

**Title 16. Board of Pharmacy
Order of Adoption**

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. 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.