July 1, 2020.

Bartels

January 13, 2020, read first time and referred to Committee on Public Health.



Second Regular Session of the 121st General Assembly (2020)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2019 Regular Session of the General Assembly.

HOUSE BILL No. 1185

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 16-18-2-106.7 IS ADDED TO THE INDIANA
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 2020]: **Sec. 106.7. "Eligible recipient", for**
4 **purposes of IC 16-42-28, has the meaning set forth in**
5 **IC 16-42-28-2.**

6 SECTION 2. IC 16-18-2-161, AS AMENDED BY P.L.113-2015,
7 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
8 JULY 1, 2020]: Sec. 161. (a) "Health care facility" includes:

9 (1) hospitals licensed under IC 16-21-2, private mental health
10 institutions licensed under IC 12-25, and tuberculosis hospitals
11 established under IC 16-11-1 (before its repeal);

12 (2) health facilities licensed under IC 16-28; and

13 (3) rehabilitation facilities and kidney disease treatment centers.

14 (b) "Health care facility", for purposes of IC 16-21-11 and
15 IC 16-34-3, has the meaning set forth in IC 16-21-11-1.

16 (c) "Health care facility", for purposes of IC 16-28-13, has the
17 meaning set forth in IC 16-28-13-0.5.



1 **(d) "Health care facility", for purposes of IC 16-42-28, has the**
 2 **meaning set forth in IC 16-42-28-3.**

3 SECTION 3. IC 16-18-2-281.2 IS ADDED TO THE INDIANA
 4 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 5 [EFFECTIVE JULY 1, 2020]: **Sec. 281.2. "Pharmacy", for purposes**
 6 **of IC 16-42-28, has the meaning set forth in IC 16-42-28-4.**

7 SECTION 4. IC 16-18-2-288, AS AMENDED BY P.L.96-2014,
 8 SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 9 JULY 1, 2020]: Sec. 288. (a) "Practitioner", for purposes of
 10 IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

11 (b) "Practitioner", for purposes of IC 16-41-14, has the meaning set
 12 forth in IC 16-41-14-4.

13 (c) "Practitioner", for purposes of IC 16-42-21, has the meaning set
 14 forth in IC 16-42-21-3.

15 (d) "Practitioner", for purposes of IC 16-42-22 and IC 16-42-25, has
 16 the meaning set forth in IC 16-42-22-4.5.

17 **(e) "Practitioner", for purposes of IC 16-42-28, has the meaning**
 18 **set forth in IC 16-42-28-5.**

19 SECTION 5. IC 16-18-2-292 IS AMENDED TO READ AS
 20 FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 292. (a) "Prescription",
 21 for purposes of IC 16-42-19, has the meaning set forth in
 22 IC 16-42-19-7.

23 **(b) "Prescription", for purposes of IC 16-42-28, has the meaning**
 24 **set forth in IC 16-42-28-6.**

25 SECTION 6. IC 16-18-2-294.5, AS AMENDED BY P.L.208-2015,
 26 SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 27 JULY 1, 2020]: Sec. 294.5. (a) "Program", for purposes of IC 16-40-4,
 28 has the meaning set forth in IC 16-40-4-3.

29 (b) "Program", for purposes of IC 16-41-7.5, has the meaning set
 30 forth in IC 16-41-7.5-2.

31 **(c) "Program", for purposes of IC 16-42-28, has the meaning set**
 32 **forth in IC 16-42-28-7.**

33 ~~(c)~~ (d) "Program", for purposes of IC 16-47-1, has the meaning set
 34 forth in IC 16-47-1-3.

