



Nevada State Board of Pharmacy

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December 21, 2017

Rick Combs, Director
Legislative Counsel Bureau
401 S. Carson Street
Carson City, NV 89701

Dear Mr. Combs:

Pursuant to NRS 639.570(3), enclosed is the Nevada State Board of Pharmacy – AB128 Marketing Code of Conduct Annual Compliance Report.

Please contact me if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Larry Pinson", followed by a horizontal line and a small flourish.

Larry Pinson, Pharm.D.
Executive Secretary

Enclosure

**NEVADA STATE BOARD OF
PHARMACY**

**AB128 MARKETING CODE OF
CONDUCT ANNUAL
GOVERNOR'S COMPLIANCE REPORT
2017**

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INTRODUCTION

In the interest of better serving the people of Nevada, AB128 was introduced in the Nevada assembly on February 20th, 2007. The intent of AB128 was to have manufacturers and wholesalers adopt a marketing code of conduct 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.

AB128 also amends NRS 639.238 to clarify provisions concerning the confidentiality of the contents of a prescription.

Existing law prohibits a person from manufacturing or engaging in the wholesale distribution of certain drugs unless the person is licensed to do so by the State Board of Pharmacy. (NRS 639.100, 639.233)

Existing law provides that prescriptions filed at a pharmacy are not a public record and prohibits, with certain exceptions, a pharmacist from divulging the contents of a prescription. (NRS 639.238) Section 2 of this bill clarifies that this prohibition applies to the divulgence of the name of the prescribing medical practitioner.

NRS 639.570 as adopted requires the adoption of a marketing code of conduct, requires reporting of training and investigative policies and requires submission of certain information to the Board for any wholesaler or manufacturer who sells or markets a drug, medicine, chemical device or appliance in Nevada.

Business Practices

NRS 639.570 Employees of wholesalers or manufacturers; adoption of marketing code of conduct; training; investigation policies; submission of information to Board; Board to report certain information to Governor and Legislature; duties of Board.

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.
- 5. Shall not disclose any proprietary or confidential business information that it receives pursuant to this section.

(Added to NRS by 2007, 1791)

The Board

The following regulations were adopted by the Board based on the direction of the legislature in NRS 639.570.

NAC 639.6053 Wholesaler who employs person to sell or market drug, medicine or chemical: Annual submission of certain information to Board; review and contents of marketing code of conduct; exemption. (NRS 639.070, 639.570)

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 NAC 639.060, 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 NAC 639.060, as its marketing code of conduct,
 - c. 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.

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.6055 Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission. (NRS 639.070, 639.570)

1. If a wholesaler has submitted to the Board the information required pursuant to NAC 639.6053 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 NAC 639.6053.
2. The submission of information to the Board pursuant to this section and NAC 639.6053 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.

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.6057 Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies. ([NRS 639.070](#), [639.570](#))

1. The Board will refuse a submittal of information from a wholesaler pursuant to [NAC 639.6053](#) or [639.6055](#) 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 [NAC 639.6053](#) or [639.6055](#) 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.

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.616 Manufacturer who employs person to sell or market drug, medicine or chemical: Annual submission of certain information to Board; review and contents of marketing code of conduct. ([NRS 639.070](#), [639.570](#))

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 [NAC 639.060](#), 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 [NAC 639.060](#), as its marketing code of conduct,
 - c. 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](#).

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.617 Manufacturer who employs person to sell or market device or appliance: Annual submission of certain information to Board; review and contents of marketing code of conduct.
([NRS 639.070](#), [639.570](#))

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 [NAC 639.060](#), 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 [NAC 639.060](#), as its marketing code of conduct,
 - c. 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](#).

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.618 Submission of certain information regarding sales and marketing staff: Submission of form after initial submittal; method of submission. ([NRS 639.070](#), [639.570](#))

1. If a manufacturer has submitted to the Board the information required pursuant to [NAC 639.616](#) or [639.617](#) 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 [NAC 639.616](#) or [639.617](#), as applicable.
2. The submission of information to the Board pursuant to this section and [NAC 639.616](#) and [639.617](#) 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.

