ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R007-22

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

AUTHORITY: §§ 1-7 and 10-12, NRS 453B.080 and 453B.120; § 8, NRS 453B.080, 453B.110 and 453B.120; § 9, NRS 453B.080, 453B.100 and 453B.120.

A REGULATION relating to prescription drugs; establishing requirements governing participating in or receiving prescription drugs through the Prescription Drug Donation Program; providing that a participating pharmacy, medical facility, health clinic or provider of health care is not required to accept a donated prescription drug; repealing certain definitions; and providing other matters properly relating thereto.

Legislative Counsel's Digest

Senate Bill No. 91 of the 2017 Legislative Session: (1) combined the HIV/AIDS Drug Donation Program and the Cancer Drug Donation Program; and (2) expanded the combined program to create the Prescription Drug Donation Program. (Chapter 153, Statutes of Nevada 2017, at page 684) Under existing law, the Prescription Drug Donation Program provides for: (1) the donation of any prescription drug, with certain exceptions, through a participating pharmacy, medical facility, health clinic or provider of health care; and (2) the dispensing of donated prescription drugs by pharmacists. (NRS 453B.080, 453B.100) **Sections 2-6 and 8-11** of this regulation revise existing regulations governing the Cancer Drug Donation Program to apply instead to the Prescription Drug Donation Program. **Sections 5, 9 and 12** of this regulation remove the requirement that a person must be approved by the State Board of Pharmacy to receive a drug through the Program, thereby authorizing any resident of this State with a valid prescription to receive such a drug.

Existing regulations prescribe criteria for a pharmacy, medical facility, health clinic or provider of health care to participate in the Program. (NAC 453B.080) **Section 6** of this regulation adds to these eligibility criteria requirements that: (1) a pharmacy must be in good standing with the Board; and (2) a pharmacy, medical facility, health clinic or provider of health care must establish procedures for receiving, inspecting, storing and disposing of donated prescription drugs, keeping records and verifying the eligibility of patients to receive donated prescription drugs through the Program.

Existing regulations require a pharmacy, medical facility, health clinic or provider of health care that wishes to participate in the Program to apply to the Board. (NAC 453B.085) **Section 7** of this regulation requires the Executive Secretary of the Board, rather than the Board, to review such applications. **Section 7** also authorizes a pharmacy, medical facility, health clinic or provider of health care that is aggrieved by the denial of an application by the Executive Secretary to appeal that denial to the Board. **Section 9** provides that a participating pharmacy,

medical facility, health clinic or provider of health care is not required to accept a prescription drug for donation. **Section 12** repeals certain unnecessary definitions and a provision concerning recordkeeping that is duplicative of existing law. **Section 1** of this regulation makes a conforming change to remove references to repealed sections.

Section 1. NAC 453B.010 is hereby amended to read as follows:

453B.010 As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC ~~[453B.015 to 453B.055, inclusive,]~~ ***453B.020, 453B.030 and 453B.035*** have the meanings ascribed to them in those sections.

Sec. 2. NAC 453B.020 is hereby amended to read as follows:

453B.020 ~~[~~"Cancer~~]~~ ***"Donated prescription*** drug" ~~[has the meaning ascribed to it in NRS 453B.160.]~~ ***means a drug that has been donated to the Program.***

Sec. 3. NAC 453B.030 is hereby amended to read as follows:

453B.030 "Distribute" means to deliver, other than by administering or dispensing, a ~~[cancer]~~ ***donated prescription*** drug.

Sec. 4. NAC 453B.035 is hereby amended to read as follows:

453B.035 "Health clinic" means a facility which provides, as a regular course of practice, medical services and goods ~~[to persons with cancer]~~ and is operated by a physician who is licensed pursuant to chapter 630 or 633 of NRS.

Sec. 5. NAC 453B.070 is hereby amended to read as follows:

453B.070 A person who wishes to receive a ~~[cancer]~~ ***donated prescription*** drug dispensed pursuant to the Program must be ~~[:~~

~~1. A]~~ ***a*** resident of this State ***.*** ~~[;~~

~~2. Diagnosed as having cancer; and~~

~~3. Approved to participate in the Program pursuant to NAC 453B.075.]~~

Sec. 6. NAC 453B.080 is hereby amended to read as follows:

453B.080 ***1.*** To be eligible to participate in the Program:

~~[1.]~~ ***(a)*** A pharmacy must ~~[be:~~

~~(a) Licensed]~~ ***:***

(1) Be licensed in this State; ~~[and~~

~~(b) Approved]~~

(2) Have established the procedures required by subsection 2;

(3) Be approved to participate in the Program pursuant to NAC 453B.085 ~~[.]~~ ***; and***

(4) Be in good standing with the Board.

