



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

TO: Board Members

FROM: Staff

**Agenda Item II. Possible Action on Proposed Regulation Section 1707.5.
To Adopt or Amend Proposed Text at Title 16 California Code of
Regulations Section 1707.5. – Requirements For Patient-Centered
Prescription Drug Container Labels, Including Comments Received During
the April 28 – May 13, 2010 Comment Period**

ATTACHMENT A

Background:

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

Since July 2009, the board has dedicated a portion of every meeting to develop this regulation, including convening two special board meetings in August 2009 and February 2010 principally to focus on the regulation.

Here is an overview of the timeline since the board initiated the rulemaking:

October 22, 2009:	Board initiates rulemaking and directs staff to release the proposed language for 45 days
Nov. 20, 2009 – Jan. 4, 2010	Initial (45-day) Comment Period
January 20, 2010:	Board hearing on regulation. Text is proposed to be modified and released for a 15-day comment period.
February 17, 2010:	Board reviews all initially submitted comments and testimony provided at January Board Meeting, modifies text and releases for 15-day comment period
Feb. 22 – Mar. 10, 2010	1 st 15-Day Comment Period
April 22, 2010	Board Meeting (day 2) - Board considers comments received during 1 st 15-day comment period, modifies proposed text of § 1707.5.(a)(1) and § 1707.5.(a)(1)(D) and directs that a 2 nd 15-day comment period be initiated.
April 28 – May 13, 2010	2 nd 15-Day Comment Period

Focus of SB 472's Requirements:

Senate Bill 472 directed the board to focus on seven items in developing its patient-centered label regulation (§ 4076.5(c)):

1. Medical literacy research that points to increased understandability of labels.
2. Improved directions for use.
3. Improved font types and sizes.
4. Placement of information that is patient-centered.
5. The needs of patients with limited English proficiency.
6. The needs of senior citizens.
7. Technology requirements necessary to implement the standards.

Materials Provided:

ATTACHMENT A includes the following:

- Draft regulatory text issued for the 2nd 15-day public comment period: April 28 - May 13, 2010
- A summary of comments received during the 2nd 15-day public comment period, indicating those which are responsive to the modified text open for comment, those which comment on the procedures followed by the board, and "other comments" which (per the ¹Administrative Procedure Act) are not specifically directed at the proposed modified text for this 2nd 15-day comment period or to the procedures followed.
- Copies of each comment received

Options:

Following the board's consideration of comments received during the 2nd 15-day public comment period, the board has various options including to:

1. Adopt the regulation as noticed for comment on April 28, 2010
2. Modify the regulation to accommodate recommendations or comments and release modified text for a 15-day comment period
3. Modify the regulation and re-notice it for 45 days

Should the board adopt the language as noticed on April 28, 2010, staff will compile and complete the rulemaking file and submit it to the Director of the Department of Consumer Affairs for review. If approved by the department, the rulemaking will be submitted to the Office of Administrative Law.

¹ Government Code section 11346.9.(a)(3)

Agenda Item III. Development of Proposed Text for Possible Future Rulemakings

ATTACHMENT B

- a. **Discussion Regarding Possible Regulation Specifying Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies**
- b. **Discussion Regarding Possible Regulation Specifying Consumer Notice About the Availability to Request Prescription Container Labels in Larger Font Sizes**

At its January, February and April 2010 Board Meetings, and within the context of discussions to develop requirements for patient-centered prescription drug container labels, the board heard suggestions that consumers should be notified of various components of the patient-centered prescription drug container label regulations – such as a consumer's right to request a larger font on their prescription label, and that language interpretation services are available. These suggestions were also included in some comments received during the public comment periods for the proposed rulemaking.

One proposal would reorganize existing Section 1707.2. (which contains requirements for two existing "Notice to Consumers") and combine these with the two new proposed notices and place them at new Section 1707.6. of Title 16 of the California Code of Regulations.

Staff is continuing to work on different "Notice" proposals. These will be shared with the board at the meeting.

ATTACHMENT B contains possible regulatory text developed by counsel and staff to facilitate the board's discussion and possible initiation of the rulemaking process for the following:

- o Notice to Consumers "Availability of Language Interpretation Services" and "Point To Your Language" Statement at the Pharmacy Counter, and
- o Notice to Consumers "Availability of Prescription Drug Container Labels in Larger Font Sizes"

Also, in establishing new requirements, the board may wish to consider adding other parameters; such as

- how many languages (e.g., five most dominant languages in CA or in the community, those for which MediCal provides written materials)
- require the board to develop the written notice(s) and make available to pharmacies (like we do for the Notice to Consumers posters required by § 1707.2.)

At this meeting, staff requests direction from the board on how it desires to proceed. If so directed, staff can have draft regulatory text for consideration and possible action at the July 2010 Board Meeting.

c. **Discussion Regarding Possible Regulations to Strengthen Board Enforcement Programs Pursuant to the Department of Consumer Affairs Consumer Protection Enforcement Initiative**

ATTACHMENT C

Since July 2009, the Department of Consumer Affairs has been working with health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. The result of these efforts yielded the Consumer Protection Enforcement Initiative (CPEI) which is a comprehensive three pronged solution: a new computer system; additional staff resources; and legislative changes. The CPEI solution will achieve the goal that average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months.

Many of the legislative changes were incorporated into SB 1111 (Negrete McLeod). During the April 2010 Board Meeting, the board was advised that SB 1111 failed passage in a policy committee, so the board did not discuss SB 1111 in any detail during that meeting. Since that time, the department has identified provisions contained in the bill that could be implemented through regulations, and further requested that all healing arts boards develop language and initiate the rulemaking process.

Included in **ATTACHMENT C** is an overview of the CPEI as well as draft regulation language that the board could consider if it chooses to implement provisions requested by the department. Given that the board has not yet had a discussion on the policy issues, staff recommends that the board discuss that first. The provided language is to facilitate initiation of the rulemaking process should the board choose to do so.

Counsel has been provided the language in advance of this meeting and will be available to discuss legal implications of such changes.

Attachment A

Proposed Text

**Title 16 Cal. Code of Regs § 1707.5.
Requirements for Patient Centered
Prescription Drug Container Labels**

**Summary of Comments Received
During 15-Day Comment Period
April 28, 2010 – May 13, 2010**

Copies of Comments Received

Title 16. Board of Pharmacy Modified Language

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

1707.5. Patient-Centered Labels on Medication Containers

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

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

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use.

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

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

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

For the second 15-day comment period:

Deletions to the regulatory text are indicated by italic bold double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by italic bold double underline, thus: **added language**.

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

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

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

For the second 15-day comment period:

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

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

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

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

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

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

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

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

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

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

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

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

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

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

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1707.5. Patient Centered Prescription Labels

2nd 15-Day Comment Period

April 28, 2010 – May 23, 2010

<u>Commenter</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	<u>Other Comments</u>
Mark W. Riggle, PharmD, RPh	Having ability to offer multiple size typefaces for the label may not be a viable option for pharmacies, as software enhancements may be necessary that would create an undo [sic.] financial burden. <i>Recommends removing "...or, if requested by the consumer, at least a 12-point typeface..."</i>	None	1707.5.(a)(4) - recommendations to dosing instructions. 1707.5.(b) to translate commonly used phrases "as needed for..." "as directed"
Evans, Martin			Changes seem fine to him.
Mikles, Roberta BA RN	Need to have at least 12 point font for patients to be able to read in order to prevent errors.		General comments to the board. "I can only hope that the final language will totally focus on patient safety."
Mikles, Roberta BA RN Patient Safety Advocate Advocates 4 Quality Safe Care	1707.5.(a)(1) as modified does not demonstrate patient-centered prescription label which supports the safe administration of medications Consumers must not be required to ask their pharmacist to increase font – that is the responsibility of those dispensing medications		<u>1707.5.(d) Translations</u> Vague language could result in patients not having translation services provided, which could result in harm. Medicare and Medicaid mandate access to translation services. The board should mandate that translation services be required.

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Lew, Donald RPh	None	None	<p><u>Oral Interpretive Services</u></p> <p>It would be a wonderful service to offer interpretive services to outpatient pharmacy patients. He believes there are a significant number of patients that would benefit. (see additional comments, below)</p> <p>Economic Impact Statement <i>Disagrees with the board's Economic Impact Statement</i> that the cost to provide the service is minimal to none. He believes the cost will be significant and very difficult to implement.</p> <p>It is unreasonable to mandate this (oral language) service from retail pharmacies. He <i>suggests that a fee be charged to the patient who utilizes the (oral language) service unless the board can mandate a professional fee</i> or reimbursement to the pharmacy for such service.</p>

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Nguyen, Chi	Re “different font sizes” please keep in mind that financial resources are limited for small, independent pharmacies.	Adding the purpose of the medication to the label should be at the discretion of the physicians and pharmacists (citing a patient’s comfort and confidentiality)	<p>Prescription labels should have a main focus on directions for use. Directions may be printed in English combined with other languages.</p> <p>1707.5.(a)(1)(B) printing manufacturer name may hamper correct name of the drug and confuse the public.</p> <p>The board has other crucial agendas that need to be addressed instead of new proposed prescription labels, such as vaccinations, pharmacy security, narcotic abuse, and/or expired meds. Comments re: drug take back at pharmacies.</p>

<ol style="list-style-type: none"> 1. Jackson, Anita 2. Miguel, Luis, PhD 3. Jain, Sharad MD 	<p>“12-point font is the minimum size for readability. It is not reasonable to put the burden on patients to ask for larger print.”</p>	<p>None</p>	<p>Oral Interpretive Services must be required for all patients Using the caveat “if available” in the regulation will leave communities vulnerable to misuse of their prescriptions</p> <p>Translated labels are essential for diverse communities to understand how to take their meds safely and effectively. Pharmacies should be required to use the translated labels provided by the board or develop their own.</p>
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1707.5. Patient Centered Prescription Labels

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Sholes, Elizabeth Director of Public Policy California Council of Churches / California Church IMPACT	Compliance “may require a simple adjustment of script from 10 to 12-point type....”	Compliance may require “a careful assessment of language skills....”	General comments to the board re: the letter and the spirit of SB 472 – insists on compliance with SB 472.
Harris, Holly S., MS, CRC Student Academic Advisor Interwork Institute Center for Distance Learning San Diego State University	There is huge room for error if patients/consumers must request the larger font....	None	Expresses disappointment in the board’s decision to not increase the minimum font size to 12-point Provided statistics on the numbers of Americans and Californians with visual impairments Huge room for error if patients / consumers must request translation Concerned the board is not taking necessary steps now to serve large numbers of citizens. Asks that the board put the health and safety of Californians above all other concerns and lobbyists – “to the right thing”

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Chan, Coralie MPH	"Please consider revising your board's stance on 12 pt font"	None	Translated Prescription Labels Requests the board reconsider its stance on ... translation of prescription labels into the top languages spoken in California.
Rosati, Stephen J. RPh	The board needs to commit to either 10-point or 12-point font – not for the use of both. Not possible to use 12-point font and have all directions fit the label with a long sig (since the board is not providing verbiage for long sigs) To accommodate 12-point, abbreviations will need to be used, which may present another set of problems for the consumer.	Recommend change to "Purpose or condition, if entered onto the prescription by the prescriber or requested by the patient or patient's representative." This will prevent confusion for a patient who self-medicates or if medication is given by another individual.	Auxiliary Labels: Recommends adding 1707.5.(a)(3) to specify that auxiliary directions be printed in a minimum 6-point serif typeface. 1707.5.(f) recommends amending to "As used in this section, "appropriate dosage form" includes pill, caplet, capsule, tablet, ml, teaspoonful or tablespoonful." This would be appropriate to accommodate liquid forms of medication.
Sturdivant, Julianne	Increase standard font size to 12-point	None	Translate labels for patients in California for whom English is not a native language.
Videgaray, Lus Elena Director of Language Avantpage	None	None	Translated Prescription Labels Very important to translate prescription drug labels and to provide medical information in a consistent, legible, and cultural appropriate manner.

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Powers, William	Print for key elements of the label should be no less than 12-point font. Urges the board to restore the 12-point font.	None	Font Size: The board has ignored science, experts and overwhelming testimony – and chose to meet the objections of corporate interests in reducing the minimum font size. Translations: Strongly urges the board to reverse its decision, and require translated drug labels into at least the five most commonly spoken languages in the state.
Samuels, Carmen	Comment that it is critical that consumers have clear and readable size printed directions, particularly for older citizens.	None	Asks the board to consider the full intent of SB 472.

1707.5. Patient Centered Prescription Labels
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Commenter

Comment specifically directed at
Proposed Modified 1707.5.(a)(1)

Comment specifically directed at
Proposed Modified 1707.5.(a)(1)(D)

Other Comments

Agarwal, Nisha
Director, Health Justice Program
New York Lawyers for the Public
Interest, Inc.

Translations:

Board should incorporate mandatory language into its regulations regarding use of label translation.

Oral Language Interpretations:

Troubled with language that pharmacies provide services only “if interpretive services in such language are available,” pharmacies should

- be bound to develop or find the proper service so that patients can receive the necessary translation
- be required to provide interpretation during medication counseling.
- be required to orally translate the container label if they do not provide translated prescription labels

Urges the board to

- Be explicit about which interpretive services the pharmacy will be required to provide
- Clarify that if an employee of the pharmacy delivers the necessary language assistance services, that the employee must also be proficient not only in the necessary language but with appropriate medical terminology
- Develop accountability measures through enforceable penalties for pharmacies that fail to provide oral language services

1707.5. Patient Centered Prescription Labels

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Proposed Modified 1707.5.(a)(1)

Comment specifically directed at
Proposed Modified 1707.5.(a)(1)(D)

Other Comments

Sayed, Syed Muhasin
Consumers Union

1707.5(a)(1) “falls short of creating a truly patient-centered, standardized prescription label for California.”
12-point font minimum for most important parts of a label would make medications safer to take for all Californians.

Consumers should receive readable med labels without having to ask for them.

If the board proceeds with (a)(1) as modified, the board must address:

- How patients can access a larger font when doctors phone-in prescriptions
- Whether pharmacies can change label formats at the point of sale
- The need for doctors to be informed of the larger font option on med labels
- Illness, age or LEP status of patients (as they may face greater difficulty in requesting changes to their prescription container)

None

1707.5.(d) “If available” language allows pharmacies to avoid providing translation services to LEP patients.

Notice Requirement:

The board should create effective notification requirements that language translation services are available.

The regulation should be accompanied by a prominent notice and counseling requirements for patients.

