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Senate  
California Legislature

ELLEN M. CORBETT

SENATOR

TENTH SENATE DISTRICT



STANDING COMMITTEES:  
CHAIR, JUDICIARY  
APPROPRIATIONS  
BUSINESS, PROFESSIONS &  
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LEGISLATIVE ETHICS

SELECT COMMITTEES:  
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CHAIR, EARTHQUAKE &  
DISASTER PREPAREDNESS

RECEIVED BY CLERK  
BOARD OF PHARMACY  
2010 MAR 12 AM 9:12

March 10, 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 prescription labeling proposal currently before the California Board of Pharmacy (Board).

In 2007, the Governor signed my Senate Bill 472, authorizing the Board to establish standards for patient-centered prescription drug labeling in California. The purpose of patient-centered labeling is to protect California's seniors and vulnerable populations from taking incorrect dosages caused by an inability to read and understand prescription drug labels. During the Board's public hearing process, witness after witness testified about their inability to read a prescription label due to font size or language barriers.

SB 472 directs the Board to consider all of the following factors when developing a new patient centered label:

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

SB 472 was introduced to address the very serious problem of patient dosing errors, which studies have concluded can lead to death and injury. At the request of the Board, the bill was amended to require public hearings. At the hearings the Board heard public testimony from consumers, advocates and experts.



Dr. Kenneth H. Schell, President  
March 10, 2010  
Page two

Taking into account the information that was gathered at the hearings, Board staff recommended, and the Board adopted, a proposal that included 12 point label font and increased assistance for patients who have language barriers. This proposal is supported by a recent report by the National Association of Boards of Pharmacy acknowledging 12 point font as an industry standard.

Therefore, it was troubling when the Board recently rejected the initial patient-centered proposal and accepted new proposed regulations supported by industry. The current proposal before the Board lack sufficient consumer protects by removes meaningful assistance for people with language barriers and adopts smaller font size, which studies show seniors have difficulty reading. By doing this the Board rejected the will of the people and the testimony of experts. Not only does this proposal lead California in the wrong direction, but it sets a standard that puts industry before consumers.

The current proposal, which will be voted on in April, flies in face of our good faith agreement to use the facts gathered at public hearings to guide the Board's decision and violates the spirit of SB 472. I urge the Board to join experts, patient advocates, consumers and the National Association of Boards of Pharmacy by rejecting the current labeling proposal before you. I encourage the Board to revisit the original proposal that contained real reform and true patient-centered labeling.

70ppx  
all  
modified  
text

Should you have any questions or if I may otherwise be of assistance, please do not hesitate to contact me.

Sincerely,

  
ELLEN M. CORBETT  
Senator, District 10

EMC:av



March 8, 2010

President Kenneth Schell  
California State Board of Pharmacy  
1625 N. Market Blvd., Suite N-219  
Sacramento, CA 95834

RE: Proposed Title 16 CCR Section 1707.5 Patient-Centered Prescription Labels

Dear President Schell:

I am writing in response to the Board of Pharmacy's decision to adopt regulations pursuant to Division 17 of Title 16 of the California Code of Regulations, Section 1707.5, regarding requirements for patient-centered prescription container labels. The Department of Consumer Affairs is opposed to the 10-point sans serif type minimum font requirement on prescription container labels and encourages the Board to reconsider the original draft regulation language that specifies the minimum font size at 12-point sans serif type.

} @ (1)  
12 pt

The number one priority of the Department is to protect the health and safety of California consumers. We believe that a minimum standard of 10-point font is inadequate. Based on the testimony received at the public hearing, the Department is especially concerned with the safety of seniors throughout the State. Many seniors have expressed their opposition to a minimum 10-point font standard because they cannot read print in 10-point font.

Approximately 750 Californians (including seniors and non-English speaking consumers) participated in a Board of Pharmacy study with open-ended questions regarding prescription labels. When asked what would make prescription labels easier to read, 60% of respondents said larger or bolder print. In addition, The National Association of Boards of Pharmacy's (NABP) Task Force on Uniform Prescription Labeling found that the model requirement would be a minimum 12-point font for critical information.

Senate Bill 472 (Corbett, Chapter 470, Statutes of 2007) called for the Board to establish standards for patient-centered prescription drug labeling in California in an effort to reduce medication errors. The Department is concerned that a 10-point font requirement does not meet the needs of patients and urges the Board to reverse its decision establishing 10-point font as the minimum standard for prescription labeling. Thank you for your consideration.

Sincerely,

Brian Stiger  
Director, California Department of Consumer Affairs

cc: Virginia Herold, Executive Officer, California State Board of Pharmacy  
Carolyn Klein, Coordinator, Legislation and Regulations, Board of Pharmacy  
Members of the California State Board of Pharmacy  
Thomas L. Sheehy, Acting Secretary, State and Consumer Services Agency



March 9, 2010

Kenneth H. Schell, PharmD, President  
California Board of Pharmacy  
Attn: Carolyn Klein  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

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

Dear Dr. Schell and Members of the California Board of Pharmacy:

I am writing to you on behalf of the members of Health Access California, a statewide coalition representing consumers, seniors, people with disabilities, religious, labor, and multi-lingual/multi-cultural groups.

We are exceedingly disappointed with the most recent actions taken by the Board to approve regulatory language that includes watered-down language that does not provide the essential consumer protections stipulated in SB 472, The California Patient Medication Safety Act (Corbett, D-San Leandro). Specifically, we request the Board to:

- reinstate the proposed regulatory language under consideration up until January 19, 2010 that contained specific patient-centered provisions regarding language accessibility and font size as required by the law and reinforced by public testimony and academic research, and
- reconvene a new public discussion of the regulatory language before the Board, prior to their vote, to provide a full opportunity for public comment in accordance with established notice and comment rules under the APA, and
- conduct a new Board discussion and subsequent vote regarding the adoption of previously proposed January 19, 2010 regulatory language.

*oppose  
all  
modification*

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. This landmark legislation requires that the regulation outline requirements for drug labeling that take into account consumers' needs, particularly those of seniors and people with little medical literacy and/or limited English proficiency.

We note that SB 472 underwent four revisions in the Senate and two in the Assembly before being signed into law. These revisions were largely to accommodate objections raised by the industry. During the process that lasted more than a year, we believe the staff of the Board of Pharmacy did an excellent job researching the issues at hand, holding public hearings, conducting surveys, and incorporating research results into the original draft regulation.

However, the Board's preliminary vote on January 20, 2010 adopted language that neither corresponded with the statute, nor was in keeping with the research, public hearing testimony, or survey results. 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.

Our specific objections are as follows:

- 1. The Board's action is not consistent with the underlying statute.**  
The most recent version of the regulatory language does not comply with the language of SB 472. While the Board's staff undertook to summarize available research and solicit opinions from consumers, this information was not ultimately incorporated into the regulatory language that the Board adopted.

The industry asserted that the cost of the law was too expensive and too cumbersome to implement. They never were called upon to make a case for how the patient-centered labels could be achieved from an industry perspective.

Consumers and researchers argued in favor of language translations and larger font size for certain key elements on the label. However, this testimony from consumers and academics was not included in the regulatory language.

The close vote by the Board relied exclusively on the industry's testimony and was influenced most significantly by the statements of the representatives from the industry who are members of the Board, including the industry representative appointed to the Board by the Governor on the day before the meeting.

In addition, Health Access over the last two decades has appeared at public hearings before various state agencies to argue in favor of specific consumer provisions in regulatory language. However, we have never participated in a public hearing where the legislator who was the author of the bill both provided written testimony and sent a

member of her staff to provide public testimony on her behalf to the Board to urge them to adopt language consistent with the statute. In this case, Senator Corbett did both, presumably because she was not confident that the Board would adopt language that was congruent with her bill. However, her recommendations regarding specific provisions contained in her bill were not included in the regulatory language adopted by the Board.

§11349 (d) establishes that **“consistency’ means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”** It is further explained that **“this situation does not present a Consistency problem so long as the tasks specified in the regulation are reasonably designed to aid a statutory objective, do not conflict with or contradict (or alter, amend, enlarge, or restrict) any statutory provision.”**

We believe this regulatory language does not meet that consistency standard. The statute requires the implementing regulation to take into account the needs of seniors, people with low health literacy, and low English proficiency. However, the arguments put forward by the industry that this law was too inconvenient and too expensive prevailed before the Board. For all intents and purposes, consumer provisions stipulated in the statute, although part of the original regulation, were not incorporated into the final regulatory language in any meaningful way.

**2. 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.

The unfolding of subsequent events raises further concerns. The Board apparently realized the fact that there was insufficient advance notice of the changes to the language before the January 20, 2010 hearing. As a result, the Board scheduled another meeting on February 17, 2010. There was only a brief discussion of the regulatory language at that meeting before another vote was taken. This vote affirmed their previous vote by adopting the pro-industry language. However, there was no opportunity for public comment before the second Board's vote. As a result, once again, the Board was not able to hear any input from many members of the public assembled at the hearing before they made their decision about the regulatory language. Although the Board did permit public comment after their vote, they did not permit any comments from those at the hearing before they took their vote.

In essence, the Board made at least three procedural errors:

- They did not give sufficient notice of revised regulatory language to the public to meet either the 15-day or 45-day requirement, and
- They scheduled a subsequent vote, but permitted no public comment whatsoever prior to their vote, and
- Board staff acknowledged that several public comment letters had inadvertently not been furnished to Board members prior to their previous vote. Although the staff had since provided those materials to the Board, what had been omitted, the identity of who was making the comments, and the nature of those comments was not communicated to the public.

Consequently, we believe the adoption of the regulatory language as drafted is flawed and the Board's vote is invalid. We believe the regulatory process at the Board of Pharmacy should be re-started with a full and complete review of the intent of the statute, the relevant research, with full consideration of the public testimony offered. We believe this will result in regulatory language being adopted that will more closely adhere to the statutory intent and contain strong consumer protections.

We believe the original draft language 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 printed in 12-point font or larger.

(a) (1)  
12 pt

Notice to  
Consumers

- The Board should provide pharmacies with standard label language in at least the 14 threshold languages delineated for language assistance in California based on population size.
- All patients with limited English proficiency should have the right to have their prescription drug instructions orally interpreted by a health professional working within his or her field of clinical expertise. (d) no recommendation
- Pharmacies should post signs explaining the availability of interpretation services of the pharmacists' instructions in languages other than English. We strongly believe that few people take advantage of their rights under the law if they are unaware that such rights exist.

The prevalence of medical prescription errors and the lack of public comprehension of prescription labels provide a compelling and urgent rationale for this regulation. 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 believe that standardized, readable, language-accessible, prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. We strongly believe that language providing these consumer protections according to the law should be adopted at the next Board meeting in April or as soon thereafter as possible to correct the procedural errors that occurred.

If you have any questions or need more information, please contact Elizabeth Abbott, Project Director at Health Access, at (916) 497-0923, ext. 201 or at [eabbott@health-access.org](mailto:eabbott@health-access.org).

