California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Consideration and Possible Adoption of Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) section 1707.5, Related to Patient-Centered Labels

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Attachment 1

Background:

At the January 2015 Board Meeting, the board approved proposed text to amend Section 1707.5 of Title 16 CCR, related to Patient-Centered Labels. The 45 day comment period began on October 23, 2015 and ended December 7, 2015.

At the April 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. The 15-day comment period began on May 11, 2016 and ended on May 26, 2016.

At the July 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 15-day comment period and initiated a second 15-day comment period. The second 15-day comment period began on August 3, 2016 and ended on August 18, 2016.

The Board received several comments during the 15-day comment period.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2016 Board Meeting and noticed for 15-day comment on August 3, 2016.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a third 15 day comment period.

The **Attachment** contains:

1. A copy of the modified text as approved at the July 2016 Board Meeting.
2. A compilation document of the comments received during the 15-day comment period.
3. The comments received during the 15-day comment period.

Staff Recommendation: Adopt the regulatory language as approved on July 27, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Attachment 1

Patient-Centered Labels: Requirements 1707.5

Patient-Centered Labels Modified Text (As Approved at the July 2016 Board Meeting)

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed text are shown by double strikethrough for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the first modified text are shown by bold wavy underline for added language. (Additionally, the modified text is listed in purple for color printers.)

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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

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

(1) Each of the following items, and only these four 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 sans serif 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 of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted ~~into the parentheses~~. If, ~~it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, **may list** the name of the manufacturer.

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

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

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

(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 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning
(F) Take 3 [insert appropriate dosage form] in the morning
(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening
(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(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

(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) 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) 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 minimum, the selected means to identify the patient's language and to provide interpretive services and translation 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)~~ (e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

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

Patient-Centered Labels

Second 15-day Comments

Comment Period Closed

August 18, 2016

Code Section	Commenter	Comment
1707.5(a)(1)(B)	**Douglas Barcon**	Current pharmacy law 4076. Prescription Container – Requirements for Labeling states in (a)(1) "…orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used." The proposed language may be in conflict with statute 4076 (a)(1), which requires the name of the manufacturer for generic drugs unless the prescriber orders otherwise on the prescription. As written in the proposed modification language, the sentence in question in 1707.5 (a)(1)(B) is targeting a narrow segment of generic drugs. Is this sentence necessary in the regulation? Regulation 4076 (a)(1) already addresses inclusion of the name of the manufacturer. The modification is not clear as written. Is the intent to make the name of the manufacturer optional or to allow placement of the name of the manufacturer outside of the 50 percent area? Perhaps the sentence should be written as: "If in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug, and the name of the manufacturer may be listed outside of the patient centered area." This may just be a punctuation issue. Perhaps there should be a comma added after "drug" and the comma after "area" and before "may" should be deleted. Depending on the Board's intent, it could be left unchanged.
1707.5(a)(1)(B)	**Mathis Abrams**	I urge the committee to reconsider the language in the last sentence of the above cited paragraph and change the last line to read "... ~~may~~ **shall** list the name of the manufacturer." The FDA has acknowledged that not all manufacturers of a generic product are equivalent to the brand name product, and has published notification of same. See, for example, the FDA statements regarding the three (3) generic alleged equivalents of Concerta (cf. ~2014). Only one (1) product was deemed equivalent, and the other two were determined to not be. This discrepancy has been clinically significant with detrimental consequences. For the above reason, the name of the generic manufacturer should be required to appear on the label, to facilitate identification of the source by the prescribing physician, and especially to identify any change in manufacturer between refills, so as to permit the prescribing or treating physician to assess whether any patient-reported, or physician identified, changes in effectiveness and/or side effects might be due to a change in manufactured source of the generic product, which may have non-equivalent efficacy. In addition, it is time consuming and inefficient for both the pharmacist and the physician for the physician to have to call the dispensing pharmacist to ascertain that information.