1707.5. Patient Centered Prescription Labels

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Guess, K. Scott PharmD RPh Owner / CEO Pain Management Pharmacy Inc.	<p><i>General comments</i> re: font, label</p> <p>Re font: “there is only so much space on a label”</p> <p>Comments on the size of the vial to accommodate a label.</p> <p>Bigger labels and resulting vial sizes result in</p> <ul style="list-style-type: none">• Increased cost• Storage issues for patients <p>Difference between 10- and 12-point font is not that great.</p> <p>As the font increases, less information will fit on a current, standard label size.</p> <p>Larger labels = larger vials = increased costs.</p>	None	<p>Agrees that a single standard layout for prescription medication labels would benefit patient understanding and patient safety</p> <p>1707.5.(a)(4) Cautions the board to not over regulate exactly how a label should read, or add a provision to allow for non-standard sigs to be entered.</p> <p>Abusive third party recovery audits could cite that a sig is not exactly as the board establishes, resulting in an invalid prescription and rescinding of payments from pharmacies that dispensed legitimate prescriptions</p> <p>1707.5.(a)(4) offers format for dosing instructions, as well as various options for dosage form, when/how often, route of administration, for what (purpose)</p> <p>1707.5.(d) – translations for LEP patients.</p> <p>Suggests this discussion be removed from the patient-centered label discussion and addressed as a stand-alone issue.</p> <ul style="list-style-type: none">• Who is going to pay for the service?• Who is liable for the accuracy of the translation? <p>It is unrealistic to expect pharmacy providers to be able to translate into whatever language might walk through the front door.</p>

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<p>1. Riley, Tom Legislative Advocate Osteopathic Physicians & Surgeons of California</p>	None	None	<p>Believes the current draft has room to improve the provisions pertaining to language assistance to limited-English speaking patients. Translations: Pharmacies should be required to print translations for use directly on the prescription label and in at least 12 point font. 1707.5.(d) Oral Interpretation: It is vital that adequate policies and procedures are in place to help LEP patients understand their prescriptions combined with translated prescription labels in a legible font.</p>
<p>2. Riley, Tom Legislative Advocate CalDerm California Society of Dermatology & Dermatologic Surgery</p>	None	None	
<p>Steinmetz, Dieter Coast Compounding Pharmacy</p>	<p>“Thumbs Up” “I changed the layout of my prescription labels to conform with the proposed requirements. I thought it would be difficult to implement, especially the 12 point size for the directions. I was pleasantly surprised that the outcome does in fact look nice and improves readability for patients.”</p>	None	<p>1707.5.(a)(4) Directions for Use “When long sigs are used e.g. prednisone decreasing dosing over a few days the point size would need to be decreased but for 90% of sigs the 12 point size will work very well.”</p>

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Schinske, Don Executive Director California Healthcare Interpreting Association	None	None	<p>Language Assistance to LEP Patients: Believes the regulatory provisions fall short of both the spirit and letter of the law.</p> <p>Regulation provisions would make language assistance for pharmacy patients almost discretionary. This compromises the basic point of SB 472</p> <p>1707.5.(b) Translated Directions for Use on Board’s Web Site: “What’s missing is a requirement that a pharmacy actually print those translations (or translations of its own) on any of its labels.” Asks that LEP patients be offered prescription labels that include high-quality translations of the directions for use.</p> <p>1707.5.(d) Policy & Procedures re: assisting LEP patients: References the requirements of 1707.5.(d)</p> <p>“LEP patients should be offered oral language assistance – either in-person or via telephone or video – at the point of the transaction”</p>

1707.5. Patient Centered Prescription Labels

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April 28, 2010 – May 23, 2010

<u>Commenter</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	<u>Other Comments</u>
Joint Letter California Pharmacists Association California Retailers Association California Grocers Association National Association of Chain Drug Stores	In an effort to avoid service disruptions for patients and pharmacy operations, request amendment of 1707.5.(a)(1) to require that the label be printed in 12-point font, if requested by the patient, when the prescription is first presented at the pharmacy counter. <i>(a)(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point font sans serif typeface or, if requested by the consumer <u>at the time the prescription is first presented</u>, at least a 12-point typeface, and listed in the following order:</i>	None	<p>Request that name of the manufacturer's trade or generic name and drug strength be removed from the list of items clustered in to 50 percent of the label. Note: the label will contain the name and strength of the drug, but it will not be part of the clustered items.</p> <p>1707.5.(a)(1)(B) Name of the drug and strength of the drug. For purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.</p> <p>Implementation of Regulation Requests an implementation phased in at least 12 months from the time the rule is finalized, citing it will be impossible to make necessary changes to pharmacy processes and systems and meet the January 1, 2011 effective date.</p> <p>Pharmacies need one year to make necessary adjustments needed for compliance.</p> <p>Consumer Notices Recommendation that the board include within its current "Notice to Consumer" signage the patient's right to request 12-point font.</p>

1707.5. Patient Centered Prescription Labels
2nd 15-Day Comment Period
April 28, 2010 – May 23, 2010

<u>Commenter</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	<u>Other Comments</u>
Joint Letter / co-signers	Commenters (<i>continued</i>):		
Hinman, Boyce and	Prag, Ken		
Allen, Christine	Schaller, Merrie		
August, Boyer C.	Sturzl, Bruce R., Jr.		
Boyd, Michael	Sunderburg, Erika		
Bridges, Breonna R.	Thoron, Samuel		
Brotherton, Kate	Todd, Debra		
Burke, Bonnie Margay	Webber, Jim		
Burnett, Clark	Webster, Ellen		
Chambers, Keith			
Clarke, Rosalee			
Collins, Steve			
Cook, Carol			
Costa, Joseph	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	
Diamond, Lele	10-point san serif typeface is too small.	Comment that purpose or condition is included “if requested by the patient.”	1707.5.(d) Oral Interpretive Services
Dore, Jay			Recommends removing the “if available” clause from 1707.5(d)
Dudley, Dennis			
Everett, Claude	All type on a medicine label should be at least 12 point – anything less is a disservice to the elderly.	Purpose or condition should be required on all prescription labels.	Comments that over 14.4 million Californians primary language is other than English. Several million will need interpretive services to fully understand the correct way to use their medications.
Fairbanks, Bruce			
Hand, Richard	Requests that the minimum font size requirement be 12 point.	Few patients know they can request such services. This information is necessary for those that take different medications.	
Hicks, Randy			
House, Adele			
Ihler, Fred			
Kean, William			
Klayman, Billie			
Krugman, Charles L.			
Lauby, Adrienne			
Mahoney, Robert J.			The law requiring health care service plans and insurance policies to pay for interpretive services is not limited as to where those services are available. There is no exclusion.
Martin, Thomas J.			
Midori, Merci			
Ozanich, James R.			
Petersen, John Richard			
Pierce, Carol PhD, MFT			
Poxon, Judith			Comments that the pharmacy can utilize a service over the phone for interpretive services.

1707.5. Patient Centered Prescription Labels
2nd 15-Day Comment Period
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<u>Commenter</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	<u>Other Comments</u>
Martinez, Martin MPP Policy Director California Pan-Ethnic Health Network	Prescription labels in 12-point font are vital for quality care.	None	

Other Comments – not specifically directed at proposed modified text 1707.5.(a)(1) or 1707.5.(a)(1)(D)

The regulations fall short of the intent of SB 472 and will not meet the health and safety needs of consumers.

The original language (noticed November 2009) represented a closer approximation of the requirements of SB 472.

Translated Prescription Labels

Translated labels in 12-point font are vital for quality care.

CPEHN remains supportive of

- Labels printed in 12-point font or larger
- Clustering and white space requirements
- Requirement that pharmacies use translated labels provided by the board or their own translated labels

- All patients who speak a language other than English should have the right to have oral interpretation of their prescription drug instructions
- Requirement that pharmacies post signs in multiple languages explaining the availability of language services

Comments specifically directed at regulatory process

The regulatory process has been flawed and further opportunities are required to debate the issue and ensure quality patient care.

The language adopted by the board neither corresponds with the underlying statute nor is it consistent with research, public testimony or board survey results.

The board did not comport with the requirements of the Administrative Procedures Act [sic]

1707.5.(d) does not comply with the clarity standard of the APA in that the board does not provide guidance to pharmacies on how to define availability. “if interpretive services in such language are available”

The board did not provide opportunity for meaningful public comment with sufficient advance notice at the public hearings.

- At the January 20, 2010 hearing, proposed regulatory language was posted to the board’s Web site the night before and did not meet the 15 day requirement for public comment.
- The advance notice requirement should fall into the “45-day rule” because of the substantial changes made to the language to accommodate industry objections.

1707.5. Patient Centered Prescription Labels
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<u>Commenter</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)</u>	<u>Comment specifically directed at Proposed Modified 1707.5.(a)(1)(D)</u>	<u>Other Comments</u>
The Honorable Ellen M. Corbett California State Senate	In the board’s latest proposal, the board recognizes it is feasible to use 12 point font on labels, but leaves it up to those most vulnerable to request larger font. If the board were truly interested in protecting vulnerable consumers, 12 point type should be the standard.	None	

Other Comments – not specifically directed at proposed modified text 1707.5.(a)(1) or 1707.5.(a)(1)(D)

The board has ignored the overwhelming response from consumers, health advocates and experts for comprehensive patient-centered prescription labeling in California

The boards latest proposal fails to protect California’s most vulnerable populations

SB 472 placed trust in the Board of Pharmacy to stand up for consumers.

The board has failed at protecting Californians and is leading California and the nation in a large step backwards.

The board has given greater weight to industry’s wishes.

Senator Corbett does not support the board’s conclusions and is disappointed that the spirit of the law established by SB 472 has not been followed.

SB 472 called on the board to set a national example for patient-centered prescription labeling.

The board’s proposals do not go far enough to address the serious problem of medical errors and misdosing.

Font Size (in general)

Staff’s original recommendation was to require a minimum 12 point font for prescription labeling. Senator Corbett calls on the board to adopt regulations that embrace these sensible proposals.

At the SB 472 hearings, experts and advocates were clear that 12 point font is the minimum size necessary to protect seniors and visually impaired consumers.

1,159 of 1,161 comments (during the 15-day comment period) were opposed to the board’s modifications (changing the minimum font size from 12 point to 10 point)

Industry’s Arguments (in general)

Arguments that larger labels and the influx of type will be confusing are not supported by fact.

Re: Industry’s argument that pharmacies will have to utilize larger pill bottles: any cost associated with larger type size is a small price to pay if it saves lives.

Language Assistance

A regulation requiring pharmacies to provide interpretive services in a patient’s language when interpretive services “are available” effectively allows pharmacies to provide no oral translations or written assistance to consumers with limited English proficiency.

The board’s regulation creates a loophole that will lead to dosing errors.



Martin Evans
<marty_evans@sbcglobal.net>
>

04/28/2010 06:38 PM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject Re: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

what's your point? i read the proposed change, seems fine to me.

From: "Carolyn_Klein@dca.ca.gov" <Carolyn_Klein@dca.ca.gov>

Sent: Wed, April 28, 2010 4:28:36 PM

Subject: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

Please disregard if this is a duplicate email.

The Board of Pharmacy today released a Notice of Availability of Modified Text to 16 California Code of Regulations beginning with section 1707.5. Patient-Centered Prescription Labels. Specifically, modifications are proposed to sections (a)(1) and (a)(1)(D).

The Board of Pharmacy will accept comments to the proposed modified text until 5:00 p.m. on Thursday, May 13, 2010.

Please visit the board's Web site at <http://www.pharmacy.ca.gov> or click on the link below to view all documents associated with this proposed regulatory action and other pending regulations or newly approved regulations.

http://www.pharmacy.ca.gov/laws_regs/regulations.shtml



RMiklesRNC@aol.com
04/28/2010 09:16 PM

To Carolyn_Klein@dca.ca.gov
cc
bcc
Subject Re: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

Dear Ms. Klein:

I want to personally thank you for sending me the below. As a patient safety advocate I must say that I am somewhat taken back that those who voted, in my opinion, did not put the patient as the priority. Having worked in health care for some thirty years, with much patient advocacy background, I can only hope that the final language will totally focus on patient safety.

Thank you,
Roberta Mikles, BA RN
Patient Safety Advocate
San Diego, CA
www.patientsafetyday.com
www.qualitysafepatientcare.com
858-675-1026

In a message dated 4/28/2010 4:30:13 P.M. Pacific Daylight Time, Carolyn_Klein@dca.ca.gov writes:

Please disregard if this email is a duplicate.

The Board of Pharmacy today released a Notice of Availability of Modified Text to 16 California Code of Regulations beginning with section 1707.5. Patient-Centered Prescription Labels. Specifically, modifications are proposed to sections (a)(1) and (a)(1)(D).

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http://www.pharmacy.ca.gov/laws_regs/regulations.shtml



RMiklesRNC@aol.com
04/28/2010 08:00 PM

To Carolyn_Klein@dca.ca.gov
cc
bcc
Subject Re: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

If this has to do with the size of the font we need to have it at least 12 pt for patients to be able to read in order to prevent errors.

Roberta Mikles BA RN
Patient Safety Advocate
California

In a message dated 4/28/2010 4:30:13 P.M. Pacific Daylight Time, Carolyn_Klein@dca.ca.gov writes:

Please disregard if this email is a duplicate.

The Board of Pharmacy today released a Notice of Availability of Modified Text to 16 California Code of Regulations beginning with section 1707.5. Patient-Centered Prescription Labels. Specifically, modifications are proposed to sections (a)(1) and (a)(1)(D).

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http://www.pharmacy.ca.gov/laws_regs/regulations.shtml



Donald Lew
<rx4bills@yahoo.com>
04/28/2010 08:54 PM

To Carolyn_Klein@dca.ca.gov
cc
bcc
Subject rx labeling proposal

Dear Ms. Klein,

First, I feel that it would be a wonderful service to offer interpretive services to outpatient pharmacy patients. I agree that there are a significant number of patients that need this type of service.

However, I disagree with the stated view that economic impact upon the pharmacies mandated to provide this type of service is minimal to none. I believe that the cost in financial and labor amounts will be significant, and very difficult to implement without further jeopardizing the financial stability of the pharmacy business.

In these times of dramatic lower reimbursements for what we do, and greater requirements in regards to everything we do, it is (in my opinion) unreasonable to mandate this service from retail pharmacies. I would suggest a recommendation that pharmacies offer this service, and that a fee may be charged to the patient to utilize this service. Unless the Board can somehow also mandate a minimum professional fee, or reimbursement to the pharmacy, this is just another legislative mandate that will further dilute the professional integrity of our profession.

Donald Lew, RPh.
Fremont, CA



Chi Nguyen
<kimrx2@yahoo.com>
05/02/2010 03:25 AM

To carolyn_klein@dca.ca.gov, Chi Nguyen
<kimrx2@yahoo.com>
Dan Thu Nguyen <nguyenhuynhdanthu@yahoo.com>, Anh &
cc Lieu Nguyen <anhlieu@comcast.net>,
asciotto@tristatedbtn.com, patw@sacymca.org, Tom Bui
bcc
Subject Prescription Labels Proposal

May 2nd, 2010

Miss Carolyn Klein, Legislation and Regulation Manager
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834
916-574-7900 • Fax 916-574-8618
carolyn_klein@dca.ca.gov

Re: Prescription Labels

Dear Mrs. Carolyn Klein:

I am writing to you regarding the proposal for new prescription labels. My name is Chi Nguyen, Pharm.D. I am a pharmacist of a small independent pharmacy in the Greenhaven/Pocket area. I am also a partner with two other independent pharmacies in the south Sacramento area.

As a pharmacist, I have provided excellent patient care, beyond the necessary duty of a pharmacist. I provided one-on-one consultations, follow-up with telephone calls, reschedule evaluation appointments for patients, as well as, home visitations, to name a few of the duties.

Although I own a small pharmacy that only has about 100 to 150 prescriptions per day (the profit margin is limited to \$2-3 per prescription), my training background dictates that excellent patient care is necessary. I graduated from UC-Davis (1990) with a Bachelor of Science Degree and completed my Doctor of Pharmacy Degree (1993) at UOP-School of Pharmacy. I enrolled for further pharmacy training at VA West Los Angeles Medical Center/UCLA Medical Center for a Geriatric Residency (1994) and at USC-School of Pharmacy for a Geriatric Fellowship (1995).

