

Title 16. Board of Pharmacy Modified Regulation

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Additional changes to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1784. Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager.

- (a) ~~The designated representative-in-charge of e~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:
- (1) A new ~~wholesaler permit~~ license is issued, ~~or~~
 - (2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.
 - (3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.
- (c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws~~

and regulations. Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the “Wholesaler/Third Party Logistics Provider Self-Assessment,” Form 17M-26 (Rev. 09/12/21) which is hereby incorporated by reference. The form shall include the information required by this section.

- (1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:
 - (A) Name, license number of the premises, and the license expiration date;
 - (B) Address, phone number, website address, if applicable, and type of ownership;
 - (C) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;
 - (D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and
 - (E) Hours of operation of the licensee.
- (2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person’s license type and number, and the expiration date for each license.
- (3) The designated representative-in-charge or responsible manager shall respond “yes”, “no” or “not applicable” (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.
- (4) For each “no” response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.
- (5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.
- (6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:

- (A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;
- (B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;
- (C) He or she understands that all responses are subject to verification by the Board of Pharmacy; and
- (D) The information provided in the self-assessment form is true and correct.
- (7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and understands that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the licensed ~~wholesale~~-premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
- (e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.
- (f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.