TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Patient-Centered Labels for Prescription Drug Containers; Requirements.

Section Affected: Amend Section 1707.5 of Article 2 of Division 17 of Title 16, California Code of Regulations.

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 adoption of the above section. The Initial Statement of Reasons is updated as follows:

The 45-day public comment period began on October 23, 2015 and ended on December 7, 2015. 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 several comments were received and those comments were addressed by modifying the proposed text. The modified text was approved by the Board at its April 27, 2016 meeting.

The modified text was noticed for a 15-day comment period that began on May 11, 2016 and ended on May 26, 2016. During the 15-day comment period several comments were received and those comments were addressed by modifying the text a second time. The second modified text was approved by the Board at its July 27, 2016 meeting.

On May 11, 2016, the following documents were added to the rulemaking file:

1. Relevant Meeting Materials from Board of Pharmacy Committee Meeting held April 1, 2014 (Materials: Agenda Item 2, Pages 1-5 plus Attachment 2)
2. Relevant Meeting Materials from Board of Pharmacy Committee Meeting held September 18, 2014 (Materials: Agenda Item 2, Pages 1-5 plus Attachment 2)
3. Relevant Meeting Materials from Board of Pharmacy Meeting held October 28-29, 2014 (Materials: Agenda Item XIV(b) Pages 1, 3-9)
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held December 10, 2014 (Materials: Agenda Item 4, Pages 1, 3-4 plus Attachment 4, Minutes: Pages 1-13)
5. Relevant Meeting Materials from Board of Pharmacy Meeting held January 27 -28, 2015 (Materials: Agenda Item VI(d) Pages 1,3)
6. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held March 23, 2015 (Materials: Agenda Item 5, Pages 1, 3-4, Minutes: Pages 1, 7)
7. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 21-22, 2015 (Materials: Agenda Item V(d) Pages 1-3, Minutes: Pages 1, 4-5)

These documents are from publicly noticed meeting and material mostly available on the board's website, but were added to the rulemaking file to ensure accuracy of the rulemaking record.

The second modified text was noticed for an additional 15-day comment period that began on August 3, 2016 and ended on August 18, 2016. During the 15-day comment period several comments were received. No additional changes were made in response to these comments.

The regulation was modified from the original proposed text as follows:

Section (a)(1)(B) was modified to remove "into the parentheses" as requested by commenters. The Board determined that this phrase was an error and parentheses are not needed and agreed with a commenter that some labeling programs may not have the ability to use the special character. Additionally, this section was modified to remove "it has been at least five years since the expiration date of the brand name's patent or, if" as requested by commenters. The board determined that the five year time frame was not needed as the pharmacist has the ability to use their professional judgment to determine at what point the brand name becomes no longer widely used. The pharmacist, in their professional judgment, would determine if the brand name should be listed. Finally, the section was modified to add "may list" in front of the manufacturer name. This change was made to address concern about the ability to list the manufacturer's name outside of the patient-centered area if the label. The manufacture name must be on the label pursuant to Business and Professions Code section 4076(a)(1). Pharmacists can use their professional judgment to determine if the manufacturer name is listed in the patient-centered area of the label or outside of the patient-centered area. This could vary depending on the medication and/or the patient. The pharmacist will decide the appropriate location depending on the needs of their patient.

On August 31, 2016, after having considered all comments in the record, the Board adopted the regulation. It also delegated authority to adopt and make non-substantive changes to the regulation to its Executive Officer.

During the final review, the Executive Officer made non-substantice changes to the text of the regulation to resolve confusion that may be created by sentence structure. Specifically, the board's intent was to allow the pharmacist to use their professional judgment when determining if the brand name is no longer widely used and the location of the manufacturer's name (inside the patient centered area or outside the patient centered area. As such, section (a)(1)(B) was amended to read:

"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, and the name of the manufacturer. In the professional judgment of the pharmacist,

(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and
(ii) The manufacturer's name may be listed outside of the patient-centered area.

Local Mandate

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

Small Business Impact

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of substantive comments and the lack of any requests for a hearing regarding this rulemaking proposal. Adopting this regulation will protect the people of California by ensuring consumers receive their prescription drugs with respective labels that are centered around the consumers' needs so that each consumer is able to understand the prescription drug is for them, the name of the prescription drug (and the brand name if a generic drug is dispensed), the directions for use of the prescription drug, and the condition or purpose for which the prescription drug was prescribed is indicated on their prescription. Additionally, the regulation would require pharmacies to have policies and procedures in place to respond to patients with limited or no English proficiency will ensure that pharmacies have the ability provide accurate information regarding prescription drugs in a language appropriate for the patient.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or 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.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from October 23, 2015 to December 7, 2015, the Board received several comments. The comments were provided to the Board in the Meeting Materials for its April 27, 2016 Board meeting, and were reviewed and considered by the Board.