Escaping from a war-ravaged country of Viet Nam in 1979, I am extremely appreciative of the “freedom” given to all citizens in America. Because of this important aspect of freedom, I must voice my opinion on the proposed changes for prescription labels.

The prescription labels should have a main focus on direction on how to take the medications. Patients need to understand the medication direction correctly and clearly from 1 tablet or 2 tablets, orally or in the eyes, how often to take the medication, and when to stop taking the medication. The directions may be printed in English combined with other languages (i.e. Spanish, Vietnamese). Therefore, the bulk of the space of the prescription labels needs to be reserved for the direction portion.

The prescription labels are being proposed to add manufacture names. This step may hamper the correct name of the drug and confuse the public. Patients may think they are taking a drug named Greenstone, Teva, Pfizer or Merck (manufacture names), instead of the correct name of the medication. The confusion is endless. In addition, the space reserved for manufacture names is wasteful. This space should be again reserved for the direction on how to take a medication accurately. The abbreviation of manufacture names is appropriate on the prescription labels.

Another proposal for the new prescription labels is adding the purpose of the medications. This point is well taken and medications for hypertension, diabetes, or high cholesterol should be labeled as such. However, the purpose of medications should be placed in the label at the discretion of the physicians and pharmacists. The reason for this discretion relates to patient’s comfort and confidentiality. Placing the medication purpose such as AIDS, bipolar, sexually transmitted disease, or yeast infection on a prescription label will be uncomfortable and unwarranted for patients.

A proposal regarding different font sizes for prescription labels was voiced. However, please keep in mind that financial resources are limited for small, independent pharmacies, when compared with large corporations. Small, independent pharmacies have focused their financial resources in more important areas such as providing more vaccination programs, education, security, and/or healthcare programs for patients and staff.

The California Board of Pharmacy has other crucial agendas that need to be

addressed, instead of the pros and cons of the new proposed prescription labels. The time spent on proposal changes for prescription labels may be better utilized on topics such as vaccination by pharmacists, pharmacy security, narcotic abuse, and/or expired medications.

Pharmacists received their bachelor degrees, doctorate degrees, and continuation educations to further their scope of pharmacy training and practice. They are qualified to give vaccinations, without any protocols. In addition and most importantly, patients are asking, demanding, and waiting to be vaccinated at pharmacies.

The rate of robberies at community pharmacies is alarming. Proposals and guidelines need to be regulated to provide a safe and secure environment for both the public and staff at a pharmacy.

Topics such as marijuana and other narcotics in pharmacies are always important. Currently, the debate regarding marijuana pharmacy dispensing is extremely volatile that need more attention from the California Board of Pharmacy.

Regarding the expired medications being “dumped” in pharmacies is impossible and ridiculous. Pharmacists are highly trained healthcare providers who have received bachelor degrees and doctorate degrees. Pharmacists are not “trash collectors”. Besides, the condition inside and outside the pharmacy area needs to be cleaned and safe for the public. In addition, patients do not take their dirty, soiled, bloody bandages and “dumped” them at their doctor’s office. Furthermore, patients do not take their old dentures and broken teeth and “dumped” them at their dentist’s office. The expired medication issue needs to be addressed clearly by the California Board of Pharmacy.

I would like to thank you in advance for all your help and hard work at the California Board of Pharmacy. I hope that you would relay my opinions to the members of the California Board of Pharmacy. Although, I am only a refugee, a woman, a small business owner, and an independent pharmacist, I strongly urge and hope that you will hear my suggestions. I look forward to hearing from you and other members of the California Board of Pharmacy.

Sincerely,
Chi Nguyen, Pharm.D.

Doctor of Pharmacy
 -Pharmacist/Manager/Owner
 Kim Leader Pharmacy
 -Preceptor
 UOP-School of Pharmacy
 -Member
 Leader Board of Pharmacy

Excellent Patient Care is Our Main Goal
Welcome to Family Medical Care (FMC)

<p> Chi Nguyen, Pharm.D. Doctor of Pharmacy KIM LEADER PHARMACY 2 Pharmacist/Manager/Owner 7248 South Land Park Dr., Suite 116 Sacramento, CA 95831 916-399-0757 Fax 916-399-0758 </p>	<p> Dan-Thu Nguyen, D.D.S Doctor of Dentistry Orthodontist NOBLE DENTISTRY 5026 Fruitridge Road, Suite 2 Sacramento, CA 95820 916-393-6253 Fax 916-424-2711 </p>	<p> Toan & Deanna On, Pharm.D. Doctors of Pharmacy THANH THUY PHARMACY KIM LEADER PHAMACY 1 Pharmacist/Manager/Owner 6830 Stockton Blvd. Sacramento, CA 95823 916-391-7210 Fax 916-391-7230 </p>
<p> Tam Nguyen, D.D.S. Doctor of Dentistry 7248 South Land Park Dr, Suite 116 Sacramento, CA 95831 916-399-0757 Fax 916-399-0758 </p>	<p> Brian Vu, Pharm.D. Doctor of Pharmacy CAREPOINT PHARMACY Pharmacist/Manager/Owner 73 W March Lane, Ste C Stockton, CA 95207 209-957-2295 Fax 209-952-7100 </p>	<p> Trinh Vu, M.D. Lien Nguyen, M.D. Doctors of Medicine Pediatricians 73 W March Lane, Ste C Stockton, CA 95207 209-957-3901 Fax 209-957-2857 </p>
<p> Hugh Vu, M.D. Doctor of Medicine Plastic & Cosmetic Surgery 1617 Saint Marks Plaza, Suite E & F Stockton, CA 95207 209-476-7074 Fax 209-476-7092 www.vuplasticsurgery.com </p>	<p> Hugh Vu, M.D. Doctor of Medicine Plastic & Cosmetic Surgery UC-Davis Medical Center 2315 Stockton Blvd., Sacramento, CA 95817 916-734-2011 Shriner's Children Hospital 2425 Stockton Blvd, Sacramento, CA 95817 916-453-2000 </p>	<p> Anh Nguyen, M.D. Doctor of Medicine General Practitioner 5026 Fruitridge Road, Suite 1 Sacramento, CA 95820 916-391-9497 Fax 916-424-2711 </p>



Anita Jackson
<anitasarahjackson@gmail.com>

05/04/2010 11:42 AM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject Prescription drug labeling

Dear Ms. Klein,

I am writing with concern about proper drug labeling in the wake of health reform. There are countless incidents of human error in labeling leading to waste, reduced drug efficacy, and adverse health outcomes. Pain, suffering and obviously higher costs are the unintended results. To minimize these errors, I support these simple and effective measures:

- **12-point font** is the minimum size for readability. It is not reasonable to put the burden on patients to ask for larger print.
- **Translated labels** are essential for our diverse communities to understand how to take their medication effectively and safely. Pharmacies should be required to use the translated labels provided by the Board or develop their own translations.
- **Oral interpretation** must be required for all patients. Using the caveat "if available" in the regulation will leave our communities vulnerable to misuse of their prescriptions.

The benefits of culturally competent care providers are significant, and will become increasingly important in the coming years. Please help ensure that drug labeling keeps up with the improving standards of care.

Thank you,
Anita Jackson



Elizabeth Sholes
<sholes@calchurches.org>

05/04/2010 01:18 PM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject Compliance with SB 472

Dear Ms. Klein:

It has come to our attention that the California Board of Pharmacy has watered down the regulations we worked to pass in SB 472 (Corbett) in 2008. These regulations - not recommendations - were to assure that patients receiving prescriptions actually knew what they were obtaining, could READ the labels both in terms of font size and language, and that those without literacy skills would have clear verbal instructions as to what they were taking, why, and how.

We represent 21 denominations within the mainstream Protestant communities of faith. Our denominations serve 6.5 MILLION members in California alone. Of these, a significant number either have vision impairments from old age or have non-English language skills. It is therefore essential that the Board of Pharmacy complies with the law - again, not a suggestion but a requirement - to make prescription labels absolutely clear.

We fully intend that the Board of Pharmacy understands that we will inform our members that they cannot trust their pharmacist to put patient well being ahead of their own convenience if compliance is thwarted. It is beyond despicable that the Board has permitted corporations to decide this is "too onerous" as if compliance were a hardship as opposed to a simple adjustment in what good pharmacists do all the time.

There is absolutely no excuse for non-compliance. None. This may require a simple adjustment of script from 10 to 12-point type and a careful assessment of language skills which *should already be the practice of pharmacists doing business in neighborhoods with ethnic diversity*. For any entity dispensing drugs, and especially controlled substances, this care for the prevention of harm is at minimum self preservation. The Board of Pharmacy must surely see that failure of any pharmacist to do his or her due diligence in compliance with SB 472 will of course result in a lawsuit or series of suits, and that is an absurd outcome for what is entirely a preventable issue.

We insist on compliance with the letter and the spirit of SB 472. It is the bare minimum all residents of California deserve.

Sincerely,

Elizabeth Sholes
Director of Public Policy
California Council of Churches/California Church IMPACT
4044 Pasadena Avenue
Sacramento, CA 95821
916.488.7300



Luis Miguel
<luis@avantpage.com>

05/04/2010 02:54 PM

To "Carolyn_Klein@dca.ca.gov" <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject: I support Translated Prescription Drug Labels

Dear Board,

- 12-point font is the minimum size for readability. It is not reasonable to put the burden on patients to ask for larger print.
- Translated labels are essential for our diverse communities to understand how to take their medication effectively and safely. Pharmacies should be required to use the translated labels provided by the Board or develop their own translations.
- Oral interpretation must be required for all patients. Using the caveat "if available" in the regulation will leave our communities vulnerable to misuse of their prescriptions.

I support Translated Prescription Drug Labels

Thanks,

/luis

--

Luis Miguel, PhD | CEO | luis@avantpage.com
530.750.2040 | cel 530.867.1148 | fax 530.750.2024

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"Jain, Sharad"
<Sharad.Jain@ucsf.edu>

05/05/2010 10:37 AM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject

Dear Ms. Klein,

I am disappointed by the implementation of SB472; the consumer protections have been watered down and do not reflect the evidence presented by research and policymakers.

I urge that the following steps be taken:

- 12-point font is the minimum size for readability. It is not reasonable to put the burden on patients to ask for larger print.
- Translated labels are essential for our diverse communities to understand how to take their medication effectively and safely. Pharmacies should be required to use the translated labels provided by the Board or develop their own translations.
- Oral interpretation must be required for all patients. Using the caveat "if available" in the regulation will leave our communities vulnerable to misuse of their prescriptions.

I look forward to hearing from you.

Thanks,

Sharad Jain, MD



Coralie.M.Chan@kp.org

05/06/2010 05:00 PM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject SB 472

Dear Ms. Klein,

I write to you as an individual who studies health disparities within our population (please do not construe my comments as representative of Kaiser Permanente). In reviewing the quality of care received by our members, we understand that it is imperative that we provide culturally appropriate care for our members - whether that be through legible prescriptions in a language that is understood by the patient, or by opening our doors during non-traditional office hours.

Watering down SB 472 will only increase the vulnerability already faced by marginalized populations: immigrants, children and the elderly. If we are able to better communicate the instructions necessary for medication adherence (e.g. prescription labeling), we will improve the health of our communities as well as reduce adverse events due to misuse of medications.

Please consider revising your board's stance on 12 pt font & translation of prescription labels into the top languages spoken in California.

Sincerely,

Coralie Chan, MPH

NOTICE TO RECIPIENT: If you are not the intended recipient of this e-mail, you are prohibited from sharing, copying, or otherwise using or disclosing its contents. If you have received this e-mail in error, please notify the sender immediately by reply e-mail and permanently delete this e-mail and any attachments without reading, forwarding or saving them. Thank you.

TO: Carolyn, Board of Pharmacy
(20 copies coming in mail!)

5/6/10

TO: California State Board of Pharmacy

FROM: Stephen J. Rosati, R.Ph.

RE: Second 15-Day Comment Period for Section
1707.5 Patient-Centered Prescription Labels

I am writing these comments in 6, 10 and 12 point font sizes in an effort to substantiate my recommendations and comments to the Board of Pharmacy.

This paragraph contains 10 and 12-point font sizes. Regarding Section 1707.5 (a) (1), the Board needs to commit to either a 10-point OR 12-point font size, not providing for the use of BOTH font sizes as currently proposed. It is not possible to use a 12-point font size and have all the directions fit the label for medications with long directions like steroids, inhalers, inhalation solutions and some psychotropics. Since the Board is not providing verbiage for the use of a smaller font size for longer directions, it makes no sense to require a 12-point font size if desired by the patient since it will not fit the label! In order to accommodate long directions with 12 point, some abbreviations will need to be used and this would open another set of problems for the consumer. Given this situation, the second sentence should read: "Each item shall be printed in at least a 10-point sans serif typeface, and listed in the following order:". I would set my computer at 12-point font size and have it automatically print at 10-point for longer directions; other pharmacies may set theirs at 10-point period, but since the Board is not addressing long directions, what logical choice is left? (a)(1)

(This paragraph contains 10 and 12-point font sizes.) Section 1707.5 (a) (1) (D), should be changed to "Purpose or condition, if entered onto the prescription by the prescriber or requested by the patient or patient's representative". In order to prevent confusion for a patient who is self medicating or make sure the proper medication is given to a patient by another individual, it is necessary to put the purpose or condition on the label. If the Board's intent is to provide the best therapeutic outcome for the patient, this change is necessary. (a)(1)(D)

(This section contains 6 and 10-point font size.) Currently, there are plenty of auxiliary labels and auxiliary directions that are using 4-point font size (again, this is 6-point). What good are the new requirements serving if the directions stating how many tablets to take per day is clear, but when or how to administer the medication is not clear? What happens when the following auxiliary labels or directions cannot be read and medication is improperly taken, administered or stored?:

- A medication that should not be taken with alcohol or have the patient limit alcohol intake.
- an eye drop for glaucoma that should not be used within 5 minutes of another eye drop.
- an antibiotic that should not be taken with minerals such as iron or calcium.
- an inhaler that needs to have its mouthpiece cleaned at least daily or weekly.
- a medication for the prostate that needs to be taken within the same 1 hour period each day.
- a medication that needs to be shaken before use or refrigerated.

If the intent of the Board is to provide the best therapeutic outcome and reduce side effects and adverse reactions, add Section 1707.5 (a) (3) Auxiliary labels or auxiliary directions shall be a minimum of 6-point sans serif typeface. Keep in mind the bullets above are in 6-point and not the 4-point font size sometimes used today! Simply providing directions on how many times to take or use a medication in readable font sizes, without providing a minimum font size for HOW TO PROPERLY TAKE OR USE THE MEDICATION in readable font sizes, is, in my opinion, unacceptable and failing to implement the original and basic intent of the enabling legislation!

(This paragraph contains 10-point font size.) Section 1707.5 (f), should be changed to "As used in this section, "appropriate dosage form" includes pill, caplet, capsule, tablet, ml, teaspoonful or tablespoonful". This would be appropriate since we also take liquid forms of medications as well as solid forms.

(This paragraph contains 10-point font size.) Again, if the Board's intent is to provide the best therapeutic outcome for the patient, with fewest side effects and adverse reactions, I am requesting your serious consideration of these comments.

