

SENATE BILL NO. 91—SENATOR HARDY

PREFILED JANUARY 27, 2017

Referred to Committee on Health and Human Services

SUMMARY—Revises provisions relating to drug donation programs. (BDR 40-271)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State: Yes.

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EXPLANATION – Matter in *bolded italics* is new; matter between brackets ~~omitted material~~ is material to be omitted.

AN ACT relating to prescription drugs; combining the HIV/AIDS Drug Donation Program and the Cancer Drug Donation Program to create the Prescription Drug Donation Program; authorizing a person or governmental entity to donate certain drugs to the Program; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law establishes the HIV/AIDS Drug Donation Program and the Cancer Drug Donation Program. (NRS 453B.010-453B.130, 453B.150-453B.240) This bill: (1) combines those Programs to create the Prescription Drug Donation Program; and (2) additionally allows a person or governmental entity to donate to the Prescription Drug Donation Program any prescription drug that has a wholesale acquisition cost of more than \$500 per month if the drug is used in accordance with the instructions of the manufacturer.

Section 2 of this bill authorizes a person or governmental entity to donate to the Prescription Drug Donation Program any prescription drug, other than marijuana and certain other drugs for which the patient must be registered with the manufacturer, that: (1) is used to treat the human immunodeficiency virus, acquired immunodeficiency syndrome or cancer; or (2) has a wholesale acquisition cost of more than \$500 per month if the drug is used in accordance with the instructions of the manufacturer. **Section 2** also authorizes a pharmacy, medical facility, health clinic or provider of health care to impose a handling fee upon a patient who receives a donated drug and imposes requirements concerning the acceptance, distribution or dispensing of a donated drug.

Section 3 of this bill prescribes certain recordkeeping requirements relating to donated drugs and the storage of donated drugs. **Section 4** of this bill requires a donated drug to be dispensed by a registered pharmacist, pursuant to a prescription, to a recipient who is eligible under regulations adopted by the State Board of Pharmacy. **Section 5** of this bill requires a pharmacy, medical facility, health clinic or provider of health care that participates in the Program to comply with all



applicable state and federal laws. **Section 5** also authorizes such a pharmacy, medical facility, health clinic or provider of health care to distribute a donated drug to another pharmacy, medical facility, health clinic or provider of health care that participates in the Program. **Section 6** of this bill requires the Board to adopt regulations to carry out the Program. **Section 7** of this bill: (1) provides immunity from liability for certain actions relating to the Program; and (2) requires a person to whom a donated drug is dispensed to sign a waiver of liability for such actions.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN
SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. NRS 453B.060 is hereby amended to read as follows:

453B.060 “Program” means the ~~HIV/AIDS~~ *Prescription* Drug Donation Program established pursuant to NRS 453B.080.

Sec. 2. NRS 453B.080 is hereby amended to read as follows:

453B.080 1. The Board shall establish and maintain the ~~HIV/AIDS~~ *Prescription* Drug Donation Program to accept, distribute and dispense ~~HIV/AIDS~~ *prescription* drugs donated to the Program.

2. ~~Any~~ *Except as otherwise provided in this section, a* person or governmental entity may donate ~~an HIV/AIDS~~ *a prescription* drug to the Program ~~An HIV/AIDS~~ *that:*

(a) Is used to treat the human immunodeficiency virus or acquired immunodeficiency syndrome;

(b) Is used to treat cancer; or

(c) Has a wholesale acquisition cost of more than \$500 per month if the drug is used in accordance with the instructions of the manufacturer.

3. *A drug described in subsection 2* may be donated *to the Program* at a pharmacy, medical facility, health clinic or provider of health care that participates in the Program.

~~3.1~~ 4. A pharmacy, medical facility, health clinic or provider of health care that participates in the Program may charge a patient who receives ~~an HIV/AIDS~~ *a donated* drug a handling fee in accordance with the regulations adopted by the Board pursuant to NRS 453B.120.

~~4.1~~ 5. A pharmacy, medical facility, health clinic or provider of health care that participates in the Program must establish written procedures for receiving and inspecting donated ~~HIV/AIDS~~ drugs. ~~which are approved by the Board.~~

~~5. An HIV/AIDS~~

6. *A drug may be accepted, distributed or dispensed pursuant to the Program only if the HIV/AIDS drug:*

(a) Is a drug described in subsection 2;



(b) Is in its original, unopened, sealed and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;

~~[(b)]~~ (c) Is not adulterated or misbranded; and

~~[(e)]~~ (d) Bears an expiration date that is 180 days or more after the date on which the drug is donated.

