ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R122-07

Effective January 30, 2008

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

AUTHORITY: §§1-16, NRS 639.070 and 639.570.

A REGULATION relating to pharmacy; establishing the time of submission and the form of certain information that is required by statute to be submitted to the State Board of Pharmacy by wholesalers and manufacturers who employ a person to sell or market a drug, medicine, chemical device or appliance in this State; adopting certain publications by reference; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 14, inclusive, of this regulation.

Sec. 2. ***As used in NAC 639.610 and 639.615 and sections 11, 12, 13 and 14 of this regulation, unless the context otherwise requires, the term "manufacturer" has the meaning ascribed to it in NRS 639.009.***

Sec. 3. ***The Board hereby adopts by reference:***

1. The Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America. A copy of this publication may be obtained, free of charge, from the Pharmaceutical Research and Manufacturers of America at the Internet address http://www.phrma.org/code_on_interactions_with_healthcare_professionals.

2. The Code of Ethics on Interactions with Health Care Professionals adopted by the Advanced Medical Technology Association. A copy of this publication may be obtained, free of

charge, from the Advanced Medical Technology Association at the Internet address http://www.advamed.org/MemberPortal/About/code.

Sec. 4. *The Board will periodically review:*

1. The Code on Interactions with Healthcare Professionals, as adopted by reference in subsection 1 of section 3 of this regulation; and

2. The Code of Ethics on Interactions with Health Care Professionals, as adopted by reference in subsection 2 of section 3 of this regulation,

➥ and determine, within 30 days after the review, whether any change made to a publication listed in subsection 1 or 2 is appropriate for application in this State. If the Board does not disapprove a change to an adopted publication within 30 days after the review, the change is deemed to be approved by the Board.

Sec. 5. *1. Except as otherwise provided in subsections 2 and 6, on or before June 1 of each year, a wholesaler who employs a person to sell or market a drug, medicine or chemical in this State shall submit to the Board the information required pursuant to subsection 2 of NRS 639.570.*

2. If a wholesaler described in subsection 1 uses, without modification, the Code on Interactions with Healthcare Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct, the wholesaler may indicate this on its submittal in lieu of submitting a copy of its marketing code of conduct.

3. If a wholesaler described in subsection 1:

(a) Develops its own marketing code of conduct; or

(b) Uses a modified version of the Code on Interactions with Healthcare Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct,

➥ *the staff of the Board shall review the marketing code of conduct to ensure that it addresses the subjects listed in subsection 4.*

4. A marketing code of conduct submitted pursuant to this section and subsection 2 of NRS 639.570 must address the following subjects:

(a) The basis of interactions;

(b) Informational presentations by or on behalf of a wholesaler;

(c) Third-party educational or professional meetings;

(d) The use of consultants;

(e) Speaker training meetings;

(f) Scholarships and educational funds;

(g) Educational and practice-related items;

(h) Independence of decision making; and

(i) Adherence to the marketing code of conduct.

5. If the staff of the Board determines that a marketing code of conduct submitted by a wholesaler described in subsection 1 does not address each of the subjects set forth in subsection 4, the marketing code of conduct shall be deemed incomplete and noncompliant with the provisions of this section and subsection 2 of NRS 639.570.

6. The provisions of this section do not apply to a wholesaler whose sole function is to distribute prescription drugs to pharmacies if the wholesaler and the pharmacy to which the prescription drugs are distributed are wholly owned by a common owner.

Sec. 6. *1. If a wholesaler has submitted to the Board the information required pursuant to section 5 of this regulation at least once, the wholesaler may subsequently submit to the Board, on a form provided by the Board, the information that has remained the same and the*

information that has changed from the date of the previous submission, in lieu of submitting the information required annually pursuant to section 5 of this regulation.

2. The submission of information to the Board pursuant to this section and section 5 of this regulation may be made by:

(a) Mail or personal delivery of a printed copy of the information required;

(b) Electronic mail to the Board at the electronic mail address pharmacy@pharmacy.nv.gov; or

(c) Such other technological means as the Board may develop, including, without limitation, through the use of the Internet website of the Board.

Sec. 7. *1. The Board will refuse a submittal of information from a wholesaler pursuant to section 5 or 6 of this regulation if the submittal is incomplete. The Board will treat such an incomplete submittal as noncompliant for the purposes of NRS 639.570.*

2. If the staff of the Board determines that a submittal of information pursuant to section 5 or 6 of this regulation is incomplete, improperly completed or noncompliant, the staff shall, as soon as practicable, notify the wholesaler who submitted the information that the submittal is incomplete, improperly completed or noncompliant and provide the wholesaler with instructions for correcting the deficiencies in the submittal. The Board may retain an incomplete, improperly completed or noncompliant submittal or return the submittal to the wholesaler.

