California State Board of Pharmacy
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XIII. Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) section 1707.5, Related to Patient-Centered Labels

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.

The Board received several comments during the 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 January 2015 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

The Attachment contains the proposed regulation text as noticed on October 23, 2015 and a compilation document of the comments received during the 45 day comment period.

Patient-Centered Labels: Requirements 1707.5

Patient-Centered Labels

45-Day Comments

Comment Period Closed December 7, 2015

Code Section	Commenter	Comment
1707.5(a)	**Dennis McAllister**	Express Scripts supports the intent of the proposal to give patients information on generic and trade names on the prescription label. However, we suggest that the "generic for" not be in the 50% white space reserved for clear instructions to the patient. It would make the reserved space more crowded and defeat the purpose of a specified, easily readable area on the label. There is sufficient remaining space on the label to insert the "generic for" information, outside the reserved 50% white space and avoid unnecessary clutter as was the intent of the Board when the patient centered label was designed.
1707.5(a)(1)(B)	**Mary Staples NACDS**	On behalf of our members operating retail pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) asks the Board of Pharmacy to amend its proposed formatting for the drug container labeling requirement regarding the drug and strength of the drug. In Section 1707.5, the Board proposes to require pharmacies to print on the drug container label "the statement 'generic for _____' where the brand name is inserted into the parentheses." We have no objections to the substantive information required on the label. However, we believe that the use of parentheses for the brand name is unnecessary and would be difficult for pharmacies to implement. Parentheses are difficult to add to labels because there are automation interfaces that sometimes have issues with special characters like parentheses. We believe that the statement "generic for _____" is clear enough without the use of parentheses. Accordingly, we request that the Board delete the requirement that the brand name be inserted into parentheses. We thank you for your consideration of our suggested revision.
1707.5(a)(1)(B)	**Lauren Berton CVS**	CVS Health appreciates the Board's effort to increase patient and consumer education on what medications they are taking by clarifying the "name of the drug" on the label. The current proposed language in 1707.5(a)(1)(B) requires that the statement "generic for ____" be included on the label unless it has been five years since the expiration of the brand name's patent or the brand name is no longer widely used, as determined by the professional judgment of the Pharmacist. We ask the board to consider amending this language to only require the "generic for" statement if a pharmacist dispenses a generic equivalent when a brand name medication is prescribed. We are concerned that the current draft language may cause additional confusion to patients on generic maintenance medications who are familiar with the current name of the drug. The current and suggested language is outlined below Suggested Language: (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, generic name of the drug or the generic name and the statement "generic for _____" if a pharmacist selects a generically equivalent drug product for the brand name drug product prescribed ~~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, the name of the manufacturer.~~ and the name of the manufacture

Code Section	Commenter	Comment
1707.5(a)(1)(B)	**Prime Therapeutics**	Prime is concerned that requiring the “Generic for “ statement in the patient-centered area of the label in 12-point font size will result in an unintended consequence of limiting the space available for medicine directions of use. The medicines our specialty pharmacy dispenses have especially long drug names. Requiring both brand and generic names in 12-point font will substantially impact the space available on the prescription label telling patients how to use their medicines. There are several complexities associated with brand names, generic names, branded generics, and authorized generics. These complexities may make it difficult for pharmacists to use their professional judgment to determine whether or not to include the brand name of the medicine. We are concerned the regulation as written may be difficult to interpret and implement
1707.5(a)(1)(B)	**Prime Therapeutics**	Prime respectfully submits the following language for your consideration: (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 outside the patient centered area, the name of the manufacturer 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, any~~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, the name of the manufacturer~~.
Overall Comment	**Diane Terada**	Please address how this will fit on the prescription bottle label while keeping the font size requirement. Will the word "generic for _____" be required? (will take up much space on the label. What if there are multiple brand names? Must all be listed? Multiple names can also be confusing for patients.