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

NAC 639.619 Submission of certain information regarding sales and marketing staff: Incomplete, improperly completed or noncompliant submittal; correction of deficiencies. ([NRS 639.070](#), [639.570](#))

1. The Board will refuse a submittal of information from a manufacturer pursuant to [NAC 639.616](#), [639.617](#) or [639.618](#) 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 [NAC 639.616](#), [639.617](#) or [639.618](#) 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.

(Added to NAC by Bd. of Pharmacy by R122-07, eff. 1-30-2008)

Overview of Compliance Results

In 2017,

782 companies, affiliated companies, or subsidiaries are listed as compliant in a new compliance report. (Reported data as of December 14, 2017)

- 65 of the submissions were manual submissions and the remaining submissions were submitted electronically.
- 68 companies, primary companies and affiliated companies or subsidiaries, that filed an AB 128 compliance report in 2016 do not submit a report in 2017 or their submission was deemed non-compliant and were contacted via e-mail to submit additional documentation.
 - Each company that did not respond on initial contact in June-July 2017 was contacted in late November to determine if the company is selling or marketing to health care professionals in Nevada and, if the company was still selling or marketing, the company was again requested to submit supplemental information.
- 16 companies have responded to the follow up contact, either in June-July or after the November contact, and have been accepted as compliant. These responses represent the companies plus an additional 9 affiliated companies, or subsidiaries for a total of 25 companies.
- 1 company has combined their submissions for all affiliated companies, or subsidiaries into one compliance report. This change affects an additional 1 affiliated company, affiliated company or subsidiary.
- No companies, affiliated or subsidiary companies have been reported as closed.
- 1 company reported that the company no longer markets or sells to Nevada health care professionals. This total includes an additional 0 company subsidiaries.
- 3 letters have been returned as not deliverable by the post office.
- No companies have requested exempt status because the company no longer sells or markets to Nevada health care professionals.
- No companies had a change of address.

In 2016,

776 companies, affiliated companies, or subsidiaries listed as compliant in a new compliance report. (Reported data as of January 26, 2016)

- 120 companies, primary companies and affiliated companies or subsidiaries, that filed an AB 128 compliance report in 2015 did not file a compliance report in 2016 or the report filed was deemed non compliant. Each company was contacted in late November to determine if the company is selling or marketing to health care professionals in Nevada and, if the company was still selling or marketing, the company was requested to submit supplemental information.
- 33 companies have responded to the follow up contact and have been accepted as compliant. These responses represent the companies plus an additional 193 affiliated companies, or subsidiaries for a total of 153 companies.
- 1 company has combined their submissions for all affiliated companies, or subsidiaries into one compliance report. This change affects an additional 1 affiliated company, affiliated company or subsidiary.

- No companies, affiliated or subsidiary companies have been reported as closed.
- 2 companies reported that the company no longer markets or sells to Nevada health care professionals. This total includes an additional 0 company subsidiary.
- 12 letters have been returned as not deliverable by the post office. This letter represents X companies, affiliated companies or subsidiaries that reported in 2015.
- 1 company requested exempt status because the company no longer sells or markets to Nevada health care professionals.
- 5 companies had a change of address.
- In 2015,
687 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant. (Reported data as of February 16, 2016)
 - 111 companies, consisting of 62 primary company submissions and 49 affiliated companies or subsidiaries, that filed an AB 128 compliance report in 2014 did not file a compliance report in 2015 or the report filed was deemed non compliant. Each company was contacted in late November to determine if the company is selling or marketing to health care professionals in Nevada and, if the company was still selling or marketing, the company was requested to submit supplemental information.
 - 23 companies have responded to the follow up contact and have been accepted as compliant. These responses represent the companies plus an additional 43 affiliated companies, or subsidiaries for a total of 66 companies.
 - 1 company has combined their submissions for all affiliated companies, or subsidiaries into one compliance report. This change affects an additional 1 affiliated company, affiliated company or subsidiary.
 - No companies, affiliated or subsidiary companies have been reported as closed.
 - 4 companies reported that the company no longer markets or sells to Nevada health care professionals. This total includes an additional 1 company subsidiary.
 - 3 follow up letters have been returned as not deliverable by the post office. This letter represents 3 companies, affiliated companies or subsidiaries that reported in 2014.
 - 1 company requested exempt status because the company no longer sells or markets to Nevada health care professionals.
 - There were no letters forwarded by the US Postal Service to companies whose address had changed.

