Amendment No. 402

Senate A	(BDR 40-271)						
Proposed by: Senator Hardy							
Amends:	Summary: No	Title: Yes	Preamble: No	Joint Sponsorship: No	Digest: Yes		

ASSEMBLY	ACT	ION	Initial and Date	SENATE ACTIO	ON Initial and Date
Adopted		Lost		Adopted	Lost
Concurred In		Not		Concurred In	Not
Receded		Not		Receded	Not

EXPLANATION: Matter in (1) blue bold italics is new language in the original bill; (2) variations of **green bold underlining** is language proposed to be added in this amendment; (3) **red strikethrough** is deleted language in the original bill; (4) purple double strikethrough is language proposed to be deleted in this amendment; (5) <u>orange double underlining</u> is deleted language in the original bill proposed to be retained in this amendment.

EWR/JWP



S.B. No. 91—Revises provisions relating to drug donation programs.

(BDR 40-271)



Date: 4/17/2017

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.

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] prescription 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 <a href="https://linear.pdf.com/theta-bases/bullet-bases/bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-bases/bullet-

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. It that: (1) is used to treat the human immunodeficiency virus, nequired 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 prescription drug and imposes requirements concerning the acceptance, distribution or dispensing of a donated prescription drug.

Section 3 of this bill prescribes certain recordkeeping requirements relating to donated prescription drugs and the storage of donated prescription drugs a donated prescription 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 prescription 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 prescription 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/AIDSI 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 fan HIV/AIDS af any 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

3

9 10

11 12

13

14

15

16 17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37 38

39

40

41

42

43 44

45

46 47

- (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 prescription 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.] 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 prescription 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] prescription drugs. [which are approved by the Board.
- An HIV/AIDSI
- A prescription drug may be accepted, distributed or dispensed pursuant to the Program only if the [HIV/AIDS] drug:
 - (a) *Hs 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
- (c) (d) Bears an expiration date that is 180 days or more after the date on which the drug is donated.
 - An HIV/AIDS
 - [6. An HIV/AIDS]7. A prescription drug donated to the Program may not be:
 - (a) Resold: or
 - (b) Designated by the donor for a specific person.
- 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

10

11

12

13

14

15

16

17

18

19

20

21

22

23 24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47 48

49

50 51 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] prescription 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] prescription 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

(j) The lot number of the drug.

- 2. Maintain the record of <code>[an HIV/AIDS]</code> a donated prescription drug that is distributed to another pharmacy, medical facility, health clinic or provider of health care which is participating in the Program separate from all other records kept by the pharmacy, medical facility, health clinic or provider of health care. The records for any <code>[HIV/AIDS]</code> donated prescription drug distributed to another pharmacy, medical facility, health clinic or provider of health care must include, without limitation:
 - (a) The information required by subsection 1;
- (b) The name, address and telephone number of the pharmacy, medical facility, health clinic or provider of health care that is distributing the drug;
 - (c) The quantity of the drug that is being distributed; and
- (d) The name, address and telephone number of the pharmacy, medical facility, health clinic or provider of health care to which the drug is distributed.
- 3. Record and retain the name and telephone number of any person to whom a donated [HIV/AIDS] prescription drug is dispensed.
 - 4. Store [an HIV/AIDS] a prescription drug that is donated to the Program:
- (a) Pursuant to the recommendations of the manufacturer of the drug concerning the storage conditions;
 - (b) Separate from all other drugs; and
 - (c) In a locked storage area.

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

453B.100 [An HIV/AIDS] A prescription drug donated for use in the Program may only be dispensed:

- 1. By a pharmacist who is registered pursuant to chapter 639 of NRS; fand
- 2. Pursuant to a prescription written by a person who is authorized to write rescriptions; and
- 3. To a person who is eligible to receive [HIV/AIDS] prescription drugs dispensed pursuant to the Program.

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

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

- 1. Shall comply with all applicable state and federal laws concerning the storage, distribution and dispensing of any [HIV/AIDS] prescription drugs donated to the Program; and
- 2. May distribute [an HIV/AIDS] a prescription drug donated to the Program to another pharmacy, medical facility, health clinic or provider of health care for use in the Program.

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

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

- 1. The requirements for the participation of pharmacies, medical facilities, health clinics and providers of health care in the Program. He For medical facilities or providers of health care who participate in the Program by accepting, distributing or dispensing a prescription drug used to treat cancer, the requirements prescribed pursuant to this subsection must include a requirement that any such medical facility or provider of health care provide, as a regular course of practice, medical services and goods to persons with cancer.
- 2. The criteria for determining the eligibility of persons to receive HIV/AIDS] prescription drugs dispensed pursuant to the Program, including, without limitation, a requirement that a person apply to the Board on a form prescribed by the Board for eligibility to receive HIV/AIDS] prescription drugs dispensed or distributed pursuant to the Program. HIV/AIDS] prescription drugs
- 3. [The categories of HIV/AIDS drugs that may be accepted for distribution or dispensing pursuant to the Program;

— 4.] The maximum fee that a pharmacy, medical facility, health clinic or provider of health care may charge to distribute or dispense [HIV/AIDS] prescription drugs pursuant to the Program. [; and

- 5.] 4. The requirements for the written procedures established by a pharmacy, medical facility, health clinic or provider of health care for receiving and inspecting [donated HIV/AIDS] prescription drugs donated to the Program and the manner in which a pharmacy, medical facility, health clinic or provider of health care must submit such procedures for approval.
 - **Sec. 7.** NRS 453B.130 is hereby amended to read as follows:
- 453B.130 1. A person who exercises reasonable care in the donation of fan HIV/AIDS a prescription drug in accordance with the provisions of this chapter and the regulations adopted pursuant thereto is not subject to any civil or criminal liability or disciplinary action by a professional licensing board for any loss, injury or death that results from the donation of the [HIV/AIDS] prescription drug.
- 2. A pharmacy, medical facility, health clinic or provider of health care which participates in the Program and which exercises reasonable care in the acceptance, distribution or dispensation of [an HIV/AIDS] a prescription drug donated to the Program is not subject to civil or criminal liability or disciplinary action by a professional licensing board for any loss, injury or death that results from the acceptance, distribution or dispensation of the [HIV/AIDS] prescription drug.
- 3. A manufacturer of [an HIV/AIDS] a prescription 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] prescription drug pursuant to this chapter and the regulations adopted pursuant thereto.
- 4. [An HIV/AIDS] A prescription drug may not be dispensed pursuant to the Program unless the person to whom the drug is dispensed has signed a waiver of

10

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] prescription 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.

Definitions. 453B.150

453B.160

"Cancer drug" defined.
"Medical facility" defined. 453B.170

"Program" defined. 453B.180

"Provider of health care" defined. 453B.190

Establishment of Program; handling fee; conditions for 453B.200 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.