Written Comment from Dennis McAllister, Express Scripts

Comment #1: Mr. McAllister indicated that Express Scripts supports the intent of the proposal, but recommended that the "generic for" be excluded from the 50% Patient-Centered Label space and be listed elsewhere on the label.

Response to Comment #1: The Board rejects this comment. The Board has found that there is sufficient space within the patient-centered area for this information. Additionally, the Board determined that it was appropriate to include this information in the patient-centered area of the label to ensure the information is in one location and reduce confusion with patients.

Written Comment from Mary Staples, National Association of Chain Drug Stores

Comment #2: Ms. Staples recommended that “inserted into the parentheses” be removed because the parentheses are not unnecessary and could pose software interface issues.

Response to Comment #2: The Board accepts and agrees with the comments provided by Ms. Staples. The Board determined that this language should not appear as there are no parentheses in the regulation text. As such, the Board amended section 1707.5(a)(1)(B) to eliminate the parentheses requirement.

Written Comment from Lauren Berton, PharmD., CVS

Comment #3: Dr. Berton expressed concern about adding “generic for” for generic maintenance medications for patients who only know the current drug name. Dr. Berton recommended removing the 5 yr patent requirement and only require “generic for” when the pharmacist selects a generic medication over a brand name.

Response to Comment #3: The Board accepts and rejects parts of this comment. The Board agreed with the recommendation to remove the 5 year from the patent expiration standard as the decision can be appropriately left to the pharmacist’s professional judgment. The Board rejected the part where “generic for” would only be required for generic substitution. The Board determined that a patient should know the names for all generic medications because they may have both brand name and generic at home from different prescribers or different pharmacies. Additionally, the pharmacist does have the ability to use professional judgment and decline to include “generic for” on the label if he or she determines that the brand name is no longer widely used.

Written Comment from Prime Therapeutics

Comment #4: Prime Therapeutics expressed concern about having the statement “generic for” be in 12-point font as it will limit the space available for directions for use. Additionally, they indicated that it would be difficult to use professional judgment because of name complexities. Finally, Prime Therapeutics recommended language to include the name of the manufacturer and the statement “generic for” outside the patient-centered area.

Response to Comment #4: The Board rejects this comment. As indicated in the response to comment #1, the Board determined that it was appropriate to include this information in the patient-centered label to ensure the information is in one location and reduce confusion with patients. Additionally, if there are multiple brand names, it is not necessary to list all the brand names. The pharmacist would use their professional judgment when deciding which to use, whether it be the most commonly known, or some other reason. The Board rejected the recommended language. The board notes that the size requirements for the patient centered area of the label are not being amended, but it is important for this information to appear prominently on the labels for patient safety.

Written Comment from Diane Terada, PharmD.

Comment #5: Dr. Terada expressed concern about the size requirement and whether the term “generic for” is required because of space limitations. Additionally, Dr. Terada asked for clarification on the requirement for multiple brand names.

Response to Comment #5: The Board rejects this comment. See response to comments #1, 3, and 4.

Written Comment from Carol Millage, PharmD.

Comment #6: Dr. Millage expressed concern about the time limit for how long the brand name needs to be listed. Dr. Millage's recommendation was three years. Additionally, she recommended that only the generic name be required because all brand names eventually go off patent.

Response to Comment #6: The Board rejects this comment, however, the Board eliminated the time limit requirement to leave it as pharmacist's professional judgment. Additionally, it is not possible to list only the generic name as there is a time frame where certain drugs do not have a generic. If only the generic name is required and a generic form isn't available, there would not be a generic name to list on the label.

Written Comment from Deborah Kelly, PharmD.

Comment #7: Dr. Kelly requested clarification if the brand name needed to be 12-point font. Additionally, she requested clarification if the word "for" needed to be used.

Response to Comment #7: The Board rejects this comment. See response to comment #4. The term "generic for" would need to be used as specified in the regulation text.

Written Comments from K. Scott Guess, PharmD.,

Comment #8: Dr. Guess requested clarification on which brand names should be used when there are multiple brand names. Additionally, he requested clarification is the brand name needed to be included if the prescription was written for the generic.

Response to Comment #8: The Board rejects this comment. See response to comment #4. Additionally, as indicated in response to comment #3, a patient may have more than one prescription for a medication. While a prescriber may write a prescription for the generic name, the patient may already have the same drug with the brand name at home. If the patient is not aware that the brand name and the generic name are the same, they may duplicate treatment and may suffer medication overdose side effects.

