

HOUSE BILL No. 1057

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-28; IC 34-30-2-83.8.

Synopsis: Prescription drug donation repositories. Establishes the prescription drug donation repository program (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 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. Allows an entity that participates in a drug donation program in another state to participate in the program in Indiana. Establishes immunity for certain persons who act reasonably and in good faith under the program.

Effective: July 1, 2022.

Bartels

January 4, 2022, read first time and referred to Committee on Public Health.



Second Regular Session of the 122nd General Assembly (2022)

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 2021 Regular Session of the General Assembly.

HOUSE BILL No. 1057

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, 2022]: **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.50-2021,
7 SECTION 16, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
8 JULY 1, 2022]: 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 16-36-7, has the
2 meaning set forth in IC 16-36-7-11.

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

5 SECTION 3. IC 16-18-2-281.2 IS ADDED TO THE INDIANA
6 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
7 [EFFECTIVE JULY 1, 2022]: **Sec. 281.2. "Pharmacy", for purposes**
8 **of IC 16-42-28, has the meaning set forth in IC 16-42-28-4.**

9 SECTION 4. IC 16-18-2-288, AS AMENDED BY P.L.96-2014,
10 SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
11 JULY 1, 2022]: Sec. 288. (a) "Practitioner", for purposes of
12 IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

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

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

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

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

21 SECTION 5. IC 16-18-2-292.2 IS ADDED TO THE INDIANA
22 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
23 [EFFECTIVE JULY 1, 2022]: **Sec. 292.2. "Prescription drug", for**
24 **purposes of IC 16-42-28, has the meaning set forth in**
25 **IC 16-42-28-6.**

26 SECTION 6. IC 16-18-2-294.5, AS AMENDED BY P.L.208-2015,
27 SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
28 JULY 1, 2022]: Sec. 294.5. (a) "Program", for purposes of IC 16-40-4,
29 has the meaning set forth in IC 16-40-4-3.

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

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

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

36 SECTION 7. IC 16-18-2-344.5 IS ADDED TO THE INDIANA
37 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
38 [EFFECTIVE JULY 1, 2022]: **Sec. 344.5. "Supplies", for purposes**
39 **of IC 16-42-28, has the meaning set forth in IC 16-42-28-8.**

40 SECTION 8. IC 16-42-28 IS ADDED TO THE INDIANA CODE
41 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE
42 JULY 1, 2022]:



Chapter 28. Prescription Drug Donation Repository Program

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

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

(c) Nothing in this chapter requires a:

(1) central repository;

(2) local repository; or

(3) person who donates, transfers, or receives medicine under this chapter; to have a license as a wholesale distributor.

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

(1) either:

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

(B) who has a short term health plan that is allowed under the federal Affordable Care Act but is not required to meet the minimum essential coverage requirements; and

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

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

(1) A physician's office.

(2) A hospital.

(3) A health clinic, including the following:

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

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

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

(5) A charitable organization that is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code that has as its primary purpose the sponsorship or support of programs designed to improve the quality, awareness, and availability of medical services to individuals.



1 (6) A health facility.

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

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

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

7 (2) A dentist licensed to practice dentistry under IC 25-14.

8 (3) A podiatrist licensed to practice podiatric medicine under
9 IC 25-29.

10 (4) An optometrist who is:

11 (A) licensed to practice optometry in Indiana; and

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

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

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

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

22 (1) A drug that suppresses the immune system to prevent or
23 reverse rejection of a transplanted organ.

24 (2) A drug that is used to treat cancer or the side effects of
25 cancer.

26 (3) A drug that is used to treat the side effects of any
27 prescription drug that is used to treat cancer or the side
28 effects of cancer.

29 (4) A drug that is used to treat human immunodeficiency
30 virus (HIV) or the side effects of HIV.

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

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

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

38 **Sec. 9. (a)** The prescription drug donation repository program
39 is established. The program allows a person to donate prescription
40 drugs and supplies to a central repository or local repository for
41 use by an individual who is an eligible recipient. However, the
42 program may permit prescription drugs and supplies to be



1 dispensed to other qualified individuals if an uninsured or indigent
2 individual is unavailable.

3 (b) The state department, in cooperation with the Indiana board
4 of pharmacy (IC 25-26-13-3), shall administer and maintain the
5 program.

6 (c) The state department may establish a central depository that
7 accepts donated prescription drugs and supplies, conducts a safety
8 inspection of the prescription drugs, and ships donated
9 prescription drugs and supplies to a local repository.