Sincerely,

/s/

Anthony Wright  
Executive Director  
Health Access  
1127 11<sup>th</sup> Street, Suite 234  
Sacramento, CA 95814

cc: Senator Ellen Corbett, author  
Senator Elaine Alquist (D-Santa Clara), Chair, Senate Health  
Senator Denise Ducheny (D-San Diego), Chair, Senate Budget  
Senator Negrete-McLeod (D-Chino), Chair, Senate Business, Professions, &  
Economic Development  
Assemblymember David Jones (D-Sacramento), Chair, Assembly Health

Assemblymember Noreen Evans (D-Santa Rosa), Chair, Assembly Budget  
Assemblymember Mary Hayashi (D-Hayward), Chair, Assembly Business &  
Professions  
Bill Leonard, Secretary, State and Consumer Services Agency

15-day



*Assisting public members and the health professional oversight bodies on which they serve*

RECEIVED BY STAFF  
BOARD OF PHARMACY  
2010 MAR 16 PM 4:00

March 10, 2010

Virginia Herold  
Executive Officer  
California Board of Pharmacy  
1625 N Market Blvd.  
Suite N-219  
Sacramento, CA 95834

Re: Section 1707.5 Patient Centered-Labels on Medication Containers  
Opposition to February 17, 2010, Revised Regulation

Dear Ms. Herold,

Consumer Action and the Citizen Advocacy Center write to oppose the revision to the above-referenced rule as approved by the Board of Pharmacy on February 17, 2010.

Consumer Action is a non-profit, membership-based organization that was founded in San Francisco in 1971. During its more than three decades, Consumer Action has continued to serve consumers nationwide by advancing consumer rights, referring consumers to complaint-handling agencies through our free hotline, publishing educational materials in Chinese, English, Korean, Spanish, Vietnamese, and other languages, advocating for consumers in the media and before lawmakers. Our website is [www.consumer-action-org](http://www.consumer-action-org).

The Citizen Advocacy Center (CAC) is a unique support program for the thousands of public members serving on health care regulatory, credentialing, oversight and governing bodies as representatives of the consumer interest. These citizen representatives are typically in the minority and are usually without the resources and technical support available to their counterparts from professional and business communities. CAC is a not-for-profit 501(c)(3) organization created to serve the public interest by providing research, training, technical support, and networking opportunities to help citizen representatives make their contributions informed, effective, and significant. Our website is [www.cacenter.org](http://www.cacenter.org).

Both of our organizations are particularly opposed to two changes contained in the February 17, 2010 revised regulations. First, the revision changes the font size on labels from 12-point to 10-point, which is more difficult to read.

oppose  
modified  
(a)(1)

Second, and more importantly, the proposed revision changes the language in section (d) that originally read:

}  
(d)

*(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.*

The revision replaces that language with:

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

In effect, the proposed revision makes oral translation in the language of the patient for persons with limited English proficiency optional. The words "if interpretive services in such language are available" create such a huge loophole that the revision might just as well have deleted section (d) altogether – the result is likely to be the same.

{  
(d)

On page three of its "initial statement of reason," the Board of Pharmacy explained the rationale for the original proposed regulation:

*In exercising its authority over the practice of pharmacy in the state of California, the board believes that this proposed regulation is necessary to implement Section 4076.5. By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California (Subsections (1), (d) of proposed Section 1707.5.)*

ISOR

The board had it right the first time, and nothing in the intervening few weeks between the time those words were written and the time the revised language was proposed has changed that. We appreciate that the board is responsible for weighing the cost concerns of the industry – in this case, the cost concerns of the chain drug stores – with the public's need to understand their prescriptions in order to reduce medication errors. In drafting the original regulation, the Board of Pharmacy heard from the industry, but wisely decided that making

available oral translation for persons with limited English proficiency was important enough to outweigh the industry's cost concerns.

We urge the board to return to the original regulation. If further justification is needed, the board should make a concerted effort to go into the communities where people with limited English proficiency live and hold well-publicized town hall meetings seeking input from those people and from the organizations that represent them. The opportunity for formal public comment by community groups is not enough. As the board well knows, industry input into this (and all other) rulemakings far outweighs comment from citizens and citizen groups. Informal town meetings are not a replacement for public comment under law, but in this case meeting with the affected communities would help the board arrive at the appropriate balance between the cost concerns of the industry with the needs of the citizenry. Meeting the needs of the public is after all the reason for the enactment of the legislation that led to this rule making.

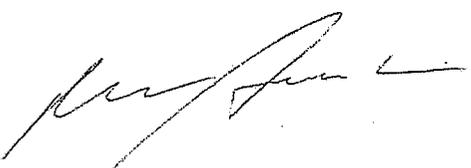
oppose all modifications

Thank you for the opportunity to submit these comments.

Sincerely,

***Ken McEldowney***

by S.P.



Ken McEldowney  
Executive Director  
CONSUMER ACTION  
221 Main Street  
Suite 480  
San Francisco, CA 94105  
415-777-9648 x304  
[ken.mceldowney@consumer-action.org](mailto:ken.mceldowney@consumer-action.org)

David Swankin  
President and CEO  
CITIZEN ADVOCACY CENTER  
1400 Sixteenth Street NW  
Suite 101  
Washington, DC 20036  
202-462-1174  
[davidswankin@cacenter.org](mailto:davidswankin@cacenter.org)

March 6, 2010

RECEIVED BY CALIF.  
BOARD OF PHARMACY

2010 MAR 15 AM 10:46

From:  
Trang T. Nguyen  
1009 Cypress Lane  
Davis, CA 95616

To:  
Carolyn Klein, Coordinator  
Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd. N 219  
Sacramento, CA 95834  
E-mail: [carolyn\\_klein@dca.ca.gov](mailto:carolyn_klein@dca.ca.gov)  
Telephone No.: (916) 574-7913  
Fax No.: (916) 574-8618

*General  
Statement  
Lang. assistance*

I am writing on behalf of California Communities United Institute as well as an advocate for drug label language assistance.

In 2007 the state legislature passed SB 472, which requires that medication container labels become more patient centered. As a result, the State Board of Pharmacy considered regulations that would establish the size and type of font to be used on the labels along with a standardized set of instructions to be used on those labels. By this, patients will be able to safely take his or her medications labeled in an understandable language.

Recently my grandfather received the wrong prescription drug from his local pharmacy that is managed by Vietnamese pharmacists and staff. No one informed him at the pharmacy that they had given him the wrong drug, an antibiotic. It was not until my aunt looked over his prescriptions two days later and notified the pharmacy about their mistake. Not only should drug labels be clearly written in his or her own preferred language, but also verbally instructed to prevent errors in prescription drug distribution.

Please enforce pharmacies and/or health institutions that distribute prescriptions to have drug labels language assistance available on the medicine bottle and/or access to a third party interpretive service. In addition, to further protect consumers, pharmacy staff should also verbally inform patients on what type of drugs they are prescribed and how to take those drugs.

Sincerely,

  
Trang T. Nguyen



3-9-2010

Please honor the

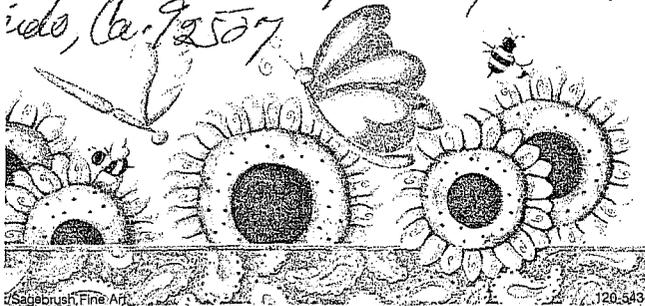
less than pre  
scription font size  
& is very difficult  
to read

Thanks

Sincerely

Isabella Gibbs  
-Blain St. 957-684-7239  
Indo, Ca. 92507

2010 MAR 17 AM 10:04  
FEDERAL BUREAU OF INVESTIGATION  
DEPARTMENT OF PHARMACY



Tom Kosakowski

RECEIVED BY CALIF.  
BOARD OF PHARMACY

**Facsimile**  
(retransmittal)  
2010 FEB 24 AM 9:45

*general  
comments  
font size*

**To: California State Pharmacy Board**

Fax: (916) 574-8618

From: Tom Kosakowski

Phone: 626-796-4911

Date: ~~Saturday, February 20, 2010~~ Tuesday, February 23, 2010

Total pages including cover: 1

*translations*

Re: Requirements for prescription drug labels

Dear Board Members

It makes no sense at all to me that seniors, who comprise the largest consumer segment of prescriptions, are supplied with drug literature in the smallest point font possible, or what appears to be the smallest. Even with glasses, I have problems reading such small fonts.

Also, I have been pleasantly surprised that pharmacists are very well qualified to talk about drug interactions, side effects, and other matters regarding prescription drugs. Frequently, they are far more knowledgeable than doctors are. The information that pharmacists can provide can be extremely helpful to patients.

To summarize, I support efforts to provide prescription drug information in larger font sizes, and I support efforts to provide such information translated into other languages, by whatever mechanism is feasible.

Regards,



Thomas J Kosakowski  
152 Annandale Road  
Pasadena, CA 91105

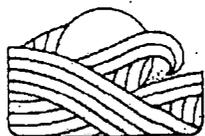
RECEIVED BY CALIF  
BOARD OF PHARMACY

2010 MAR -8 AM 8:42

*General  
Comments*

*font  
translation  
was long*

1145 Wilshire Blvd., Second Floor  
Los Angeles, CA 90017  
(213) 977-7500 • Fax (213) 977-7595  
www.apalc.org



**ASIAN PACIFIC  
AMERICAN  
LEGAL CENTER**  
OF  
SOUTHERN CALIFORNIA

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

Via Fax: (916) 574-8618

**Re: Concern for Provisions of SB 472 Draft Regulations**

Dear Ms. Klein:

The Asian Pacific American Legal Center (APALC) is the largest organization in Southern California providing legal services, community education and civil rights advocacy on behalf of Asians and Pacific Islanders (APIs). As such, APALC is concerned about the revisions the Board of Pharmacy approved on February 17th to the draft regulations required by SB 472, outlining improvements to prescription drug labels. In particular, APALC is concerned about the changes made to font size, translation of labels and the availability of oral interpretations for limited English proficient patients.

Asian American and Pacific Islander communities living in Southern California face alarming rates of limited English proficiency (LEP), meaning they speak English less than 'very well'. In fact, a report APALC released in 2007 identified that 43% of the API community living in Los Angeles County is LEP<sup>1</sup>. Translated labels are essential for our communities to understand how to take their medication effectively and safely, and pharmacies should be required to use the translated labels provided by the Board or develop their own translations. In addition, 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.

Without translated labels, patients whose primary language is not English will not be able to read instructions on how to take their medication, leaving them vulnerable to ingesting incorrect dosages that could be seriously harmful and in some cases lethal. We urge the Board of Pharmacy to reconsider these regulations and to strengthen the provisions requiring label translations and oral interpretations.

