LCB File No. R211-09

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Amended Workshop for Regulations for AB 213 Cancer Drug Donation Program

September 25, 2009

Authority: AB 213

Section 1. Chapter 457 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 18, inclusive, of this regulation.

Sec. 2. ***"Board" means the Nevada State Board of Pharmacy.***

Sec. 3. ***"Cancer Drug" means a dangerous drug that is indicated by the FDA to treat cancer.***

Sec. 4. ***"Cancer Patient" means a patient who has cancer and is a resident of the State of Nevada.***

Sec. 5. ***"Dispense" has the meaning ascribed to it in NRS 639.0065.***

Sec. 6. ***"Medical Facility" has the meaning ascribed to it in NRS 449.0151.***

Sec. 7. ***"Program" means the Cancer Drug Donation Program established pursuant to Assembly Bill 213; Nevada Statutes, Chapter 409 (effective July 1, 2009).***

Sec. 8. ***"Person" means a resident of the State of Nevada***

Sec. 9. ***"Pharmacy" has the meaning ascribed to it in NRS 639.012.***

Sec. 10. ***"Practitioner" means a person authorized by law to prescribe dangerous drugs, acting within the scope of such authority, pursuant to NRS chapters 630, 632 and 633.***

Sec. 11. ***"Unit Dose" means that quantity of a drug which is packaged as a single dose.***

Sec. 12. ***"Dispensing Practitioner" is a practitioner who has a dispensing registration pursuant to NAC 639.742.***

Sec. 13. ***"Reissue" means to fill a lawful prescription for a person with a cancer drug that has been donated pursuant to this program.***

Sec. 14. ***Program Goals: The Cancer Drug Donation Program is established for the purpose of allowing any person to donate unused cancer drugs for dispensing to cancer patients in the State of Nevada. The program allows any person to donate unused cancer drugs to a practitioner, medical facility, or pharmacy that elects to participate in the program. A pharmacy that receives a donated cancer drug under the program may dispense to an eligible cancer patient.***

Sec. 15.

1. Any person, ~~[or]~~ practitioner, medical facility, or pharmacy may donate cancer drugs to the program that have been dispensed from a Nevada licensed pharmacy. A cancer drug may not be designated by the donor for a specific person or resold. There is no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of these regulations.

2. Any practitioner, medical facility, or pharmacy as defined above, is eligible to participate in the program.

3. Nothing in these rules is intended to supersede or negate any other state or federal laws or administrative rules applicable to practitioners, medical facilities, or pharmacies participating in the program.

4. A practitioner, medical facility or pharmacy may accept and dispense cancer drugs donated under the program to ~~[eligible]~~ patients, if all of the following requirements are met:

(a) The cancer drug is in its original manufacturer's packaging, unopened, sealed, and tamper-evident unit dose packaging;

(b) The cancer drug is prescribed by a practitioner for use by a ~~[eligible]~~ patient;

(c) The cancer drug donated for use in the program bears an expiration date that is later than 30 days after the drug is donated; and

(d) A dispensing practitioner or pharmacist has inspected the cancer drug packaging prior to dispensing it and has determined that the cancer drug is not adulterated or misbranded.

5. Donated cancer drugs under this program shall be stored separately from other stock and stored ~~[under]~~ according to the manufacturer's recommended storage conditions. If the drug is expired it must be destroyed and not returned for credit.

6. A practitioner, medical facility, or pharmacy shall maintain records of receipt of all ~~[returned or]~~ donated cancer drugs, which shall include at least the following information:

(a) Date of receipt;

(b) Original date dispensed;

(c) Original prescription number;

(d) Drug name and strength;

(e) Quantity ~~[returned]~~ donated;

(f) Expiration date of drug;

(g) Name, address and phone number of the original dispenser; ~~[and]~~

(h) Name, address and phone number of person donating the drug~~[.]~~*; and*

(i) Lot number.

7. A practitioner, medical facility, or pharmacy shall maintain records of cancer drugs transferred to other eligible dispensing practitioners, medical facilities, or pharmacies, which shall include at least the following information:

(a) All of the information required in subsection 6;

(b) Name, address and phone number of transferring entity;

(c) The quantity of drug transferred; and

(d) The name and address of the receiving dispensing practitioner, medical facility, or pharmacy.

8. Nothing in these rules is intended to supersede or negate any of the recordkeeping requirements established by the Nevada State Board of Pharmacy for dispensing drugs.

Sec. 16.

1. *Cancer drug dispensing shall be prioritized first to cancer patients who are uninsured, then to any other cancer patient if an uninsured patient is not available.*
2. *A dispensing practitioner, medical facility, or pharmacy may exercise discretion in determining eligibility of cancer patients when an uninsured patient is not available.*

3. ***Cancer drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner.***

Sec. 17.

1. ***No cancer drug donated under the program may be resold.***
2. ***A dispensing practitioner, medical facility, or pharmacy may charge a handling fee of no more than $10.00 per prescription for distributing or dispensing donated cancer drugs.***
3. ***A*** ~~[provider of health care]~~ ***dispensing practitioner, medical facility or pharmacy may exercise discretion as to whether a handling fee may be waived.***

Sec. 18. ***A cancer drug is not acceptable for donation or distribution through the program if it meets any of the following:***

1. ***It is a controlled substance;***
2. ***It bears an expiration date of less than 30 days from the day the cancer drug was donated;***
3. ***The receiving practitioner or dispensing pharmacist*** ~~[believes]~~ ***suspects the cancer drug may have been adulterated or misbranded, or the effectiveness and safety of the cancer drug cannot be ensured;***
4. ***The packaging*** ~~[that]~~ ***has been opened, unsealed, or tampered with or is no longer in its original container;***
5. ***It requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature;***
6. ***It can only be dispensed to a patient registered with the drug manufacturer; or***

7. It was not originally dispensed from a licensed Nevada pharmacy or Nevada dispensing practitioner.

Sec. 19. *1. The Board will establish and maintain a registry for* ~~[the program]~~ *participating entities which will include:*

(a) Participant's name, address and telephone number; and

(b) Whether the participant is a practitioner, medical facility, or pharmacy.

2. It is the responsibility of the participant to notify the Board of the desire to participate in the program and provide the required registry information to the Board.

3. Any participant in the program will be entered on the registry by the board.

4. It is the responsibility of the participant to notify the board of:

(a) A change in name, address, telephone number, or participant type; and

(b) When the participant no longer wishes to participate in the program.

5. The Board will make the registry information available to any person or entity wishing to donate cancer drugs to the program by its web site, by contacting the Board in person, by telephone, or in writing.