



Nonprofit Publisher
of Consumer Reports

January 19, 2010

Virginia Herold
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Re: Section 1707.5 Patient Centered-Labels on Medication Containers – Support

Dear Ms. Herold:

Consumers Union, the nonprofit publisher of *Consumer Reports*, is writing in support of the adoption of proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations. The proposal would make labels on prescription medication containers safer and better-suited for patients' needs by requiring pharmacies to use standardized font type and size, placement of information, and directions for use on prescription labels. The regulation also would require pharmacies to provide oral language translation of label information for patients with limited English proficiency at the request of the patient. Consumers Union supports the proposed regulation as a way to reduce the rate of medication errors and increase health care literacy regarding prescription drugs. Further, Consumers Union urges the Board of Pharmacy to further assist Californians with limited English proficiency by strengthening the language translation requirement in the manner proposed below.

Consumers Union has worked for years to improve drug safety by ensuring that consumers have full information about prescription drugs. Consumer Reports Best Buy Drugs provides free, unbiased analysis of prescription drugs to consumers, recommends safe, effective, and affordable drugs, and provides detailed reports for consumers and doctors to make decisions regarding prescription medications. Consumers Union works with grassroots activists as part of the California Safe Patient Project to advocate for safer healthcare.

California Business and Professions Code section 4076.5, enacted in 2007, mandates that the Board of Pharmacy adopt regulations to implement a standardized, "patient-centered" prescription drug container label statewide. This mandate followed increasing concerns about the safety of self-administered medications and the role of medication labeling. Confusing or inadequate labeling can lead to harmful or even deadly mistakes, particularly for consumers with poor vision, limited English, and literacy or cognitive difficulties. Label definitions or abbreviations that vary among different pharmacies can cause consumers to confuse dosage information.

To reduce medication error rates, the Institute of Medicine, a division of the National Academies, recommended in its 2006 report *Preventing Medication Errors* a shift from “paternalistic, provider-centric model of care” to one where consumers are “empowered as partners in their care, with appropriate communication, information, and resources in place to support them.” As the healthcare system supplies more and more medications, patients will become more involved in dosing these medications. Patient involvement will be part of the solution to medication error through increased patient-centered safety measures. Standardizing prescription drug labels and making them easier to read and understand will help consumers avoid medication errors.

Consumers Union believes that proposed Section 1707.5 will promote patient safety, as it would:

- require that all drug containers dispensed to patients feature a standardized label format that places priority on the information that is most important to patients, by requiring that 50 percent of the label be comprised of the name of the patient, name and strength of the drug, directions for use, and purpose or condition, if known to the pharmacy and if the patient wants it included on the label;
- require use of a 12-point, sans serif font for the essential information and encourages the use of bold typeface or color highlighting;
- mandate use of standardized phrases for directions for use, designed to prevent dosing errors and require the Board to publish on its web site translation of the directions for use into at least five languages other than English to facilitate use of the translated directions of use by pharmacies;
- require pharmacies to provide, upon request by the patient, oral language translation of the patient-centered information on prescription container labels.

While Consumers Union supports all of these requirements, we recommend strengthening the regulation on behalf of consumers with limited English by providing translations of the directions of use on the Board’s web site in at least 14 of the most commonly used languages in California and by requiring pharmacies to use translated directions for use in the patient’s language on the prescription drug labels.

Because Section 1707.5 will help reduce medical errors by providing safer, more patient-centered prescription drug labeling, we urge the Board of Pharmacy to strengthen and enact the regulation. Thank you for the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in cursive script that reads "Syed Muhasim Sayeed". The signature is written in black ink and is positioned above the printed name.

Syed Sayeed

Policy Analyst

A handwritten signature in black ink that reads "Sondra Roberto". The signature is written in a cursive style with a large initial 'S' and 'R'.

Sondra Roberto
Staff Attorney