35 SECTION 7. IC 16-18-2-344.5 IS ADDED TO THE INDIANA
 36 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 37 [EFFECTIVE JULY 1, 2020]: **Sec. 344.5. "Supplies", for purposes**
 38 **of IC 16-42-28, has the meaning set forth in IC 16-42-28-8.**

39 SECTION 8. IC 16-42-28 IS ADDED TO THE INDIANA CODE
 40 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE
 41 JULY 1, 2020]:

42 **Chapter 28. Prescription Drug Donation Repository Program**



1 **Sec. 1. (a) Nothing in this chapter restricts the use of samples by**
 2 **a physician or other person legally authorized to prescribe drugs**
 3 **under state and federal law during the course of the physician's or**
 4 **other person's duties at a health care facility or pharmacy.**

5 **(b) Nothing in this chapter authorizes the resale of prescription**
 6 **drugs by any person.**

7 **Sec. 2. As used in this chapter, "eligible recipient" means an**
 8 **individual:**

9 **(1) with an income that is below two hundred percent (200%)**
 10 **of the federal poverty level, as defined by the most recently**
 11 **revised poverty income guidelines published by the federal**
 12 **Department of Health and Human Services; and**

13 **(2) who is not eligible for pharmaceutical coverage through a**
 14 **government program or private health insurance.**

15 **Sec. 3. As used in this chapter, "health care facility" means any**
 16 **of the following:**

17 **(1) A physician's office.**

18 **(2) A hospital.**

19 **(3) A health clinic, including the following:**

20 **(A) A federally-qualified health center as defined in 42**
 21 **U.S.C. 1396d(l)(2)(B).**

22 **(B) A rural health clinic described in section 42 U.S.C.**
 23 **1396d(l)(1).**

24 **(4) A nonprofit health clinic that provides medical care to**
 25 **patients who are indigent, uninsured, underinsured, or unable**
 26 **to pay for the services.**

27 **(5) A charitable organization described in Section 501(c)(3) of**
 28 **the Internal Revenue Code that has as its primary purpose the**
 29 **sponsorship or support of programs designed to improve the**
 30 **quality, awareness, and availability of medical services to**
 31 **individuals.**

32 **(6) A health facility.**

33 **Sec. 4. As used in this chapter, "pharmacy" has the meaning set**
 34 **forth in IC 25-26-13-2.**

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

37 **(1) A physician licensed under IC 25-22.5.**

38 **(2) A dentist licensed to practice dentistry IC 25-14.**

39 **(3) A podiatrist licensed to practice podiatric medicine under**
 40 **IC 25-29.**

41 **(4) An optometrist who is:**

42 **(A) licensed to practice optometry in Indiana; and**



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(B) certified under IC 25-24-3.

(5) An advanced practice registered nurse who meets the requirements of IC 25-23-1-19.5.

(6) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.

Sec. 6. As used in this chapter, "prescription" means a drug, as classified by the federal Food and Drug Administration, that is required by the federal Food and Drug Administration to be prescribed or administered to a patient by a practitioner before dispensation, including the following:

- (1) A drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ.
- (2) A drug that is used to treat cancer or the side effects of cancer.
- (3) A drug that is used to treat the side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

The term does not include controlled substances (as defined in IC 35-48-1-9).

Sec. 7. As used in this chapter, "program" refers to the prescription drug donation repository program established by section 9 of this chapter.

Sec. 8. As used in this chapter, "supplies" means the supplies necessary to administer the donated prescription drugs.

Sec. 9. (a) The prescription drug donation repository program is established. The program allows a person to donate prescription drugs and supplies to a central repository or local repository for use by an individual who is an eligible recipient. However, the program may permit prescription drugs and supplies to be dispensed to other qualified individuals if an uninsured or indigent individual is unavailable.

- (b) The state department, in cooperation with the Indiana board of pharmacy (IC 25-26-13-3), shall administer and maintain the program.
- (c) The state department may establish a central depository that accepts donated drugs and supplies, conducts a safety inspection of the drugs, and ships donated drugs and supplies to a local repository.
- (d) The state department may contract with a third party to implement and administer the program.

Sec. 10. (a) A health care facility or pharmacy may elect to participate as a local repository in the program.



