Amendment No. 92

Senate A	enate Amendment to Senate Bill No. 91				(BDR 40-271)
Proposed	d by: Senator H	Hardy			
Amends:	Summary: No	Title: No	Preamble: No	Joint Sponsorship: No	Digest: Yes

ASSEMBLY	ACT	TION	Initial and Date	SENATE ACTIO	ON Initial and Date
Adopted		Lost	1	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 <u>green bold underlining</u> is language proposed to be added in this amendment; (3) <u>red strikethrough</u> is deleted language in the original bill; (4) <u>purple double strikethrough</u> 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)

* A S B 9 1 9 2 *

Date: 3/25/2017

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.

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.

EXPLANATION - Matter in bolded italics is new; matter between brackets formitted material is material to be omitted.

Legislative Counsel's Digest:

Existing law establishes the HIV/AIDS Drug Donation Program and the Cancer Drug Donation Program. (NRS 453B.010-453B.130, 450B.150-450B.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 may cost more than \$10,000 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 $\frac{1}{100}$ 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) may cost more than \$10,000 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) May cost more than \$10,000 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.] 4. A pharmacy, medical facility, health clinic or provider of health care that participates in the Program may charge a patient who receives fan HIV/AIDS a donated drug a handling fee in accordance with the regulations adopted by the Board pursuant to NRS 453B.120.
- [4.] 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

(c) (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.
- 17.1 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.
 - **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;

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- (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.
- Maintain the record of [an HIV/AIDS] a donated 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 [HIV/AIDS] donated 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.
- Record and retain the name and telephone number of any person to whom a donated [HIV/AIDS] drug is dispensed.
 4. Store [an HIV/AIDS] a 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 drug donated for use in the Program may only be dispensed:
 - By a pharmacist who is registered pursuant to chapter 639 of NRS; [and]
- Pursuant to a prescription written by a person who is authorized to write prescriptions; and
- 3. To a person who is eligible to receive [HIV/AIDS] drugs dispensed pursuant to the Program.
 - 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] drugs donated to the Program; and
- May distribute [an HIV/AIDS] a 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. [:] For medical facilities or providers of health care who participate in the Program by accepting, distributing or dispensing a 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] 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] drugs dispensed or distributed pursuant to the Program.

pursuant to the Program . [;]

3. [The categories of HIV/AIDS drugs that may be accepted for distribution or dispensing pursuant to the Program:

or dispensing pursuant to the Program;

4.1 The maximum fee that a pharmacy, medical facility, health clinic or provider of health care may charge to distribute or dispense [HIV/AIDS] 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 **Idonated HIV/AIDS** 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 [an HIV/AIDS] a 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] 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 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] drug.

 3. A manufacturer of [an HIV/AIDS] a drug donated to the Program is not
- 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" define	453B.030	"HIV/AID	S drug"	' defined
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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.