

## TITLE 16: BOARD OF PHARMACY FINAL STATEMENT OF REASONS

**Subject Matter of Proposed Regulations:** Compounding Self-Assessment

**Section Affected:** Amend Title 16 California Code of Regulations (CCR) section 1735.2

### **Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on July 1, 2022 and ended on August 15, 2022. The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the board during the 45-day comment period.

During the 45-day comment period one comment was received. At its October 25-26, 2022 board meeting, the board adopted the regulation text as noticed on July 1, 2022 and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Following adoption by the board, staff made non-substantive changes on the assessment form by striking gendered language and replacing it with non-gendered language to conform with Assembly Concurrent Resolution (ACR) 260 of 2018, in which the Legislature resolved that "state agencies should ... use gender-neutral pronouns and avoid the use of gendered pronouns when drafting policies, regulations, and other guidance." These changes were made in two instances, the first on page 5, section 2.9.1.7, where "his or her" was replaced with "their," and the second on page 17, section 16.2.13, where "his or her" was replaced with "their." Because these changes are grammatical, they are without regulatory effect.

On page 25 of the self-assessment form, section 21.1, the reference to Chapter 797 of the United States Pharmacopeia has been updated to mirror the language of Business and Professions Code (BPC) 4126.8, which requires all compounding to be completed consistent with the standards established by the current version of the United States Pharmacopeia-National Formulary. The reference has been updates from "sterility testing found in Chapter 797 of the United States Pharmacopeia" to "sterility testing found in the current version of Chapter 797 of the United States Pharmacopeia-National Formulary". The establishment of the BUD is a requirement of Chapter 797 and, therefore, compliance is required by BPC 4126.8.

### **Local Mandate**

A mandate is not imposed on local agencies or school districts.

### **Small Business Impact**

While the board does not have nor does it maintain data to determine if any of its licensees (pharmacies and clinics) are a “small business,” as defined in Government Code section 11342.610, the board has made a determination that the proposed regulatory action will not have a significant adverse economic impact on small businesses. This determination is based upon the facts that the board already requires pharmacists to complete a self-assessment form, so the board finds that correcting and updating the form used to conduct the self-assessment will have no impact on small businesses.

### **Incorporation by Reference**

Existing regulation incorporates the previous version of this form (17M-39) by reference. This rulemaking continues the incorporation by reference of the new form. Continued incorporation is appropriate because the 31-page form is cumbersome and contains formatting that would not be publishable in the CCR. The previous version of form 17M-39 and the new version were both available for public inspection during the 45-day comment period.

### **Nonduplication Statement - 1 CCR § 12**

The proposed form being incorporated by reference in this regulation partially duplicates or overlaps federal and state statutes and regulations. Because the incorporated form is a self-assessment, which is essentially a compliance checklist, references to applicable law are essential. Repeating (and citing to) key language from these statutes or regulations within the form allows for greater clarity and enables users to find the relevant area of law for further research should questions arise. In sum, to ensure accuracy, duplication or overlap is necessary to effectively implement the self-assessment form in a way that satisfies the “clarity” standard of Government Code section 11349.1, subdivision (a)(3).

### **Consideration of Alternatives**

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The board considered continuing use of the self-assessment form last revised in 2012 and not provide updated forms. This alternative was rejected as PICs who fill out the 2012 version of the forms will not be using an up-to-date assessment tool that helps them measure compliance with the significant changes to the laws and regulations. This could jeopardize the health and welfare of California residents.

## **Objections or Recommendations/Responses to Comments**

During the public comment period from July 1, 2022 to August 15, 2022, the board received one comment. The comment was provided in the meeting materials for the October 25-26, 2022 board meeting, and the board reviewed and considered it.

### **Summarized 45-day Comments Regarding Compounding Self-Assessment:**

#### **Written Comments from Jeremiah Joson, Pharm.D.**

**Comment 1:** The commenter requested that the Board clarify section 1715 with respect to inpatient hospitals vs outpatient hospitals.

**Response to Comment 1:** The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside the scope of this rulemaking, which is specific to section 1735.2, whereas the commenter is requesting clarification to section 1715.