

**PROPOSED REGULATION OF THE  
STATE BOARD OF PHARMACY**

**LCB FILE NO. R007-22I**

**The following document is the initial draft regulation proposed  
by the agency submitted on 01/14/2022**

# Proposed Regulation of the Nevada State Board of Pharmacy

Workshop January 13, 2022

Explanation – Language in *blue italics* is new; language in *red text* [~~omitted material~~] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: §1, NRS 639.070

## A REGULATION relating to the donation of prescription medications.

~~NAC 453B.015 “Board” defined. (NRS 453B.230) “Board” means the State Board of Pharmacy.~~

NAC 453B.020 *“Cancer Donated prescription drug” defined. (NRS 453B.230010)*  
~~“Cancer Donated prescription drug” has the meaning ascribed to it in~~ NRS 453B.160 *means a Dangerous Drug as defined in NRS 454.201 that has been previously dispensed on a prescription as defined by NRS 639.013 to an Ultimate User as defined in NRS 454.00978 which has been transferred to the Program. The term does not include a drug donated pursuant to NRS 638.200.*

~~NAC 453B.025 “Dispense” defined. (NRS 453B.230) “Dispense” has the meaning ascribed to it in~~ NRS 639.0065.

NAC 453B.030 **“Distribute” defined.** “Distribute” means to deliver, other than by administering or dispensing, a *cancer donated prescription* drug.

NAC 453B.035 **“Health clinic” defined. (NRS 453B.230010)** “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.

~~NAC 453B.040 “Medical facility” defined. (NRS 453B.230) “Medical facility” has the meaning ascribed to it in~~ NRS 449.0151.

~~NAC 453B.045 “Pharmacy” defined. (NRS 453B.230) “Pharmacy” has the meaning ascribed to it in~~ NRS 639.012.

~~NAC 453B.050 “Program” defined. (NRS 453B.230) “Program” has the meaning ascribed to it in NRS 453B.180.~~

~~—NAC 453B.055 “Provider of health care” defined. (NRS 453B.230) “Provider of health care” has the meaning ascribed to it in NRS 629.031.~~

### Participation of Persons in *the* Program

NAC 453B.070 Eligibility for participation in *the* Program to receive ~~cancer a~~ *donated prescription drug*. (NRS 453B.230~~120~~) A person who wishes to receive a ~~cancer~~ *donated prescription drug* dispensed pursuant to the Program must ~~be~~:

1. ~~Be~~ *A* resident of this State;
- ~~2. Diagnosed as having cancer; and~~
2. ~~3. Approved to participate in the Program pursuant to~~ NAC 453B.075. ~~Receive a~~ *diagnosis from, and a valid prescription written by, a practitioner authorized to prescribe for a drug available through the Program; and*
3. *Sign a waiver of liability provided by the pharmacist that is a participant in the Program and provided care to the patient through the Program for any action described in NRS 453B.130.*

NAC 453B.075 Submission of application to participate; written notice of approval or denial by Board. (NRS 453B.230)

1. A ~~person~~ *pharmacy* who wishes to participate in the Program must submit an application to the Board on a form prescribed by the Board.
2. The ~~Board Executive Secretary~~ will review the application and determine if the ~~person~~ *pharmacy* is qualified to participate in the Program *and has established procedures for:*
  - (a) *Receiving, inspecting, and storage of Donated Prescription Drugs;*
  - (b) *Recording and tracking the source and receipt of Donated Prescription Drugs;*
  - (c) *Verifying and recording the eligibility of persons to receive Donated Prescription Drugs; and*
  - (d) *Disposal of the Donated Prescription Drugs.*
3. If the ~~Board Executive Secretary~~ approves a ~~person~~ *pharmacy* to participate in the Program, the ~~Board Executive Secretary~~ will provide written notice of its approval of the application to the ~~person~~ *pharmacy* not later than 30 days after its decision.