Sincerely,

Sara D. Sathwani  
Immigrant Rights Project Director

<sup>1</sup> LA Speaks: Language Diversity and English Proficiency by Los Angeles County Service Planning Area. Asian Pacific American Legal Center of Southern California. 2007 Available: <http://demographics.apalc.org/wp-content/uploads/2008/03/la-speaks-final-031908.pdf>

Mary P. Magill

654 East L. St.

Benicia, Ca. 94510-3513

Mar. 2, 2010

Re: Jan. 20th hearing and the Feb. 17 hearing

RECEIVED BY CALIF.  
BOARD OF PHARMACY  
2010 MAR -4 PM 4:37

*no recommendation(s)  
general comments  
font size  
language*

Dear President Schell and Members of the Board of Pharmacy,

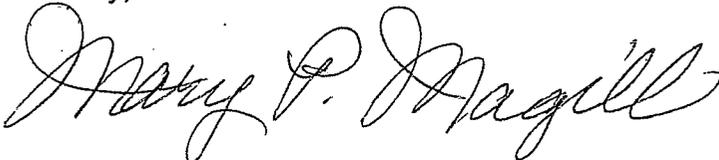
I am writing this letter to protest the decisions you have made and the manner in which you came to those decisions. To vote before any testimony was given really puts into question your role as a public agency..

Those of us that had come long distances were so insulted by the very manner in which you conduct your public hearing. You are given expert testimony in January and have it repeated to you from one of your own board members that 12 point font is the bare minimum that could possibly save the lives of the 300,000 over 75 whose lives are put at risk by unreadable prescription labels. In spite of all this, you vote to require 10 point font a still unreadable font size. WHAT A TRAVESTY! And then to give native language no consideration, as though it were some kind of big effort to ask a computer to print in other than English. A push of a button for the pharmacy, life and death for the patient.

*} 12 pt  
comment*

I speak with many senior and community groups. I hope that you will reconsider your manner of fulfilling your duties to the public. You have a duty to hear them and to respond truthfully to their concerns. And that was not done on February 17th. We deserve better. You can do better!

Sincerely,



Mary Magill, CARA Action Team Leader

Feb 27, 2010

To Whom it may concern;

RECEIVED BY  
BOARD OF PHARMACY

2010 MAR 12 AM 8:19

I am appalled at the way you are treating the seniors of California.

You believe, you, can play God with our lives.

Seniors need Patient - Centered Rx Labels.

The pharmaceutical companies can afford to make the changes, they have the money! Their greed is costing human lives.

There is a television program on cable called American Greed.

The pharmaceutical companies should be on it.

I'm 60 years old, I've struggled all my life to get this far. Only to find that my coming golden years won't be golden. It's not my fault I'm a baby boomer. Talk to my parents!

Blair P. Ogg

**Board of  
Directors**

**March 10, 2010**

**Donn Ginoza, Chair**  
California Public  
Employment  
Relations Board

**Carolyn Klein**  
California Board of Pharmacy  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

**Byron Gross,**  
**Vice-Chair**  
Hooper, Lundy &  
Bookman

**Lola FitzPatrick,**  
**Treasurer**  
Consumer  
Representative

**Re: 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Drug Labels**

Dear Ms. Klein:

**Elisabeth Benjamin**  
Community Service  
Society of New York

On behalf of the National Health Law Program (NHeLP), I am submitting comments in response to the modified proposed regulations issued on February 22, 2010. NHeLP is a national public interest legal organization seeking to improve health care for America's low-income population, including people of color, women, children, the elderly and people with special needs, immigrants, and limited-English proficient (LEP) individuals

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**Procedural Defects**

As we have noted before, we believe that there are problematic procedural issues with the flawed regulatory process followed by the Board of Pharmacy (Board). First, there was a the lack of notice provided to the public -- less than fifteen (15) days -- when there was a substantial change from the prior text provided for the January 20<sup>th</sup> meeting. The revised language that was adopted by the Board at the January 20, 2010 meeting substantially changed the font size from 12 point to 10 point and changed the text regarding the language assistance provisions of the proposed regulations. There was little time to consider the proposed language recommending the change in font size from 12 point to 10 point and the changes requiring limited interpreter services rather than translation services for LEP patients. The proposed changes did not fall within the two exceptions allowed to avoid the additional 15 day public comment period. This is in violation of Cal. Gov't Code § 11346.8(c).<sup>1</sup>

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<sup>1</sup> The statute states that "[n]o state agency may adopt, amend, or repeal a regulation which has been changed from that which was originally made available to the public pursuant to § 11346.5, unless the change is (1) nonsubstantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. If a sufficiently related change is made, the full text of the resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made available to the public for at least 15 days before the agency adopts, amends, or repeals the resulting regulation. Any written comments received regarding the change must be responded to in the final statement of reasons required by Section 11346.9." Cal. Gov't Code § 11346.8(c).

Second, the public did not have an adequate opportunity to comment on the proposed changes shared with the public on the morning of January 20, 2010. The proposed language was not available until the morning of January 20<sup>th</sup> and merely placed in the back of the room, with no reference to its existence by the Board. Having seen the changes for the first time that day, most of the public did not see the revised text and did not have a chance to include comments on the proposed changes in our testimony. By the time many of us reviewed the changes, we had already testified and lost our opportunity to address the proposed language. So we could only sit and listen while the Board discussed proposed changes to the regulations without adequate public input. The Board subsequently voted for the changes on January 20, 2010 and reaffirmed the final vote on February 17, 2010. The Board refused to hold another public hearing and would only allow public comment after it voted on the proposed regulations at the February 20, 2010 meeting. Thus, the only time that we were allowed to speak was after their final vote at the end of the morning agenda. This violates Cal. Gov't Code § 11346.45, which requires those parties who would be affected by the proposed regulations to have an opportunity to participate in public discussions of the proposed regulations.

Finally, we were never informed that any member of the public could request additional time if comments were made that raises new issues concerning a proposed regulation if a member of the public needs more time to respond to the new issue before the agency takes final action, pursuant to Cal. Gov't Code §§ 11346.45(a) and 11346.8(a)&(c). We believe that the lack of time to review the revised text that was presented on the morning of the January 20<sup>th</sup> public hearing required at least another fifteen (15) day period for reconsideration, and arguably another 45 days since it was such a substantial change, and public input BEFORE the final Board vote accepting the modifications on February 17<sup>th</sup>. Therefore, the public was not allowed adequate time to respond and to fully address the substantial changes adopted by the Board. We are hereby requesting additional time and/or another public hearing to provide an opportunity for the public to properly respond to the changes adopted by the Board at its January 20<sup>th</sup> and February 17, 2010 meetings. Unless the additional time is provided for public comment, we recommend the rejection of the modified text of 16 California Code of Regulations § 1707.5 by the Office of Administrative Law.

### **Substantive Comments to the Modified Text**

As expressed in prior comments and testimony regarding the proposed regulations submitted on November 20, 2008, July 15, 2009, October 19, 2009, October 22, 2009, November 17, 2010, November 20, 2010, January 4, 2010, January 20, 2010 and February 17, 2010, we believe that SB 472 requires the Board to issue clearer and stronger regulations in order to address the needs of LEP patients and seniors as directed by SB 472. The current proposed regulations violate the intent and statutory requirements of SB 472 as confirmed by its legislative sponsor and author, Senator Ellen Corbett. She has stated in letters and testimony to the Board at its January 20<sup>th</sup> and February 17<sup>th</sup> meetings that she preferred the Board's originally proposed draft regulations and was very disappointed by the Board's changes in its current form, which violated the intent of the statute. The modified regulations also are inconsistent with federal and state law and fail to comply with the federal and state obligations of pharmacists to effectively communicate with their patients and provide meaningful access to their services because the regulations do not adequately address the needs of LEP patients.

We are again submitting an attached document with recommended changes to the proposed regulations for your review and the comments below provide support for the proposed changes in the order presented by the proposed regulations, and not necessarily the order of importance.<sup>2</sup> Many of our concerns and recommendations have not been addressed or responded to in the Board's "Initial Statement of Reasons" or its "Review of All Comments Submitted During the 45-day Comment Period and Testimony Provided During the Regulation Hearing Held January 20, 2010."

### **Modified Sections (a) & (c)**

We strongly recommend that the modified regulations must be changed back to the Board's original requirement of a 12-point font size from its revised 10-point font size requirement. The larger font size must be adopted in order to ensure that seniors and older patients will be able to read the labels. There was overwhelming testimony in support of the 12 point font size, specifically provided by an expert, Dr. Michael Wolf, who is providing the Board with expertise in translation of the sixteen directions, and clearly stated that the current standard in the industry and at the National Institute of Health was the 12 point font size. There were numerous seniors and others who consistently testified about the need and importance of the size and legibility of directions for their medication. Studies also support this requirement, as well as official federal agencies, such as the Centers for Medicare and Medicaid Services (CMS). For example, in its Prescription Drug Benefit Manual, Ch. 2 at 40.1, there is guidance that requires a 12 point font size for beneficiary communications by plans for its Medicare Part D Program.<sup>3</sup>

(a)(1)  
12 pt.

With regard to subsection (a)(1)(D), we recommend that the requirement of the patient to request the inclusion of the purpose or condition on the drug label is too great a burden on the patient and should be deleted. Since the patient is unlikely to know to ask for the information, it does not seem reasonable to require the patient to ask for the "purpose or condition" to be included. As will be explained below to support the notice requirement for patients, if the patient does not know what rights she or he has, or what to ask for or to expect, he or she will not know to make specific requests such as this. The requirement that the patient "requests" the information is *not* required in the container and labeling requirements in Cal. Business & Professions Code Section 4076(a)(10).

(a)(1)(D)

### **Modified Section (b)/NHeLP Recommendation (d)**

We also recommend that the number of languages for which the Board should translate the sixteen (16) directions listed in subdivision (a)(4) be expanded to match the twelve (12) non-English Medi-Cal Managed Care threshold languages.<sup>4</sup> These languages have been identified by

<sup>2</sup> See Attachment 1 (Recommended Changes to Modified Text of 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Drug Labels)

<sup>3</sup> Available at:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Chapter%2020Medicare%20Marketing%20Guidelines.pdf>

<sup>4</sup> In recognition of the large health benefit for LEP patients, its commitment to linguistic sensitivity in the provision of medical care, and ensuring effective communication with patients for maintaining quality care and patient compliance with treatment plans, the California Medical Association also supports the expansion of published translation of directions by the Board into 14 languages spoken by groups of 10,000 or more LEP speakers in the state. Letter from Veronica Ramirez, Research Associate, California Medical Association (Jan 4, 2010).

the Department of Health Care Services as the top languages of Medi-Cal LEP beneficiaries and can be a useful guide to identify the most common languages spoken by LEP patients. In fact, for those in the Medi-Cal program, translated materials must already be provided to LEP beneficiaries and it is likely that most pharmacies in the state accept Medi-Cal patients.<sup>5</sup> It would also expedite the Board's identification of the languages for which the labels should be translated. There is precedent for the Board to defer to the Department of Health Care Services to designate the languages for the translation of information, such as the lists of drugs covered in the state's AIDS drug program, in which pharmacies may participate. See Cal. Health & Safety Code Section 120970(j). The Board has also translated Emergency Contraception Fact Sheets into ten (10) non-English languages.<sup>6</sup>

#### **NHeLP Recommendations (d)-(g)**

According to the 2006 American Community Survey of the U.S. Census, over 42% of Californians speak a language other than English at home, which is significantly above the national figure of 19.7%. Of these, 47% report that they do not speak English "very well" and thus could be considered LEP (representing just over 20% of all Californians). Given the large LEP population in California, and after hearing repeatedly from LEP patients at these Board hearings about the serious consequences of misunderstanding medication instructions, there should not be any question of the critical need for translated labels.