Code Section	Commenter	Comment
1707.5(a)(1)(B)	**Rami Maria**	I would like to suggest that the board not require such specific words as “generic for” to be printed on the label. Here are Sharp HealthCare we print “equivalent to” and use this both for brand and generic drugs so that no matter what we dispense, the patients gets both brand and generic names on the label and they are better informed. The way § 1707.5(a)(1)(B) is currently proposed, the pharmacy must use only the words “generic for” which is not appropriate in cases where the drug dispensed is a brand and we want to inform the patient of the generic name. Simply adding “…, or similar” after the “generic for” in the currently proposed text would allow pharmacies some flexibility in satisfying the requirement of better informing patients without forcing them to misprint in cases of non-generic equivalents being dispensed. Please let me know if you need examples and I can provide some. Also, we have found that patients believe generic drugs are not as good as brand drugs and printing “generic for” on the label keeps this notion alive.
1707.5(a)(1)(D)	**K. Scott Guess**	I would like to propose that professional, educated pharmacist, be allowed to add a (parenthetical) purpose or condition for use of the drug onto the patient label if the patient requests such. This (parenthetical) indication would be based on the usual indication of the drug, AND a patient interview. Furthermore, the (parenthetical) indication may be "translated" into terms easily understood by older patients, i.e. Diuretic= "water pill", anti-diabetic agents regardless of mechanism of action= "Blood Sugar", any anti-hypertensive agent = "blood pressure". The purpose of this (parenthetical) indication is NOT to diagnose, or usurp the patient-prescriber relationship. The intent is strictly to make it easier for patients to discern which pill does what for them. Because it is at the patient's request, it still protects privacy where needed.

Patient-Centered Labels

Second 15-day Comments

Martinez, Lori@DCA

From:	Doug Barcon <dougbarcon@gmail.com>
Sent:	Thursday, August 11, 2016 3:31 PM
To:	Martinez, Lori@DCA
Subject:	Comments on Title 16 CCR 1707.5, Patient-Centered Labels
Attachments:	Board of Pharm 1707_5 Pt Centered Labels Comments 8-2015 - Barcon.doc

Hi Lori.

Attached are my comments on Title 16 CCR 1707.5, related to Patient-Centered Labels for Prescription Drug Containers second modified text.

Thanks,

Douglas Barcon, Pharm.D.

Institution/Contact	Douglas Barcon, Pharm.D., Barcon & Associates, P.O. Box 5646, Diamond Bar, CA 91765	
Subdivision (e.g., a, b, c)	Proposed Language	Recommendation/Comments
1707.5 Patient-Centered Labels for Prescription Drug Containers; Requirements. (a)(1)(B)	If in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, **may list** the name of the manufacturer.	Current pharmacy law 4076. Prescription Container – Requirements for Labeling states in (a)(1) "…orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used." The proposed language may be in conflict with statute 4076 (a)(1), which requires the name of the manufacturer for generic drugs unless the prescriber orders otherwise on the prescription. As written in the proposed modification language, the sentence in question in 1707.5 (a)(1)(B) is targeting a narrow segment of generic drugs. Is this sentence necessary in the regulation? Regulation 4076 (a)(1) already addresses inclusion of the name of the manufacturer. The modification is not clear as written. Is the intent to make the name of the manufacturer optional or to allow placement of the name of the manufacturer outside of the 50 percent area? Perhaps the sentence should be written as: "If in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug, and the name of the manufacturer may be listed outside of the patient centered area." This may just be a punctuation issue. Perhaps there should be a comma added after "drug" and the comma after "area" and before "may" should be deleted. Depending on the Board's intent, it could be left unchanged.

Martinez, Lori@DCA

From: Mathis Abrams, M.D., J.D. <Dr.Mathis@Abrams.tv>
Sent: Sunday, August 07, 2016 10:13 PM
To: Martinez, Lori@DCA
Subject: comment re § 1707.5.(a)(1)(B)

§ 1707.5.(a)(1)(B)

I urge the committee to reconsider the language in the last sentence of the above cited paragraph and change the last line to read "... ~~may~~ shall list the name of the manufacturer."

