

Title 16. Board of Pharmacy Proposed Regulation Text

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

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(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 this assessment shall be on~~ Form 17M-13 (Rev. 40/44 07/18) 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 ~~an~~ Form 17M-14 (Rev. 40/44 07/18) entitled "Hospital Pharmacy Self-Assessment," which are ~~Both forms are hereby incorporated by reference, and contain the following components: to evaluate compliance with federal and state laws and regulations.~~

- (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 he or she has completed the self-assessment of the pharmacy of which he or she is 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 he or she has 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.