~~[6. — An HIV/AIDS]~~

7. A drug donated to the Program may not be:

(a) Resold; or

(b) Designated by the donor for a specific person.

~~[7-]~~ 8. The provisions of this section do not require a pharmacy, medical facility, health clinic or provider of health care to participate in the Program.

9. *Marijuana, as defined in NRS 453.096, or any drug that may only be dispensed to a patient registered with the manufacturer of the drug pursuant to requirements of the United States Food and Drug Administration may not be donated, accepted, distributed or dispensed pursuant to the Program.*

10. *As used in this section, "wholesale acquisition cost" means the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.*

Sec. 3. NRS 453B.090 is hereby amended to read as follows:

453B.090 A pharmacy, medical facility, health clinic or provider of health care that participates in the Program shall:

1. Maintain the records for any ~~[HIV/AIDS]~~ drug that is donated to the Program separate from all other records kept by the pharmacy, medical facility, health clinic or provider of health care. Records for any ~~[HIV/AIDS]~~ drug donated to the Program must include, without limitation:

(a) The date the pharmacy, medical facility, health clinic or provider of health care received the drug;

(b) The date the drug was dispensed pursuant to the original prescription;

(c) The original prescription number of the drug;

(d) The name of the drug;

(e) The dosage of the drug;

(f) The quantity of the drug that is donated;

(g) The date of expiration of the drug;

(h) The name, address and telephone number of the person who originally dispensed the drug;

(i) The name, address and telephone number of the person who donated the drug; and



1 (j) The lot number of the drug.
2 2. Maintain the record of ~~{an HIV/AIDS}~~ *a donated* drug that
3 is distributed to another pharmacy, medical facility, health clinic or
4 provider of health care which is participating in the Program
5 separate from all other records kept by the pharmacy, medical
6 facility, health clinic or provider of health care. The records for any
7 ~~{HIV/AIDS}~~ *donated* drug distributed to another pharmacy, medical
8 facility, health clinic or provider of health care must include,
9 without limitation:

- 10 (a) The information required by subsection 1;
11 (b) The name, address and telephone number of the pharmacy,
12 medical facility, health clinic or provider of health care that is
13 distributing the drug;
14 (c) The quantity of the drug that is being distributed; and
15 (d) The name, address and telephone number of the pharmacy,
16 medical facility, health clinic or provider of health care to which the
17 drug is distributed.

18 3. Record and retain the name and telephone number of any
19 person to whom a donated ~~{HIV/AIDS}~~ drug is dispensed.

20 4. Store ~~{an HIV/AIDS}~~ *a* drug that is donated to the Program:

- 21 (a) Pursuant to the recommendations of the manufacturer of the
22 drug concerning the storage conditions;
23 (b) Separate from all other drugs; and
24 (c) In a locked storage area.

25 **Sec. 4.** NRS 453B.100 is hereby amended to read as follows:

26 453B.100 ~~{An HIV/AIDS}~~ *A* drug donated for use in the
27 Program may only be dispensed:

28 1. By a pharmacist who is registered pursuant to chapter 639 of
29 NRS; ~~{and}~~

30 2. *Pursuant to a prescription written by a person who is*
31 *authorized to write prescriptions; and*

32 3. To a person who is eligible to receive ~~{HIV/AIDS}~~ drugs
33 dispensed pursuant to the Program.

34 **Sec. 5.** NRS 453B.110 is hereby amended to read as follows:

35 453B.110 A pharmacy, medical facility, health clinic or
36 provider of health care that participates in the Program:

37 1. Shall comply with all applicable state and federal laws
38 concerning the storage, distribution and dispensing of any
39 ~~{HIV/AIDS}~~ drugs donated to the Program; and

40 2. May distribute ~~{an HIV/AIDS}~~ *a* drug donated to the
41 Program to another pharmacy, medical facility, health clinic or
42 provider of health care for use in the Program.