In 2014,

566 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant. (Reported data as of December 17, 2014)

- 72 companies, affiliated companies, or subsidiaries that filed an AB 128 compliance report in 2013 did not file a compliance report in 2014 or the report filed was deemed non compliant. Each company was contacted in late November to determine if the company is selling or marketing to health care professionals in Nevada and, if the company was still selling or marketing, the company was requested to submit supplemental information.
- 2 companies have combined their submissions for all affiliated companies, or subsidiaries into one compliance report. This change affects 16 affiliated companies, or subsidiaries.
- 20 companies have responded to the follow up contact and been accepted as compliant.

These responses represent the companies plus 43 affiliated companies, or subsidiaries.

- No companies, affiliated or subsidiary companies have been reported as closed.
- 1 company reported that the company no longer markets or sells to Nevada health care professionals.
- 11 follow up letters have been returned by the post office. These letters represent 21 companies, affiliated companies or subsidiaries that reported in 2013.
- 1 company requested exempt status because the company does not sell or market to Nevada health care professionals.
- 2 new submissions were received after the June 1 submission date.
- The US Postal Service forwarded letters to 6 companies whose address had changed. These companies represent 8 companies, affiliated companies, or subsidiaries. No responses have been received from these companies.

In 2013,

648 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant. (Reported data as of December 22, 2013)

- 54 companies that filed an AB 128 compliance report in 2012 did not file compliance report in 2013 or the report filed was deemed non compliant. Each company was contacted to determine if the company is selling or marketing to health care professionals in Nevada and, if the company was still selling or marketing, the company was requested to submit supplemental information.
- 4 companies were contacted to provide additional information to evaluate their compliant status at the time of the company's initial submission and in early December 2013 with no response.
- 1 company has responded to the follow up contact and been accepted as compliant. These responses represent the companies plus affiliated companies, or subsidiaries.
- No companies, affiliated or subsidiary companies have been reported as closed.
- 1 company reported that the company no longer markets or sells to Nevada health care professionals.
- No follow up letters have been returned by the post office.
- 1 company requested and was granted exempt status since the company does not sell or market to Nevada health care professionals.
- 1 company filed a new submission. These responses represent the 1 company plus affiliated companies, or subsidiaries.

In 2012, 592 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant. (Reported data as of December 20, 2012)

- 63 companies that filed an AB 128 compliance report in 2011 did not file a compliance report in 2012 and were contacted to determine if the company is selling or marketing to health care professionals in Nevada.
- 22 companies have responded and been accepted as compliant. These responses represent the 22 companies plus 47 affiliated companies, or subsidiaries.
- 3 companies, affiliated or subsidiary companies have closed.
- 3 companies no longer market or sell to Nevada health care professionals.
- 5 companies had the Board's follow up letter returned by the post office and are no longer active in Nevada.
- 6 companies were contacted to provide additional information to evaluate their

compliant status at the time of the company's initial submission and in November 2012 with no response.

- 2 companies requested and were granted exempt status since the company does not sell or market to Nevada health care professionals.
- 2 companies filed a new submission. These responses represent the 2 companies plus 25 affiliated companies, or subsidiaries.

In 2011, 495 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant.

- 5 companies have been contacted to provide additional information to evaluate their compliant status.
- 69 companies that filed an AB 128 compliance report in 2010 did not file a compliance report in 2011 and are being contacted to determine if the company is selling or marketing to health care professionals in Nevada.
- 4 companies requested and were granted exempt status.

In 2010, 469 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant.

- In 2010, 2 companies have been contacted to provide additional information to evaluate their compliant status.
- 64 companies that filed an AB 128 compliance report in 2009 did not file a compliance report in 2010 and are being contacted to determine if the company is selling or marketing to health care professionals in Nevada.

In 2009, 501 companies, affiliated companies, or subsidiaries were listed as compliant and 2 companies requested and were granted exempt status.

In 2008, 337 companies, affiliated companies, or subsidiaries were listed as compliant and 12 companies requested and were granted exempt status.

Status of the Board Website

The Board website of companies, affiliated companies, or subsidiaries compliant is updated monthly as needed. <http://bop.nv.gov/resources/ALL/WholesalersEPP/>