

**Department of Consumer Affairs
Title 16. Board of Pharmacy**

**Proposed Regulation Text
Self-Assessment Forms
(Pharmacy, Hospital, Wholesaler)**

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

Amend section 1715 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

- (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed 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 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
- (1) A new pharmacy permit has been issued, or
 - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
 - (3) There is a change in the licensed location of a pharmacy to a new address.
- (c) A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using the components of Form 17M-13 (Rev. ~~1/22~~1/24) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers shall assess compliance with current laws and regulations using the components of Form 17M-14 (Rev. ~~01/22~~1/24) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference, and contain the following components:
- (1) The pharmacist-in-charge shall provide identifying information about the pharmacy including:
 - (A) Name and any license number(s) of the pharmacy and their expiration date(s);
 - (B) Address, phone number, ownership type, and website address, if applicable, of the pharmacy;
 - (C) Federal Drug Enforcement Agency (DEA) registration number, its expiration date, and date of most recent DEA inventory;
 - (D) Hours of operation of the pharmacy; and
 - (E) Accreditation by third party, if applicable, and dates of accreditation.
 - (2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.
 - (3) The pharmacist-in-charge shall respond "yes", "no," or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

- (4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
- (5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials on the self-assessment.
- (6) The pharmacist-in-charge shall certify on the final page of the self-assessment that they have completed the self-assessment of the pharmacy of which they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature on the self-assessment.
- (7) The pharmacy owner or hospital administrator shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the Board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature on the self-assessment.
- (d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the Board.
- (e) Any identified areas of noncompliance shall be corrected as specified in the certification.

NOTE: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, Business and Professions Code.

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

- (a) Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of 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 license is issued.
 - (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) 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~~1/24) 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) They have completed the self-assessment of the licensed premises for which they are responsible;
 - (B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;
 - (C) They understand 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 they have read and reviewed the completed self-assessment and understand that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the ~~h~~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 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 ~~h~~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.