



Nonprofit Publisher  
of Consumer Reports

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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.**

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.

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<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.

Sincerely,

A handwritten signature in black ink that reads "Syed Muhasim Sayeed". The signature is written in a cursive style with a large initial 'S'.

Syed Sayeed  
Policy Analyst  
Consumers Union

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<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.