Numerous articles and studies have highlighted the language barriers faced by LEP patients and shown that providing adequate language services improves health outcomes and patient satisfaction, comports with existing federal and state requirements, and achieves long-term cost savings.<sup>7</sup> Language services do so by facilitating effective communication between medical care providers and patients, thereby reducing medical errors, ensuring better health outcomes and lessening health disparities. In contrast, language barriers impede access and quality of care, and also result in costly, unnecessary testing due to the lack of a thorough patient interview.<sup>8</sup>

In order to ensure that LEP patients understand medication instructions, at a minimum, the seventeen (17) directions that the Board will translate and post on its website must be used by pharmacists/pharmacies. Title VI of the 1964 Civil Rights Act<sup>9</sup> prohibits discrimination on the basis of race, color, or national origin and provides the framework to support the provision of

<sup>5</sup> See Attachment 2 (Medi-Cal Managed Care Division All Plan Letter 02003, *Cultural and Linguistic Contractual Requirements*, June 7, 2002)

<sup>6</sup> See [http://www.pharmacy.ca.gov/consumers/emergency\\_cont.shtml](http://www.pharmacy.ca.gov/consumers/emergency_cont.shtml); Cal. Business and Professions Code Section 4052.3(e).

<sup>7</sup> See e.g., Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health* at 71-72 (2002); Chattanooga Times Free Press, *Language problems at the pharmacy*, at: <http://www.timesfreepress.com/news/2009/apr/27/language-problems-pharmacy>; National Health Museum, *Medical Misunderstandings*, <http://www.accessexcellence.org/HHO/qow/qow06/qow061204.php>; and *Language Barriers Plague Almost Half of U.S. Drug Stores*, <http://health.usnews.com/usnews/health/healthday/070806/language-barriers-plague-almost-half-of-us-drug-stores.htm>.

<sup>8</sup> See e.g., L. Ku and G. Flores. Pay Now or Pay Later: Providing Interpreter Services in Health Care;

<sup>9</sup> 42 U.S.C. § 2000d. See also Executive Order 13166, 65 Fed. Reg. 50121 (August 11, 2000); *Lau v. Nichols*, 414 U.S. 563 (court found national origin discrimination included discrimination based on language.; 68 Fed. Reg. 47311, 47312 (Aug. 8, 2003); National Health Law Program, *Ensuring Language Access in Health Care Settings: Legal Rights and Responsibilities*, (2003) for a fuller discussion of the federal language access requirements.

language assistance services, including the translation of vital documents, such as prescription drug labels. Any provider that receives federal funding, which include pharmacists and pharmacies, must take reasonable steps to ensure that LEP individuals have meaningful access to their programs and services. Since most pharmacies receive some form of federal funding through their participation in the Medi-Cal, Healthy Families, Medicare, or any other federal program.

The Office for Civil Rights (OCR) of the U.S. Department of Health and Human Services (DHHS) has issued policy guidance that requires all recipients of federal financial assistance from DHHS to provide meaningful access for Limited-English Proficient (LEP) persons.<sup>10</sup> The OCR Guidance provides strong support for the translation of "vital documents," such as prescription drug labels, dosage instructions, and warning labels.<sup>11</sup> Recently, on June 15, 2009, a key case involving the nation's largest mail order pharmacy operation and benefit management company, Medco, was settled with OCR. The resolution agreement with Medco required it to improve access to its pharmacy services for its LEP members.<sup>12</sup> The civil rights complaint was filed by a complainant on behalf of his Spanish speaking mother and alleged that Medco discriminated against LEP members in a number of ways, including failing to translate important documents or telephone recordings, leaving voicemail messages only in English, sending written documents only in English and cancelling the prescription request if an LEP member did not respond. The member belonged to a specific health plan that contracted with Medco to manage its prescription drug benefit and administer the prescription drug claims of the health plan members, which allowed the member to use Medco's mail-order pharmacy and its network of retail pharmacies.

Medco agreed to implement the following measures to improve its provision of language assistance services to its LEP members:

- Institute an "Other Than English Language" Project to identify and track LEP members' language preferences, beginning with Spanish and phasing in other languages after 2009,
- Flag language preference on an ongoing basis in Medco's internal computer systems to aid effective communication during any member contact with Medco,
- Ensure that certain written communications are sent and certain outbound telephone calls are placed to LEP members in their primary language,

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<sup>10</sup> 68 Fed. Reg. at 47311.

<sup>11</sup> U.S. Department of Health and Human Services, Office for Civil Rights (OCR), Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (OCR LEP Guidance), 68 Fed. Reg. 47311 (Aug. 8, 2003). There is a four factor analysis to determine compliance with Title VI: 1) the number or proportion of LEP persons eligible or likely to be served, directly affected, or encountered by the program, 2) the frequency with which LEP persons have or should have contact with the service, 3) the nature and importance of the program or service to the people's lives, and 4) the resources available to the federal fund recipient and costs. 68 Fed. Reg. 47314-15. OCR balances the four factors on a case-by-case basis. With regard to written translation, the guidance designates "safe harbors" that provides evidence of compliance if met (if the language groups constitutes 5% or 1000, whichever is less, of the population of persons to be served or likely to be served or encountered, or if fewer than 50, the recipient provides written notice in the primary language of the right to receive competent oral interpretation of vital materials, free of cost. *Id.* at 47319.

<sup>12</sup> See Attachment 3 (OCR Resolution Agreement with Medco).

- Conduct ongoing assessments of which communications must be offered in languages other than English and which languages are required to be supported,
- Continue its telephonic interpreter services available for over 150 languages,
- Expand the number of bilingual Spanish-speaking staff and improve its current telephone systems to route Spanish-speaking members to bilingual staff who can communicate with LEP members,
- Improve the provision of notice to its LEP members about the availability of language assistance services,
- Develop a process to assess the proficiency and competency of bilingual staff at call centers and pharmacies who communicate directly with LEP members or act as interpreters for LEP members,
- Train all relevant staff on its language access systems, processes, policies, and procedures, and
- Monitor, assess and evaluate its language access procedures and systems.

In most cases, any federally funded entity must assess the needs of its LEP population, provide competent interpreter and translation services (such as translation of readily understandable print materials, provide notice of the availability of free language assistance services, train staff, and adopt, monitor and update an adequate language services plan.<sup>13</sup> These elements of an effective language services plan provide useful guidance and support for NHeLP recommendations for sections (d)-(g).

There is also an analogous state statute that prohibits any state-funded entity from discriminating on the basis of race, color, national origin, ethnic group identification, religion, age, sex, or disability.<sup>14</sup> Since many pharmacies and pharmacists participate in state-funded health programs, including programs which are joint federal-state programs, such as Medi-Cal and Healthy Families, they must ensure full and equal access to their services to all patients and cannot subject LEP patients to any discriminatory activity.

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<sup>13</sup> In the DHHS LEP guidance, it set out procedures for federal fund entities to ensure compliance with Title VI by balancing four factors to determine the level of language assistance services the federal fund recipient must provide. To determine what reasonable steps a federal fund recipient must take to ensure meaningful access to their programs and activities by LEP persons, the following four factors must be balanced on a case-by-case basis: 1) the number or proportion of LEP persons served or encountered in the eligible service population; 2) the frequency with which the LEP individuals come in contact with the program, activity or service; 3) the nature and importance of the program, activity or service, and 4) the resources available to the recipient and costs. *Id.* at 68 Fed. Reg. 47311, 47314-15 (Aug. 8, 2003); For further explanation of the elements of an effective plan on language assistance for LEP persons, *see id.* at 68 Fed. Reg. 47319-21.

<sup>14</sup> Cal. Govt. Code Section 11135 et al. Regulations implementing the statute address language-based discrimination and provide a clear list of general discriminatory practices, including specific types of discrimination based on ethnic group identification. 22 Cal. Code Reg. §§ 98101 & 98211. One provision states that it is a "discriminatory practice for a recipient to fail to take appropriate steps to ensure that alternative communication services are available to ultimate beneficiaries. 22 Cal. Code Reg. §98211(c). "Alternative communication services" means the method used or available for purposes of communicating with a person unable to read, speak, or write in the English language, including the provision of a multilingual employee or an interpreter, or written translated materials in a language other than English. 22 Cal. Code Reg. §98210(a).

As noted in prior comments, a complaint based upon Title VI and two state pharmacy provisions related to counseling and label misbranding was filed with the New York Attorney General's office against chain pharmacists in New York. This resulted in a settlement that should guide the Board's current deliberation. It required seven major pharmacy chains to provide free language assistance services and required pharmacies to: (1) identify whether a customer needs assistance in understanding their prescription medication, (2) provide oral counseling in a patient's primary language regarding prescriptions, (3) translate prescription labels and directions regarding dosage and safety information, warning information, and other written important information in languages that are spoken by more than one per cent (1%) of the population in New York, which is currently Spanish, Chinese, Italian, Russian, French, and Polish, (4) train staff in language assistance polices, and (5) inform customers of their right to free language assistance services, including free oral interpretation and/or assistance in reading and understanding their prescription medication in multi-lingual signs. Written translation of other written important or vital information includes notices of privacy, written offers of counseling and any other materials that the pharmacy considers important to a customer's safe and effective use of the prescription medication. Therefore, translation of the prescription drug label is only the initial step in addressing the translation needs of the LEP patients.

There is further support for the translation of prescription drug labels and other clinical information in the Office of Minority Health's National Standards on Culturally and Linguistically Appropriate Services in Health Care.<sup>15</sup> One of its mandates based on Title VI, Standard 7, states that health care organizations, including pharmacies, "must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area."<sup>16</sup> Patient-related materials include "medical and treatment instructions" and "clinical information."<sup>17</sup> Therefore, usage of the 17 translated directions should not only be mandated by pharmacies and pharmacies, but translation of all of the items in the standardized label as described in subdivision (a)(1) must be required.

As noted in previous comments, there are also state pharmacy requirements that require written information, which should also be translated: 1) for refills, the patient must be provided with written information, either on the prescription label or with the prescription container, which describes which pharmacy to contact if the patient has any questions about the prescription or medication;<sup>18</sup> and 2) if the patient is not in the pharmacy (including drugs shipped by mail), a

<sup>15</sup> Office of Minority Health, *National Standards on Culturally and Linguistically Appropriate Services in Health Care (OMH CLAS Standards)*, 65 Fed. Reg. 80865 (Dec. 22, 2000), reprinted at: <http://www.omhrc.gov/clas>.

<sup>16</sup> *Id.*, *Final Report* at 13 available at t: <http://minorityhealth.hhs.gov/assets/pdf/checked/finalreport.pdf>.