Sincerely,

Stephen J. Rosati, R.Ph. 549 San Benito St. Hollister, CA 95023



Julianne Sturdivant
<julianne@avantpage.com>

05/07/2010 12:00 PM

To Carolyn_Klein@dca.ca.gov

cc

bcc

Subject Culturally Appropriate Prescription Drug Labels

Hello Carolyn,

Thank you for the work you're doing on stronger regulations for the standards for prescription drug labels. I believe they still can go farther. I think incorporating these changes in stronger regulations is the next important step:

- Increase the standard font size to 12-point.
- Translate labels for patients in California for whom English is not a native language.

Thank you for taking these important steps forward which support language access for all patients in this state.

Julianne Sturdivant | julianne@avantpage.com

916-337-7151

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GloPow@aol.com
05/09/2010 12:35 PM

To carolyn_klein@dca.ca.gov
cc mmartinez@cpehn.org
bcc
Subject Fwd: Changes to Prescription Drug Labels

Ms. Klein:

I am resubmitting my comments on the proposed changes to the California Code of Regulations, Section 1707.5. I believe these comments are still more than relevant given the unwillingness of the Board of Pharmacy to consider facts and science. Thank you.

William Powers

----- Message from GloPow@aol.com on Sun, 7 Mar 2010 20:11:27 EST -----

To: Carolyn_Klein@dca.ca.gov

cc: jreid@californiaalliance.org

Subject: Re: Changes to Prescription Drug Labels

Ms Klein:

The following are my comments on the action of the California Board of Pharmacy(Board) at it's February 2010 meeting regarding prescription drug labels.

My name is William Powers and I am the immediate past president of the Board having served in that post for two terms. I was a public member of the Board for over eight years. During that time I considered the Board to be primarily a consumer protection agency and not an industry protection group. That is why it is located in the Department of Consumer Affairs.

Medical errors continue to plague our society on many levels causing suffering and sometimes even death. SCR 49 created a taskforce to address these problems and seek solutions.

One of the recommendations of the taskforce was that the Board look at the standardization of prescription drug labels as one way of addressing this vexing problem. The Board held hearings around the state to hear from consumers, invited experts to provide testimony and generally tried to

be open to all suggestions. As one who was intimately in this process, I believe the Board acted in a responsible and prudent manner.

Among the suggestions that emerged from this lengthy process was that the size of the print on the labels should meet certain criteria and the research provided by the experts was that the print for key elements of the label should be no less than a 12 point font. Anything less would make it difficult for a large number of consumers to read the print. This recommendation was presented to the Board at the February 2010 meeting. And despite all of the science and the overwhelming testimony of seniors, who are the group most affected by medical errors, the Board chose to ignore the staff recommendation and reduced the font size to 10 point to meet the objections of the large corporate interests. How sad and disappointing it is to see a governmental agency dedicated to consumer protection bend to the will of industry causing potential harm to seniors and other consumers.

In addition, the Board refused to consider requiring that prescription drug labels be translated into at least the five most commonly spoken languages in the state. This despite the fact that the populations that speak these languages are expanding in the state. There was recent testimony that the technical capacity to easily produce these translations is available.

Once again the Board chose the interests of the corporate retailers over the safety needs of consumers. I am strongly urging the Board to reverse these two unfortunate decisions and restore the 12 point font and require the above noted translations. While these by themselves will not eliminate medical errors they will get our state on the right track and not go backwards. I trust you will do the right thing by the seniors and consumers of our state.



"Nisha Agarwal"
<Nagarwal@nylpi.org>
05/10/2010 03:02 PM

To <Carolyn_Klein@dca.ca.gov>
cc "Katherine Terenzi" <kterenzi@nylpi.org>
bcc
Subject comments on California Code of Regulations s1707.5

Dear Ms. Klein,

Please find attached comments by the New York Lawyers for the Public Interest (NYLPI) on proposed California Code of Regulations Section 1707.5 relating to patient-centered prescription labels. Please do not hesitate to contact us if you have any questions or concerns. A hard copy is being sent to you under separate cover.

Many thanks for your consideration.

Best regards,

Nisha Agarwal

Nisha Agarwal

Director, Health Justice Program

New York Lawyers for the Public Interest, Inc.

151 West 30th Street, 11th Floor, New York, NY 10001-4017

Tel 212-244-4664 x353 Fax 212-244-4570 TDD 212-244-3692

www.nylpi.org | healthjustice.wordpress.com | [@healthjustice](https://twitter.com/healthjustice)

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NYLPI Comments - Proposed BOP regs - 5.11.2010.pdf

May 13, 2010

Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834
Fax: (916) 574-8618
Email: Carolyn.Klein@dca.ca.gov

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels – Second 15 Day Comment Period

Dear Ms. Klein,

Thank you for giving New York Lawyers for the Public Interest (“NYLPI”) the opportunity to comment on the modifications to section 1707.5 of Title 16 California Code Regulations. NYLPI is a nonprofit civil rights law firm in New York City that has been a national leader in the effort to promote language access in pharmacies for people with limited English proficiency (“LEP”).¹ We continue to watch California’s efforts to create accessible pharmacies that respect the civil rights of all consumers. Your achievements thus far are admirable, and we submit these comments to strengthen the regulations.

We would like to reiterate that we were pleased that the proposed regulations require the State Board of Pharmacy (“The Board”) to publish on its website translations of all of the standardized directions for medication use into at least five languages by October 2011. However, we are concerned that there is no requirement in the regulations for pharmacies to make these translated labels available to their customers. A 2007 study by the New York Academy of Medicine found that New York City pharmacies overwhelmingly failed to provide their LEP customers with translated medication labels *despite having the capacity to do so in at least some languages*.² Absent regulation and enforcement of existing laws, pharmacies in New York were not voluntarily offering the language assistance services necessary to ensure their patients’ health and safety. To avoid a similar problem in California, we encourage The Board to incorporate stronger, mandatory language into its proposed regulations regarding label translation.

¹ For more information related to NYLPI’s efforts with regard to language access in pharmacies, please visit: <http://healthjustice.wordpress.com/resources/#Rx>.

² See: Linda Weiss, et. al., “Access to Multilingual Medication Instructions at New York City Pharmacies,” Journal of Urban Health: Bulletin of the New York Academy of Medicine, vol. 84, no. 6 (2007), pp. 742-754.

We would also like to commend The Board for requiring that pharmacies create explicit policies and procedures to assist LEP patients. However, we were troubled by the language in the proposed regulation which suggests that pharmacies must provide interpretation assistance only “if interpretive services in such language are available.” Providing interpretive services to patients is an essential civil right. If the language service is not yet easily available, the pharmacies should be bound to develop or find the proper service so that their patients can receive the necessary translation. Services such as Language Line and Pacific Interpreters have over 180 languages available 24 hours a day, so pharmacies should be able to find most necessary translations in a timely fashion for their patients. In New York City, for example, major national chain pharmacies such as Rite Aid have partnered with telephonic language services providers like Language Line to enable the provision of oral interpretation in every language spoken in the city.³

Similarly, it is essential to be explicit about which interpretive services the pharmacy will be required to provide. At a minimum, a pharmacy must be required to provide interpretation during the process of medication counseling, which, as discussed above, is possible in virtually every language likely to be encountered given current technology. In addition, if a pharmacy does not provide translated medication labels, it should be required to orally translate the container label for LEP consumers to ensure that patients understand how to take their prescription medications safely and effectively. We attached a portion of the text from New York City’s local law regarding language services in pharmacies for your convenience as it may be a helpful model as California finalizes its regulations.

We would also encourage California to clarify that if an employee of the pharmacy delivers the necessary language assistance services, that employee must also be proficient not only in the necessary language but also with the appropriate medical terminology. Therefore, we suggest that “qualified” or “competent” be added to section (d) before “pharmacy staff.” This addition will ensure that patients receive appropriate and accurate translation services.

Finally, we urge The Board to develop accountability measures through enforceable penalties for pharmacies that fail to provide these services. The attached language from New York City’s law may be useful in deciding on appropriate penalties. We have found that few pharmacies provide language services if there are no repercussions for failing to do so, therefore, we suggest The Board adopt penalties as means of ensuring these regulations are obeyed.

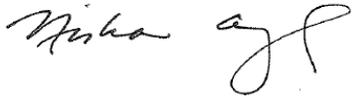
We commend California for actively working to protect the rights of Limited English Proficient individuals. We strongly urge The Board to include these necessary changes to the regulations in order to guarantee pharmacies provide the proper language services necessary to protect the health and safety of California’s residents. If you have any questions or would like to contact us

³ See Jennifer 8 Lee, “What Is That Two-Headed Phone?”, *New York Times* blog (May 13, 2009), available at: <http://cityroom.blogs.nytimes.com/2009/05/13/what-is-that-two-headed-phone/?scp=1&sq=two-headed%20phone&st=cse>

please do not hesitate to email me at nagarwal@nylpi.org or to call me at 212-453-5861. We will continue to follow California's efforts and your Board's progress on this matter.

Many thanks for your consideration.

With best wishes,

A handwritten signature in black ink, appearing to read "Nisha agf". The signature is written in a cursive, flowing style.

Nisha Agarwal
Director, Health Justice Program

Int. No. 859-A: A Local Law to amend the administrative code of the city of New York, in relation to the provision of language assistance services in pharmacies.

§ 20-621 Provision of interpretation services required. a. Every chain pharmacy shall provide free, competent oral interpretation services to each LEP individual filling a prescription at such chain pharmacy in the LEP individual's primary language for the purposes of counseling such individual about his or her prescription medications or when soliciting information necessary to maintain a patient medication profile, unless the LEP individual is offered and refuses such services.

b. Every chain pharmacy shall provide free, competent oral interpretation of prescription medication labels, warning labels and other written material to each LEP individual filling a prescription at such chain pharmacy, unless the LEP individual is offered and refuses such services.

c. The services required by this section may be provided by a staff member of the pharmacy or a third-party paid or volunteer contractor. Such services must be provided on an immediate basis but need not be provided in-person or face-to-face in order to meet the requirements of this section.

§ 20-622 Provision of translation services required. Every chain pharmacy shall provide free, competent translation of prescription medication labels, warning labels and other written material to each LEP individual filling a prescription at such chain pharmacy if that individual's primary language is one of the pharmacy primary languages, in addition to providing such labels and materials in English. Nothing in this section shall prohibit a chain pharmacy from providing dual- or multi-language medication labels, warning labels or other written materials to

LEP individuals who speak one of the pharmacy primary languages if one of the languages included on such labels or sheets is the LEP individual's primary language.

§ 20-623 Notification relating to language assistance services. a. Every chain pharmacy shall conspicuously post, at or adjacent to each counter over which prescription drugs are sold, a notification of the right to free language assistance services for limited English proficient individuals as provided for in sections 20-621 and 20-622 of this subchapter. Such notifications shall be provided in all of the pharmacy's primary languages. The size, style and placement of such notice shall be determined in accordance with rules promulgated by the department.

§ 20-624 Penalties. a. Any chain pharmacy that violates the provisions of sections 20-621 or 20-622 of this subchapter or any rules promulgated pursuant to such sections shall be liable for a civil penalty of not less than two hundred fifty dollars nor more than two thousand five hundred dollars for the first violation and for each succeeding violation a civil penalty of not less than five hundred dollars nor more than five thousand dollars.

b. Any chain pharmacy that violates the provisions of section 20-623 of this subchapter or any rules promulgated pursuant to such section shall be liable for a civil penalty of not less than two hundred dollars nor more than five hundred dollars for the first violation and for each succeeding violation a civil penalty of not less than three hundred dollars nor more than one thousand dollars.

§ 20-625 Hearing authority. a. Notwithstanding any other provision of law, the department shall be authorized upon due notice and hearing, to impose civil penalties for the violation of any provision of this subchapter and any rules promulgated thereunder. The department shall have the power to render decisions and orders and to impose civil penalties not to exceed the amounts specified in section 20-624 of this subchapter for each such violation. All

proceedings authorized pursuant to this section shall be conducted in accordance with rules promulgated by the commissioner. The penalties provided for in section 20-624 of this subchapter shall be in addition to any other remedies or penalties provided for the enforcement of such provisions under any other law including, but not limited to, civil or criminal actions or proceedings.



Luz Elena
<luz.elena@avantpage.com>
05/11/2010 10:27 AM

To Carolyn_Klein@dca.ca.gov
cc
bcc
Subject In re to prescription drug labels

Ms. Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy,

Dear Carolyn,

My name is Luz Elena Videgaray, and I'm the Director of Language for Avantpage, a translation agency based in California. As a Spanish speaker and translator, I consider it is very important to translate prescription drug labels and to provide medical information in a consistent, legible, and cultural appropriate manner. There is linguistic research on the importance of having medical instructions translated, and it frequently shows the impact of people not understanding information completely and accurately in a situation in which time and precision are essential. In a multicultural State such as California, measures need to be taken so that every language community living there be able to understand medical information appropriately.

Thank you very much for your attention,

Luz Elena.

--

Luz Elena Videgaray | Director of Language | luz.elena@avantpage.com
530.750.2040 ext. 2 | fax 530.750.2024
Avantpage | Connect in any Language® | <http://www.avantpage.com/>
Follow us on Twitter—<http://twitter.com/Avantpage>



"Sayeed, Syed"
<SSayeed@consumer.org>

05/12/2010 10:36 AM

To "Carolyn_Klein@dca.ca.gov" <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject Consumers Union letter to Board on 1707.5

Hi Carolyn,
Here is our comment for the most recent round of comments on 1707.5.
Thanks,
-Syed

Syed Muhasin Sayeed
Assistant Policy Analyst
Consumers Union
1535 Mission St.
San Francisco, CA 94103
415.431.6747 x137
415.421.0906 fax
Email: SSayeed@consumer.org

**

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Nonprofit Publisher
of Consumer Reports

May 12, 2010

By email to Carolyn.klein@dca.ca.gov

By fax to (916) 574-8618

Carolyn Klein
California Board of Pharmacy
1625 N. Market Blvd. N 219
Sacramento, CA 95834

Dear Ms. Klein,

Consumers Union, the nonprofit publisher of Consumer Reports, is concerned that the modified text of Section 1707.5 (a) (1) falls short of creating a truly patient-centered, standardized prescription label for California.

As demonstrated by expert testimony, scientific research, and the letters of over a thousand of our consumer activists, a 12 point font minimum for the most important parts of a label—the patient's name, the name of the drug, and the instructions—would make medications safer to take for all Californians. As demonstrated by sample labels produced by the Board, it is possible to accomplish this without increasing label or container size. As demonstrated by testimony from Kaiser Permanente representatives and other pharmacists, it is possible for pharmacists to provide medications that would conform to this requirement. Rather than putting the onus on consumers to request a safe medication font, all consumers should receive readable medication labels without having to ask for them.

If the Board is to proceed with the modified section (a) (1), the Board must also address concerns which have not been fully addressed by the discussion on this issue so far, including how patients can access a larger font when doctors phone-in prescriptions; whether pharmacies will be able to change label formats at the point of sale; and the need for doctors to be informed of the larger font option on medication labels. It is also essential that the regulation be accompanied by a prominent notice and counseling requirements for patients. It will be important for the Board to consider the illness, age, or limited English-proficient status of many patients. These patients, who are already the most vulnerable to medication errors, will also face greater difficulty in requesting changes to their prescription container.