10 (d) The state department shall contract with a third party to
11 implement and administer the program.

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

14 (b) Donations of prescription drugs and supplies under the
15 program may be made on the premises of the central repository or
16 a local repository.

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

18 (1) Comply with all laws applicable to the storage and
19 distribution of prescription drugs.

20 (2) Provide to the state department the name, street address,
21 and telephone number of the pharmacy or health care facility,
22 and any state license or registration number issued to the
23 pharmacy or health care facility, including the name of the
24 issuing agency or board.

25 (3) The name and telephone number of the responsible
26 practitioner who is employed by or under contract with the
27 pharmacy or health care facility.

28 (4) A statement, signed and dated by the responsible
29 practitioner, indicating that the pharmacy or health care
30 facility meets the eligibility requirements under this chapter.

31 Sec. 11. A local repository may withdraw from participation in
32 the program at any time by providing written notice to the state
33 department.

34 Sec. 12. Any individual who is at least eighteen (18) years of age
35 may donate legally obtained prescription drugs or supplies to the
36 central repository or a local repository. A practitioner who is
37 employed by or under contract with the central repository or local
38 repository shall determine that the prescription drugs or supplies
39 meet the requirements of this chapter.

40 Sec. 13. (a) Except for prescription drugs donated directly from
41 a drug manufacturer, a prescription drug that requires storage
42 temperatures other than normal room temperature as specified by



1 the drug manufacturer or the United States Pharmacopoeia, or its
2 supplements, may not be donated or accepted as part of the
3 program.

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

6 (1) The drug is in its original sealed and tamper evident
7 packaging. However, a prescription drug in a single unit dose
8 or blister pack with the outside packaging opened may be
9 accepted if the single unit dose packaging is undisturbed.

10 (2) The drug has been stored according to manufacturer or
11 United States Pharmacopoeia, or its supplements, storage
12 requirements, unless a United States Pharmacopoeia
13 recognized method to detect improper temperature variations
14 has been used.

15 (3) The packaging contains the expiration date of the drug
16 and the drug has not expired.

17 (4) The drug has an expiration date that is more than six (6)
18 months after the date that the drug was donated. However, a
19 prescription drug bearing an expiration date that is less than
20 thirty (30) days after the date the drug was donated may be
21 accepted and distributed if the drug is in high demand and
22 can be dispensed for use before the drug's expiration date.

23 (5) The drug or its packaging does not have any physical signs
24 of tampering, misbranding, deterioration, compromised
25 integrity, or adulteration.

26 (c) The donated prescription drugs and supplies must be
27 inventoried at the central repository or a local repository. If the
28 drug:

29 (1) has been continually under the control of a practitioner or
30 drug manufacturer, the inventory must include the name of
31 the drug, strength of the drug, quantity of the drug, and date
32 of donation; or

33 (2) has not been continually under the control of a
34 practitioner or drug manufacturer, the repository shall collect
35 a donation form that is signed by the person making the
36 donation or the person's authorized representative.

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

40 (e) The central repository or a local repository may repackage
41 donated medicine as necessary for storage, dispensing,
42 administration, or transfers if the repackaged medicine is:



1 (1) labeled with the drug name, strength, and expiration date;
2 and

3 (2) kept in a separate designated area until inspected and
4 initialed by a health care professional.

5 If multiple packaged donated medicines with varied expiration
6 dates are repackaged together, the shortest expiration date shall be
7 used. A drug manufacturer's original expiration date may be used
8 in place of a beyond use date.

9 (f) Donated medicine that does not meet the requirements of this
10 section must be disposed of by:

11 (1) returning it to the drug donor;

12 (2) destroying it by an incinerator, medical waste hauler, or
13 other lawful method; or

14 (3) transferring it to a returns processor.

15 (g) A record of disposed medicine under subsection (f) must
16 contain the following information:

17 (1) The disposal method that was used.

18 (2) The date of disposal.

19 (3) The name, strength, and quantity of each drug disposed.

20 Any other information concerning the disposal of the medicine is
21 not required.

22 Sec. 14. The central repository or a local repository may charge
23 an individual who receives a prescription drug or supplies a
24 handling fee that may not exceed the repository's cost of providing
25 the drug or supplies including the following:

26 (1) The current and anticipated costs of educating eligible
27 donors.

28 (2) Providing technical support to participating donors.