The FDA has acknowledged that not all manufacturers of a generic product are equivalent to the brand name product, and has published notification of same. See, for example, the FDA statements regarding the three (3) generic alleged equivalents of Concerta (cf. ~2014). Only one (1) product was deemed equivalent, and the other two were determined to not be. This discrepancy has been clinically significant with detrimental consequences.

For the above reason, the name of the generic manufacturer should be required to appear on the label, to facilitate identification of the source by the prescribing physician, and especially to identify any change in manufacturer between refills, so as to permit the prescribing or treating physician to assess whether any patient-reported, or physician identified, changes in effectiveness and/or side effects might be due to a change in manufactured source of the generic product, which may have non-equivalent efficacy. In addition, it is time consuming and inefficient for both the pharmacist and the physician for the physician to have to call the dispensing pharmacist to ascertain that information.

Thank you for your consideration.

Mathis Abrams, M.D., J.D.
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eMail: <Dr.Mathis@Abrams.tv>

Martinez, Lori@DCA

From: Rami Maria <Rami.Maria@sharp.com>
Sent: Friday, August 05, 2016 12:42 PM
To: Martinez, Lori@DCA
Cc: Kim Allen
Subject: § 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

Hi Lori,

I would like to suggest that the board not require such specific words as "generic for" to be printed on the label. Here are Sharp HealthCare we print "equivalent to" and use this both for brand and generic drugs so that no matter what we dispense, the patients gets both brand and generic names on the label and they are better informed. The way § 1707.5(a)(1)(B) is currently proposed, the pharmacy must use only the words "generic for" which is not appropriate in cases where the drug dispensed is a brand and we want to inform the patient of the generic name. Simply adding "..., or similar" after the "generic for" in the currently proposed text would allow pharmacies some flexibility in satisfying the requirement of better informing patients without forcing them to misprint in cases of non-generic equivalents being dispensed. Please let me know if you need examples and I can provide some. Also, we have found that patients believe generic drugs are not as good as brand drugs and printing "generic for" on the label keeps this notion alive.

Thank you for your consideration,

Rami Maria, PharmD
Pharmacist Informaticist, Sharp Rees-Stealy Pharmacy
2001 Fourth Avenue San Diego, CA 92101
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Lori Martinez
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

3 August, 2016

Re: proposed modifications to the text of Title 16 CCR § 1707.5.

Dear distinguished members of the California Board of Pharmacy;

I have no objections to the proposed modifications for patient centered labels. But I would like the Board to consider an addition; an addition that supports the provider status recently given to pharmacists.

As a retail community pharmacist, the most common request I get from patients is to indicate on the label what the indicated use of the medication is. 1707.5 (a)(1)(D) asks the label to indicate "the purpose or condition for which the drug was prescribed if the condition or purpose ***if indicated on the prescription***"

I would like to propose that professional, educated pharmacist, be allowed to add a (parenthetical) purpose or condition for use of the drug onto the patient label **if the patient requests** such. This (parenthetical) indication would be based on the usual indication of the drug, AND a patient interview. Furthermore, the (parenthetical) indication may be "translated" into terms easily understood by older patients, i.e. Diuretic = "water pill", anti-diabetic agents regardless of mechanism of action = "Blood Sugar", any anti-hypertensive agent = "blood pressure".

The purpose of this (parenthetical) indication is NOT to diagnose, or usurp the patient – prescriber relationship. The intent is strictly to make it easier for patients to discern which pill does what for them. Because it is at the patient's request, it still protects privacy where needed.

1707.5 creates a great deal of much needed continuity and consistency in label appearance across all pharmacies. This is a great benefit for all consumers and the next step to promote the pharmacist-as-provider concept in the eyes of the patient by allowing pharmacists to fulfill the most common patient request..."Will you put what this is for on the label?"

Best regards,

Scott pharm.D. MS Pharm.

K. Scott Guess, PharmD. MS Pharm, RPh, DAAPM