3. If the staff of the Board provides notice of an incomplete, improperly completed or noncompliant submittal to a wholesaler pursuant to this section, the wholesaler must comply with the instructions for correcting the deficiencies in the submittal within 120 days after the receipt of the instructions. Within the 120-day period, the wholesaler may request a meeting

with the staff of the Board to discuss the deficiencies in its submittal. If the wholesaler corrects the deficiencies in its submittal within the 120-day period, the Board will accept and file the submittal.

Sec. 8. *1. Except as otherwise provided in subsection 2, on or before June 1 of each year, a medical products wholesaler who employs a person to sell or market a device or appliance in this State shall submit to the Board the information required pursuant to subsection 2 of NRS 639.570.*

2. If a medical products wholesaler who employs a person to sell or market a device or appliance in this State uses, without modification, the Code of Ethics on Interactions with Health Care Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct, the medical products wholesaler may indicate this on its submittal in lieu of submitting a copy of its marketing code of conduct.

3. If a medical products wholesaler:

(a) Develops its own marketing code of conduct; or

(b) Uses a modified version of the Code of Ethics on Interactions with Health Care Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct,

➥ the staff of the Board shall review the marketing code of conduct to ensure that it addresses the subjects listed in subsection 4.

4. A marketing code of conduct submitted by a medical products wholesaler pursuant to this section and subsection 2 of NRS 639.570 must address the following subjects:

(a) Providing or sponsoring product training and education;

(b) Supporting third-party educational conferences;

(c) Sales and promotional meetings;

(d) Arrangements with consultants;

(e) Gifts;

(f) Providing reimbursement and other economic information; and

(g) Grants and other charitable donations.

5. If the staff of the Board determines that a marketing code of conduct submitted by a medical products wholesaler does not address each of the subjects set forth in subsection 4, the marketing code of conduct shall be deemed incomplete and noncompliant with the provisions of this section and subsection 2 of NRS 639.570.

Sec. 9. *1. If a medical products wholesaler has submitted to the Board the information required pursuant to section 8 of this regulation at least once, the medical products wholesaler may subsequently submit to the Board, on a form provided by the Board, the information that has remained the same and the information that has changed from the date of the previous submission, in lieu of submitting the information required annually pursuant to section 8 of this regulation.*

2. The submission of information to the Board pursuant to this section and section 8 of this regulation may be made by:

(a) Mail or personal delivery of a printed copy of the information required;

(b) Electronic mail to the Board at the electronic mail address pharmacy@pharmacy.nv.gov; or

(c) Such other technological means as the Board may develop, including, without limitation, through the use of the Internet website of the Board.

Sec. 10. *1. The Board will refuse a submittal of information from a medical products wholesaler pursuant to section 8 or 9 of this regulation if the submittal is incomplete. The Board will treat such an incomplete submittal as noncompliant for the purposes of NRS 639.570.*

2. If the staff of the Board determines that a submittal of information pursuant to section 8 or 9 of this regulation is incomplete, improperly completed or noncompliant, the staff shall, as soon as practicable, notify the medical products wholesaler who submitted the information that the submittal is incomplete, improperly completed or noncompliant and provide the medical products wholesaler with instructions for correcting the deficiencies in the submittal. The Board may retain an incomplete, improperly completed or noncompliant submittal or return the submittal to the medical products wholesaler.

3. If the staff of the Board provides notice of an incomplete, improperly completed or noncompliant submittal to a medical products wholesaler pursuant to this section, the medical products wholesaler must comply with the instructions for correcting the deficiencies in the submittal within 120 days after the receipt of the instructions. Within the 120-day period, the medical products wholesaler may request a meeting with the staff of the Board to discuss the deficiencies in its submittal. If the medical products wholesaler corrects the deficiencies in its submittal within the 120-day period, the Board will accept and file the submittal.

Sec. 11. *1. Except as otherwise provided in subsection 2, on or before June 1 of each year, a manufacturer who employs a person to sell or market a drug, medicine or chemical in this State shall submit to the Board the information required pursuant to subsection 2 of NRS 639.570.*

2. If a manufacturer described in subsection 1 uses, without modification, the Code on Interactions with Healthcare Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct, the manufacturer may indicate this on its submittal in lieu of submitting a copy of its marketing code of conduct.

3. If a manufacturer described in subsection 1:

(a) Develops its own marketing code of conduct; or

(b) Uses a modified version of the Code on Interactions with Healthcare Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct,

➥ the staff of the Board shall review the marketing code of conduct to ensure that it addresses the subjects listed in subsection 4.