Code Section	Commenter	Comment
Overall Comment	**Carol Millage**	With regard to the following pending regulation: (Patient Centered Label) This proposal further specifies the patient-centered prescription drug container label in 16 CCR section 1707.5(a)(1)(B) by clarifying the meaning of "name of the drug." By requiring the brand name when a generic drug is dispensed, patients will be further educated as to what medications they are taking. This may reduce incidence of and/or prevent accident drug overdoses. Additionally, by amending 1707.5(d) to include translation services, pharmacies will be required to include means of providing translation services to patients with limited or no English proficiency. Having policies and procedures in place that identify how to provide translation services will make the services more readily available to those patients that need them. (entire proposal: http://www.pharmacy.ca.gov/laws_regs/1707_5_ntc.pdf) I understand the logic, but disagree with the highlighted (in Red) portion of above, unless a limit of how long a branded item must be listed is incorporated into the law. Most providers/patients/and pharmacists forget the older brand names. For example, how many people are familiar with the brand names for Chlorothalidone or Hydrochlorothiazide tablets? I never see Esidrix or Hygroton written on a prescription anymore. Those branded names are long forgotten. I do not think a brand name should be required after 3 years of being off patent. What make more sense to me is that the generic name be required on all prescriptions, rather than the brand name, since eventually all branded items go off patent. Many computers can be programmed to print only the generic name and the manufacturer name distinguishes the product.
Overall Comment	**Deborah Kelly**	In reading the proposed changes to the patient centered label information, we had a question about the use of the brand name on the label when a generic drug is dispensed. At this time we have the generic name and strength of the generic drug prominently displayed. Would the brand name have to be in the 12 pt font and would we have to use the word "for" i.e. Acyclovir 400 mg (for Zovirax)? We are currently doing a software upgrade to our label program and are concerned with the width of the label fitting the bottle. We may need new programming and I wanted to anticipate the change.

Code Section	Commenter	Comment
Overall Comment	**K. Scott Guess**	A critical component of patient-centric medicine is patient education; educating the patient as to the name of their medication and why it was prescribed, proper user, storage, potential adverse events, and disposal. Brand names are sometimes easier to pronounce (Zyvox®), sometimes not (Xifaxin®). Brand name or generic name is much less relevant to patient-centered medicine than teaching the patient the name of their medication and what it is to do for you (Metoprolol Succinate is for your blood pressure). What this proposed regulatory change does not address is: 1. Generic medications that were originally marketed under two distinct brand names: a. Diabeta®, and Micronase® for example. b. All of the Ditiazem names c. All of the Verapamil names, Calan® or Isoptin® d. Which brand name do we link to? 2. How do we address the Branded generics? Cheratussin AC®, Dilt-XR®, Endocet®, nearly all of the generic oral contraceptives have some trade name rather than active drug names (Acyclen 7-7-7, Cyclafem 7-7-7, Dasetta 7-7-7, or Ortho Novum 7-7-7.) Do we link this type of name back to the FDA Reference Listed Drug brand name? 3. What if the prescriber writes the prescription by its generic name? Are pharmacists to insert a brand name? Again what if there are two? There will be more confusion generated when “Generic for Micronase” appears on a label for a patient who has taken generic Diabeta all her life.
Overall Comment	**K. Scott Guess**	Many, if not most pharmacy software systems will automatically insert “generic for_____” if the data entry clerk enters the brand name product, the selects the appropriate generic when offered. In my practice I have more patients ask me to write ‘what it’s for’ on the package rather than another product name that has no meaning to them. I truly do not see the need to make “generic for_____” a regulatory issue, although a pharmacist is welcome to add it to the verbal consultation. Because of the multiple brand names and the loosely defined ‘widely used,’ regulation such as this will cause more harm than good and it is not necessarily patient-centered.

Patient-Centered Labels Initial Proposed Text

Title 16. Board of Pharmacy

Proposed Regulations

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, 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.