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: Agenda Item XI. Discussion and Consideration 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.

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 April 2016 Board Meeting and noticed for 15-day comment on May 11, 2016.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a second 15 day comment period.

The **Attachment** contains:

1. A copy of the modified text as approved at the April 2016 Board Meeting.
2. A compilation document of the comments received during the 15-day comment period with Staff Recommendations.
3. The comments received during the 15-day comment period.
4. A compilation document of the comments received during the 45-day comment period.
5. The comments received during the 45-day comment period.
6. The initial proposed text as noticed for 45-day comment on October 23, 2015.

Staff Recommendation: Adopt the regulatory language as noticed on May 11, 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 April 2016 Board Meeting)

Title 16. Board of Pharmacy

Modified Text

Changes made to the originally proposed language 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.)

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.

Patient-Centered Labels

15-Day Comment Log

Comment Period Closed

May 26, 2016

Code Section	Commenter	Comment	Staff Recommendation
1707.5(a)(1)(B)	**Annoymous**	"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. As worded, this is saying that if a pharmacy elects to list the brand name (in addition to the generic name) the name of the manufacturer can be included INSIDE the patient centered area. Is this the intent? Or is the intent to list the manufacturer ALWAYS outside of the patient centered area? Also consider some wording may want to be added that either the manufacturer name OR Manufacturer Abbreviation can be used. For example, BAXTER HEALTHCARE CORPORATION - ANESTHESIA & CRITICAL CARE PHARMACEUTICALS would take up the majority of the prescription label if we must list the name of the mfg.	Reject Comment: The manufacture name can be included in the patient centered area. Additionally, the language does not restrict the use of abbreviations.
1707.5(a)(1)(B)	**Lauren Berton CVS**	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. A prescription written generically by the prescriber should not be subject to this language. We are concerned that the current draft language may cause additional confusion to patients on generic maintenance medications who are already familiar with the current generic name of the drug. We would also request that the Board consider allowing the "generic for____" statement to be in a font less than 12 point sans serif typeface to allow for other patient centered required elements of the label to be easily readable by patients of California. (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 _____" with the brand name inserted if prescribed~~. 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 prescription was written as the generic name or 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. The "generic for" statement may be in less than the required 12 point sans serif typeface.	Reject Comment: It is possible that a patient could have a prescription for the Brand name at home. The intent of the regulation is to reduce confusion when patients have received multiple prescriptions for the same drug.
1707.5(a)(1)(B)	**Mary Staples NACDS**	In Section 1707.5(a)(1)(B), the Board's proposal appears to require that the statement "generic for" plus the brand name be placed on the label whenever a generic drug is dispensed. In other words, the "generic for" language would be required whether or not the prescriber prescribed a brand or a generic. We do not believe that the intent of the Board was to require the "generic for" language appear on labels where the prescriber actually prescribed the generic version of the drug. Accordingly, we request that the Board modify the language to state: 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, *where the prescriber has prescribed a brand name drug and a generic substitution is made* , the statement "generic for _____" where the brand name is inserted into the parentheses.	Reject Comment: It is possible that a patient could have a prescription for the Brand name at home. The intent of the regulation is to reduce confusion when patients have received multiple prescriptions for the same drug.

Patient-Centered Labels 15-Day Comments

Martinez, Lori@DCA

From: VERCP@aol.com
Sent: Thursday, May 12, 2016 11:40 AM
To: Martinez, Lori@DCA
Subject: Comment on 1707.5

Please clarify the following; 1707.5(a)(1)(B)

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.

As worded, this is saying that if a pharmacy elects to list the brand name (in addition to the generic name) the name of the manufacturer can be included INSIDE the patient centered area. Is this the intent? Or is the intent to list the manufacturer ALWAYS outside of the patient centered area?

Also consider some wording may want to be added that either the manufacturer name OR Manufacturer Abbreviation can be used.

For example, BAXTER HEALTHCARE CORPORATION - ANESTHESIA & CRITICAL CARE PHARMACEUTICALS

would take up the majority of the prescription label if we must list the name of the mfg.