4. A marketing code of conduct submitted pursuant to this section and subsection 2 of NRS 639.570 must address the following subjects:

(a) The basis of interactions;

(b) Informational presentations by or on behalf of a manufacturer;

(c) Third-party educational or professional meetings;

(d) The use of consultants;

(e) Speaker training meetings;

(f) Scholarships and educational funds;

(g) Educational and practice-related items;

(h) Independence of decision making; and

(i) Adherence to the marketing code of conduct.

5. If the staff of the Board determines that a marketing code of conduct submitted by a manufacturer does not address each of the subjects set forth in subsection 4, the marketing

code of conduct shall be deemed incomplete and noncompliant with the provisions of this section and subsection 2 of NRS 639.570.

Sec. 12. *1. Except as otherwise provided in subsection 2, on or before June 1 of each year, a manufacturer who employs a person to sell or market a device or appliance in this State shall submit to the Board the information required pursuant to subsection 2 of NRS 639.570.*

2. If a manufacturer described in subsection 1 uses, without modification, the Code of Ethics on Interactions with Health Care Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct, the manufacturer may indicate this on its submittal in lieu of submitting a copy of its marketing code of conduct.

3. If a manufacturer described in subsection 1:

(a) Develops its own marketing code of conduct; or

(b) Uses a modified version of the Code of Ethics on Interactions with Health Care Professionals, as adopted by reference in section 3 of this regulation, as its marketing code of conduct,

➥ the staff of the Board shall review the marketing code of conduct to ensure that it addresses the subjects listed in subsection 4.

4. A marketing code of conduct submitted by a manufacturer pursuant to this section and subsection 2 of NRS 639.570 must address the following subjects:

(a) Providing or sponsoring product training and education;

(b) Supporting third-party educational conferences;

(c) Sales and promotional meetings;

(d) Arrangements with consultants;

(e) Gifts;

(f) Providing reimbursement and other economic information; and

(g) Grants and other charitable donations.

5. If the staff of the Board determines that a marketing code of conduct submitted by a manufacturer does not address each of the subjects set forth in subsection 4, the marketing code of conduct shall be deemed incomplete and noncompliant with the provisions of this section and subsection 2 of NRS 639.570.

Sec. 13. *1. If a manufacturer has submitted to the Board the information required pursuant to section 11 or 12 of this regulation at least once, the manufacturer may subsequently submit to the Board, on a form provided by the Board, the information that has remained the same and the information that has changed from the date of the previous submission, in lieu of submitting the information required annually pursuant to section 11 or 12 of this regulation, as applicable.*

2. The submission of information to the Board pursuant to this section and sections 11 and 12 of this regulation may be made by:

(a) Mail or personal delivery of a printed copy of the information required;

(b) Electronic mail to the Board at the electronic mail address pharmacy@pharmacy.nv.gov; or

(c) Such other technological means as the Board may develop, including, without limitation, through the use of the Internet website of the Board.

Sec. 14. *1. The Board will refuse a submittal of information from a manufacturer pursuant to section 11, 12 or 13 of this regulation if the submittal is incomplete. The Board will treat such an incomplete submittal as noncompliant for the purposes of NRS 639.570.*

2. If the staff of the Board determines that a submittal of information pursuant to section 11, 12 or 13 of this regulation is incomplete, improperly completed or noncompliant, the staff shall, as soon as practicable, notify the manufacturer who submitted the information that the submittal is incomplete, improperly completed or noncompliant and provide the manufacturer with instructions for correcting the deficiencies in the submittal. The Board may retain an incomplete, improperly completed or noncompliant submittal or return the submittal to the manufacturer.

3. If the staff of the Board provides notice of an incomplete, improperly completed or noncompliant submittal to a manufacturer pursuant to this section, the manufacturer must comply with the instructions for correcting the deficiencies in the submittal within 120 days after the receipt of the instructions. Within the 120-day period, the manufacturer may request a meeting with the staff of the Board to discuss the deficiencies in its submittal. If the manufacturer corrects the deficiencies in its submittal within the 120-day period, the Board will accept and file the submittal.

Sec. 15. NAC 639.585 is hereby amended to read as follows:

639.585 As used in NAC 639.585 to 639.607, inclusive, ***and sections 5, 6 and 7 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.587 to 639.592, inclusive, have the meanings ascribed to them in those sections.

Sec. 16. NAC 639.693 is hereby amended to read as follows:

639.693 As used in NAC 639.693 to 639.6958, inclusive, ***and sections 8, 9 and 10 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.6931 to 639.6938, inclusive, have the meanings ascribed to them in those sections.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R122-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R122-07 which pertain to chapter 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

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 one public response expressed relative to this proposed regulation.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

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 ___1__.
The number of persons who testified at the hearing was __1___.
The number of agency submitted statements was __1___.

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.

A copy of the letter is attached to this notice.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

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 with minor changes.

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 should have only a minor economic impact on affected businesses and should have no economic impact on 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.