<sup>17</sup> *Id.* "An effective language assistance program ensures that written materials routinely provided in English to applicants, patients/consumers, and the public are available in commonly encountered languages other than English. It is important to translate materials that are essential to patients/consumers accessing and making educated decisions about health care. Examples of relevant patient-related materials include applications, consent forms, and medical or treatment instructions." *Final Report* at 77. *Clinical information*—"prevention and treatment instructions, including how to prevent transmission of a contagious disease, what to do before, during, and after a procedure or treatment (e.g., surgery, chemotherapy), how to take medications, and how to perform routine self-care or self-monitoring." *Final Report* at 78, available at:

<http://www.minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>.

<sup>18</sup> Cal. Code Regs. tit 16 § 1707.4(a)(3).

pharmacy must ensure that the patient receives written notice of her right to request consultation, and a telephone number from which the patient may speak to a pharmacist.<sup>19</sup> In order for an LEP patient to receive written information, it must also be translated for the LEP patient. So the requirement for translation of materials goes beyond the prescription drug labels.

Many of the major chains, which operate in California, including CVS, Rite Aid,<sup>20</sup> Costco, Target and Wal-Mart, are currently or will be translating prescription drug labels by May 2010 and can provide guidance to, and share promising practices with, smaller pharmacies. However, we understand that some of the independent pharmacies may take longer to develop procedures for providing bilingual staff and interpreters, and written language assistance, including translated prescription drug labels, for their LEP patients. Therefore, the Board may decide to phase-in the translation requirement if necessary. However, as many LEP patients have been experiencing serious harm and suffering over the years and have been waiting for translated labels for many years, we would urge a deadline, such as a phase-in period no more than a year from the effective date of the regulations.

#### **Section (d)/NHLP Recommendation (f)**

This section allowing pharmacists to “provide interpretive services in the patient’s language, if interpretive services in such language are available” is vague and unclear, as well as inconsistent with current law. The phrase allows pharmacist to merely state that an interpreter is not available in order to avoid providing one to the LEP patient. There are telephone interpreter vendors who can provide interpreters in hundreds of languages so there should only be a problem with rare languages. Title VI allows for those exceptions by balancing the four factors and using a case-by-case analysis of the provider’s situation. Thus, there is no need for the phrase “if available.”

All stakeholders agree that LEP patients must be provided oral language assistance, and in fact, pharmacy representatives have testified that they are already providing interpreter services. Thus, it is recognized that oral language assistance must be provided to the LEP patients in order to ensure that they understand how to take their medications and can ask questions and receive responses from the pharmacists.<sup>21</sup> It is clear that the burden cannot be placed on the LEP patient and that the pharmacy or pharmacist is responsible for providing interpreters to ensure effective communication is provided to the LEP patient. This is not only required by previously discussed federal and state statutes and regulations but specifically with regard to counseling requirements in federal and state law.

<sup>19</sup> Cal. Code Regs. tit. 16 § 1707.2(b)(2).

<sup>20</sup> See e.g., Rite Aid Now Offers Prescription Bottle Labels In 11 Different Languages (2005), [http://www.riteaid.com/company/news/news\\_details.jsf?itemNumber=728](http://www.riteaid.com/company/news/news_details.jsf?itemNumber=728).

<sup>21</sup> Many of the same federal and state requirements for written language assistance services, such as translation of materials, also apply even more clearly to the provision of oral language assistance services, such as interpreter services. See *infra*, footnotes 2-6. See also *OMH CLAS Standards*, Standard 4: Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation. **Standard 6:** Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), which amended a section of the Medicaid Act, had a significant impact on standardizing pharmacy laws.<sup>22</sup> In order to receive federal Medicaid matching funds, OBRA requires standards for dispensing prescriptions to assure the quality of use and distribution of prescription drugs. Each state must have a Prospective Drug Use Review (DUR) Program, which sets forth minimum standards in patient counseling and requirements for recording and maintaining a patient medication profile.<sup>23</sup>

With respect to counseling of Medi-Cal recipients, the DUR requires that a pharmacist offer to counsel each individual (or a caregiver) who presents a prescription. The counseling should be done in person whenever practicable, or through a telephone service, which must be toll-free for long-distance calls.<sup>24</sup> When applying these standards to LEP patients, pharmacist should conduct in-person counseling when possible and not charge LEP patients any long-distance charges.

According to state regulations, pharmacists must provide oral consultation to patients in all care settings when the patient is present in the pharmacy for new prescriptions and when a prescription has not been dispensed to the patient in the same dosage, form, strength, or with the same directions.<sup>25</sup> Further, a pharmacist must provide counseling in all care settings upon request or when the pharmacist deems it warranted in his or her professional judgment.<sup>26</sup> When oral consultation is provided, it shall include directions for use and storage and the importance of compliance with directions and precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.<sup>27</sup> In order to comply with these counseling requirements, the pharmacist must engage the use of bilingual staff and/or competent interpreters to communicate with the patient effectively, and must do so regardless if the patient requests such counseling.

#### **NHeLP Recommendation (g)**

The issue of providing notice to LEP patients of their right to free interpreter and translation services needs to be addressed in the regulations. Title VI recommends notice to LEP persons about available language assistance services through, for example, posting signs in intake areas and other entry points.<sup>28</sup> One of the OMH CLAS Standards, Standard 5, states that health care organizations "must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services."<sup>29</sup>

State pharmacy requirements also recognize the need for consumer notices. For example, pharmacies must have a prominent and conspicuous notice, readable by prescription drug consumers, that includes information about the availability of prescription drug prices, generic drugs, *services provided by pharmacies*, and a statement of patients' rights (emphasis added).<sup>30</sup> The notices also encourage patients to talk to their pharmacists with concerns or questions.

<sup>22</sup> 42 U.S.C. § 1396r-8(g).

<sup>23</sup> *See id.*

<sup>24</sup> *Id.*

<sup>25</sup> Cal. Code Regs. Tit. 16, §1707.2(b).

<sup>26</sup> *Id.* at § 1707.2(a).

<sup>27</sup> *Id.* at §1707.2(c).

<sup>28</sup> *See infra* footnote 5, OCR LEP Guidance, 68 Fed. Reg. at 47319-21

<sup>29</sup> *See infra* footnote 7, *Final Report* at 70.

<sup>30</sup> Cal. Bus. & Prof. Code § 4122(a); *see also* Cal. Code Regs. tit. 16, § 1707.2(f).

If an LEP patient is not provided notice of his or her rights to an interpreter or translated written materials, he or she will not ask for any language assistance services. Therefore, similar to the need for required consumer notices, notices informing LEP patients of the availability of language assistance services is necessary to ensure that such services will be provided when needed.

**NHeLP Recommendation (h)**

Pharmacies must maintain medication profiles for all patients that contain demographic and medical information, as well as additional information the pharmacist deems appropriate in his or her professional judgment.<sup>31</sup> As mentioned above, OBRA also requires the pharmacist to make a reasonable effort to obtain, record, and maintain certain information, including comments relevant to the individual's drug therapy.<sup>32</sup> Pharmacists should record a patient's language in the patient medication profile under a "comment relevant to drug therapy" or other appropriate field capturing individual demographic information and history. The pharmacist's knowledge of the patient's primary oral and written language is not only relevant, but critical to being able to communicate with the patient regarding her or his drug therapy to achieve optimum results. Having the information in the medication profiles would also help facilitate and expedite any necessary language assistance services the LEP patient may need.

**Modified Section(e)/NHeLP Recommendation (i)**

We believe that the proposed time period of nearly four years to re-evaluate the requirements in these regulations is too long. The pharmacies have been on notice since the passage of SB 472 in 2007 and the Board must submit another report to the Legislature by January 1, 2013 regarding the status of implementation of the requirements. It would be more useful if the Board evaluates the implementation of the regulations before it must submit its report to the Legislature in December 2011, which would be close to two years to evaluate the implementation and effectiveness of the regulations.

Our prior submissions also included many resources for pharmacists to assist them in providing needed language assistance services. Without repeating the various best practices and websites, we hope that the Board finds them useful. We also hope that you seriously consider these latest recommendations and reconsider your past decision to decrease the font size and language assistance requirements. The Board has an opportunity to show other states how to ensure that patients can fully understand their medication regimen and avoid medical errors and encourage the Board to lead the nation in improving access to pharmacy services for seniors and LEP patients. If you have any questions, please do not hesitate to contact me at [wong@healthlaw.org](mailto:wong@healthlaw.org) or call (310) 204-6010, ext. 107.

Sincerely,

Doreena Wong  
Senior Attorney

<sup>31</sup> Cal. Code Reg. tit. 16 §1707.1

<sup>32</sup> See *infra* footnote 13, §1396r-8(g).



**CPEHN**

California Pan-Ethnic Health Network

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Director of Policy  
Center for Energy, Efficiency &  
Renewable Technologies

Jennifer Hernandez, MPP  
Founder and Partner  
Cultivo Consulting

Al Hernandez-Santana, JD, MCP  
Executive Director  
Latino Coalition for a  
Healthy California

Miya Iwataki  
Director, Office of Diversity Programs  
Los Angeles County  
Department of Health Services

Kathy Lim Ko, MS  
President and Chief Executive Officer  
Asian & Pacific Islander American  
Health Forum

Donzella Lee, MPH, CHES  
Director of Operations  
The Saban Free Clinic

Delight Satter, MPH  
Umpqua/Kickitat of the Confederated  
Tribes of Grand Ronde  
Director

American Indian and Alaska Native  
Research Program, UCLA Center for  
Health Policy Research

Dong Suh, MPP  
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Asian Health Services

Kevin Williams, JD, MPH  
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Antronette Yancey, MD, MPH  
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Rachel Larson, MPH  
Communications Coordinator

Martin Martinez, MPP  
Policy Director

Cary Sanders, MPP  
Director of the Having Our Say Coalition  
and Senior Policy Analyst

12 pt  
transl.

March 10, 2010

Kenneth H. Schell, PharmD  
President  
California Board of Pharmacy  
1625 N Market Blvd, N219  
Sacramento, CA 95834  
Via Fax (916) 574-8618

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

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the California Pan-Ethnic Health Network (CPEHN) we submit the following comments to proposed regulations related to patient-centered prescription drug labeling.

CPEHN's mission is to improve access to health care and eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of communities of color. CPEHN works to ensure that all Californians have access to health care and can live healthy lives.

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, including the 40% of Californians who speak a language other than English at home. 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. Our specific objections are as follows:

**The Board's action is not consistent with the underlying statute, and does not meet the APA's consistency standard.** The statute requires the implementing regulation to take into account the needs of seniors, people with low health literacy, and low English proficiency. 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 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

(d)  
clarity  
(no recommendation)

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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.

notice

The unfolding of subsequent events raises further concerns. The Board apparently realized the fact that there was insufficient advance notice of the changes to the language before the January 20, 2010 hearing. As a result, the Board scheduled another meeting on February 17, 2010. There was only a brief discussion of the regulatory language at that meeting before another vote was taken. This vote affirmed the previous vote by adopting the pro-industry language. However, there was no opportunity for public comment before the second Board's vote. As a result, once again, the Board was not able to hear any input from many members of the public assembled at the hearing before they made their decision about the regulatory language. Although the Board did permit public comment after their vote, they did not permit any comments from those at the hearing before they took their vote.

