



NEVADA STATE BOARD OF PHARMACY

431 W. Plumb Lane • Reno, NV 89509
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

E-mail: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

COMPLIANCE PACKET FOR MANUFACTURERS AND WHOLESALEERS OF DRUGS, MEDICINES, CHEMICALS, DEVICES, OR APPLIANCES

AB 128, Statutes of Nevada Chapter 409 (effective October 1, 2007) requires that all wholesalers or manufacturers who employ a person to sell or market a drug, medicine, chemical, device, or appliance in Nevada must comply with certain requirements regarding their marketing practices. On January 30, 2008, regulations promulgated by the Nevada State Board of Pharmacy to implement AB 128 became effective. This packet contains:

- Instructions;
- The Compliance Form necessary for a wholesaler or manufacturer subject to AB 128 to comply with the requirements of AB 128 and the Board's regulations; and
- Copies of AB 128 and the Board's regulation implementing AB 128.

Because the definition of "drug" and "medicine" under Nevada law (NRS 639.007) includes both prescription drugs and OTC medicines, manufacturers and wholesalers of both prescription drugs and OTC medicines are required to comply with AB 128. You do not need to complete a Compliance Form or otherwise comply with AB 128 if any of the following apply to your company:

- Your company does not sell or market a drug, medicine, chemical, device or appliance in Nevada.
- The only product or products you market or sell in Nevada are food, aspirin, or effervescent saline analgesics. *See* NRS 639.007(3).

We will also be providing a compilation of the information received to the Governor's Office and the Director of the Legislative Counsel Bureau.

We intend this packet to contain everything needed to comply with AB 128. If you have questions or need information not contained in this packet, please call or e-mail this office at the above numbers or e-mail address.

Which form do I submit? Submit the Compliance Pack (this form) the first year your company sells or markets to health care professions who practice in Nevada. Submit the AB128 Certification of Completion of Annual Audit each year after your first filing. **You only need to file the Compliance Pack once, the initial year of filing. If your company doesn't file in a prior reporting period (5/1 through 4/30) this initial Compliance Pack report will need to be filed again.**

INSTRUCTIONS

Please follow all of the following instructions closely when completing the attached Compliance Form:

- Fill out the form by typing, printing, or in ink.
- Fill out the form completely. Incomplete forms will be returned and will not be treated as filed.
- To be deemed compliant, the form must be received by the Board's office at the above address by 5:00 p.m. P.S.T. on June 1. Mail postmarked by June 1 will be deemed to be compliant even if it is received later than June 1. The annual compliance period is from May 1 through April 30 of each year.
- For the initial filing period, you will not be required to certify that you have conducted the required annual audit, but for every year thereafter such a certification will be required. The annual certification forms will be available on the Board's website, and your company will be responsible to download, complete, and mail in the form by June 1 of every year starting June 1, 2009.
- You should indicate on each document attached to the form the number of the item for which the document is being submitted.
- Please clearly indicate on any document submitted with the form any claim that the document is confidential or proprietary business information subject to the disclosure protections of Section 1, subsection 4(d) of AB 128.



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COMPLIANCE FORM FOR MANUFACTURERS AND WHOLESALEERS OF DRUGS, MEDICINES, CHEMICALS, DEVICES, OR APPLIANCES

Name of Company: _____
Street Address: _____
City: _____
State and Zip Code: _____
Telephone Number: _____
Name of Person Completing Form: _____
Title of Person Completing Form: _____

Please indicate your business type (check all that apply):

- Manufacturer of Drug, Medicine, or Chemical
Wholesaler of Drug, Medicine, or Chemical
Manufacturer of Device or Appliance
Wholesaler of Device or Appliance

1. Does your company use one of the two model codes of conduct [*Code of Interactions with Healthcare Professionals* by PhRMA (for manufacturers or wholesalers of drugs, medicines, or chemicals) or *Code of Ethics on Interactions with Health Care Professionals* by AdvaMed (for manufacturers or wholesalers of devices or appliances)] without modification? The Board accepts the current or the prior model Code of Conduct for PhRMA or ADvaMed.

Yes No Adopted PhRMA or ADvaMed Code with more stringent elements

If the answer is "Yes," you do not need to attach a copy of your code of conduct. If the answer is "No," then please attach a copy of your code of conduct.

If your company adopts either the PhRMA or ADvaMed Code with more stringent elements, you may indicate so and do not need to attach a copy of your code.

2. Please describe the training program by which your company will provide regular training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct. [You may attach your description as a separate document.]

3. Please describe your investigation policies for investigating instances of noncompliance with your marketing code of conduct, including addressing the items contained in Section 1, subsection 1(d) of AB 128. [You may attach your description as a separate document.]

4. Please indicate any other companies, affiliated companies, or subsidiaries for which this form will also apply (if any). [Please attach your descriptions as a separate document.]

5. Please provide the following information regarding your company's compliance officer responsible for developing, operating, and monitoring your marketing code of conduct:

Name: _____

Title: _____

Street Address: _____

City: _____ State: _____ Zip: _____

E-mail Address: _____

Signed this _____ day of _____, 20_____

Signature: _____ Title: _____

TEXT OF ASSEMBLY BILL 128
2007 SESSION OF THE NEVADA LEGISLATURE
EFFECTIVE OCTOBER 1, 2007

1. A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in this State shall:

(a) Adopt a written marketing code of conduct which establishes the practices and standards that govern the marketing and sale of its products. The marketing code of conduct must be based on applicable legal standards and incorporate principles of health care, including, without limitation, requirements that the activities of the wholesaler or manufacturer be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care professionals. Adoption of the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America satisfies the requirements of this paragraph.

(b) Adopt a training program to provide regular training to appropriate employees, including, without limitation, all sales and marketing staff, on the marketing code of conduct.

(c) Conduct annual audits to monitor compliance with the marketing code of conduct.

(d) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct, including, without limitation, the maintenance of effective lines of communication for employees to report noncompliance, the investigation of reports of noncompliance, the taking of corrective action in response to noncompliance and the reporting of instances of noncompliance to law enforcement authorities in appropriate circumstances.

(e) Identify a compliance officer responsible for developing, operating and monitoring the marketing code of conduct.

2. A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in this State shall submit to the Board annually:

(a) A copy of its marketing code of conduct;

(b) A description of its training program;

(c) A description of its investigation policies;

(d) The name, title, address, telephone number and electronic mail address of its compliance officer; and

(e) Certification that it has conducted its annual audit and is in compliance with its marketing code of conduct.

3. On or before January 15 of each odd-numbered year, the Board shall prepare and submit to the Governor, and to the Director of the Legislative Counsel Bureau for transmittal to the Legislature, a compilation of the information submitted to the Board pursuant to this section, other than any information identified as a trade secret in the information submitted to the Board.

4. The Board:

(a) Shall adopt regulations providing for the time of the submission and the form of the information required pursuant to this section and defining "compliance" for the purposes of this section.

(b) May not require the disclosure of the results of an audit conducted pursuant to this section.

(c) Shall post on its Internet website information concerning the compliance of all wholesalers and manufacturers with the requirements of this section.

(d) Shall not disclose any proprietary or confidential business information that it receives pursuant to this section.

**ADOPTED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R122-07

Effective January 30, 2008

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 63 9.570 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.