29 (3) Shipping and handling, labor, storage, licensing, utilities,
30 advertising, technology, supplies, and equipment.

31 Sec. 15. (a) The central repository or a local repository:

32 (1) that receives prescription drugs or supplies may transfer
33 the prescription drugs or supplies to:

34 (A) the central repository or a local repository for use in
35 the program; or

36 (B) a central repository or local repository located in
37 another state; and

38 (2) may receive prescription drugs or supplies from a central
39 repository or local repository located in another state.

40 (b) The state department may receive prescription drugs or
41 supplies directly from a prescription drug donation repository
42 contractor and may distribute the prescription drugs and supplies



1 through practitioners licensed to dispense prescription drugs and
2 supplies to an eligible recipient or qualified individual.

3 (c) The state department may receive and distribute the
4 prescription drugs or supplies under this section during or in
5 preparation for a state of disaster emergency proclaimed by the
6 governor or during or in preparation for a public health
7 emergency.

8 Sec. 16. The prescription drugs or supplies that are prescribed
9 by a practitioner for use by an eligible recipient or other qualified
10 individual must be dispensed by:

11 (1) a pharmacist; or

12 (2) the prescribing practitioner or the practitioner's
13 authorized agent.

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

16 (1) The prescription drugs or supplies are prescribed for the
17 individual by a practitioner.

18 (2) The:

19 (A) individual attests that the individual is an eligible
20 recipient; or

21 (B) prescribing practitioner attests that an uninsured or
22 indigent individual is unavailable.

23 Sec. 18. (a) A prescription drug or supplies donated under this
24 chapter may not be resold.

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

27 Sec. 19. (a) If a person who donates prescription drugs under
28 this chapter to the central repository or a local repository receives
29 a notice from a pharmacy that a prescription drug has been
30 recalled, the person shall inform the central repository or local
31 repository of the recall.

32 (b) If the central repository or local repository receives a recall
33 notification from a person who donated prescription drugs under
34 this chapter, the central repository or local repository shall
35 perform a uniform destruction of all of the recalled prescription
36 drugs in the central repository or local repository. However, a
37 prescription drug may be retained if the drug has an affixed lot
38 number to exclude it from the recall.

39 Sec. 20. (a) An entity that participates in a drug donation or
40 repository program in another state may participate in the
41 program.

42 (b) If the entity under subsection (a) is a pharmacy that is



1 licensed in another state, the pharmacy may dispense donated
2 prescription drugs and supplies to residents of Indiana.

3 (c) The central repository or a local repository may donate or
4 transfer drugs and supplies to an out-of-state entity that
5 participates in a drug donation or repository program in another
6 state.

7 (d) Notwithstanding any other law, an out-of-state entity that
8 participates in the program is required to comply with the laws
9 and rules of Indiana, unless the law or rule is in conflict with a law
10 or rule in the state where the entity is located.

11 **Sec. 21. (a) A drug manufacturer acting reasonably and in good
12 faith is not subject to criminal prosecution or civil liability for
13 injury, death, or loss to a person or property for matters related to
14 the donation, acceptance, or dispensing of a prescription drug
15 manufactured by the drug manufacturer that is donated under this
16 chapter, including liability for failure to transfer or communicate
17 product or consumer information or the expiration date of the
18 donated prescription drug.**

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

22 (1) immune from civil liability and criminal prosecution for
23 injury to or the death of an individual to whom a donated
24 prescription drug is dispensed under this chapter; and

25 (2) exempt from disciplinary action related to the person's
26 acts or omissions related to the donation, acceptance,
27 distribution, or dispensing of a donated prescription drug
28 under this chapter.

29 (c) The immunity and exemption provided in subsection (b) do
30 not extend to the following:

31 (1) The donation, acceptance, distribution, or dispensing of a
32 donated prescription drug under this chapter by a person if
33 the person's acts or omissions are not performed reasonably
34 and in good faith.

35 (2) Acts or omissions outside the scope of the program.

36 **Sec. 22. The department may adopt rules under IC 4-22-2 to
37 administer the program.**

38 SECTION 9. IC 34-30-2-83.8 IS ADDED TO THE INDIANA
39 CODE AS A NEW SECTION TO READ AS FOLLOWS
40 [EFFECTIVE JULY 1, 2022]: **Sec. 83.8. IC 16-42-28-21 (Concerning
41 drug manufacturers and a person acting reasonably and in good
42 faith).**