In essence, the Board made at least three procedural errors:

- They did not give sufficient notice of revised regulatory language to the public;
- The changes made to the regulations on February 17 should have met the threshold of changes major enough to trigger a 45-day public comment period, not just the 15-day comment period, and
- They scheduled two identical votes, one on January 20 and another on February 17, with no clarity as to the difference in the purpose of the votes, and no opportunity to provide public comment prior to the final vote, and
- Board staff acknowledged that several public comment letters had inadvertently not been furnished to Board members prior to their previous vote. Although the staff had since provided those materials to the Board, what had been omitted, the identity of who was making the comments, and the nature of those comments was not communicated to the public.

Consequently, we believe the adoption of the regulatory language as drafted is flawed and the Board's vote is invalid. The regulatory process at the Board of Pharmacy should be re-started with a full and complete review of the intent of the statute, the relevant research, with full consideration of the public testimony offered. This will result in regulatory language being adopted that will more closely adhere to the statutory intent and contain strong consumer protections.

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):

Support  
45 days  
not

- Labels should be printed in 12-point font or larger.
- 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. Language providing these consumer protections according to the law should be adopted at the next Board meeting. Thank you for receiving these comments.

Sincerely,

Marty Martinez, MPP  
Policy Director

15-day

California State Board of Pharmacy  
Department of Consumer Affairs  
1625 North Market Blvd., N219  
Sacramento, CA 95834

March 7, 2010

To: Distinguished State Board of Pharmacy Members,

I am writing to you with regards to the proposed changes to the language of Section 17177.5 of Division 17 of Title 16, which addresses the standardization for patient-centered prescription labels. I was in attendance during the special meeting that was held at the Department of Consumer Affairs on February 17, 2010, with my own concern regarding the proposed changes set forth for the new law.

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As a pharmacy technician (CPhT), public health and future pharmacy student, it is my concern that the proposed changes to the standardization of a 10-point font, does not meet the board's intention to improve patient-centered care. I regard the minute increase from a 9-point font as being negligent and defeats the initial proposed purpose of improving legibility of labels.

It is my belief that the standardization of a 12-point font, which was originally proposed, be reset into the proposed language. By doing so, the State Board will reach the original goal that it has set forth for itself, to ensure the safety of the patients whom we all serve. As stated during the February meeting, increasing legibility of prescription labels will reduce the likelihood medication errors in over 300,000 patients; which should be reason enough to enact the change.

(1) return to 12 pt.

I appreciate the board for taking the time to review my concern over the proposed language and commend the board for the changes thus far to improve patient centered care.

Best regards,

Ryan Ko C.Ph.T,  
Touro University, California - MPH/Pharm.D. Candidate  
Ryan.Ko@tu.edu

# Consumers Union

Nonprofit Publisher  
of Consumer Reports

March 9, 2010

By email to [carolyn\\_klein@dca.ca.gov](mailto:carolyn_klein@dca.ca.gov)

By fax to (916) 574-8618

Carolyn Klein  
California State Board of Pharmacy  
1625 North Market Blvd, Suite N219  
Sacramento, CA 95834

**Re: Modified Text of Section 1707.5 Patient Centered-Labels on Medication Containers**

Dear Ms. Klein,

Consumers Union, the non-profit publisher of Consumer Reports, is writing to express concerns that the modified text of proposed Section 1707.5 does not sufficiently improve prescription labeling requirements in a manner that protects seniors and those with limited English proficiency from the dangers of medication errors.

Consumers Union supported proposed Section 1707.5 in its original draft form, which would have required pharmacies to use a minimum 12-point font on prescription labels for the most important patient information, and would have required pharmacies to provide oral translation of important information when requested by a patient with limited English proficiency. We urged the Board to strengthen the language requirements by requiring written translations on labels for patients who need it. Instead, the Board has watered down the font and translation requirements. The Board has voted to change the proposed regulation to require only a minimum 10-point font, and require oral translation only "if available" to the pharmacy. If these regulations are enacted, Californians who are most vulnerable to misreading labels – those with limited eyesight and limited English proficiency – will continue to be at grave risk of suffering harm from a medication error.

**A 12-Point Font Minimum is Necessary to Reduce Risk for Seniors and Others with Limited Eyesight.**

12 pt  
(a)(1)

Consumers Union's activists have indicated that readability of prescription medication labels is a widely held concern. As of March 9, 2010, more than 1050 of our activists submitted letters to the board in favor a 12-point font minimum.

Support for a 12-point font minimum comes from the Board's own findings from a review of scientific research and medical opinion on the issue. The Board's own survey found that 60% percent of respondents thought that larger or bolder print would make prescription labels easier to read. The American College of Physicians recommended the use of a 12-point

font minimum on prescription medication container labels in its 2007 white paper "Improving Prescription Drug Container Labeling in the United States." In reducing the minimum required font size under the new proposal, the Board did not cite any evidence-backed study or expert recommendation in favor of a 10-point font.

Addressing the needs of seniors with diminished vision is a pressing concern. Presbyopia, a condition that makes it hard for the eyes to focus on close objects, is a nearly universal part of the aging process, and approximately one in three Americans have a vision-reducing eye disease such as macular degeneration, glaucoma, cataract and diabetic retinopathy by the age of 65.<sup>1</sup>

Arguments against a 12-point font minimum are unfounded. The California Retailers Association and chain pharmacy representatives (who offered the only comments in opposition to the 12-point minimum) testified that larger bottles would be needed to fit a 12-point font, causing environmental damage, increasing costs, and making it more difficult for patients to handle. However, they presented no evidence that requiring just the most essential information to be in 12-point font will require anything but marginal increases in the size of bottles. Furthermore, no scientific evidence was presented showing that the increased font would cause environmental damage, increase costs, or increase medication errors. Testimony presented to the Board by pharmacists indicates that costs will not rise significantly. Consumers Union believes that the resultant increase in safety from a 12-point font is well worth the additional cents that may be spent on plastic or ink for a marginally larger bottle or label.

Pharmacies may also consider the use of alternative label designs to account for a lack of space. A 1996 study of the use of alternative label designs for pharmaceutical containers (tag and fold-out) found that both young and older adults preferred the alternative design to the standard, and rated it higher for readability, noticeability, and likelihood of reading.<sup>2</sup>

The Board should consider findings that the average font size for medication instructions was 9.3-point and the average for drug name was 8.9-point, while the average for the pharmacy name was 13.6-point in a study led by Harvard Medical School's Dr. William Shrank published in 2007 in the Archives of Internal Medicine. Dr. Shrank's study, which evaluated 85 labels from pharmacies in four different metropolitan areas, reported that "[w]arnings or instructions were frequently printed in a small font, smaller than many elderly patients can read even with the assistance of refractive glasses." The current draft of the regulations does not represent a significant improvement over this status quo.

### **The Board Should Strengthen – Not Weaken – Requirements for Language Translation**

Consumers Union also calls upon the Board to reverse changes to the regulations that weaken protections for limited-English proficient patients. As in the case of the font size requirements, the current version of the regulations does not do much to improve the status quo.

<sup>1</sup> Quillen, DA. "Common Causes of Vision Loss in Elderly Patients." American Family Physician July 60 (1999): 99-108.

<sup>2</sup> Kalsher, MJ et al. "Pharmaceutical container labels: enhancing preference perceptions with alternative designs and pictorials." International Journal of Industrial Ergonomics 18 (1996):83-90

The current draft regulation requires oral translation "if available" and does not require written translation of pharmacy labels. At the January 17<sup>th</sup> Pharmacy Board meeting, Consumers Union, along with the California Medical Association and many groups representing limited-English proficient Californians, called on the Board to issue stronger translation regulations, but the Board chose instead to weaken those regulations. Pharmacy drug labels play a significant role in the appropriate administration of prescription medications. If a patient cannot understand the label instructions, there is a higher chance of error. Californians with limited English proficiency were 50% more likely to report trouble understanding labels and were more than twice as likely to report a bad reaction to medication, according to a 2005 study.<sup>3</sup>

### Conclusion

Consumers Union urges the Board to reconsider changes made on January 21<sup>st</sup> to weaken the draft regulations on medication labeling. Elderly and limited-English proficient Californians currently are not well-served by pharmacy labeling practices, and the current incarnation of Section 1707.5 will do little to improve the status quo and reduce the risk of medication errors. Seniors and limited-English proficient patients will continue to be vulnerable if the regulations are passed in their current form. Consumers Union urges the Board to return to a 12-point font minimum for the most important pieces of information on a prescription label and establish strong oral and written translation requirements.

(d)  
12 pt

(d)  
oral

no specific recommendation

Sincerely,



Syed Sayeed  
Policy Analyst  
Consumers Union

<sup>3</sup> Wilson, E et al. "Effects of Limited English Proficiency and Physician Language on Health Care Comprehension." Journal of General Internal Medicine 20 (2005): 800-806.



Dear President Schell and Members of the California Board of Pharmacy,

March 1, 2010

I am writing this letter on behalf of the California Alliance for Retired Americans (CARA) to again express our continued disappointment and disgust with the proposed regulations for patient-centered labels that you passed at your February 17<sup>th</sup> Board of Pharmacy meeting. What you approved made the entire process for developing these regulations a joke, and completely disregarded not only the concerns expressed by dozens of consumers and consumer advocacy groups, but also the wisdom and experience of organizations such as the World Health Organization, and Northwestern University and other academics and professionals in the field. Furthermore, the issues outlined in our previous letter, and those presented in other letters, were not adequately addressed by the Board and appear to be in violation of the intent of the legislation.

Specifically CARA is concerned with the regulation establishing 10 point font as the standard. All of the testimony presented by every group and individual, with the sole exception of the Retail Association and Pharmacy chains, has clearly indicated that 12 point font is the MINIMUM standard for readability. One of the Board members, Ramon Castellblanch shared some statistics at the Feb. 17<sup>th</sup> meeting clearly indicating that over 300,000 seniors over the age of 75 will be immediately at risk if these lower font standards go forward, and many more will be at risk as more and more seniors age in California. The issue of translation on the labels was also not adequately addressed, as was required and expected in the original language of SB 472. *12 pt comment*

These two concerns are enough, in our opinion, to put the entire process and final recommendations in question. But, to add insult to injury, we believe that the process itself was flawed. The revised language that was presented to the Board at the January 20<sup>th</sup> hearing was released only 14 hours prior to the hearing. No one had time for thoughtful review and consideration, yet the Board voted on these recommendations and reaffirmed them at the Feb. 17<sup>th</sup> hearing. The hearing on Feb. 17<sup>th</sup> took public comment only after a vote was taken – clearly an undemocratic and flawed procedure at best. The Board failed to consider pertinent testimony prior to voting – an issue we believe must be addressed by the Office of Administrative Law. *trans-lations*

Finally, the author of the statute, Senator Ellen Corbett, expressed her disappointment in the way the Board interpreted the intent of SB 472, which was shared at the Feb. 17<sup>th</sup> by her staff person, Anthony Valdez. We believe that her concerns must be addressed by the Board and by the OAL before the regulations are finally adopted.

We urge the Board of Pharmacy to reconsider these regulations, and at least increase the font size standard to 12 point font and translation of the labels into key languages before finalizing these regulations. Let's turn the Board's lemon of a proposal into lemonade while we still have time. *}*

Sincerely,

A handwritten signature in cursive script, appearing to read "Nan Brasmer".