~~[2.]~~ ***(b)*** A medical facility must:

~~[(a)]~~ ***(1)*** Be licensed in this State;

~~[(b) Provide, as a regular course of practice, medical services and goods to persons with cancer; and~~

~~(c)]~~ ***(2) Have established the procedures required by subsection 2; and***

(3) Be approved to participate in the Program pursuant to NAC 453B.085.

~~[3.]~~ ***(c)*** A health clinic must ~~[be]~~ ***:***

(1) Have established the procedures required by subsection 2; and

(2) Be approved to participate in the Program pursuant to NAC 453B.085.

~~[4.]~~ ***(d)*** A provider of health care must:

~~[(a)]~~ ***(1)*** Be licensed in this State;

~~[(b)]~~ ***(2)*** Provide, as a regular course of practice, medical services and goods ~~[to persons with cancer; and~~

~~(c)]~~ ***;***

(3) Have established the procedures required by subsection 2; and

(4) Be approved to participate in the Program pursuant to NAC 453B.085.

2. To be eligible to participate in the Program, a pharmacy, medical facility, health clinic or provider of health care must have established procedures for:

(a) Receiving, inspecting and storing donated prescription drugs in accordance with NAC 453B.105.

(b) Keeping the records required by NRS 453B.090.

(c) Verifying and recording verification that each person who receives a donated prescription drug:

(1) Meets the requirements of NAC 453B.070;

(2) Has been issued a prescription as required by NRS 453B.100; and

(3) Has signed the waiver of liability required by NRS 453B.130.

(d) Disposing of donated prescription drugs.

Sec. 7. NAC 453B.085 is hereby amended to read as follows:

453B.085 1. A pharmacy, medical facility, health clinic or provider of health care that wishes to participate in the Program must submit an application to the Board on a form prescribed by the Board.

2. The ***Executive Secretary of the*** Board ~~[will]~~ ***shall*** review the application and determine if the pharmacy, medical facility, health clinic or provider of health care is qualified to participate in the Program.

3. If the ~~[Board]~~ ***Executive Secretary*** approves a pharmacy, medical facility, health clinic or provider of health care for participation in the Program, the ~~[Board will]~~ ***Executive Secretary shall*** provide written notice of ~~[its]~~ ***his or her*** approval of the application to the pharmacy,

medical facility, health clinic or provider of health care not later than 30 days after ~~[its]~~ ***his or her*** decision.

4. If the ~~[Board]~~ ***Executive Secretary*** denies a pharmacy, medical facility, health clinic or provider of health care from participating in the Program, the ~~[Board will]~~ ***Executive Secretary shall*** provide written notice of ~~[its]~~ ***his or her*** denial of the application to the pharmacy, medical facility, health clinic or provider of health care not later than 30 days after ~~[its]~~ ***his or her*** decision.

5. A pharmacy, medical facility, health clinic or provider of health care that is aggrieved by a decision of the Executive Secretary to deny participation in the Program may appeal that decision by submitting a written notice of appeal to the Board not later than 30 days after receiving notice of the decision pursuant to subsection 4.

Sec. 8. NAC 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 ~~[must]~~ ***shall*** comply with all applicable federal and state laws and regulations when accepting, distributing and dispensing a ~~[cancer]~~ ***donated prescription*** drug pursuant to the Program.

Sec. 9. NAC 453B.105 is hereby amended to read as follows:

453B.105 1. ~~[Except as otherwise required for the storage of cancer drugs pursuant to subsection 3, a]~~ ***A*** pharmacy, medical facility, health clinic or provider of health care ~~[shall not limit the amount of cancer drugs that a person may donate to]~~ ***that participates in*** the Program ~~[.]~~ ***is not required to accept a prescription drug for donation.***

2. In addition to the requirements of NRS ~~[453B.210,]~~ ***453B.100 and 453B.130 and NAC 453B.110,*** a pharmacist may dispense a ~~[cancer]~~ ***donated prescription*** drug to a person ~~[who is participating in the Program]~~ if:

(a) The pharmacist has inspected the packaging of the ~~[cancer]~~ ***donated prescription*** drug to determine if the ~~[cancer]~~ ***donated prescription*** drug meets the requirements of subsection ~~[4]~~ ***6*** of NRS ~~[453B.200;]~~ ***453B.080; and***

(b) ~~[The person requesting the cancer drug presents to the pharmacist the written notice of approval from the Board which states that the person is approved to participate in the Program; and~~

~~(c)]~~ The person requesting the ~~[cancer]~~ ***donated prescription*** drug presents to the pharmacist ~~[a]~~ ***:***

(1) Proof that the person meets the requirements of NAC 453B.070; and

(2) A prescription written by a person who is authorized to write prescriptions.