Consumers Union is also concerned that the requirement in 1707.5 (d) to provide translation services "if available" will allow pharmacies to avoid providing translation services to limited English-proficient patients. Access to translation services is mandated by Medicare and Medicaid, and should be available in all pharmacies. In addition to making translation services a requirement, the Board should also create effective notification requirements that language translation services are available.

Thank you for considering our comments.

Sincerely,

A handwritten signature in black ink that reads "Syed Muhasin Sayeed". The signature is written in a cursive style with a large initial 'S' and a long, sweeping underline.

Syed Muhasin Sayeed
Assistant Policy Analyst
Consumers Union



RMiklesRN@aol.com

05/12/2010 11:24 AM

To carolyn_klein@dca.ca.gov

ssayed@consumer.org, mmartinez@cpehn.org,
cc wong@healthlaw.org, jreid@californiaalliance.org,
imhobe@consumer.org, henrsu@consumer.org,

bcc

Subject Board of Pharmacy COMMENT - Modified Text -Section
1707.5

Dear Ms. Klein:

Re: Comment - Modified Text Section 1707

I am the spokesperson for *Advocates4QualitySafeCare*. We are a group of individuals who strive for quality safe care in all healthcare settings. Our group is comprised of many individuals who wish to remain anonymous due to their having experienced retaliation as a result of speaking out to ensure delivery of quality safe care for themselves or a loved one.

We believe that Section 1707.5 (a) (1) - modified text - does not demonstrate a patient-centered prescription label for Californians which supports the safe administration of medication.

In serving Californians with a focus on patient safety, we must not rely on consumers to ask their pharmacists to increase font. This is the responsibility of those dispensing medications. It must be kept in the forefront that many patients when having their prescription filled are sick, therefore, might forget to ask to have larger font, thereby the potential for error exists. Further, many prescriptions are directly called in, or faxed, to the pharmacy from physician offices, which then places more responsibility on physicians to ensure that they identify which prescriptions require larger font. Some offices allow non-physicians to call in prescriptions e.g. nurses, therefore, placing even more responsibility and liability onto physician's shoulders. And, we must not forget those with visual impairments. It is even more important to protect consumers, especially, with the senior population rising in California, and the increased numbers of medications that they will be taking for many comorbid conditions, thereby, even more potential for error and harm. We can not stress enough the fact that consumers must be protected and the only way to ensure safe administration of medications is to have labels that support such. This is, we believe, the responsibility of those who dispense medications.

We have further concerns with 1707.5 (d) in respect to the vague language that could result in many patients not having translation services provided, thereby, resulting in not fully understanding directions, which possibly could result in harm. As you are aware, Medicare and Medicaid mandate access to translation services. We believe the Board should support and also mandate that translation services be required.

Thank you, and we appreciate our comments being considered and urge the Board to continue to protect Californians through language revision as stated above.

Respectfully,

Roberta Mikles, BA RN

Roberta Mikles, BA RN
Advocates4QualitySafeCare
Patient Safety Advocate
San Diego, California
858-675-1026 -o
619-204-7465 - c
RMiklesRN@aol.com



"Holly Harris"
<hsharris@att.net>
05/12/2010 03:18 PM

To <carolyn_klein@dca.ca.gov>
<ssayed@consumer.org>, <bimholz@consumer.org>,
cc <lmcgiffert@consumer.org>, <dnunez@consumer.org>,
<hharris@interwork.sdsu.edu>
bcc
Subject Section 1707.5 (a) (1)

Dear Ms. Klein:

I would like to express my recent disappointment in the California Pharmacy Board's decision to not increase the font size on medication labels to the 12 point font recommended by both individuals and groups representing California citizens with visual impairments. Honestly, it appears to me that the Board agreed to a lower font size specifically at the recommendation of pharmacies doing business in California. Their concerns were of a monetary nature, not one of patient/consumer health and/safety.

Here are some current statistics for your consideration regarding the numbers of Americans and Californians with visual impairments:
(from 2008 National Health Interview Survey (NHIS) Provisional Report stated:

*25.2 million adult Americans report that they "either have trouble seeing even when wearing glasses or contact lenses or that they are blind or unable to see at all";

According to report prepared in March, 2010 by American Federation for the Blind, in California, prevalence rates of vision loss include:

*723,231 Californians;
Age breakdowns:
*8,652: under age 5;
*47,742: ages 5-17;
*355,626 ages 18-64;
*93,087 ages 65-74;
*218,124 ages 75 and older.

As you see, the "Baby Boomers" will be bringing the numbers up significantly, and it is my great fear, that we are not taking necessary steps now to serve the needs of these large numbers of citizens. It also seems like anyone can logically see the huge room for error, if individual patients/consumers must request the larger font and/or translation. I am a strong advocate for patient responsibility, but in this case, it is illogical and, bottom line, if we care about the financial factor, will be quite costly if/when (and they will) errors occur due to such labeling and/or translation problems. However, I'm sure that is not the "pharmacies" concern, but it certainly should be the concern of the Pharmacy Board.

I respectfully ask that you and the Pharmacy Board put the health and safety of the citizens of California above all other concerns and lobbyists who have their own agendas. I'm sure your work is difficult, but it is time to be strong and protect those who are depending on you to "do the right thing".

Most Sincerely and Respectfully,

Holly S. Harris, M.S., CRC
Student Academic Advisor
Interwork Institute Center for Distance Learning
San Diego State University
3590 Camino Del Rio North
San Diego CA 92108
Voice: (619)368-4244
FAX: (619)594-4208

http://www.interwork.sdsu.edu/cdl/pro_courses/rcp_prog_dl.html



PAIN MANAGEMENT PHARMACY, INC.

Quality Compassionate Care for Patients with Pain

Phone: (805) 928-4700

Fax: (805) 928-4710

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BOARD OF PHARMACY
FAXED MAY 12 2010
3:50 PM
3 pages

Tuesday, May 11, 2010

Dear Members of the Board of Pharmacy,

In response to your call for public comment on the Patient Centered Label: I agree there would be great benefit to patient understanding and patient safety by implementing a single standard layout for prescription medication labels. Over the years I have seen many different label formats. Lately, it seems that some PBM run pharmacies pride themselves with making a label that facilitates their computerized robotic filling systems, but are almost impossible for the patient to read or understand. A prescription label should be clear, concise and consistently uniform in layout from pharmacy to pharmacy.

I have 3 points I would like the board to consider further:

1. I would caution the board to not over regulate exactly how a label should read, or add a provision to allow for non-standard sigs to be entered. It would be impossible for any entity to cover all the possible sig combinations a prescriber might use. You cannot know what new dosage form will pop up next. You would also open the opportunity for abusive third party recovery audits, citing a sig not exactly as the board has established as an invalid prescription, then rescinding thousands of dollars of payments from pharmacies that had dispensed legitimate prescriptions for valid medical purpose.

Rather than generating a long list of acceptable sigs simply leave it at:

[how] [amount] [Dosage form] [route][when or how often] [for what if supplied by prescriber]

How = take, apply, insert, instill.....

Amount = the quantity (# of units) per dose, I would encourage the use of numerals (2) rather than written (two) numbers

Dosage form = Capsule, Tablet, Suppository, Lozenge, spray, teaspoon, ml ... this field could be omitted for creams, and lotions.

Route= oral, rectal, topical, bucal, Transmucosal, ear, eye (specify which one or both), nare...

When, how often = qid, q4h, hs,.....again encourage the use of numerals (4) over written (four) numbers.

For what = for pain (routine, around-the clock dosing), as needed for pain (episodic pain issues, breakthrough pain, acute pain conditions), for asthma, for allergies emphasize the correct use of "for" And "as needed for...". The former being a scheduled (routine) dose, the later being episodic (the classic PRN)dosing.

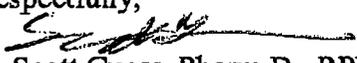
The above system does not lock pharmacist and prescribers into set sigs, and allows for sigs not considered or published by the board. This system also allows for the arrival of other dosage forms and routes of administration without the need to rewrite the regulation.

b. Pharmacists' education is supervised by the Board of Pharmacy for a reason. Pharmacist must use rational, educated judgment. Label requirements must allow a pharmacist to use her professional judgment to make the label more understandable to the patient.

2. Font size issues. There is only so much space on a label. The font can only be so big before patients start getting #30 Lasix 40mg Tabs in a 60 dr. vial just so the label will fit. Most pharmacists I know gave up using 8 dr. vials years ago because the label and now all the auxiliary labels just won't fit on an 8 dr. vial. If labels get too big, and minimum vial size to accommodate that label grows, 2 things happen; costs go up, and there become storage issues for the patient (at home and for travel) for all these bigger vials to support bigger labels. Those who would require us to use less plastic will make this a problem as well. As for the interchangeable font, the difference between 10 point type and 12 point type is not that great. Patients with less than perfect sight are accustomed to having magnifiers around. I have asked my software vendor to comment on the feasibility of variable size fonts. Take home message here is: as the font increases less information that will fit on the current standard label size, or the size of the label must increase, which translates to the size of the vial increasing, which translates into increased cost for the pharmacy and the patient.
3. My last area of concern is the requirement to translate for non- or limited-English speaking patients. This discussion should be removed from the patient centered label and addressed as a stand alone issue. Better communication with patients is an admirable goal, but the logistics haven't been worked through. I am a Pharmacist, not a linguist.
 - a. Just who is going to pay for this service?
 - i. Pharmacy reimbursements have been steadily declining for years now.
 - ii. Saddling pharmacy providers with the expense of subscription translational services is an undue burden.
 - b. Just who is liable for the accuracy of the translation?
 - i. Will translation be allowed only by licensed translators?
 - ii. What if this means that the patient cannot get a medication because there is no translator?
 - iii. If a patient gets a poor or incorrect translation, is the pharmacist liable for the translator's error? Does this dis-allow the usual situation of the patient's bringing in a family translator?
 - iv. Will pharmacists have to be licensed to translate just like other translators?
 - v. How does this translate to hospitals? What about the night shift in the ER?

- vi. Where do we draw the line for available languages? Locally, we have a large population that speaks Oaxacan (even the school district has problems with this), but we also have Basque and Maya. How many of the Chinese dialects are we responsible for trying to translate?
- c. It is certainly desirable that each patient have a meaningful conversation with his pharmacist but, America, and California especially, is a land of immigrants (from countries world wide). It is unrealistic to expect pharmacy providers (or any service provider for that matter) to be able to translate into whatever language might walk through the front door.

Respectfully,


 K. Scott Guess, Pharm.D., RPh
 Owner/CEO Pain Management Pharmacy, Inc.
 Diplomate, American Academy of Pain Management,
 Adjunct, Clinical Faculty, USC School of Pharmacy

Pain Management Pharmacy, Inc
 2003 S. Miller St., Santa Maria, CA 93454
 Phone: 805-928-4700 Fax: 805-928-4710
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

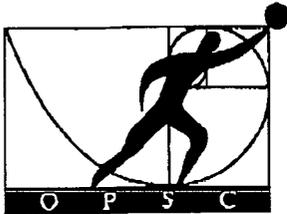
Rx 123456 Dr. Last, First
 Patient Name MM/DD/YY

Directions for use

#XX Drug Name (mfq)
 generic for _____
 x refills DISCARD _____

med description

Sample Label Format
 Patient Centered Labels
 should also address
 uniform label format
 across all pharmacies.



OSTEOPATHIC
Physicians & Surgeons
OF CALIFORNIA

RECEIVED BY CALIF.
BOARD OF PHARMACY

2010 MAY 13 AM 8:19

May 12, 2010

Carolyn Klein
Manager, Legislation and Regulation
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Draft Regulations
Patient-Centered Labels on Medication Containers

Dear Ms. Klein,

The Osteopathic Physicians and Surgeons of California (OPSC) appreciates the opportunity to comment on the draft regulations implementing SB 472 (Corbett, 2008). OPSC is a state wide organization whose mission is to advance the practice of osteopathic medicine as an independent, scientific and complete system of medicine for the restoration and preservation of good health.

OPSC believes the current draft has room to improve the provisions pertaining to language assistance to limited-English speaking patients. SB 472 requires that the Board, in developing the new labeling requirements, consider "the needs of patients with limited English proficiency." However, the current draft requires only that the Board of Pharmacy post to its website the translations (in five languages) of a basic set of directions for use. Although this is a step in the right direction, OPSC feels the pharmacies should be required to print translations for use directly on the prescription label and in at least 12 point font.

Similarly, the draft would require a pharmacy to provide interpreting services only if they are "available" in the patient's language, whether through pharmacy staff or telephonic interpreting service. It is vital that adequate policies and procedures are set in place to help LEP patients understand their prescriptions combined with translated prescription labels in a legible font.

Thank you for your consideration, and don't hesitate to contact us if we can be of help.

Sincerely,

Tom Riley
Legislative Advocate

CalDerm

The Voice of California Dermatology

California Society of Dermatology & Dermatologic Surgery

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Sacramento
Anthony Petelin, M.D.
Resident, UC Irvine
Christina Mumm, M.D.
Resident, UC Davis

May 12, 2010

Carolyn Klein
Manager, Legislation and Regulation
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

**RE: Draft Regulations
Patient-Centered Labels on Medication Containers**

Dear Ms. Klein,

The California Society of Dermatology and Dermatologic Surgery (CalDerm) would like to take the opportunity to comment on the draft regulations on implementing SB 472 (Corbett, 2008). CalDerm is recognized state wide as an organization dedicated to advancing the practice of Dermatologic medicine through quality patient care.

CalDerm is confident that the current draft can improve the provisions pertaining to language assistance to limited-English speaking patients. SB 472 requires that the Board, in developing the new labeling requirements, consider "the needs of patients with limited English proficiency." However, because the current draft only requires that the Board of Pharmacy post the five language translations of a basic set of directions for use to its website, CalDerm feels pharmacies should be required to print translations directly on the prescription label and in at least 12 point font.

In addition, the draft would insist pharmacies provide interpreting services only if they are "available" in the patient's language, whether through pharmacy staff or telephonic interpreting service. It is critical that adequate policies and procedures are in place to help LEP patients understand their prescriptions and translated prescription labels in a legible font.

Thank you for your consideration, and don't hesitate to contact us if we can be of help.

Sincerely,



Tom Riley
Legislative Advocate



Mark <mark@riggle.net>

05/12/2010 01:21 PM

Please respond to
mark@riggle.net

To carolyn_klein@dca.ca.gov

cc

bcc

Subject Comment on 1707.5

Dear Ms. Klein,

First, I would like to commend the California State Board of Pharmacy and the Department of Consumer Affairs for striving to enforce uniformity in labeling of prescription drug containers.

Regarding 1707.5(a)(1):

"...or, if requested by the consumer, at least a 12-point typeface..."

Having the ability to offer multiple size typefaces for the prescription label may not be a viable option for many pharmacies. Software enhancements may be necessary that would create an undo financial burden. I ask that you remove this phrase from this section and retain the original 10-point facetype requirement.

Regarding 1707.5(a)(4):

This section only addresses directions for use when a solid oral dosage form is given a certain number of times per day. This creates confusion and should also include appropriate directions for use for oral liquid medications, including whether measurements shall be in milliliters or teaspoons (or both); topical medications, such as creams and ointments; ophthalmic and otic product; inhaled products; and injectable medications. I recommend the addition of examples for medications administered every x number of hours. For the sake of space, I recommend you phrase as follows, where x is the appropriate number.

Take x [dosage form] in the morning.

Take x mL once daily.

Take x [dosage form] every x hours.