Nan Brasmer, CARA President

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@ (1)*



# Gray Panthers Sacramento

P.O. Box 19438  
Sacramento, CA 95819  
916-921-5008  
[www.gpcal.org](http://www.gpcal.org)

March 1, 2010

Dear President Schell and Members of the California Board of Pharmacy,

I write this letter on behalf of the Sacramento Gray Panthers to again let you know how disappointed and angered we continue to be about the regulations for patient-centered labels passed at your February 17<sup>th</sup> Board of Pharmacy meeting. Your decisions ignored all the scientific studies cited, including those of the World Health Organization, Northwestern University and others. The only apparent consumer representative on the Board, Ramon Castellblanch, presented evidence that clearly indicated that as many as 300,000 seniors in California are at risk of harm because of your recklessness in mandating a minimum 10 point font rather than 12 point font that all these studies recommended. This harm to seniors will increase dramatically as the Baby Boomers age and will be a real black mark on your reputation.

In addition, the issue of translations on labels was flippantly disregarded, deadly indeed in the most diverse state in the nation. You have shown a callous disregard to the millions of limited English speakers in California.

We in Gray Panthers have been involved with this bill from the very beginning, and were thrilled to have Senator Ellen Corbett carry the bill to passage. Your actions have made a mockery of SB 472's spirit and intent, as was expressed at the Feb. 17<sup>th</sup> meeting by her staff person, Anthony Valdez. This flagrant disregard of both the California Legislature and seniors is a real slap in the face.

Your decision has caused us to question the commitment of the Board of Pharmacy and the corporate members of that Board to the wellbeing of all consumers. Furthermore, I doubt that I will ever have the trust I used to have in Rite-Aid and CVS.

We urge the Board of Pharmacy to reconsider these regulations, and at least increase the font size standard to 12 point font and translation of the labels into key languages before finalizing these regulations.

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12 pt.

Sincerely,

Margie Metzler  
[margiemetz@hotmail.com](mailto:margiemetz@hotmail.com)  
Convenor, Sacramento Gray Panthers



READY FOR ACTION

TO TAKE ON THE FUTURE

# CALIFORNIA STATE RETIREES



1108 O Street • Sacramento, CA 95814 • (916) 326-4292 • (888) 808-7197

CSEA RETIREES, INC.

An Affiliate of the California State Employees Association

Feb. 24, 2010

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

Dear California Board of Pharmacy Members:

As president of CSEA Retirees, Inc. – representing 29,000 state retirees throughout California – I strongly oppose using font sizes smaller than 12 points on drug labels and prescription instructions.

It goes without saying that many retirees have a harder time reading the names of their medications and the instructions for taking them. To help reduce the millions of prescription errors occurring every year, the board should help – not hinder – by requiring the bare minimum of 12-point type on drug labels and instructions.

The 12-point standard coincides with the recommendations made by your own staff and the National Association of Boards of Pharmacy. The standard is also in line with what many of the 29,000 members of CSEA Retirees, Inc. have told me they want and need. Both verbal and written communication is essential to ensure the best outcome for patients, as well as pharmacists, doctors and the entire health care industry.

Please take a proactive stand toward reducing dangerous prescription errors by making labels and instructions user-friendly for California seniors.

Sincerely,

Roger Marxen  
President, CSEA Retirees, Inc.  
1108 O St.  
Sacramento, CA 95814

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pharmacists planning service, inc.

101 Lucas Valley Road, Suite 384 San Rafael, California 94903  
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

March 9, 2010

*general statements*

Virginia Herald, CEO  
California Board of Pharmacy  
1625 N. Market Boulevard, Suite N219  
Sacramento, CA 95834

Kenneth H. Schell, Pharm.D., Pres.  
California Board of Pharmacy  
Prescription Solutions  
2300 Main Street  
Irvine, CA 92614

Dear Ms. Herald and Dr. Schell:

Re: 1707.5 Patient Centered Labels & SB 472 (Corbett Legislation issues)  
Comments to be sent on to Office of Administrative Law

Pharmacists Planning Service, Inc. (PPSI), a 501 C (3) nonprofit public health, consumer, pharmacy education organization, submits the following comments and testimony regarding 1707.5 Patient Centered Labels, and SB 472 implementation issues to the Office of Administrative Law with additional comments for the upcoming April California State Board of Pharmacy meeting in Riverside (which I am unable to attend):

1. I and many consumer advocates were unable to attend the January 20, 2010 Board of Pharmacy meeting in Sacramento due to five days of extremely heavy rain.
2. Due to this poor weather it is my understanding the electricity went off during the meeting including the lights and audio visual. Many of the consumer advocates could not testify, could not be heard or hear the other speakers on this crucial issue.
3. At the February 17th Board meeting I asked the Board prior and during to the meeting:
  - a. Could we, consumers and patient advocates in the audience, address the Board prior to its vote? It was stated the January meeting was for testimony and we could comment after the vote on SB 472.

Board prior to its vote? It was stated the January meeting was for testimony and we could comment after the vote on SB 472.

b. I asked the Board before the vote if the Board could poll the members present on the voting so the consumers in the room would know how each member of the Board voted.

c. I was told that the Board does not poll its Board on individual votes.

d. I mentioned that some of the Board members had a conflict of interest and represented chain drug store management and did not represent the public health and safety of the patients/consumers in the audience even though they are in managerial positions at major chain stores.

e. The Board's response was that they represented the people of California and not their corporate interest.

4. In an article in the Los Angeles Times "Drug Executive Cast Key Vote to Kill Labeling Law....Pharmacy Board was Posed to OK Measure Opposed by One of the Governor's Major Donors Until he Named a CVS/Pharmacy Official to the Panel" written by Shane Goldmacher, February 20, 2010. This article stated "CVS/Pharmacy Official, Deborah Veale, provided the vote that killed a plan to require large type on drug labels and instructions to make oral translation of them available for all non-English speakers". This was after the California Retailers Association donated \$400,000 to Governor Schwarzenegger's political committees and campaign.

5. For those members of the Board who belong to the California Retailers Association, PPSI submits there appears to be a conflict of interest as in testimony it was brought out that enlarging the labels under SB 472 it would cost one to three cents.

6. In the January/February material sent by the Board to all consumers, patients and interested parties, the material specifically stated that a 12-point font is the minimum standard for readability. Before the assembled Board at the February 17th meeting and before the vote was taken, it was reiterated by one of the Board members, a consumer advocate, Dr. Ramon Castellblanch, with documented statistics that yes indeed that the 12-point font is the minimum standard for readability and that 300,000 seniors over 75 with macular degeneration and glaucoma along with cataracts and poor vision, would not be able to read the labels.

7. In my testimony after the vote was taken, I mentioned Lucian Leape, M.D.,

Harvard Medical and Public Health Schools, authored a study showing that 107,000 Americans die each year from mixing their prescriptions, taking the incorrect medication, mixing their Rx's with herbals and over-the-counter products and that by not increasing the label print to a 12-point font another 300,000 Californians could be injured.

8. I pointed out again that the injury takes the shape of increased medical, hospital and emergency room visits. I suggested the Board could rescind its vote to include a 12-point font which fell on deaf ears.

9. In my testimony I mentioned that by lowering the font size of the drug manufacturer who produces the product, the patient would not be able to return these prescription drug products to the pharmacies if they could not read the manufacturer's name on all recalls by the Federal Food and Drug Administration (FDA).

10. I mentioned that in the most recent FDA Recall, November 19, 2009 to December 18, 2009 a major drug company, Apotex, Inc., Ontario, Canada, announced by letter on August 28, 2009 a firm initiated recall for 73 products due to current good manufacturing practices deviations. The company reported that 4,578,203 boxes and bottles were affected and the letter stated "CONTACT YOUR PHARMACIST TO INQUIRE IF YOUR'S (PRODUCT) IS ONE OF THE AFFECTED LOTS". This was a Class II Recall indicating a problem which may have caused temporary or reversible health effects.

11. After the 5-4 vote which defeated the labeling consumer action issues, a discussed on No. 10 (above) took place as to whether to put the labeling of the drug manufacturer in small font. In my opinion the print would be too small for patients to read "Contact Your Pharmacist if Your's is One of the Affected Lots" for all FDA recalls which would cause further serious harm to California consumer/patients. I was under the impression that this kind of conversation which is part of the 1707.5 proposed modifications under SB 472 should have taken place before the vote was taken.

12. Perhaps the mass confusion on most seniors' minds in my discussion with them seems to be that the print-size and font-size should be separated from the issue of labels being printed in various languages as languages were not discussed in the February 17th meeting. The language issue is more complicated than the print-size issue. This was never made clear to the audience.

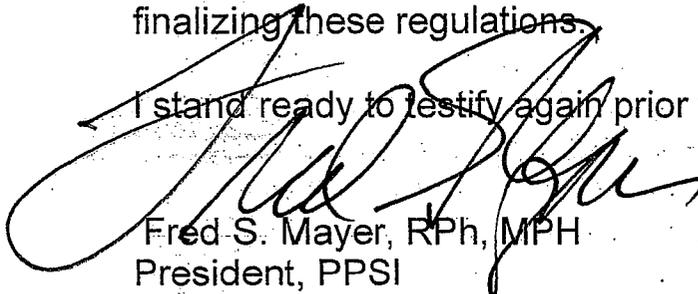
In summary, I would like the above information sent on to the Office of Administrative Law for its opinion as the proposed regulations for patient-

centered labels is confusing, the issues which were discussed were not discussed before the vote was taken by the Board, there appears to be a conflict of interest among the California Board of Pharmacy members who represent the chain pharmacies with the passing of \$400,000 through the California Retailers Association to the Governor's political committees.

PPSI is asking OAL to separate the two major issues, print-size and the printing of labels in various languages. 12-point font is the MINIMUM standard for readability which is the Board's own documentation but was completely ignored. There is a conflict, confusion and a public health and safety hazard which has been ignored at these hearings with the request of an individual poll vote of the Board members. The issue of various languages on the labels was also completely ignored as originally requested in the original language of SB 472.

For the above reasons, I request the Office of Administrative Law turn back this entire packet to the California Board of Pharmacy for a re-hearing before finalizing these regulations.

I stand ready to testify again prior to the voting once the conflicts are corrected.



Fred S. Mayer, RPh, MPH  
President, PPSI  
101 Lucas Valley Road, Suite 384  
San Rafael, CA 94903  
Telephone: 415 479-8628  
Fax: 415 479-8608  
Email: [ppsi@aol.com](mailto:ppsi@aol.com)  
Website: [www.ppsinc.org](http://www.ppsinc.org)

Ruth M. Ryan  
2101 Lambert Dr.  
Pasadena, CA 91107



(a)(1)  
12 pt.

2/25/10

Pharmacy BA  
1625 No. Market Blvd - N 219  
Sacramento 95835

CA

Attn Mrs. Carolyn Klein

Dear Ms. Klein -

I want to vigorously protest  
the use of #10 font on the  
labels of prescription medications.

The size of printing is  
very difficult for most people -  
certainly retired, older teachers.

Please have the font in  
at least #12 font.

