

Title 16. Board of Pharmacy Modified Language

To Add Section 1707.5. of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5. Patient-Centered Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~12-point, 10-point,~~ sans serif typeface **or, if requested by the consumer, at least a 12-point typeface,** and listed in the following order:

(A) Name of the patient

(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, or the generic name and the name of the manufacturer.

(C) Directions for use.

(D) Purpose or condition, if entered onto the prescription by the prescriber, ~~or otherwise known to the pharmacy and its inclusion on the label is desired requested by the patient~~

(2) For added emphasis, the label ~~may~~ shall also highlight in bold typeface or color, or use "white space" blank space to set off the items listed in subdivision (a)(1).

~~(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.~~

For the second 15-day comment period:

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(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
- (B) Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (C) Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (D) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning
- (E) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning
- (F) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning
- (G) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, and Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
- (H) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (I) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (J) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, and 1 ~~tablet~~ [insert appropriate dosage form] in the evening
- (K) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon, and 2 ~~tablets~~ [insert appropriate dosage form] in the evening
- (L) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, 3 ~~tablets~~ [insert appropriate dosage form] at noon, and 3 ~~tablets~~ [insert appropriate dosage form] in the evening

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(M) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, 1 ~~tablet~~ [insert appropriate dosage form] in the evening, and 1 ~~tablet~~ [insert appropriate dosage form] at bedtime

(N) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon, 2 ~~tablets~~ [insert appropriate dosage form] in the evening, and 2 ~~tablets~~ [insert appropriate dosage form] at bedtime

(O) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, 3 ~~tablets~~ [insert appropriate dosage form] at noon, 3 ~~tablets~~ [insert appropriate dosage form] in the evening, and 3 ~~tablets~~ [insert appropriate dosage form] at bedtime

~~(P) Take 1 tablet as needed for pain. You should not take more than ___ tablets in one day~~

(P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

~~(Q) Take 2 tablets as needed for pain. You should not take more than ___ tablets in one day~~

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, 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.

~~(d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.~~

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at

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minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

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