1 **(b) Donations of prescription drugs and supplies under the**
2 **program may be made on the premises of the central repository or**
3 **a local repository.**

4 **(c) A local repository must meet the following requirements:**

5 **(1) Comply with all laws applicable to the storage and**
6 **distribution of drugs.**

7 **(2) Provide to the state department the name, street address,**
8 **and telephone number of the pharmacy or health care facility,**
9 **and any state license or registration number issued to the**
10 **pharmacy or health care facility, including the name of the**
11 **issuing agency or board.**

12 **(3) The name and telephone number of the responsible**
13 **practitioner who is employed by or under contract with the**
14 **pharmacy or health care facility.**

15 **(4) A statement, signed and dated by the responsible**
16 **practitioner, indicating that the pharmacy or health care**
17 **facility meets the eligibility requirements under this chapter.**

18 **Sec. 11. A local repository may withdraw from participation in**
19 **the program at any time by providing written notice to the**
20 **department.**

21 **Sec. 12. Any individual who is at least eighteen (18) years of age**
22 **may donate legally obtained prescription drugs or supplies to the**
23 **central repository or a local repository. A practitioner who is**
24 **employed by or under contract with a drug repository shall**
25 **determine that the drugs or supplies meet the requirements of this**
26 **chapter.**

27 **Sec. 13. (a) Except for drugs donated directly from a drug**
28 **manufacturer, a drug that requires storage temperatures other**
29 **than normal room temperature as specified by the manufacturer**
30 **or the United States Pharmacopoeia, or its supplements, may not**
31 **be donated or accepted as part of program.**

32 **(b) The central repository or a local repository may accept and**
33 **dispense a prescription drug if the following requirements are met:**

34 **(1) The drug is in its original sealed and tamper evident**
35 **packaging. However, a drug in a single unit dose or blister**
36 **pack with the outside packaging opened may be accepted if**
37 **the single unit dose packaging is undisturbed.**

38 **(2) The drug has been stored according to manufacturer or**
39 **United States Pharmacopoeia, or its supplements, storage**
40 **requirements.**

41 **(3) The packaging contains the lot number and expiration**
42 **date of the drug.**



1 **(4) The drug has an expiration date that is more than six (6)**
2 **months after the date that the drug was donated. However, a**
3 **donated prescription drug bearing an expiration date that is**
4 **six (6) months or less after the date the prescription drug was**
5 **donated may be accepted and distributed if the drug is in high**
6 **demand and can be dispensed for use before the drug's**
7 **expiration date.**

8 **(5) The drug or its packaging does not have any physical signs**
9 **of tampering, misbranding, deterioration, compromised**
10 **integrity, or adulteration.**

11 **(c) The donated prescription drugs and supplies must be**
12 **inventoried at the central repository or a local repository. If the**
13 **drug:**

14 **(1) has been continually under the control of a practitioner or**
15 **drug manufacturer, the inventory must include the name of**
16 **the drug, strength of the drug, quantity of the drug, and the**
17 **date of donation; or**

18 **(2) has not been continually under the control of a**
19 **practitioner or drug manufacturer, the repository shall collect**
20 **a donation form that is signed by the person making the**
21 **donation or the person's authorized representative.**

22 **(d) The central repository or a local repository shall maintain**
23 **records of the prescription drugs and supplies that are donated,**
24 **accepted, distributed, and dispensed under the program.**

25 **Sec. 14. The central repository or a local repository may charge**
26 **an individual who receives a prescription drug or supplies a**
27 **handling fee that may not exceed two hundred percent (200%) of**
28 **the Medicaid professional dispensing fee.**

29 **Sec. 15. (a) The central repository or a local repository that**
30 **receives prescription drugs or supplies may transfer the**
31 **prescription drugs or supplies to the central repository or a local**
32 **repository for use in the program.**