Apply to the affected area x times a day.

Inhale x puffs every x hours.

Instill x drops into right/left/both eye/ear x times a day.

Inject x units at bedtime.

Regarding 1707.5(b):

I recommend that several commonly used phrases be translated, such as:

"as needed for..."

"as directed"

various conditions (cough, pain, infection, sleep, itching, nausea, vomiting, diarrhea, etc.)

These additions will help provide more effective communication with patients of limited English proficiency, and provide a valuable resource for pharmacists.

Respectfully submitted, Mark W. Riggle, Pharm.D.
RPH44310



"Dieter Steinmetz"
<dsteinmetz@compoundingpr
o.com>

05/13/2010 10:28 AM

To <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject RE: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

Hi Carolyn,

I changed the layout of my prescription labels to conform with the proposed requirements. Initially thought it would be difficult to implement, especially the 12 point size for the directions. I was pleasantly surprised that the outcome does in fact look nice and improves visibility for patients. When long sigs are used e.g. prednisone decreasing dosing over a few days the point size would need to be decreased but for 90% of sigs the 12 point size will work very well.

I am sure the Board does not usually receive complements for new regulations, but this one deserves a thumbs up.

Sincerely

Dieter Steinmetz
Coast Compounding Pharmacy
1838 S Coast Hwy
Oceanside, CA 92054
760-433-6232
760-730-8147 (fax)

From: Carolyn_Klein@dca.ca.gov [mailto:Carolyn_Klein@dca.ca.gov]
Sent: Wednesday, April 28, 2010 4:31 PM
Subject: 1707.5. Patient Centered Prescription Labels - Notice of Modified Text

Please disregard if this is a duplicate email.

The Board of Pharmacy today released a Notice of Availability of Modified Text to 16 California Code of Regulations beginning with section 1707.5. Patient-Centered Prescription Labels. Specifically, modifications are proposed to sections (a)(1) and (a)(1)(D).

The Board of Pharmacy will accept comments to the proposed modified text until 5:00 p.m. on Thursday, May 13, 2010.

Please visit the board's Web site at <http://www.pharmacy.ca.gov> or click on the link below to view all documents associated with this proposed regulatory action and other pending regulations or newly approved regulations.

http://www.pharmacy.ca.gov/laws_regs/regulations.shtml

The message was checked by ESET Smart Security.

<http://www.eset.com>



"Don Schinske"
<dschinske@chiaonline.org>

05/13/2010 01:54 PM

To <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject CHIA comments on labeling regs

Dear Ms. Klein,

Attached find comments from the California Healthcare Interpreting Association (CHIA) regarding the proposed labeling regulations.

Thanks much,

Don

Don Schinske • Executive Director
California Healthcare Interpreting Association
1020 12th St., Ste. 303
Sacramento, CA 95814
(916) 444-1506 • f (916) 444-1501



CHIAPharmacyRegs5.14.10.doc

May 11, 2010

Carolyn Klein
Manager, Legislation and Regulation
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834



**RE: Draft Regulations
Patient-Centered Labels on Medication Containers**

Dear Ms. Klein,

The California Healthcare Interpreting Association (CHIA) appreciates the opportunity to comment on the draft regulations implementing SB 472 (Corbett, 2008). CHIA is a statewide nonprofit organization of interpreters, educators, language companies, and healthcare providers working to improve the quality and availability of language assistance in the delivery of healthcare.

We are dismayed by the current iteration of the draft, and believe the provisions pertaining to language assistance to limited-English speaking patients fall short of both the spirit and letter of the law.

SB 472 requires that the Board, in developing the new labeling requirements, specifically consider “the needs of patients with limited English proficiency.” However, the current draft requires only that the Board of Pharmacy post to its website the translations (in five languages) of a basic set of directions for use. What’s missing is a requirement that a pharmacy actually print those translations (or translations of its own) on any of its labels.

Similarly, the draft would require a pharmacy to have written “policies and procedures” to help LEP patients understand their prescription, with the means for identifying a patient’s language needs and providing interpreting services. However, the interpreting services need only be provided if they are “available” in the patient’s language, be it through pharmacy staff or telephonic interpreting service.

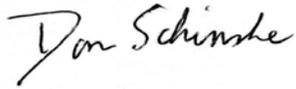
Together provisions would make language assistance for pharmacy patients almost discretionary. We believe this compromises the basic point SB 472, which was to improve patient understanding, compliance, and safety.

Please, we would ask that LEP patients be offered prescription labels that include high-quality translations of the directions for use. In addition, LEP patients should be offered oral language assistance -- either in-person or via telephone or video – at the point of the

transaction. Any less than that, we believe, and pharmacies would be failing in their fundamental obligation to provide safe and equitable services.

Thank you for your consideration, and don't hesitate to contact us if we can be of help.

Kind regards,

A handwritten signature in black ink that reads "Don Schinske". The signature is written in a cursive, flowing style.

Don Schinske
Executive Director



"Carmen Samuels"
<cksamuels@cox.net>

05/13/2010 12:57 PM

To <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject Prescription Drug Labels

It is critical that consumers have clear and readable size printed directions - particularly for the many older citizens we have in our communities- when they receive a prescription from the pharmacy. Please consider the full intent of SB 472 (Corbett) passed in 2008 regarding prescription drug labels.

Carmen Samuels
2657 Citronella Ave.
Lemon Grove, CA 91945



Sieglinde Johnson
<sjohnson@calretailers.com>

05/13/2010 12:11 PM

To carolyn_klein@dca.ca.gov

cc Mary Staples <mstaples@NACDS.org>, "Lynn W. Rolston"
<lrolston@cpha.com>, Kara Bush <kbush@cagrocers.com>

bcc

Subject Joint Comments on the Proposed Rx Label Regulation

Carolyn,

Attached are comments submitted by the California Retailers Assn, the California Pharmacists Assn, the California Grocers Assn and the National Assn of Chain Drug Stores in response to the BOP's latest notice on the modified Title 16 CCR Section 1707.5 text. Please let me know if you have any questions. Thank you.



5.13.10 BOP Rx Regs Comment Letter.pdf

Sieglinde (Missy) Johnson
Director, Government Affairs
California Retailers Association
980 Ninth Street, Suite 2100
Sacramento, CA 95814
(916) 443-1975 phone
(916) 441-4218 fax
sjohnson@calretailers.com



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



May 13, 2010

Via email Carolyn_Klein@dca.ca.gov

Carolyn Klein
1625 N Market Blvd, N219
Sacramento, CA 95834

RE: Proposed Title 16 CCR Section 1707.5 Delivery of Prescriptions

Dear Ms. Klein:

On behalf of its members operating retail pharmacies in the State of California, the California Retailers Association (CRA), the National Association of Chain Drug Stores (NACDS), the California Pharmacists Association, (CPhA) and the California Grocers Association (CGA) write to acknowledge the amount of work, time and resources the Board of Pharmacy (Board) has devoted to the development of the proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations regarding Patient Centered Labels on Medication Containers. We appreciate that this has been a long and difficult task and thank the Board for soliciting comments from interested parties to draft a regulation that balances the concerns of all stakeholders. We share the Board's goal of ensuring prescription labels provide patients with information necessary to ensure the safe and proper use of prescription medications.

We greatly appreciate the Board's willingness work with pharmacies on the concerns we raised on previous versions of the regulation and offer the following comments on the latest draft.

12-Point Font Requested by the Patient

In an effort to reduce service disruptions for our patients and pharmacy operations and ensure patients have a positive pharmacy experience, we request the regulation be amended to require the label be printed in 12-point font, if requested by the patient, when the prescription is first presented at the pharmacy counter. This clarification will allow pharmacy staff to process and dispense prescriptions, according to the patients' wishes in an efficient and customer service oriented manner, without having to interrupt our pharmacy systems and avoid significant service disruptions for other pharmacy patrons. Many pharmacy operations are highly automated and pharmacies are better able to accommodate patients' concerns on the front end of the process rather than on the tail end.

To that end, we request the regulation be amended to read as follows:

§1707.5. (a)(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point, sans serif typeface **or, if requested by the consumer at the time the prescription is first presented, at least a 12-point typeface**, and listed in the following order:

Inclusion of Name and Strength of Drug in Patient-centered elements

We request the name of the manufacturer's trade or generic name and drug strength be removed from the list of items that are to be listed and clustered in to 50 percent of the prescription label. Business and Professions Code § 4076 requires the drug name and strength to be included on all prescription drug labels (and therefore will remain on the label), but we are concerned that having them in larger font in the clustered field will compromise pharmacies' ability to accommodate, in a 12-point font, all of the other patient-specific items listed in the regulation without providing a clear benefit to patients. We agree that there are certain elements on a label that are very critical to patients' understanding of their medication (i.e. patient name, directions for use and purpose or condition). However, given the limited space on prescription drug labels, we would like the flexibility to use the space to highlight the elements that are most important to ensuring patient understanding and compliance with prescribed drug therapies. Therefore, we request that the following be struck from the proposed regulation:

~~§1707.5(a)(1)(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.~~

Again to be clear, the label will contain the name and strength of the drug, but will not be part of the "cluster" required by 1707.5(a)(1).

Implementation of the Regulation

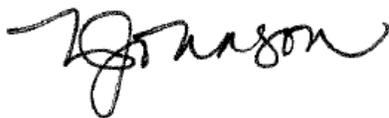
In order to ensure our pharmacies' compliance with the final version of this regulation, we request an implementation phased in at least 12 months from the time the rule is finalized. As drafted, SB 472 requires the regulation to be in effect on January 1, 2011. Given that it is already May 2010, it would be impossible for us to meet the January 1st date. Additionally, our members will not begin to make the necessary changes to their pharmacy processes and systems until the regulation's provisions of are finalized. The changes proposed by this new rule will require significant investment and changes to our pharmacy operations. Therefore, it is imperative that pharmacies be given one year to make the necessary adjustments required to comply with this new regulation.

Consumer Notices

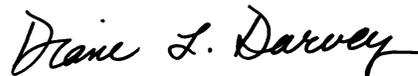
At the last Board meeting, there was some discussion on requiring pharmacies to post notices informing consumers of the availability of 12-point font prescription drug labels. Pharmacies are already required to post a number of notices and we are concerned that mandating additional signage requirements will have the adverse effect of creating visual clutter and could result in patients being so overwhelmed by signs that they ignore them all. Since the Board already produces the "Notice to Consumer" sign that contains that a list of patients' pharmacy rights, we believe it is appropriate that the information regarding the availability of 12-point font be included on it. That way, patients' rights would be listed on one single comprehensive sign.

We thank Board for the opportunity to submit comments and to testify during public meetings on the proposed rule and urge the Board to consider the two technical amendments suggested above. We thank you in advance for consideration of our comments and please do not hesitate to contact us with any questions.

Sincerely,



Missy Johnson
CRA Government Affairs Director



Diane L. Darvey, Pharm.D., JD
NACDS Public Policy Director



Lynn Rolson
CPhA Chief Executive Officer



Kara Bush
CGA Government Relations Manager

California Communities United Institute
6529 Cowboy Way
Citrus Heights, CA 95621
(916) 728-1261
www.calcomui.org

RECEIVED BY CALIF
BOARD OF PHARMACY
2010 MAY 13 PM 2:41

Members of the Board of Pharmacy
c/o Carolyn Klein, Coordinator
Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd. N 219
Sacramento, CA 95834

Dear Board Member,

In order to save paper, the following letter is being sent to you with the names and addresses of those who asked it be sent to you listed at the end of the letter. Please consider it to be a letter from each of them.

Sincerely,

Boyce Hinman
California Communities United Institute

Dear Board Member,

Thank you for giving me the opportunity to respond to your latest revision of the proposed regulations regarding patient friendly medication labeling.

However, I must say that I am very disappointed in the latest revision of those regulations. For example, your proposed regulations say that the type on the label can be in 10 point sans serif typeface. That print size is too small. All type on a medicine label should be at least 12 point.

According to the US Census Bureau's latest data there are 5.7 million people over the age of 60 in California and those numbers are growing every year. One common characteristic of the elderly is that their eyesight is failing. They need print to be larger and larger. You will be doing a great disservice to these Californians if you allow the print on medicine bottles to be anything smaller than a 12 point typeface. Please change your proposed regulations to require a font of that size or larger.

Your proposed regulations also would require pharmacists to include the purpose of the medicine, or the condition it is meant to treat, "IF REQUESTED BY THE PATIENT". This information should be required on all labels. First of all, few patients will know they can request such services. So your requirement is meaningless.

Also, it is typical of the 5.7 million senior citizens in California that they must take several different medicines to treat several different conditions. And for many, their memory is failing. Many will forget which medicine is for one problem and which is for another. They must have clear written instructions on which medicine to take for difficulty breathing as opposed to which to take for chest pain. The purpose of the medicine must be clearly stated on each medicine label.

Your proposed regulations say that interpretive services shall be provided in the patient's language IF INTERPRETIVE SERVICES IN SUCH LANGUAGE ARE AVAILABLE.

According to the latest data from the Census Bureau, there are over 14.4 million Californians whose primary language is other than English. Probably several million of them will need interpretive services to fully understand the correct way to use their prescription medicines.

A law that has been on the books for several years requires all health care services plans and insurance policies to pay for interpretive services when needed in doctors visits and hospital stays. This law does not limit the provision of such interpretive services to situations where those services are available. There are no such exclusions in that law.

If there are no staff in the doctor's office, or the hospital, that speak the necessary language, the doctor or hospital simply telephones a service that can provide the service in that language. The translation service is provided over the phone. There is nothing to prevent a pharmacy from providing interpretive services in this way. Therefore I urge you to remove the "if available" clause from the regulation on interpretive services.

I look forward to hearing that you have made all these changes in your proposed regulations. These changes are needed by the people of California.