Very truly yours,

Ruth M. Ryan

Ms. Carolyn Klein, Coordinator  
Legislation and Regulations  
California State Board of Pharmacy  
1625 N. Market Blvd. N 219  
Sacramento, CA 95834

*font size  
translated labels  
oral language*

Dear Ms. Klein,

I am writing to express my concerns about changes that the State Board of Pharmacy has made to proposed regulations regarding patient centered drug labeling.

In these revisions, the Board backed away from an earlier requirement that labels be printed in a font no smaller than 12-points. The new requirement will be 10-points. Considerable research has shown that a minimum of a 12-point font size is needed for readability.

The Board eliminated a requirement for pharmacies to translate drug labels. Even though the Board will be providing some translated labels on their website, the regulations do not require the pharmacies to use them. Without translated labels, patients whose primary language is not English will not be able to read instructions on how to take their medication.

The Board also weakened the requirement to provide patients with oral interpretation of the drugs' directions, with a caveat that translation will be provided only "if available".

These issues are no small matter. According to the US Census Bureau, over 14 million people in California speak English less than well. For their sake, and for the general welfare of us all, we need to do all that we can to assure that people clearly understand the instructions for use of their prescription medications.

To that end, please make sure the Board understands these following points.

- 12-point font is the minimum size for readability.
- Translated labels are essential for our 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 people who speak limited English vulnerable to misuse of their prescriptions.

*(a) 12-pt*

*(b)*

I look forward to hearing that these important points will be reflected in the final regulations issued by the Board.

Sincerely,



Mary Grisaffi  
<mjg.mail@sbcglobal.net>  
02/25/2010 04:34 PM

To Carolyn\_Klein@dca.ca.gov  
.cc  
bcc

Subject: prescription labels

*support 12 pt*

I am a senior, wear glasses, & 12 point font is the minimum I am able to read. It is important for me to be able to read my prescription labels easily. Since most of take several different medications it could be a matter of life & death to take the wrong medication or the wrong dosage of one or more. PLEASE reconsider the 10 point font. It is ridiculous to have a problem due to this new idea. Many of us live alone & have no one to help us read our prescription labels, so please do NOT use the 10 point font. Mary Grisaffi---a concerned senior in California.

mjg.mail@sbcglobal.net

*oppose  
modified  
(a)(1)*



Margaret Murphy  
<murphthesurph@sbcglobal.net>

02/26/2010 01:18 AM

To <Carolyn\_Klein@dca.ca.gov>

cc

bcc

Subject Labels on drugs

Please stop the proposed changes to drug labeling (the size of the type and absence of translation). I would be adversely affected by the reduced size of type since I take multiple drugs and have difficulty seeing. I hate to think of the dangers of compounding these problems with the lack of primary language support.

Sincerely yours,  
Margaret Murphy

oppose  
modified(a)

oppose  
modified(d)

(a)(1)  
font size

translations

att: Pharmacy labels

Dear Carolyn Klein,

I am 83 yrs. old and still take + care for my own medication. I usually have 3 or 4 all the time. I think it would be very important for the pharmacist to put on the label what the medication<sup>(a)(1)(D)</sup> is used for. For instance I usually write on the label what I am taking the meds for.

Pravastatin Sodium - "Cholesterol"

Cozaar - Blood Pressure

Warfare Sodium - Blood thinner.

Atendol - Vibration + Blood Pressure

There are so many uses for the same drugs + many people would be more apt to take drugs if they understand + know what the drug is used for.

I'm just a new member of C.A.R.A. not to forward about suggesting in the meeting but can write as they ask us to do so. I want to help anyway I'm able. I can no longer take long bus trips or walk a great length. So this is one way of helping other seniors. My grammar + spelling is not the best

but hope you can see what I am  
trying to accomplish.

Thank you, Leona Harris  
Registered Vote name Leona Marie Smith Harris  
309 E. Adams St.  
Long Beach, California  
90805-7230

RECEIVED BY CALLIE  
BOARD OF PHARMACY  
2010 MAR 10 AM 8:10

From: Diana Madoshi <quemere@sbcglobal.net>  
Subject: **Patient centered labeling**  
Date: March 10, 2010 12:44:52 AM PST  
To: carolyn\_klein@dca.ca.gov



March 9, 2010

To the Board of Pharmacy Board

We the undersigned are writing in response to the Board of Pharmacy devastating blow to consumers on enacting provisions for patient centered labels, especially who comprise of 48% of all prescription drugs.

The board were given responsibility to address the needs of seniors, patients with limited English and improved the font size and listen to medical literacy research in helping to implement the bill once it became law.

We listened and observed the board fail in their mandate. They failed California consumers big time with two of the most important requests; at least medication labels in at least 12-points (the standard for newspapers) and that labels be translated into most common languages spoke in California. It was outrageous. The drug chains won the day when the board vote for a 10 point standards and no translations.

Despite evidence based testimonies that supported what seniors needed to avoid medication errors and injuries, a 12 point at minimal, this board did not stand up for seniors and consumers. Those on the board with recent drug industry and chain employment ties should have excused themselves. The consumers reps on the voice should have acted in the consumers best interest. Obvious to me and others, the bill/law should have been more specifics with the font size and translation, because the board did not close the deal in consumers best interest.

There is still time for the Board of Pharmacy to act on behalf of the seniors and consumers of California. Reverse the vote for the 10 point standard. Then you will still be protecting and ensuring the safety seniors and all Californians..

Please don't disregard our input.

Respecially,

*Diana Madoshi & all*

Diana Madoshi, 3220 Santa Fe Wy #108 Rocklin, CA; Blair P. Ogg, Villa Serena Circle, Rocklin; Deloris Bennett, 11 Villa Serena Circle, Rocklin; Adrienne Forrest, 3704 Villa Serena Circle, Rocklin; marian L. Benson, Villa Serena Circle, Rocklin; Lorenie Ware 209 Villa Serena Circle, Rocklin, Christina Rojas, 3220 Santa Fe Wy #201, Rocklin; Frances Hernandez, 1711 Villa Serena Circle, Rocklin; Marie H. Risucci, Villa Serena Circle, Rocklin; Barbara Coats, 3220 Santa Fe Wy #149, Rocklin, Ruth Nonnenberg, 415 Villa Serena, Rocklin; Mary Lou Hill, 3703 Villa Circle, Rocklin; Mrs. Barbara Ulrici, 2709 Villa Serena Circle, Rocklin

*(a) (1) 12 pt*

*translated labels*

RECEIVED BY C...  
BOARD OF PHARM...

2010 MAR 17 AM 10:05

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Adriene Forest*  
3704 Villa Serena Way,  
Rocklin, Ca. 95765

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Adriene Forest*  
3704 Villa Serena Way  
Rocklin, Ca. 95765

February 23, 2010

Senior request,

Please enlarge <sup>labels</sup> prescription numbers on  
medication bottles.

Thank you,

*Delora Bennett*  
*611 Villa Serena Cir.*  
*Rocklin, Ca. 95765*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Mary Lou Hill*  
*3703 Villa Serena Cir.*  
*Rocklin, Ca., 95765*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Ruth Nonnenberg*  
*415 Villa Serena*  
*Rocklin CA 95765*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Barbara Coats*  
*3220 Santa Fe Way # 149*  
*Rocklin, CA 95765*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Mauro J. Risucci*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Frances Mendez*  
*1711 Villa Serena Cvd.*  
*Rocklin, California*  
*95765*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

Christina Rojas  
3220 Santa Fe Way # 201  
Rocklin Ca. 95765

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

Laure Ware  
2609 Villa Serena Ct.  
Rocklin, Ca. 95765

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Marian D. Denson*

February 23, 2010

Senior request,

Please enlarge prescription <sup>labels</sup> numbers on  
medication bottles.

Thank you,

*Barbara D. Ulrici*



Mrs. Barbara Ulrici  
2709 Villa Serena Cir.  
Rocklin, CA 95765-5532



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES



californiapharmacistsassociation

March 10, 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 – Technical Amendments**

Dear Ms. Klein:

On behalf of its members operating retail pharmacies in the State of California, the California Pharmacists Association, (CPhA), the California Retailers Association (CRA), the California Grocers Association (CGA) and the National Association of Chain Drug Stores (NACDS) 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 the previous draft of the regulation. In the interests of clarity, we would like to offer a couple of technical amendments that we believe will clarify the regulation. The first suggested amendment is intended to clarify the requirement to list the name of the manufacturer in way that is consistent with state law. The second technical suggestion would offer pharmacists latitude, based upon their education and training, in providing instruction for usage information to patients.

**Suggested technical amendment 1:**

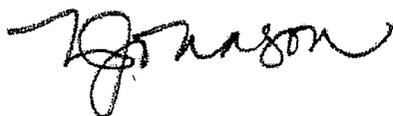
1707.5(a)(1)(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or generic name and the name of the labeler or manufacturer pursuant to sections 4033 and 4076 of the Business and Professions Code.

**Suggested technical amendment 2:**

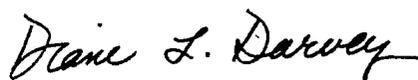
1701(a)(4) When applicable clinically appropriate and in the professional judgment of the pharmacist, directions for use shall use one of the following phrases:

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.

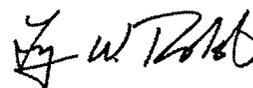
Sincerely,



Missy Johnson  
CRA



Diane L. Darvey, Pharm.D., JD  
NACDS



Lynn Rolston  
CPhA



Kara Bush,  
CGA

March 3, 2010

Virginia Herold, Executive Officer  
California Board of Pharmacy  
1625 N. Market Blvd. N219  
Sacramento, California 95834  
[Virginia\\_Herold@dca.ca.gov](mailto:Virginia_Herold@dca.ca.gov)

**RE: 1707.5 Patient Centered Labels on Medication Containers**  
**CSHP Position: Support**

Dear Ms Herold:

The California Society of Health-System Pharmacists (CSHP) is pleased to inform you that our organization continues to support the addition of Section 1707.5 Patient Centered Labels on Medication Containers of Division 17 of Title 16 of the California Code of Regulations.

According to the findings of the 2005 Senate Concurrent Resolution (SCR) 49 Medication Errors Panel, medication errors cost California \$17.7 billion dollars and causes harm to 150,000 Californians every year. In an effort to address this alarming rate of fiscal and physical damage, the Medication Errors Panel recommended that the California Board of Pharmacy examine the existing requirements for prescription container labels and prescription containers. Senate Bill (SB) 472, authored by Senator Ellen Corbett, was adopted and requires the Board of Pharmacy to promulgate regulations on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. CSHP supported SB 472 and continues to assert that having a standardized prescription label would reduce medication errors and protect Californian consumers.

In 2007, the Institute of Medicine published Preventing Medication Errors, a report by its Committee on Identifying and Preventing Medication Errors. They identified eight elements contributing to communication lapses that lead to medication errors. Cluttered labeling, ie, font size, poor typeface, no background contrast, and overemphasis on company logos was included on this list amongst others. We support adopting the proposed language of this section to reduce medication errors and maintain safe medication use.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact Bryce W.A. Docherty, CSHP's legislative advocate at (916) 446-4343 or me at (916) 447-1033.

Respectfully,



Dawn Benton  
Executive Vice President/CEO