ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R211-09

Effective July 22, 2010

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

AUTHORITY: §§1-18, 20 and 21, NRS 457.480; §19, NRS 457.450 and 457.480.

A REGULATION relating to cancer; prescribing provisions for the Cancer Drug Donation Program; establishing the application process and requirements for participation in the Program; prescribing categories of cancer drugs that may be donated to the Program; establishing the maximum fee that may be charged for distributing and dispensing a cancer drug pursuant to the Program; and providing other matters properly relating thereto.

Section 1. Chapter 457 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 21, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 21, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 11, inclusive, of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Board" means the State Board of Pharmacy.***

Sec. 4. ***"Cancer drug" has the meaning ascribed to it in NRS 457.410.***

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

Sec. 6. ***"Distribute" means to deliver, other than by administering or dispensing, a cancer drug.***

Sec. 7. ***"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. 8. ***"Medical facility" has the meaning ascribed to it in NRS 449.0151.***

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

Sec. 10. ***"Program" has the meaning ascribed to it in NRS 457.430.***

Sec. 11. ***"Provider of health care" has the meaning ascribed to it in NRS 629.031.***

Sec. 12. ***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 cancer drug pursuant to the Program.***

Sec. 13. ***A person who wishes to receive a cancer drug dispensed pursuant to the Program must be:***

1. A resident of this State;

2. Diagnosed as having cancer; and

3. Approved to participate in the Program pursuant to section 14 of this regulation.

Sec. 14. ***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.

Sec. 15. *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 section 16 of this regulation.

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 section 16 of this regulation.

3. A health clinic must be approved to participate in the Program pursuant to section 16 of this regulation.

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 section 16 of this regulation.

Sec. 16. *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.

Sec. 17. *1. 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 457.460, a pharmacist may dispense a cancer drug to a person who is participating in the Program if:

(a) The pharmacist has inspected the packaging of the cancer drug to determine if the cancer drug meets the requirements of subsection 4 of NRS 457.450;

(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 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 drug that is donated to the Program:

(a) Pursuant to the recommendations of the manufacturer of the cancer drug concerning the storage conditions;

(b) Separately from all other drugs; and

(c) In a locked storage area.

4. If a cancer 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 drug.

Sec. 18. *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.

Sec. 19. *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 drug that is donated to the Program.*

Sec. 20. *1. In addition to the requirements of NRS 457.450, a cancer 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 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 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 drug for which a program of restrictive distribution has been established by the manufacturer of the cancer drug.

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

(h) Must be a cancer 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.

Sec. 21. ***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.

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INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __30___.
The number of persons who testified at the hearing was __1___.
The number of agency submitted statements was __0___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without change.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the board for enforcement of this regulation.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.