

SUPPLEMENT TO FINAL STATEMENT OF REASONS

Non-Substantive Changes to Regulatory Text

The following non-substantive changes were made to the regulatory text:

Heading. To more accurately identify the content of the regulation, the heading was modified to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

Subdivision (a) was modified to remove the words at the end of the sentence “to ensure patient-centeredness” as the words are unnecessary. Thus, the text of subdivision (a) now reads:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

Section (a)(1)(B) was modified to add the words “of the drug” in the second sentence. These words were added to reflect the statutory language found in section 4076(a)(1) of the Business and Professions Code. As a result, the text of section (a)(1)(B) now reads:

(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name *of the drug*, or the generic name and the name of the manufacturer.

Section (a)(1)(C) was modified to mirror statutory text in section 4076(a)(2). Thus, the text of section (a)(1)(C) now reads:

(C) The directions for the use of the drug.

Section (a)(1)(D) was modified to mirror statutory text in section 4076(a)(10). Thus, the text of section (a)(1)(D) now reads:

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

Subdivision (c) was modified to eliminate the introductory phrase “Beginning in October 2010” as the board does not possess the authority to establish a requirement retroactive to the effective date of a regulation. The board’s requirement to collect and publish on its Web site examples of labels conforming to the requirements of the regulation remains. Thus, the text of subdivision (c) now reads:

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

Final Statement of Reasons

Page 2 of the Final Statement of Reasons (FSOR) states that the Board of Pharmacy accepted comments during public comment periods, and referenced a 2nd 15-day comment period as follows:

April 28, 2010 – May 23, 2010 – Modified Text (2nd 15-day)

The closing date of the 2nd 15-day comment period concluded on May 13, 2010 (not May 23rd), thus, the text is corrected to read as follows:

April 28, 2010 – May 13, 2010 – Modified Text (2nd 15-day)

Also on Page 2 of the Final Statement of Reasons, the board indicates that it prepared a summary and response to objection(s) or recommendation(s) received. The board stated it did not summarize comments that did not specifically address the proposed or modified action [text] or address the procedures followed in adopting the action.

With respect to *general* comments received on the subject matter of the rulemaking, or those comments that were not specific to any proposed regulatory text, the board stands by its rationale to establish a patient-centered prescription drug container label based on statements contained in the Initial Statement of Reasons; the Final Statement of Reasons; as well as in the board's comments and rationale expressed during the regulatory hearing, at forums, and at subsequent board proceedings, as documented in the rulemaking record.