4. If the **Board Executive Secretary** denies a **person pharmacy** from participating in the Program, the **Board Executive Secretary** will provide written notice of its denial of the application to the person not later than 30 days after its decision. *If the pharmacy does not agree with the decision made by the Executive Secretary, the pharmacy may appeal the decision to the Board within 30 days.*

### Participation of ~~Pharmacists, Medical Facilities, Health Clinics and Providers of Health Care Pharmacies~~ in the Program

NAC 453B.080 Eligibility for participation in *the* Program. (NRS 453B.230~~120~~) To be eligible to participate in the Program:

1. A pharmacy must be:

(a) Licensed in this State; ~~and~~

(b) Approved to participate in the Program pursuant to NAC 453B.085~~75~~; ~~and~~

(c) *In good standing with the Board.*

~~—2. A medical facility must:~~

~~—(a) Be licensed in this State;~~

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

~~—(c) Be approved to participate in the Program pursuant to NAC 453B.085.~~

~~—3. A health clinic must be approved to participate in the Program pursuant to NAC 453B.085.~~

~~—4. A provider of health care must:~~

~~—(a) Be licensed in this State;~~

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

~~—(c) Be approved to participate in the Program pursuant to NAC 453B.085.~~

~~—NAC 453B.085—Submission of application to participate; written notice of approval or denial by Board. (NRS 453B.230)~~

~~—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 Board will 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 approves a pharmacy, medical facility, health clinic or provider of health care for participation in the Program, the Board will provide written notice of its approval of the application to the pharmacy, medical facility, health clinic or provider of health care not later than 30 days after its decision.~~

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

**NAC 453B.090 Compliance with federal and state laws and regulations required.** (NRS 453B.200~~110~~, 453B.230) A pharmacy, ~~medical facility, health clinic or provider of health care~~ that participates in the Program must comply with all applicable federal and state laws and regulations when accepting, distributing and dispensing a *donated prescription ~~caner~~* drug pursuant to the Program.

#### **Administration of Program; Fees**

**NAC 453B.100 Board to establish and maintain registry of participants; notification to Board of certain changes in information or status.** (NRS 453B.230~~080~~)

1. The Board will establish and maintain a registry of pharmacies, ~~medical facilities, health clinics and providers of health care~~ that participate in the Program, which must include, without limitation, the name, address and telephone number of each pharmacy, ~~medical facility, health clinic and provider of health care~~ that is authorized by the Board to participate in the Program.

2. A pharmacy, ~~medical facility, health clinic or provider of health care~~ must notify the Board, on a form prescribed by the Board, if the pharmacy, ~~medical facility, health clinic or provider of health care~~:

- (a) Has a change in its name, address or telephone number; or
  - (b) No longer wishes to participate in the Program.
3. The Board will post the registry on the Internet website maintained by the Board.

**NAC 453B.105 Donating, dispensing and storage of ~~cancer~~ donated prescription drugs.** (NRS 453B.230~~080~~; *NRS 453B.090*; *NRS 453B.100*)

1. *Participation in the Program does not mandate a pharmacy to accept donated prescription drugs. Except as otherwise required for the storage of cancer drugs pursuant to subsection 3, 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 the Program.*

2. In addition to the requirements of NRS 453B.210~~100~~, 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~~080~~;

(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 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.

**NAC 453B.110 Restrictions on donated ~~caner~~ prescription drugs.** (NRS 453B.230~~080~~)

1. In addition to the requirements of NRS 453B.200~~080~~, a ~~caner~~ 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 ~~caner~~ donated 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 ~~caner~~ donated 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 ~~caner~~ prescription drug for which a program of restrictive distribution has been established by the manufacturer of the ~~caner~~ donated prescription drug.
- (g) Must not be a ~~caner~~ donated prescription drug for which an ongoing clinical trial or study is being conducted.
- (h) Must be a ~~caner~~ prescription drug that was dispensed ~~pursuant to an original 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.

~~—NAC 453B.115—Maintenance of records by pharmacy, medical facility, health clinic or provider of health care that participates in Program.—(NRS 453B.230)~~

~~—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.~~

**NAC 453B.120 Handling fee.** (NRS 453B.200~~120~~, 453B.230) 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.