LCB File No. R122-07

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

REGULATIONS TO IMPLEMENT AB 128

Section 1. NAC chapter 639 shall be amended to add the following new language:

1. Commencing on June 1, 2008 and by every June 1 thereafter, every manufacturer or wholesaler subject to AB 128 shall submit to the board:

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

(b) A description of it 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.

2. If a manufacturer or wholesaler uses the PhRMA Code on Interactions with Healthcare Professionals, without modification, as its marketing code of conduct, it may indicate this in its submittal in lieu of submitting its marketing code of conduct pursuant to subparagraph (a) of paragraph 1. If the manufacturer or wholesaler develops its own marketing code of conduct, or uses as its marketing code of conduct the PhRMA Code on Interactions with Healthcare Professionals that has been modified or augmented in any way, then the board's staff shall review the marketing code of conduct to assure that it addresses each of the following subjects:

(a) The basis of interactions;

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

(i) Adherence to the marketing code of conduct.

A marketing code of conduct that does not address each of the nine subjects in this paragraph shall be deemed incomplete and non-compliant.

3. If a wholesaler of medical devices, equipment, and gases uses the AdvaMed Code of Ethics on Interactions with Health Care Professionals, without modification, as its marketing code of conduct, it may indicate this in its submittal in lieu of submitting its marketing code of conduct pursuant to subparagraph (a) of paragraph 1. If the wholesaler or medical devices, equipment, and gases develops its own marketing code of conduct, or uses as its marketing code of conduct the AdvaMed Code of Ethics on Interactions with Health Care Professionals that has been modified or augmented in any way, then the board's staff shall review the marketing code of conduct to assure that it addresses each of 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;

(g) Grants and other charitable donations.

A marketing code of conduct that does not address each of the seven subjects in this paragraph shall be deemed incomplete and non-compliant.

4. After a manufacturer or wholesaler has submitted all of the information required in paragraph 1, in subsequent years it may indicate on a form provided by the board what information is the same from the previous submittal and what information has changed from the previous submittal.

5. The submittals made pursuant to paragraphs 1, 2 and 3 may be made:

(a) By mail or delivery of a printed copy of the submittal;

(b) By e-mail to pharmacy@pharmacy.nv.gov; or

(c) By such other technological means as the board may develop, such as through the use of the board's website.

6. The board shall refuse to receive and file any submittal that is not wholly complete, and will treat any such incomplete submittal as being non-compliant.

7. After reviewing the submittals, if the board's staff determines that a submittal is incomplete or non-compliant, the board shall notify the submitting manufacturer or wholesaler that the submittal is incomplete or non-compliant and identify the information that must be provided in order for the submittal to be deemed complete and compliant. The manufacturer or wholesaler shall have 120 days to supply the requested information. Within the 120 day period, the manufacturer or wholesaler may request a meeting with the board's staff to discuss the board's staff's concerns with the information submitted by the manufacturer or wholesaler. Once the board's staff is satisfied that the manufacturer or wholesaler has submitted complete and compliant information, it shall accept and file the submittal.