



To: Board Members

Subject: Discussion and Consideration of the Proposed Regulations to Amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment Form 17M-39 and Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

Attachment 1

Relevant Law

Title 16 CCR Section 1735.2(k) establishes the requirement for the pharmacist-in-charge of a pharmacy to complete a Compounding Self-Assessment Form.

Title 16 CCR Section 1715 establishes the requirement for the pharmacist-in-charge of a pharmacy to complete a self-assessment form.

Title 16 CCR Section 1784 establishes the requirement for the designated representative-in-charge of a wholesaler to complete a self-assessment form.

Background

The purpose of a self-assessment is to promote compliance of businesses regulated by the board through self-examination and education. Because the self-assessment forms are compilations of Pharmacy Law, modification must be made on an annual basis to incorporate changes in the law. Further, because of the mandate for licensees to complete the forms no later than July 1 of each odd-numbered year, it is necessary to update the forms and complete the rulemaking process within a very narrow time period.

Regrettably, because the timeframe to promulgate a regulation is generally at least 12 months, the current versions of the forms were not promulgated in sufficient time to ensure changes to Pharmacy Law are captured.

To address this issue, board staff is requesting the board's consideration of a new streamlined process for updating the self-assessment forms. Currently, under the relevant sections cited above, the self-assessment form is incorporated by reference. The form contains the essential elements inherent within the regulation, e.g., the requirement for the form to be signed under penalty of perjury.

Staff is proposing an alternative that will instead establish all of the requirements currently established in the form to instead be detailed in the regulation itself. The form itself could then be updated through a streamlined rulemaking process (referred to as a Section 100 change) that the Executive Officer has delegate authority to perform.

At this Meeting

Board staff requests consideration of the proposed alternative. Should the board determine it appropriate, below is a motion that could be used to initiate a rulemaking process to amend the relevant sections. Board staff believe this regulation change would be noncontroversial.

Staff Recommendation: Initiate the formal rulemaking process to amend the text of Title 16 CCR Sections 1715, 1735.2 and 1784 relating to self-assessment form requirements as proposed and authorize the Executive Officer to make any nonsubstantive changes to the rulemaking package, and provide a 45-day public comment period.

Attachment 1 includes a copy of the proposed regulation language for each section cited above.

Attachment 1

Proposal to Amend 16 CCR § 1715

§ 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 use the the components of this assessment shall be on Form 17M-13 (Rev. 10/14 16) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment". Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment and on Form 17M-14 (Rev. 10/14 16) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference ~~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 license number of the pharmacy
- (B) address, phone number, and website address, if applicable, of the pharmacy
- (C) DEA Registration number, expiration date and date of most recent DEA inventory
- (D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the board, 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 each of the requirements 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 form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and 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.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and 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.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(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 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code.

Proposal to Amend 16 CCR Amend § 1784

§ 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~~ 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 "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) 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 and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) 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 kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(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.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

Proposal to Amend Section 1735.2(k)

...

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. ~~02/12~~ 12/2016.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name of the pharmacy and the license number of the pharmacy as well as the license numbers for any specialty licenses issued by the board including sterile compounding license number and centralized hospital packaging license number, if applicable.

(B) Address, phone number, fax number, and website address, if applicable, of the pharmacy

(C) Hours of operation of the pharmacy

(D) Name of Accreditation Agency and dates, if applicable

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person’s license number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond “Yea”, “no” or “not applicable” (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that 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 form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficient identified within the self-assessment will be corrected and 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.

(7) The pharmacy owner or hospital administrator shall provide certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in revocation of the pharmacy’s license issued by the board. This certification shall be made under penalty of perjury of the State of California.

(8) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(9) Any identified areas of noncompliance shall be corrected as specified in the certification.

(I) ...

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.