Sincerely,

Breonna R. Bridges

3311 Winter Park Drive Apt#9

Sacramento CA 95834

Keith Chambers

1820 Capitol Avenue Apt 204

Sacramento, CA 95811

Claude Everett

625 El Dorado Ave. #307

Oakland Ca 94611

William Kean

2264 Bayberry Cir

Pittsburg, Ca 94565

Kate Brotherton

25885 Trabuco Rd. #136

Lake Forest, CA 92630

Adrienne Lauby

1 Kingston Way

Cotati, CA 94931

Dennis Dudley

2520 La France Drive

Carmichael, CA 95608

Jay Dore

2005 Carpinteria Dr.

Antioch, CA 94509

Judith Poxon

2708 Matheson Way

Sacramento, CA 95864-3717

Erika Suderburg
1807 Effie St.
L.A. CA. 90026

Ms. Bonnie Margay Burke
4378 33rd Place
San Diego CA 92104-1405

Boyer c. August
1957 East ave
Hayward, ca 94541

Ken Prag and Steve Collins
486 Laidley St
San Francisco, CA 94131

Samuel Thoron
3045 Pacific Avenue
San Francisco, CA 94115

John Richard Petersen
10 Las Flores
Aliso Viejo, CA 92656-6203

Bruce R. STÜRZL, Jr.
1853 Webster #2
San Francisco, CA 94115-2837

Carol Cook
282 La Casa Ave.
San Mateo, CA 94403

Robert J. Mahoney
7 Mountain View Road
94930

Carol Pierce, PhD, MFT
3126 31st Street
San Diego, CA 92104

Billie Klayman
618 N. Hayworth Ave., #6
Los Angeles, CA 90048

Charles L. Krugman
1237 P Street
Fresno, CA 93721

Clark Burnett
302 Thom St #15
San Diego, CA 92103

James R Ozanich
2633 Marshall Way
Sacramento, CA 95818

Ellen Webster
55 Southwind Circle
Richmond, CA 94804

Merrie Schaller
10400 Lake Blvd
Felton, CA 95018

Merci Midori
6922 Burning Tree Court
San Jose California 95119

Debra Todd
8220 Villaview Dr.
Citrus Heights, CA 95621

Adele House
Valley Village, CA

Lele Diamond
111 Forrest Avenue
Fairfax, CA 94930

Bruce Fairbanks
2525 H Street Apt 6
Sacramento, CA 95816

Jim Webber
2617 Stonecreek Dr. #28
Sacramento, CA 95833

Joseph Costa
9740 Fair Oaks Blvd
Fair Oaks, CA 95628

Thomas J. Martin
2513 Twin Peaks Road
Mariposa, CA 95338

Rosalee Clarke
876 Spinosa Drive
Sunnyvale, CA 94087

Fred Ihler
1174 E. Main St., SPC 143
El Cajon, CA 92021

Randy Hicks
1375 Sonoma Ave.
Sacramento, CA 95815

Richard Hand
7815 State Hwy 99 W
Gerber, CA 96035

Christine Allen
1733 63rd AV
Sacramento, CA 95822

Michael Boyd
2933 35th Street
Sacramento, CA 95817

Boyce Hinman
6529 Cowboy Way
Citrus Heights, CA 95621



"Marty Martinez"
<mmartinez@cpehn.org>

05/13/2010 05:06 PM

Please respond to
<mmartinez@cpehn.org>

To <Carolyn_Klein@dca.ca.gov>

cc <mmartinez@cpehn.org>

bcc

Subject Regulations Section 1707.5 Relating to Patient-Centered
Prescription Container Labels

Hello! Please find the sign on letter from:
California Alliance for Retired Americans
California Pan-Ethnic Health Network
Latino Coalition for a Healthy California
National Health Law Program
Pharmacists Planning Service, Inc.
Villa Senior Network

thanks!

Martin Martinez, MPP
Policy Director
California Pan-Ethnic Health Network
654 Thirteenth St.
Oakland, CA 94612
(510)832-1160
fax: (510) 832-1175
mmartinez@cpehn.org

Unite and fight for better health - visit www.cpehn.org and follow us on Twitter @CPEHN.



Please consider the environment before printing this e-mail



board of Pharm comments May2010 SIGN ON fin.doc

May 13, 2010

Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834
Fax: (916) 574-8618
Email: Carolyn_Klein@dca.ca.gov

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Ms. Klein and Members of the California Board of Pharmacy:

On behalf of the undersigned organizations, we submit the following comments to proposed regulations related to patient-centered prescription drug labeling.

We are extremely concerned that the current draft regulations fall short of the intent of the statute, and will not meet the health and safety needs of consumers. Prescription drug labels in 12-point font and that are translated into the patient's language are vital for quality care, but the current regulations address neither. We also believe the process for ensuring adequate public comment and participation since the adoption of the formal rulemaking process has been flawed. We need further opportunities to debate this issue and ensure quality patient care.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. However, the Board adopted language that neither corresponded with the statute, nor was in keeping with the research, public hearing testimony, or results of the survey conducted by the Board staff. Furthermore, we believe the process used by the Board did not comport with the requirements outlined in the Administrative Procedures Act (APA) as enforced by the Office of Administrative Law.

The Board's action is not consistent with the underlying statute, and does not meet the APA's consistency standard. The statute reads as follows:

- (c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:
- (1) Medical literacy research that points to increased understandability of labels.
 - (2) Improved directions for use.
 - (3) Improved font types and sizes.
 - (4) Placement of information that is patient-centered.
 - (5) The needs of patients with limited English proficiency.
 - (6) The needs of senior citizens.

This regulation falls short of the requirements specified above. Even the author of the legislation, Senator Corbett, provided comments in writing and through an in-person comment by her staff that the proposed regulatory language was inconsistent with the intent of her legislation. However, the arguments put forward by the industry that this law was too inconvenient and too expensive prevailed before the Board. The decisions by the Board are in direct contradiction to the research conducted by the Board staff that indicated that translated labels and 12-point font are necessary for quality care. The Board also heard directly from seniors and people with low English proficiency about their need for 12-point font and translated labels. Yet, the Board decided to go in a different direction and provided no rationale or evidence that 10-point font meets patient needs, and that oral interpretation services (to be provided only if they are available) are an adequate and safe substitute for a translated, written label.

The change made at the Board's April meeting, to allow consumers to receive labels in 12-point upon request, will not help consumers. Even with a significant education campaign and signage (neither of which is addressed in this regulatory proposal) consumers will not feel empowered to take advantage of this right, or understand how important it could be to their health.

The Board also heard repeated testimony from consumers who speak a language other than English on how important labels in their language will be to their health. It is our opinion that requiring oral interpretation by itself, with no written translated label, does not meet the intent of the statute that the Board develop requirements *for prescription drug labels* that take into account the needs of persons who speak limited English.

The Board's action does not comply with the clarity standard of the APA. At 1707.5.(d), the proposed regulation reads, "...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."

The inclusion of the phrase, "*if interpretive services in such language are available*," does not meet the clarity standard. No guidance is provided to pharmacies on how to define availability. The language of this part of the regulation conflicts with the description of its effect. The Board discussion on January 20 implies that the Board's intent here is to make allowance for infrequently encountered languages for which finding interpretation services would be almost impossible for the pharmacist. Such a situation would very rarely be encountered. Although in-person interpretation is preferred for patient comprehension, there are phone-based interpretation services that can provide interpretation in over 170 languages. A person who did not attend the hearing would not understand the intent of this provision just by reading it.

The Board did not provide an opportunity for meaningful public comment with sufficient advance notice at the public hearings. The APA requires The Board to "make each substantial, sufficiently related change to its initial proposal available for public comment for at least 15 days before adopting such a change." The Board did not do so. The changes to the proposed regulatory language were posted to the official agency website in the evening of January 19, 2010 before the hearing was set to begin on January 20, 2010. This was approximately 14 hours before the commencement of the hearing and in no way could be construed to meet the 15 day

advance notice that is required to be available for public comment. We also believe that the advance notice requirement should fall into the “45-day rule” because of the substantial changes to the language to accommodate industry objections to the relatively pro-consumer original language. However, regardless of the rule that is invoked, less than a day’s advance notice cannot be considered to even remotely meet either of the requirements.

We believe the original draft language developed by the Board staff before their first vote represented a closer approximation of the requirement of this statute. We remain particularly supportive of the following provisions which we believe should be included in the Board’s regulatory language to implement SB 472 (as reflected in the research, survey and public hearing testimony):

- Labels should be required to be printed in 12-point font or larger.
- The clustering and white space requirements must be maintained.
- Pharmacies should be required to use the translated labels provided by the Board on its website, or provide their own translated labels.
- All patients who speak a language other than English should have the right to have their prescription drug instructions orally interpreted to them.
- Pharmacies should post signs in multiple languages explaining the availability of language services. Few people take advantage of their rights under the law if they are unaware that such rights exist.

We urge strong action to implement what California’s policymakers have determined is needed to increase consumer protection and improve the health, safety, and well-being of consumers. We strongly believe that standardized, readable, language-accessible, prescription labels are a vital element in appropriate health care delivery.

Thank you for receiving these comments. If you have any questions please contact Marty Martinez, Policy Director, CPEHN at (510) 832-1160.

Sincerely,

California Alliance for Retired Americans
California Pan-Ethnic Health Network
Latino Coalition for a Healthy California
National Health Law Program
Pharmacists Planning Service, Inc.
Villa Senior Network

CAPITOL OFFICE
STATE CAPITOL
SACRAMENTO, CA 95814
(916) 651-4010
(916) 327-2433 FAX

DISTRICT OFFICES
1057 MACARTHUR BLVD., STE 206
SAN LEANDRO, CA 94577
(510) 577-2310
(510) 577-2308 FAX

(408) 286-0329 SAN JOSE

39155 LIBERTY ST., STE F-610
FREMONT, CA 94538
(510) 794-3900
(510) 794-3940 FAX

Senate

California Legislature

ELLEN M. CORBETT

SENATOR
TENTH SENATE DISTRICT



STANDING COMMITTEES
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APPROPRIATIONS
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COMMUNICATIONS
ENVIRONMENTAL QUALITY
LEGISLATIVE ETHICS

SELECT COMMITTEES
CHAIR BIOTECHNOLOGY
CHAIR EARTHQUAKE &
DISASTER PREPAREDNESS

TO: Carolyn Klein

DATE/TIME: May 13 FAX NUMBER: 574 8618

From: Capitol Office of Senator Ellen Corbett, 10th Senate District
State Capitol Room 5108, Sacramento, CA 95814
916-651-4010 (Phone) 916-327-2433 (Fax)

- | | | |
|---|--|--|
| <input type="checkbox"/> Peggy Collins | <input checked="" type="checkbox"/> Lynda Gledhill | <input type="checkbox"/> Julie Lujano |
| <input type="checkbox"/> Michael Jarred | <input checked="" type="checkbox"/> Anthony Valdez | <input type="checkbox"/> Renee Sanchez |
| <input type="checkbox"/> Alison Merrilees | <input type="checkbox"/> Seyron Foo | |

Delivery Status:			
<input checked="" type="checkbox"/> Urgent	<input type="checkbox"/> Routine	<input type="checkbox"/> Please Reply	<input type="checkbox"/> Reply as soon as Possible

Re: Please attached.

Number of Pages (Including Coversheet): 3



CAPITOL OFFICE
STATE CAPITOL
SACRAMENTO, CA 95814
(916) 651-4010
(916) 327-2433 FAX

DISTRICT OFFICES
1057 MACARTHUR BLVD, STE 208
SAN LEANDRO, CA 94577
(510) 577-2310
(510) 577-2308 FAX

(408) 286-0329 SAN JOSE

39155 LIBERTY ST, STE F-810
FREMONT, CA 94538
(510) 794-3900
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DISASTER PREPAREDNESS

May 13, 2010

Dr. Kenneth H. Schell, President
California Board of Pharmacy
1625 N. Market Boulevard, Suite N 219
Sacramento, CA 95834

Dear Dr. Schell:

I wish to share my concerns with the revised prescription labeling regulations currently before the California Board of Pharmacy.

With the proposed regulations, the Board has ignored the overwhelming response from consumers, health advocates and experts for comprehensive patient-centered prescription labeling in California. The latest proposal by the Board fails to protect California's most vulnerable populations.

Font Size

At the hearings required by Senate Bill 472, experts and advocates were clear that 12 point font is the minimum size necessary to protect seniors and visually impaired consumers. The Board recognizes that it is feasible to use 12 point font on labels, but leaves it up to those who are the most vulnerable to request larger font. If the Board is truly interested in protecting vulnerable consumers, 12 point type should be the standard.

Language Assistance

A regulation requiring pharmacies to provide interpretive services in a patient's language when interpretive services "are available" effectively allows pharmacies to provide no oral translations or written assistance to consumers with limited English proficiency. This regulation creates a loophole that will lead to dosing errors.

Dr. Kenneth H. Schell, President

May 13, 2010

Page two

SB 472 was introduced to address the very serious problem of patient dosing errors, which studies prove to cause death and injury. The bill placed trust in the Board of Pharmacy to stand up for consumers. It appears to me that the Board has not been up to the task and has not only failed at protecting Californians but may be leading California and the nation in a large step backwards.

Experts point to the fact that there are nearly 1.5 million medication errors a year. Industry advocates argue that larger font requires larger labels and the influx of type will be confusing. Providing font too small to read or illegible to seniors and people with language barriers is a greater risk to consumers. That argument is not supported by fact. Industry also argues that they will have to use larger pill bottles which come at a cost. Any cost associated with larger type size is a small price to pay if it saves lives.

Following the hearings and subsequent questionnaire, staff proposed regulations that included a minimum 12 point font for prescription labeling, as well as comprehensive oral and written assistance for those with language barriers. Again, I call on the Board to adopt regulations that embrace these sensible proposals.

According to Board documents, the Board received 1,161 letters during the last public comment period. 1,159 letters were in opposition to the last proposal.

SB 472 called on the Board to set a national example in the area of patient-centered labeling. What followed was a series of proposals that do not go far enough to address the serious problem of medical errors and misdosing. It appears that the Board has given greater weight to industry wishes.

I deeply regret that the Board has not reached a conclusion that I can support. I am very disappointed that the spirit of the law established by SB 472 has not been followed. I will continue to work with my colleagues in the California State Legislature to explore options to achieve real patient-centered labeling in California.

I look forward to reviewing the Board's Final Statement of Reasons, including its response to all comments about this proposed revised regulation, as required by Government Code section 11346.9.

Sincerely,



ELLEN M. CORBETT
Senator, District 10

EMC:av

Attachment B

Possible Language for Future Rulemakings

**Possible Text For
Notice to Consumers Re:
Language Assistance Interpretive Services
Provided in Pharmacies and
“Point To Your Language” Statement
At the Pharmacy Counter**

**Possible Text For
Notice to Consumers Re:
Availability to Request Prescription
Container Labels in Larger Font Sizes**

Potential Regulatory Proposal(s) re Pharmacy Notice(s)

Amend 16 CCR § 1707.2 – Strike subdivisions (f) and (g)

Add 1707.6. Posted Notices Required in Pharmacies

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, notices containing the text in subdivisions (b), (c), (d), and (e). The board has previously developed and distributed standardized posters for the notices that are required by subdivisions (b) and (c). The board shall similarly develop a standardized poster for the notice required by subdivision (d). For the notices required by subdivisions (b), (c), and (d), the pharmacy shall display the poster developed by the board, or a full-color duplicate thereof.

As an alternative to printed notices, the pharmacy may display one or more required notices on a video screen located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, where the video screen display meets the following requirements:

- (1) The video screen is at least 30 inches, measured diagonally;
- (2) The text and format of the notice(s) is the same as it would be in printed form, including the size of the notice(s), the size of the text, and the colors utilized;
- (3) The text of the notice(s) remains on the screen for a minimum of 30 seconds;
- (4) Where the entire text of a notice does not fit onto a single screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least 30 seconds; and
- (5) No more than four minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

(b) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?

How and when do I take it - and for how long? What if I miss a dose?

What are the possible side effects and what should I do if they occur?

Will the new medicine work safely with other medicines and herbal supplements I am taking?

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

(c) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy,
2. The pharmacist, based upon his or her professional judgment determines providing the item:

- is against the law.
- could cause harmful drug interaction, or
- could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

(d) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

The container label for your prescription medication contains vital information. Please take a moment to check the container label before you leave the pharmacy to be sure that:

The container label has the correct patient name;

The container label has the correct medication name and strength;

The container label has the correct directions for use; and

The container label includes the purpose or condition for which the medication was prescribed, if that information was included in the prescription.

All of these four categories of information must be clustered into one area of the label, and must appear on the label, in the order given above, in at least a 10 point font.

If you would like the text on your container label to be larger, please ask. Upon request, the pharmacy will print a label with the text for these four categories of information in at least a 12-point font. This may result in use of a larger label and/or a larger container.

If you have questions about any of the information on the label, ask the pharmacist.

