

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

AB128 requires that each year a manufacturer or wholesaler certify that an annual audit to monitor compliance with the manufacturer or wholesaler's marketing code of conduct has been done. It is the manufacturer or wholesaler's responsibility to download, complete, and mail in the form by June 1st of every year.

- 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.
- 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.

You do not need to complete an Annual Audit Certification Form or otherwise comply with AB 128 if any of the following apply to your company:

- Your company no longer sells or markets 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).

Which form do I submit? Submit the AB128 Annual Audit Certification (this form) each year after your first filing. **If your company doesn't file in a prior reporting period (5-1 through 4/30) the initial Compliance Packet will need to be filed.**

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

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

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

- | | | |
|---|--------------------------|--------|
| Manufacturer of Drug, Medicine, or Chemical | <input type="checkbox"/> | Page 4 |
| Wholesaler of Drug, Medicine, or Chemical | <input type="checkbox"/> | Page 5 |
| Manufacturer of Device or Appliance | <input type="checkbox"/> | Page 6 |
| Wholesaler of Device or Appliance | <input type="checkbox"/> | Page 7 |

2. 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?

Yes No

If you answered No to item 2, please fill out the form on the page indicated above for your business type and submit with this page. If you indicate more than 1 business type, you only need to fill out one of the pages that apply to your business type, not individual pages for each business type.

If you answered Yes to item 2, please fill out the form on Page 3 and submit with this page.

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

If you answered Yes to item 2, have you made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct?

Yes No If you have made changes, please describe your current training program. [Please attach your description as a separate document.]

If you answered Yes to item 2, have you 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? Yes No If you have made changes, please describe your current investigative policies. [Please attach your description as a separate document.]

1. Are there any other companies, affiliated companies, or subsidiaries for which this form will also apply? Yes No Please list. Please separately list any deletions from your last year's submission (if any). If there has been a change of address or name change for your company please note the old/new address and/or old/new company name: [Please attach your descriptions 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.

Signed this _____ day of _____
Signature: _____ Title: _____

**AB128 CERTIFICATION OF COMPLETION OF ANNUAL AUDIT MONITORING
COMPLIANCE WITH CODE OF CONDUCT FOR MANUFACTURER OF DRUG,
MEDICINE, OR CHEMICAL USING A MODIFIED CODE OF CONDUCT**

LCB file R122-07 Sec. 11

Have you made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? Yes No

If you have made changes, please describe your current training program. [Please attach your description as a separate document.]

Have you 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? Yes No If you have made changes, please describe your current investigative policies. [Please attach your description as a separate document.]

Have you made any changes to the following subjects required in your code of conduct? If yes, please submit your changes in writing. . [Please attach your description as 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.

Signed this _____ day of _____
Signature: _____ Title: _____

**AB128 CERTIFICATION OF COMPLETION OF ANNUAL AUDIT MONITORING
COMPLIANCE WITH CODE OF CONDUCT FOR WHOLESALER OF DRUG,
MEDICINE, OR CHEMICAL USING A MODIFIED CODE OF CONDUCT**
LCB file R-122-07 Sec 5

Have you made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? Yes No

If you have made changes, please describe your current training program. [Please attach your description as a separate document.]

Have you 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? Yes No If you have made changes, please describe your current investigative policies. [Please attach your description as a separate document.]

Have you made any changes to the following subjects required in your code of conduct? If yes, please submit your changes in writing. . [Please attach your description as 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.

Signed this _____ day of _____
 Signature: _____ Title: _____

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

LCB file R-122-07 Sec 12

Have you made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? Yes No

If you have made changes, please describe your current training program. [Please attach your description as a separate document.]

Have you 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? Yes No If you have made changes, please describe your current investigative policies. [Please attach your description as a separate document.]

Have you made any changes to the following subjects required in your code of conduct? If yes, please submit your changes in writing. [Please attach your description as 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.

Signed this _____ day of _____
Signature: _____ Title: _____

**AB128 ANNUAL AUDIT CERTIFICATION OF COMPLIANCE FOR MEDICAL
PRODUCTS WHOLESALER OF DEVICE OR APPLIANCE USING A MODIFIED CODE
OF CONDUCT**

LCB file R-122-07 Sec 8

Have you made any changes in your training to appropriate employees, including all sales and marketing staff, regarding your marketing code of conduct? Yes No

If you have made changes, please describe your current training program. [Please attach your description as a separate document.]

Have you 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? Yes No If you have made changes, please describe your current investigative policies. [Please attach your description as a separate document.]

Have you made any changes to the following subjects required in your code of conduct? If yes, please submit your changes in writing. [You may attach your description as 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.

Signed this _____ day of _____
Signature: _____ Title: _____