Thank you

Martinez, Lori@DCA

From: Berton, Lauren N. <Lauren.Berton@CVSHealth.com>
Sent: Sunday, May 22, 2016 3:59 PM
To: Martinez, Lori@DCA
Cc: Berton, Lauren N.
Subject: CVS Health Comments in Reference to Amendments to § 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations
Attachments: CVS Health Comments to Proposed Amendments of Section 1707 5 Comments.pdf

Good Afternoon Lori,

Please find attached CVS comments in reference to modified amendments to § 1707.5 Patient-Centered Labels for Prescription Drug Containers in Article 2 of Division 17 of Title 16 of the California Code of Regulations. Please feel free to reach out to me with any additional questions on the attached comments.

Thank you,

Lauren Berton, PharmD | Director, Pharmacy Regulatory Affairs
c 540-604-3661 | **f** 401-733-0479
CVS Health | One CVS Drive, Mail Code 2325, Woonsocket, RI 02895

CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

May 22 , 2016

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Proposed amendments to Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the modified text to proposed amendments to Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations regarding Patient-Centered Labels for Prescription Drug Containers.

CVS Health appreciates the Board's effort to increase patient and consumer education on the 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 for all prescriptions, regardless of how prescribed, unless the pharmacist using professional judgement feels the brand name is no longer widely used. 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**. A prescription written generically by the prescriber should not be subject to this language. We are concerned that the current draft language may cause additional confusion to patients on generic maintenance medications who are already familiar with the current generic name of the drug. We would also request that the Board consider allowing the "generic for____" statement to be in a font less than 12 point sans serif typeface to allow for other patient centered required elements of the label to be easily readable by patients of California. The current and suggested language is outlined below.

Current 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, 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.

Suggested Language:

CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

(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 _____" with the brand name inserted if prescribed. ~~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 prescription was written as the generic name or 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. The "generic for" statement may be in less than the required 12 point sans serif typeface.

CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

Martinez, Lori@DCA

From: Mary Staples <mstaples@NACDS.org>
Sent: Thursday, May 26, 2016 11:58 AM
To: Martinez, Lori@DCA
Cc: Sodergren, Anne@DCA; Herold, Virginia@DCA
Subject: NACDS Comments on Title 16, California Code of Regulations, Section 1707.5, Proposed Rule on Patient-Centered Labels for Prescription Drug Containers: Requirements
Attachments: CA NACDS Cmts Pat_Ctr_Label 5-26-2016.pdf

Please accept this comment letter for the record.

Mary Staples
Director, State Government Affairs

NACDS
1560 E. Southlake Blvd., Suite 230
Southlake, TX 76092
817.442.1155
817.442.1140 Fax
817.308.2103 Cell
mstaples@nacds.org

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 26, 2016

Lori Martinez
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Title 16, California Code of Regulations, Section 1707.5, Proposed Rule on Patient-Centered Labels for Prescription Drug Containers: Requirements

Dear Ms. Martinez:

On behalf of our members that operate approximately 3,394 chain pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) is writing to request a small modification to the Board's proposed rule on patient-centered labels. We believe that the proposed provision addressing labeling of generic drugs is unclear and confusing and needs to be revised.

In Section 1707.5(a)(1)(B), the Board's proposal appears to require that the statement "generic for" plus the brand name be placed on the label whenever a generic drug is dispensed. In other words, the "generic for" language would be required whether or not the prescriber prescribed a brand or a generic. We do not believe that the intent of the Board was to require the "generic for" language appear on labels where the prescriber actually prescribed the generic version of the drug. Accordingly, we request that the Board modify the language to state:

> 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, *where the prescriber has prescribed a brand name drug and a generic substitution is made,* the statement "generic for _____" where the brand name is inserted into the parentheses.

(Suggested revision italicized and underlined)

In conclusion, we generally support the Board's proposed revisions to patient-centered labeling. However, we ask that the Board clarify the labeling requirements for generic drugs, so that brand drug labeling references are only required where there is a generic substitution for a prescribed brand name drug.

Sincerely,

Mary Staples

NACDS Regional Office
1560 East Southlake Boulevard, Suite 230 • Southlake, TX 76092 • 817.442.1155 • www.NACDS.org

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 45-Day Comments

Martinez, Lori@DCA

From: Millage, Carol <Carol.Millage@sbcphd.org>
Sent: Monday, November 16, 2015 3:42 PM
To: Martinez, Lori@DCA
Subject: 45-Day Comment Period on Patient Centered Label pending regulation

Dear DCA,

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 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.