(e) There shall be a notice containing the following text, repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice:

NOTICE TO CONSUMERS

It is very important that you understand the information on the container label for your prescription medication. If you have trouble reading or understanding English, this pharmacy will make interpretive services available to you in your own language.

(f) The pharmacy shall also post or provide the following statement, repeated in English and in each of the languages for which interpretive services are available, written in at least an 18-point boldface type in a color that sharply contrasts with the background color of the statement, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This statement, repeated in all available languages, may be made available by posted notice or by video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance.

If the posted notice or video screen is not positioned so that a consumer can easily point to and touch the notice or video screen, the statement, repeated in all available languages, shall be made available on a cardstock flyer or handout kept within reach of consumers at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Such flyer/handout shall be at least 8 inches by 11 inches, on at least 8 point cardstock, which may be laminated. At least one copy of the flyer/handout shall be available at all hours that the pharmacy is open.

Existing 1707.2.

§ 1707.2. ~~Notice to Consumers and Duty to Consult.~~

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

Possible Changes To Reflect Reorganization of Consumer Notices to New Section of Title 16

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

Possible Changes To Reflect Reorganization of Consumer Notices to New Section of Title 16

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

~~(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~“NOTICE TO CONSUMERS”~~

~~At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.~~

~~Ask your pharmacist if a lower cost generic drug is available to fill your prescription.~~

~~Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.~~

~~Before taking any prescription medicine, talk to your pharmacist; be sure you know:~~

~~What is the name of the medicine and what does it do?~~

Possible Changes To Reflect Reorganization of Consumer Notices to New Section of Title 16

~~How and when do I take it – and for how long? What if I miss a dose?~~

~~What are the possible side effects and what should I do if they occur?~~

~~Will the new medicine work safely with other medicines and herbal supplements I am taking?~~

~~What foods, drinks or activities should I avoid while taking this medicine?~~

~~Ask your pharmacist if you have additional questions.~~

~~(g) In addition to the “NOTICE TO CONSUMERS” referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~Know your rights under California law concerning medicine and devices prescribed to you.~~

~~You have the right to receive medicine and devices legally prescribed to you, unless:~~

- ~~1. The medicine or device is not in stock in the pharmacy,~~
- ~~2. The pharmacist, based upon his or her professional judgment determines providing the item:~~
 - ~~• is against the law,~~
 - ~~• could cause harmful drug interaction, or~~
 - ~~• could have a harmful effect on your health~~

Possible Changes To Reflect Reorganization of Consumer Notices to New Section of Title 16

~~This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.~~

~~The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.~~

~~If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.~~

~~Any questions? Ask the pharmacist!~~

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: ~~Sections 733, Section~~ Section 4005 and 4122, Business and Professions Code.



CONSUMER PROTECTION ENFORCEMENT INITIATIVE

"A Systematic Solution to a Systemic Problem"

The Department of Consumer Affairs (DCA) is the umbrella agency that oversees 19 healing arts boards that protect and serve California consumers. The healing arts boards regulate a variety of professions from doctors and nurses to physical therapists and optometrists. These licensees are some of the best in the country and provide excellent care to Californians on a daily basis. However, when a licensee violates the laws that govern his or her profession, enforcement action must be taken to protect the public.

In recent years some of DCA's healing arts boards have been unable to investigate and prosecute consumer complaints in a timely manner. In fact, some boards take an average of three years to investigate and prosecute these cases; this is an unacceptable timeframe that could put consumers' safety at risk.

DCA reviewed the existing enforcement process and found systemic problems that limit the boards' abilities to investigate and act on these cases in a timely manner. These problems range from legal and procedural challenges to inadequate resources. In response, DCA launched the Consumer Protection Enforcement Initiative (CPEI) to overhaul the enforcement process at the healing arts boards. The CPEI is a systematic approach designed to address three specific areas:

- Administrative Improvements
- Staffing and IT Resources
- Legislative Changes

Once fully implemented, DCA expects the healing arts boards to reduce the average enforcement completion timeline from 36 months to between 12 and 18 months.

I. Administrative Improvements

During the review of the enforcement process, DCA worked with the boards to identify areas that could be improved administratively to better coordinate broad enforcement objectives, improve the services provided to the healing arts boards, and establish streamlined enforcement processes and procedures that can be used by all boards. The following are some of the efforts that emerged from those discussions:

“365 Project”

DCA's Division of Investigation (DOI) embarked on a project in 2009 to strategically focus on cases that were one year or older. DOI worked closely with boards to identify the cases upon which they should focus their resources. This project has produced impressive results, and in 2009 the DOI closed 50% more cases than the comparable period in 2008.

Delegation of Subpoena Authority

One of the initial administrative changes implemented by DCA was delegating subpoena authority to each executive officer as a tool to gather evidence and interview witnesses. DCA's Legal Office conducted subpoena training for board staff, and this authority has started being exercised by boards. We expect to see increased use of subpoenas as a result of this change, and boards will be able to pursue cases that they otherwise would not have pursued.

Process Improvement

DCA and the boards are working to identify best practices for a number of enforcement processes and procedures, such as complaint intake, handling of anonymous complaints, vote by email protocols, and adjudication procedures. This effort will take advantage of the most effective practices utilized by the various boards, and entities in other states, and will ultimately shave time off all aspects of the enforcement process.

Enforcement Academy

DCA's Strategic Organization, Leadership, & Individual Development Division is developing enhanced training programs for enforcement staff. The enforcement academy will teach investigators and other enforcement staff key skills used in complaint intake, investigation procedures, case management, database use, and other areas. Never before has DCA offered such a comprehensive enforcement training program. An initial training was offered in November 2009, and the full enforcement academy will begin its regular cycle in April 2010.

Deputy Director for Enforcement and Compliance

DCA established an executive level position that reports to the Director and is responsible for regularly examining each board's enforcement program to monitor enforcement performance and compliance with all applicable requirements. This position monitors performance measures so that boards' enforcement programs can be continuously assessed for improvement.

Performance Expectations with Other Agencies

DCA has been working with the Attorney General's Office and the Office of Administrative Hearings (OAH) to establish performance agreements that will expedite the prosecution of cases. DCA and the AG's Office are developing expectations for filing accusations, setting settlement conferences, and filing continuance requests. Further, DCA is working with OAH to establish timelines for setting cases for hearings, which, once implemented, could reduce a case timeline by months.

II. Enhancing Enforcement Resources

There are 36 licensing entities under the DCA (of which are 19 healing arts boards) and, with a few exceptions, all of these programs share the resources of the Department, from Division of Investigations (DOI), to Personnel to IT Support. While the healing arts boards fall under the umbrella of DCA they are separate semi-autonomous groups overseen by board members appointed by the Governor and the Legislature. Additionally, all of the licensing entities under DCA are special fund agencies funded exclusively through fees collected through licensees with no general fund support.

Enforcement Staff

DCA's review of the enforcement process identified a need for more focused staff resources in the areas of investigations and complaint intake. The majority of DCA's licensing entities share the resources of DCA's overburdened DOI. Annually, DOI's 48 investigative staff members receive over 1,300 cases, in topics ranging from nurses to repossessioners to smog check stations. Having so many investigations performed by DOI has resulted in a number of problems, including loss of control over the investigation by the boards, a lack of investigators with expertise in specific licensing areas, and excessive caseloads. These problems have led to excessive turn-around times and growing backlogs. Through the 365 Project, the DOI has worked with boards to reduce the case backlog, but the current structure has revealed a need for more significant changes.

In order to increase accountability in the investigative process, DCA is working to provide boards with the authority to hire non-sworn investigators to be housed within each board. This will enhance boards' control over investigations, allow for more appropriate workload distribution, and enable investigators to develop expertise. Additionally, to coincide with process improvement efforts, some boards will increase complaint intake staff. DCA is seeking a total of approximately 140 new enforcement positions (full year equivalent) across all healing arts boards. The vast majority of these positions are investigators and investigative supervisors, and the remainder is mostly complaint intake staff. In addition to increasing staffing, DCA will ensure that staff are properly trained, monitored, and assessed so that cases are expedited as quickly as possible.

Because DCA's boards are special fund agencies, new positions will not place a drain on the General Fund and boards will pay for new staff with existing resources or with fee increases where necessary. The number of positions requested is a result of an individual assessment of each board, and assumes workload savings associated with DCA's current process improvement efforts. The Governor's Budget includes the initial phase-in of these positions beginning July 2010.

Create a New Licensing and Enforcement Database

DCA's current licensing and enforcement database systems are antiquated and impede the boards' ability to meet their program goals and objectives. Over the past 25 years, these systems have been updated and expanded, but system design and documentation have deteriorated to such an extent that it has left the systems unstable and difficult to maintain. These systems have inadequate performance measurement, data quality errors, an inability to quickly adapt to changing laws and regulations, and a lack of available public self-service options. The CPEI relies on advanced workflow capabilities and cross-entity external system communications that the aging system's technology cannot provide.

The implementation of a replacement system is needed to support enforcement monitoring, automate manual processes, streamline processes, and integrate information about licensees. DCA intends to procure a Modifiable Commercial Off-The-Shelf (or "MOTS") enterprise licensing and enforcement case management system. DCA's research has shown various MOTS licensing and enforcement systems exist that can provide intelligent case management to reduce enforcement and licensing turnaround times, detailed performance measurements, increased data quality, advanced configurability, and robust web presences for public self-service.

The Governor's Budget authorizes DCA to redirect existing funds to begin implementation of this system in FY 2010-11.

III. Statutory Changes: Putting Consumers First

Each board within DCA has a statutory mandate to hold consumer protection as its paramount objective. Over the years, boards' enforcement authorities have been slow to keep up with legal trends and changes in the professions regulated, and due process protections have grown to protect licensees above consumers. DCA believes that now is the time to re-align consumer protection laws so that they place public protection first. In 2010, the DCA will pursue legislation to help boards carry out their critical missions of protecting consumers.

Increased Suspension Authority

One of the most important roles that professional licensing boards do to protect consumers is preventing potentially dangerous individuals from practicing. The CPEI would strengthen the boards' ability to do this in a number of ways, including authorizing the DCA Director to issue an order for a licensee to cease practice or restrict practice, upon the request of a board executive officer. This authority is necessary in the most egregious cases because the standard enforcement process can take a year to complete, at best, and even the expedited process in existing law (interim suspension order) can take months to complete. This proposal would also seek the statutory authority to revoke or deny a license to an individual for acts of sexual misconduct with a patient or conviction as a felony sex offender. Additionally, the CPEI would provide for the automatic suspension of convicted felons for the duration of their sentence.

Increased Access to Critical Information

The CPEI would make improvements to the information that boards receive, so they can investigate possible violations of law. Specifically, it would prohibit the use of a gag clause in a civil settlement that would prohibit consumers or their legal counsel from filing a complaint with the appropriate board. Regulatory gag clauses are explicitly prohibited in legal malpractice settlements and there have been numerous court decisions that describe a compelling public interest in voiding regulatory gag clauses in other professions. The Center for Public Interest Law notes that the inclusion of gag clauses is an alarmingly pervasive practice that thwarts the ability of boards to carry out their consumer protection mission. The CPEI would also require court officials to report to the healing arts boards convictions and felony charges filed against the boards' licensees, and expand reporting by employers and supervisors regarding individuals who were suspended or terminated for cause.

Adequate access to medical records can shave months off the process to investigate a licensee. Medical records are used by healing arts boards' to determine whether a licensee caused harm to a patient. Any delay in an investigation of a licensee may result in a potentially dangerous licensee continuing to practice. Thus, it is essential that healing arts boards have quick access to medical records. The CPEI gives all of the healing arts boards the authority to inspect and copy, as applicable, any documents and records relevant to an investigation. In cases where a licensee fails to cooperate with an investigation, the CPEI provides boards with additional authorities to ensure compliance.

Enforcement Process Efficiencies

DCA proposes to remove unnecessary workload and costs from the enforcement process. This can be done by streamlining the appeal process for citations, permitting boards to contract with collection agencies to retrieve unpaid fines and fees, authorizing executive officers to sign default decisions and certain stipulated settlements, and allowing licensees to agree to stipulated settlements before a formal accusation is filed. These are relatively small changes that could result in significant workload savings.

Efficiency and accountability will also be improved by establishing a deadline for the Department of Justice (DOJ) to notify healing arts boards of arrests and convictions of licensees, which would greatly improve the board's ability to pursue cases in a timely manner. Additionally, it requires DOJ to serve accusations, default decisions and set hearing dates within a specified period of time.

Licensing Fees

Lastly, DCA is seeking to tie the maximum licensing fee amounts to the Consumer Price Index to keep up with inflation and ensure the boards have the resources to adequately run their enforcement programs.

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/2007), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Neither the board nor an Administrative Law Judge may deviate from these guidelines if the decision findings include that the licensee engaged in any act of sexual abuse, misconduct, or relations with a patient, client or customer, or has been convicted of sexual misconduct, in which case the discipline must be revocation. The board may revoke the license of any licensee who is registered as a sex offender. This subdivision shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides care to his or her spouse or person in an equivalent domestic relationship.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Entering into any settlement containing a confidentiality clause that would prevent the board from receiving information or that would otherwise thwart the board's effort to investigate possible violations of law.

(b) Failure to comply with a request for records or subpoena issued by the board or other law enforcement agency.

(c) Failure of a licensee to identify himself or herself as a licensee of the board to law enforcement and the court upon being arrested or charged with a misdemeanor or felony.

(d) The commission of any act of sexual abuse, misconduct, or relations with a patient, client or customer. This subdivision shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides care to his or her spouse or person in an equivalent domestic relationship.

Authority cited: 4005, Business and Professions Code. Reference: Sections 4300 and 4301 Business and Professions Code.

§1769. Application Review and Criteria for Rehabilitation.

(a) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

(b) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

- (1) Nature and severity of the act(s) or offense(s).
- (2) Total criminal record.
- (3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

(c) As part of its review and investigation of any application for a facility or personal license, the board or its designee may order an applicant to be examined by a physician, psychiatrist, psychologist, or other licensed professional selected by the board or its designee, if it appears the applicant may be unable to safely practice due to physical or mental illness. Upon issuance of such order, the board shall not issue the license until evidence is received demonstrating the applicant's ability to safely practice . Failure to comply with such order will result in denial of the application.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

§1770. Substantial Relationship Criteria.

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

(b) The board shall deny a license to an applicant who is registered as a sex offender.

Authority cited: Sections 481, 4005, Business and Professions Code. Reference: Sections 4300, 4309 and 4301, Business and Professions Code.



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

June 3, 2010

To: Board Members

From: Virginia Herold
Executive Officer

Subject: Agenda Item IV: Discussion Regarding Cost Recovery in Disciplinary Cases

Over the last year, several board members have asked for a discussion of why not full cost recovery is not obtained in every disciplinary action the board takes. During this meeting, the board will have an opportunity to discuss the subject of cost recovery in a general sense.

California Business and Professions Code section provides the authority for cost recovery:

125.3. (a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licentiate to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of

payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licentiate who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licentiate who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

(k) Notwithstanding the provisions of this section, the Medical Board of California shall not request nor obtain from a physician and surgeon, investigation and prosecution costs for a disciplinary proceeding against the licentiate. The board shall ensure that this subdivision is revenue neutral with regard to it and that any loss of revenue or increase in costs resulting from this subdivision is offset by an increase in the amount of the initial license fee and the biennial renewal fee, as provided in subdivision (e) of Section 2435.