

**AB128 CERTIFICATION OF COMPLETION OF ANNUAL AUDIT MONITORING
COMPLIANCE WITH CODE OF CONDUCT FOR MANUFACTURERS AND
WHOLESALEERS OF DRUGS, MEDICINES, CHEMICALS, DEVICES, OR
APPLIANCES**

This form is to be used for a company's initial filing and the annual certification of audit.

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.

- To be deemed compliant, the form must be received by the Board's office by 5:00 p.m. P.S.T. on June 1st of every year. Mail postmarked by June 1st each year will be deemed to be compliant even if it is received later than June 1st. Forms dated prior to May 1 will be deemed non-compliant.
- The annual certification period is from 5/1 through 4/30 each year.
- 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.

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).

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

Please only submit the required compliance pages and not the pages of the text of assembly bill 128 or regulations as adopted by the Board of Pharmacy.

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

(Circle business model type) Manufacturer Wholesaler

Please indicate your business type (check all that apply-fill out form on appropriate page):

Manufacturer or Wholesaler of Drug, Medicine, or Chemical Page 3
 Manufacturer or Wholesaler of Device or Appliance Page 4

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 Adopted without modification. Fill out the questions on training and investigative polices on the form page noted above, based on your business type, and submit with this page. You do not need to fill in the check boxes for modified codes of conduct. You do not need to submit a copy of your Code of Conduct.

No Attach a copy of your Code of Conduct. Your initial submission of your Code of Conduct must address the subjects noted on page 3 or 4 depending on your business type. On subsequent annual submissions fill out the form on the page noted above, based on your business type, and submit with this page. Fill out the questions on training and investigative polices. Answer yes or no to the elements check boxes. If your company made a change to any element, describe the changes in a separate document. If your company did not submit a certification the prior year or was not deemed compliant the prior year, your company must submit your current code.

Your company needs to provide a complete overview of investigation of instances of noncompliance and training program. These two submissions must be submitted annually even if no changes were made. If changes were made, describe the changes.

Section 1, subsection 1 (d) AB128 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.

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.

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COMPLIANCE WITH CODE OF CONDUCT FOR MANUFACTURER OR
WHOLESALE OF DRUG, MEDICINE, OR CHEMICAL**

Has your company made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? **Yes** **No** Please attach a description of your current training program as a separate document. [Identify any changes from prior year]

Has your company made any changes to 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? (see page 2) **Yes** **No** Please attach a description your current investigative policies as a separate document. [Identify any changes from prior year]

If your company did not adopt PhRMA or ADvaMed Code without modification or if your company made any changes to the following subjects required in your code of conduct then please answer the questions listed below. [Please address changes in your code in a separate document.]

- | | | |
|--|------------------------------|-----------------------------|
| a. The basis of interactions | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| b. Information presentations by or on behalf of a manufacturer | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| c. Third-party educational or professional meetings | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| d. The use of consultants | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| e. Speaker training meetings | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| f. Scholarships and educational funds | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| g. Educational and practice-related items | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| h. Independence of decision making | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| i. Adhere to market code of conduct | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Are there any other companies, affiliated companies, or subsidiaries for which this form will also apply? **Yes** **No** [Please provide a list as a separate document.]

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 Code: _____
E-mail _____
Address: _____

I certify that the annual audit to monitor compliance with the code of conduct for the named company and all other companies, affiliated companies, or subsidiaries listed has been completed and the named company and all other companies, affiliated companies, or subsidiaries are in compliance with the code of conduct.

Date: _____

Signature: _____ Title: _____

**AB128 CERTIFICATION OF COMPLETION OF ANNUAL AUDIT MONITORING
COMPLIANCE WITH CODE OF CONDUCT FOR MEDICAL PRODUCTS
MANUFACTURER OR WHOLESALER OF DEVICE OR APPLIANCE**

Has your company made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? **Yes** **No** Please attach a description of your current training program as a separate document. [Identify any changes from prior year]

Has your company made any changes to 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? (see page 2) **Yes** **No** Please attach a description your current investigative policies as a separate document. [Identify any changes from prior year]

If your company did not adopt PhRMA or ADvaMed Code without modification or if your company made any changes to the following subjects required in your code of conduct then please answer the questions listed below. [Please address changes in your code in a separate document.]

- | | | |
|---|------------------------------|-----------------------------|
| a. Providing or sponsoring product training and education | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| b. Supporting third-party educational conferences | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| c. Sales and promotional meetings | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| d. Arrangements with consultants | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| e. Gifts | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| f. Providing reimbursement and other economic information | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| g. Grants and other charitable donations | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Are there any other companies, affiliated companies, or subsidiaries for which this form will also apply? **Yes** **No** [Please provide a list as a separate document.]

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 Code: _____
E-mail Address: _____

I certify that the annual audit to monitor compliance with the code of conduct for the named company and all other companies, affiliated companies, or subsidiaries listed has been completed and the named company and all other companies, affiliated companies, or subsidiaries are in compliance with the code of conduct.

Date: _____

Signature: _____ Title: _____