Sincerely,

Carol Millage, PharmD
Pharmacy Director
300 N. San Antonio Road
Santa Barbara, CA 93110
805-681-5164

Martinez, Lori@DCA

From: Debby Kelly <dkelly@pharmpakinc.com>
Sent: Wednesday, November 18, 2015 1:21 PM
To: Martinez, Lori@DCA
Subject: Proposed label changes

Dear Ms. Martinez:

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.

Thanks in advance for any insight you can provide.

Deborah Kelly
Director of Operations
PharmPak, Inc.

Martinez, Lori@DCA

From: Mcallister, Dennis (WDC) <Dennis_McAllister@express-scripts.com>
Sent: Wednesday, November 25, 2015 7:39 AM
To: Martinez, Lori@DCA
Subject: Comments on proposed regulation amendments to 1707.5
Attachments: Generic For, comments 1707.5 Express Scripts.docx

Lori,
Please find an attached letter with our comments regarding the proposed changes to the patient centered label.

Thank you,

Dennis McAllister R.Ph., D.Ph., FASHP
Senior Director, Pharmacy Regulatory Affairs
Express Scripts, Inc.
602-513-2759 (AZ time zone)
dennis_mcallister@express-scripts.com

EXPRESS SCRIPTS®

November 25, 2015

Lori Martinez
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Comments on proposal to amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations.

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.

Thank you for the opportunity to share our comments.

Cordially,

Dennis K. McAllister R.Ph., FASHP
Senior Director, Pharmacy Regulatory Affairs
dennis_mcallister@express-scripts.com
602-513-2759

Martinez, Lori@DCA

From: scott guess <guesses4@msn.com>
Sent: Friday, October 23, 2015 4:39 PM
To: Martinez, Lori@DCA
Subject: 1707.5 with the attachment this time
Attachments: Pt centered Lable Generic for.pdf; PastedGraphic-8.pdf

Dear Ms. Martinez,

Please accept my public comment on proposed changes to 1707.5 as the attached PDF file.

Thanks,

Scott

K. Scott Guess Pharm.D., RPh.
Diplomate, American Academy of Pain Management
Pain Management Pharmacy, Inc.
2003 S. Miller St.
Santa Maria, CA 93454
805-928-4700 (work)
805-714-3908 (cell)

K. Scott Guess, Pharmacist

Pharm.D., RPh., DAAPM

2003 S. Miller St. Santa Maria, CA 93454

Voice: 805-928-4700 Fax: 805-928-4710 Cell: 805-714-3908

KSG.PharmD@outlook.com

Lori Martinez
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834
Lori.Martinez@dca.ca.gov
(916) 574-8618

23 October, 2015

Re: **To Amend** Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations

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.

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.

Thank you for your thoughtful consideration,

Scott Guess

Martinez, Lori@DCA

From: Lauren Berton <laurennberton@gmail.com>
Sent: Monday, December 07, 2015 2:41 PM
To: Martinez, Lori@DCA
Subject: Fwd: CVS Health Comments in Reference to Amendments to § 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations
Attachments: image001.jpg; ATT00001.htm; CVS Health Comments to Proposed Amendments to Section 1707.5.pdf; ATT00002.htm

Hi Lori,

I apologize if you receive these twice, but I feel we may be having email issues on our side with CVS Health and I wanted to make sure you received my comments.

Regards,

Lauren Berton

Begin forwarded message:

> **From:** "Berton, Lauren N." <Lauren.Berton@CVSHealth.com>
> **Date:** December 7, 2015 at 2:33:31 PM PST
> **To:** "'Martinez, Lori@DCA'" <Lori.Martinez@dca.ca.gov>
> **Cc:** "Berton, Lauren N." <Lauren.Berton@CVSHealth.com>
> **Subject: CVS Health Comments in Reference to Amendments to § 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations**
>
> Good Afternoon Lori,
>
> Please find attached CVS comments in reference to amendments to § 1707.5 Patient-Centered Labels for Prescription Drug Containers in Article 2 of Division 17 of Title 16 of the California Code of Regulations. Please feel free to reach out to me with any additional questions on the attached comments.
>
> Thank you,

CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

December 4, 2015

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Proposed amendments to Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the proposed amendments to Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations regarding Patient-Centered Labels for Prescription Drug Containers. We would like to thank the Board for their continued vigilance to continuously improve the laws and rules that guide pharmacists serving California patients.

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.

Current 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, 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.

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 o f the manufacture.

CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

Martinez, Lori@DCA

From:	LuGina Mendez-Harper <LMendezharper@primetherapeutics.com> on behalf of Professional Practices <professionalpractices@primetherapeutics.com>
Sent:	Monday, December 07, 2015 10:17 AM
To:	Martinez, Lori@DCA
Cc:	Laura Watkins
Subject:	Comments Regarding Proposed Changes to Prescription Patient-Centered Labels (CCR 1707.5)
Attachments:	Prime Therapeutics CA BoP Comments_12072015.pdf

Ms. Martinez and California Board of Pharmacy Members:

Attached please find comments from Prime Therapeutics LLC and Prime Therapeutics Specialty Pharmacy LLC regarding the California Board of Pharmacy's proposed action to amend Section 1707.5 of the California Code of Regulations on Patient-Centered Labels for Prescription Drug Containers.

We thank you in advance for your consideration of these comments.

Please feel free to contact me at 505-206-1089 or lmendezharper@primetherapeutics.com if further information is needed.

Thank you,

LuGina Mendez-Harper, PharmD, RPh
Manager, Professional Practices
Prime Therapeutics LLC

.....
Professional Practices
Prime Therapeutics

PrimeMail
4580 Paradise Boulevard NW
Albuquerque, New Mexico 87114

December 7, 2015

Lori Martinez
California Board of Pharmacy
1625 North Market Boulevard, N219
Sacramento, CA 95834
Fax 916-574-8618
Email Lori.Martinez@dca.ca.gov

Re: Proposed Rules Changes to Title 16, California Code of Regulations Section 1707.5

Dear Ms. Martinez and California Board of Pharmacy Members:

Thank you for the opportunity to comment on California Board of Pharmacy's proposed action to amend Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations (CCR) Patient-Centered Labels for Prescription Drug Containers.

Prime Therapeutics LLC ("Prime") operates mail service pharmacies in Albuquerque, New Mexico and Irving, Texas. We also operate a mail service specialty pharmacy in Orlando, Florida. These pharmacies are all licensed with the California Board of Pharmacy.

Concerns:
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.

Proposed Solution
Prime respectfully submits the following language for your consideration.

§ 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 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~~.

(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.

Prime supports the California Board of Pharmacy's mandates to protect the public health by ensuring patients are educated as to what medicines they are taking. Please feel free to contact me at 505-206-1089 or lmendezharper@primetherapeutics.com if further information is needed.

Sincerely,

LuGina Mendez-Harper

LuGina Mendez-Harper, RPh, PharmD
Professional Practices Manager
Prime Therapeutics

cc: Laura Watkins, RPh, Senior Director, Professional Practices

Martinez, Lori@DCA

From:	Mary Staples <mstaples@NACDS.org>
Sent:	Wednesday, December 16, 2015 10:55 AM
To:	Martinez, Lori@DCA
Cc:	Jennifer Snyder; Angie Manetti (amanetti@calretailers.com); Brian Warren; Herold, Virginia@DCA; Jon Roth
Subject:	NACDS Comments on Proposed Rule Section 1707.5, Patient-Centered Labels for Prescription Drug Containers

I know I missed the December 7 deadline, but I have been on vacation since Thanksgiving. Our suggestion is simple and we hope the Board will consider it.

California Board of Pharmacy
Attn: Lori Martinez
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: NACDS Comments on Proposed Rule Section 1707.5, Patient-Centered Labels for Prescription Drug Containers

Dear Ms. Martinez:

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.

Mary Staples
Director, State Government Affairs

NACDS
1560 E. Southlake Blvd., Suite 230

Southlake, TX 76092
817.442.1155
817.442.1140 Fax
817.308.2103 Cell
mstaples@nacds.org

Martinez, Lori@DCA

From: Pharmacy <pharmacy@LCTHC.ORG>
Sent: Monday, October 26, 2015 8:45 AM
To: Martinez, Lori@DCA
Subject: Re: proposed tex 1707.5 title 16.

Re:
Proposed Action to adopt section 1707.5 of Title 16 of the California Code of Regulations related to Patient-Centered Labels for Prescription Drug Containers: Requirements. The Board of Pharmacy will accept written comments to the proposed text until 5:00 p.m. on Monday, December 7, 2015, to the following:
Contact Person: Lori Martinez

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.

Thank you for taking these things into consideration.
Diane Terada Pharm D

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.