33 **(b) The state department may receive prescription drugs or**
34 **supplies directly from a prescription drug donation repository**
35 **contractor and may distribute the prescription drugs and supplies**
36 **through practitioners licensed to dispense prescription drugs and**
37 **supplies to an eligible recipient or qualified individual.**

38 **(c) The state department may receive and distribute the**
39 **prescription drugs or supplies under this section during or in**
40 **preparation for a state of disaster emergency proclaimed by the**
41 **governor or during or in preparation for a public health**
42 **emergency.**



1 **Sec. 16. The prescription drugs or supplies that are prescribed**
2 **by a practitioner for use by an eligible recipient or other qualified**
3 **individual must be dispensed by:**

4 **(1) a pharmacist; or**

5 **(2) the prescribing practitioner or the practitioner's**
6 **authorized agent.**

7 **Sec. 17. An individual may receive prescription drugs or**
8 **supplies under the program if the following conditions are met:**

9 **(1) The prescription drugs or supplies are prescribed for the**
10 **individual by a practitioner.**

11 **(2) The:**

12 **(A) individual attests that the individual is an eligible**
13 **recipient; or**

14 **(B) prescribing practitioner attests that an uninsured or**
15 **indigent individual is unavailable.**

16 **Sec. 18. (a) A prescription drug or supplies donated under this**
17 **chapter may not be resold.**

18 **(b) A prescription drug dispensed through the program is not**
19 **eligible for reimbursement under a medical assistance program.**

20 **Sec. 19. (a) If a person who donates prescription drugs under**
21 **this chapter to the central repository or a local repository receives**
22 **a notice from a pharmacy that a prescription drug has been**
23 **recalled, the person shall inform the central repository or a local**
24 **repository of the recall.**

25 **(b) If the central repository or a local repository receives a**
26 **recall notification from a person who donated prescription drugs**
27 **under this chapter, the central repository or a local repository shall**
28 **perform a uniform destruction of all of the recalled prescription**
29 **drugs in the central repository or local repository.**

30 **Sec. 20. (a) A drug manufacturer acting reasonably and in good**
31 **faith is not subject to criminal prosecution or civil liability for**
32 **injury, death, or loss to a person or property for matters related to**
33 **the donation, acceptance, or dispensing of a prescription drug**
34 **manufactured by the drug manufacturer that is donated under this**
35 **chapter, including liability for failure to transfer or communicate**
36 **product or consumer information or the expiration date of the**
37 **donated prescription drug.**

38 **(b) Except as provided in subsections (a) and (c), a person,**
39 **including the state department or the department's employees,**
40 **agents, or volunteers, acting reasonably and in good faith, is:**

41 **(1) immune from civil liability and criminal prosecution for**
42 **injury to or the death of an individual to whom a donated**



1 **prescription drug is dispensed under this chapter; and**
 2 **(2) exempt from disciplinary action related to the person's**
 3 **acts or omissions related to the donation, acceptance,**
 4 **distribution, or dispensing of a donated prescription drug**
 5 **under this chapter.**
 6 **(c) The immunity and exemption provided in subsection (b) do**
 7 **not extend to the following:**
 8 **(1) The donation, acceptance, distribution, or dispensing of a**
 9 **donated prescription drug under this chapter by a person if**
 10 **the person's acts or omissions are not performed reasonably**
 11 **and in good faith.**
 12 **(2) Acts or omissions outside the scope of the program.**
 13 **Sec. 21. The department may adopt rules under IC 4-22-2 to**
 14 **administer the program.**
 15 SECTION 9. IC 34-30-2-83.9 IS ADDED TO THE INDIANA
 16 CODE AS A NEW SECTION TO READ AS FOLLOWS
 17 [EFFECTIVE JULY 1, 2020]: **Sec. 83.9. IC 16-42-28-20 (Concerning**
 18 **drug manufacturers and a person acting reasonably and in good**
 19 **faith).**