Comment #9: Dr. Guess indicated that he did not see the need for adding "generic for" and indicated that he gets more questions for what the drug is for rather than the name of the drug.

Response to Comment #9: The Board rejects this comment. See response to comments 1 and 8. Additionally, while the Board agrees that this information should be discussed during patient consultation, the patient may not fully understand or remember what the pharmacist advised them orally while they are at home reviewing the prescription containers.

At its April 27, 2016, meeting, the Board considered all of the comments and voted to modify the proposed text and initiate a 15-day comment period.

First 15-Day Public Comment Period

During the first 15-day public comment period from May 11, 2016 to May 26, 2016, the Board received several comments. The comments were provided to the Board in the Meeting Materials for its July 27, 2016 Board meeting, and were reviewed and considered by the Board.

Written Comments from an Annoymous commenter,

Comment #10: The commenter requested clarification on whether the manufacturer name must be in the patient-centered area or outside the patient-centered area. Additionally, the commenter requested clarification on whether abbreviations can be used.

Response to Comment #10: The Board accepts this comment and modified the regulation text to include "may list" in front of the name of the manufacturer. The Board's intent with the manufacturer name is to allow a pharmacist to use their judgment on whether the manufacturer name is within the patient-centered area or outside the area. Additionally, the language does not restrict the use of abbreviations and abbreviations are permitted by Business and Professions Code (B&P) section 4076.

Written Comments from Lauren Berton, PharmD., CVS,

Comment #11: Dr. Berton requested that the language be modified to only require "generic for" if the brand name was prescribed and the patient is receiving the generic. Additionally, Dr. Berton requested that the statement "generic for" be in less than the required 12-point font.

Response to Comment #11: The Board rejects this comment. See response to comments 3 and 4.

Written Comments from Pharmacist Mary Staples, National Association of Chain Drug Stores,

Comment #12: Ms. Staples expressed concern that the language requires "generic for" on all labels, even when the prescriber prescribed the generic drug. Ms. Staples indicated she did not believe that to be the Board's intent.

Response to Comment #12: The Board rejects this comment. The requirement to indicate "generic for ____" on all prescriptions is the Board's intent. A patient may receive a prescription for the generic, but still have a prescription for the brand name at home. If the patient is not aware that the medications are the same, they could duplicate treatment and suffer from side effects.

At its July 27, 2016, meeting, the Board considered all of the comments and voted to modify the proposed text initiating a second 15-day comment period.

Second 15-Day Public Comment Period

During the second 15-day public comment period, from August 3, 2016 to August 18, 2016, the Board received several comments. The comments were provided to the Board in the Meeting Materials for the August 31, 2016, Board meeting, and were reviewed and considered by the Board.

Comment from Douglas Barcon, PharmD.,

Comment #13: Dr. Barcon requested clarification if the Board is requiring the name of the manufacturer to be optional or allow placement of the manufacturer outside the patient-centered label.

Response to Comment #13: The Board rejects the comment. The name of the manufacturer is required by B&P section 4076. The regulation language allows for the manufacturer name to be placed outside the patient-centered area in the professional judgment of the pharmacist.

Comment from Mathis Abrams, M.D.,

Comment #14: Dr. Abrams expressed concern that the regulation text appears to allow the manufacturer name to be removed from the label. Dr. Abrams recommended that "may list" be changed to "shall list."

Response to Comment #14: The Board rejects this comment. See response to comment 13.

Comment from Rami Maria, PharmD.,

Comment #15: Dr. Maria asked the Board to consider allowing variances of "generic for" such as "equivalent to" because some patients believe generic drugs are not as good as brand name drugs and putting "generic for" will keep this belief.

Response to Comment #15: The Board rejects this comment. The Board determined that this is a patient education issue. Patients need to be aware that they are receiving a generic medication and that it is inappropriate to try to hide this information from the patient.

Comment from K. Scott Guess, PharmD.,

Comment #16: Dr. Guess asked the Board to modify section (a)(1)(D) to include a requirement to list the purpose or condition on the label. Additionally, he requested that pharmacists be permitted to add the purpose or condition to the label if requested by the patient.

Response to Comment #16: The Board rejects this comment as outside the scope of the proposed changes. The Board notes that the pharmacist can use their professional judgment and add the purpose or condition to the label if it's on the prescription or the patient makes the request.

At its August 31, 2016, meeting, the Board considered all of the comments and voted to adopt the regulation text as it was noticed on August 3, 2016.