1 **Sec. 6.** NRS 453B.120 is hereby amended to read as follows:

2 453B.120 The Board shall adopt regulations to carry out the
3 provisions of this chapter. The regulations must prescribe, without
4 limitation:

5 1. The requirements for the participation of pharmacies,
6 medical facilities, health clinics and providers of health care in the
7 Program. ~~{†}~~ *For medical facilities or providers of health care who*
8 *participate in the Program by accepting, distributing or dispensing*
9 *a drug used to treat cancer, the requirements prescribed pursuant*
10 *to this subsection must include a requirement that any such*
11 *medical facility or provider of health care provide, as a regular*
12 *course of practice, medical services and goods to persons with*
13 *cancer.*

14 2. The criteria for determining the eligibility of persons to
15 receive ~~{HIV/AIDS}~~ drugs dispensed pursuant to the Program,
16 including, without limitation, a requirement that a person apply to
17 the Board on a form prescribed by the Board for eligibility to
18 receive ~~{HIV/AIDS}~~ drugs dispensed or distributed pursuant to the
19 Program. ~~{†}~~

20 3. ~~{The categories of HIV/AIDS drugs that may be accepted for~~
21 ~~distribution or dispensing pursuant to the Program;~~

22 ~~—4.†~~ The maximum fee that a pharmacy, medical facility, health
23 clinic or provider of health care may charge to distribute or dispense
24 ~~{HIV/AIDS}~~ drugs pursuant to the Program. ~~{† and~~

25 ~~—5.†~~ 4. The requirements for the written procedures established
26 by a pharmacy, medical facility, health clinic or provider of health
27 care for receiving and inspecting ~~{donated HIV/AIDS}~~ drugs
28 *donated to the Program* and the manner in which a pharmacy,
29 medical facility, health clinic or provider of health care must submit
30 such procedures for approval.

31 **Sec. 7.** NRS 453B.130 is hereby amended to read as follows:

32 453B.130 1. A person who exercises reasonable care in the
33 donation of ~~{an HIV/AIDS}~~ *a* drug in accordance with the
34 provisions of this chapter and the regulations adopted pursuant
35 thereto is not subject to any civil or criminal liability or disciplinary
36 action by a professional licensing board for any loss, injury or death
37 that results from the donation of the ~~{HIV/AIDS}~~ drug.

38 2. A pharmacy, medical facility, health clinic or provider of
39 health care which participates in the Program and which exercises
40 reasonable care in the acceptance, distribution or dispensation of ~~{an~~
41 ~~HIV/AIDS}~~ *a drug donated to the Program* is not subject to civil or
42 criminal liability or disciplinary action by a professional licensing
43 board for any loss, injury or death that results from the acceptance,
44 distribution or dispensation of the ~~{HIV/AIDS}~~ drug.



3. A manufacturer of ~~an HIV/AIDS~~ a drug *donated to the Program* is not subject to civil or criminal liability for any claim or injury arising from the donation, acceptance, distribution or dispensation of the ~~HIV/AIDS~~ drug pursuant to this chapter and the regulations adopted pursuant thereto.

4. ~~An HIV/AIDS~~ A drug may not be dispensed pursuant to the Program unless the person to whom the drug is dispensed has signed a waiver of liability for any action described in this section performed by any person, pharmacy, medical facility, health clinic, provider of health care or manufacturer of the ~~HIV/AIDS~~ drug.

Sec. 8. NRS 453B.030, 453B.150, 453B.160, 453B.170, 453B.180, 453B.190, 453B.200, 453B.210, 453B.220, 453B.230 and 453B.240 are hereby repealed.

Sec. 9. This act becomes effective upon passage and approval for the purpose of adopting regulations and performing any other preparatory administrative tasks that are necessary to carry out the provisions of this act, and on January 1, 2018, for all other purposes.

LEADLINES OF REPEALED SECTIONS

- 453B.030** “HIV/AIDS drug” defined.
- 453B.150** Definitions.
- 453B.160** “Cancer drug” defined.
- 453B.170** “Medical facility” defined.
- 453B.180** “Program” defined.
- 453B.190** “Provider of health care” defined.
- 453B.200** Establishment of Program; handling fee; conditions for acceptance, distribution and dispensing of donated drugs; certain restrictions.
- 453B.210** Dispensing of donated drug.
- 453B.220** Compliance with applicable laws; authority to distribute donated drug to another participant in Program.
- 453B.230** Regulations.
- 453B.240** Limitation on civil and criminal liability; limitation on disciplinary action by professional licensing board.