3. A pharmacy, medical facility, health clinic or provider of health care shall store a ~~[cancer]~~ ***donated prescription*** drug ***:*** ~~[that is donated to the Program:]~~

(a) Pursuant to the recommendations of the manufacturer of the ~~[cancer]~~ ***donated prescription*** drug concerning the storage conditions;

(b) Separately from all other drugs; and

(c) In a locked storage area.

4. If a ~~[cancer]~~ ***donated prescription*** drug ~~[that is donated to the Program]~~ expires before it is dispensed, the pharmacy, medical facility, health clinic or provider of health care shall destroy the ~~[cancer]~~ ***donated prescription*** drug.

Sec. 10. NAC 453B.110 is hereby amended to read as follows:

453B.110 1. In addition to the requirements of NRS ~~[453B.200,]~~ ***453B.080,*** a ~~[cancer]~~ ***donated prescription*** drug ***:*** ~~[that is donated to the Program:]~~

(a) Must not be a controlled substance.

(b) Must not be a compounded drug product.

(c) Must not be dispensed by a pharmacist if the pharmacist suspects that the ~~[cancer]~~ ***prescription*** drug is adulterated or misbranded.

(d) Must not be dispensed by a pharmacist if, in the professional judgment of the pharmacist, there is a reasonable concern relating to the safety or efficacy of the ~~[cancer]~~ ***prescription*** drug.

(e) Must not require refrigeration or freezing or other temperature requirements that are not a controlled room temperature.

(f) Must not be a ~~[cancer]~~ ***prescription*** drug for which a program of restrictive distribution has been established by the manufacturer of the ~~[cancer]~~ ***prescription*** drug.

(g) Must not be a ~~[cancer]~~ ***prescription*** drug for which an ongoing clinical trial or study is being conducted.

(h) Must be a ~~[cancer]~~ ***prescription*** drug that was ***originally*** dispensed pursuant to ~~[an original]~~ ***a*** prescription by a pharmacy licensed pursuant to chapter 639 of NRS.

2. As used in this section, "program of restrictive distribution" means a program that is developed in collaboration with the United States Food and Drug Administration by a manufacturer of a drug to reduce the risks associated with that drug by limiting the persons who can prescribe the drug and who can receive the drug.

Sec. 11. NAC 453B.120 is hereby amended to read as follows:

453B.120 A pharmacy, medical facility, health clinic or provider of health care may charge a handling fee of not more than $10 for distributing or dispensing a ~~[cancer]~~ ***donated prescription*** drug **.** ~~[that is donated to the Program.]~~

Sec. 12. NAC 453B.015, 453B.025, 453B.040, 453B.045, 453B.050, 453B.055, 453B.075 and 453B.115 are hereby repealed.

TEXT OF REPEALED SECTIONS

453B.015 "Board" defined.

"Board" means the State Board of Pharmacy.

453B.025 "Dispense" defined.

"Dispense" has the meaning ascribed to it in NRS 639.0065.

453B.040 "Medical facility" defined.

"Medical facility" has the meaning ascribed to it in NRS 449.0151.

453B.045 "Pharmacy" defined.

"Pharmacy" has the meaning ascribed to it in NRS 639.012.

453B.050 "Program" defined.

"Program" has the meaning ascribed to it in NRS 453B.180.

453B.055 "Provider of health care" defined.

"Provider of health care" has the meaning ascribed to it in NRS 629.031.

453B.075 Submission of application to participate; written notice of approval or denial by Board.

1. A person who wishes to participate in the Program must submit an application to the Board on a form prescribed by the Board.

2. The Board will review the application and determine if the person is qualified to participate in the Program.

3. If the Board approves a person to participate in the Program, the Board will provide written notice of its approval of the application to the person not later than 30 days after its decision.

4. If the Board denies a person from participating in the Program, the Board will provide written notice of its denial of the application to the person not later than 30 days after its decision.

453B.115 Maintenance of records by pharmacy, medical facility, health clinic or provider of health care that participates in Program.

1. In addition to the requirements of NRS 639.2801 and NAC 639.708, a pharmacy, medical facility, health clinic or provider of health care that participates in the Program shall maintain records for a cancer drug that is donated to the Program. The records must include, without limitation:

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

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

(c) The original prescription number of the cancer drug;

(d) The name of the cancer drug;

(e) The dosage of the cancer drug;

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

(g) The date of expiration of the cancer drug;

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

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

(j) The lot number of the cancer drug.

2. A pharmacy, medical facility, health clinic or provider of health care shall maintain records of a cancer drug that is distributed to another pharmacy, medical facility, health clinic or provider of health care that is participating in the Program. The records must include, without limitation:

(a) The information required pursuant to 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 cancer drug;

(c) The quantity of the cancer drug that is being distributed; and

(d) The name and address of the pharmacy, medical facility, health clinic or provider of health care to which the cancer drug is distributed.