

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Patient-Centered Labels for Prescription Drug Containers; Requirements.

Section Affected: Amend Section 1707.5 of Article 2 of Division 17 of Title 16, California Code of Regulations

Specific Purpose of the Proposed Changes/Problems Addressed

The Board of Pharmacy (Board) proposes to amend Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of amending the Board's regulations specific to the requirements for patient-centered labels for prescription drug containers, as specified below.

As mandated by Business and Professions Code (B&P) section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Corbett, Chapter 470, Statutes of 2007) and to make specific the prescription drug container label requirements found in B&P section 4076, the Board has proposed to amend Section 1707.5 to Title 16 of the CCR.

This proposal further specifies the patient-centered prescription drug container label in CCR section 1707.5(a)(1)(B) by clarifying the meaning of "name of the drug." By requiring the brand name when a generic drug is dispensed, patients will be further educated as to what medications they are taking. This may reduce incidence of and/or prevent accidental drug overdoses. Additionally, by amending 1707.5(d) to include translation services, pharmacies will be required to include a means of providing translation services to patients in their policies and procedures. Having policies and procedures in place that identify how to provide translation services will make the services more readily available to patients with limited or no English proficiency.

The purpose of the Board's proposal makes the following changes:

Subdivision (a)(1)(B) is amended to add statement "generic for _____" where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name's patent or, if in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the." This amendment requires that the brand name be included in the patient-centered portion of the label when a generic drug is dispensed. Additionally, an exemption is authorized to remove the brand name if the brand name patent expired and allow for a pharmacist to use their judgment when the brand name is not widely used. This exemption allows for the manufacturer's name to be placed outside of the patient-centered area of the label in lieu of the brand name. These changes are necessary to prevent accidental overdoses by patients who are unclear as to the brand name versus the generic name of their medications.

Subdivision (d) is amended to add "and translation services" after "provide interpretive services" and before "in the patient's language." This amendment will require that the pharmacy have policies and procedures in place to assist patients with limited or no English proficiency. This amendment is needed to make translation services more widely available to the estimated 8.7

million Californian's who have limited or no English proficiency.

Subdivision (e) is removed from the regulation text as it is outdated. The Board re-evaluated the patient-centered label requirements in 2013 and promulgated new regulations in 2014 to ensure optimal conformance. These new regulations became effective April 1, 2015.

Subdivision (f) is renumbered to subdivision (e) due to the deletion of the text of previous subdivision (e).

Factual Basis/Rationale

B&P section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy (Board) in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of the Pharmacy Law (Chapter 9 of Division 2 of the Business and Professions Code).

B&P section 4076 specifies information that is required to be placed on a prescription drug container label dispensed to a patient in California.

B&P section 4076.5 required the Board to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. It also specifies what factors the Board must consider in establishing such a label. Those factors include:

- Medical literacy research.
- Improved directions for use.
- Improved font types and sizes.
- Placement of information that is patient-centered.
- Needs of patients with limited English proficiency.
- Needs of seniors.
- Technology requirements for implementation.

Title 16 CCR section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the Board promulgated these requirements, it included in subdivision (e) a requirement that the Board re-evaluate the requirements by December 2013 to ensure optimal conformance with B&P section 4076.5.

Further specifications to the patient-centered label requirements went into effect on April 1, 2015 following promulgation of a regulation in 2014. The new specifications included a standardized, patient-centered prescription drug container label. These specifications mandated the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, and placement of words. These changes were necessary to ensure patient safety and compliance of prescription medications through patient-centered labels that consider the following: 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; and

technology requirements necessary to implement the standards.

As one patient may have three prescriptions for the same medical condition, the Board determined that requiring the brand name when a generic drug is dispensed will further educate the patient and may prevent accidental drug overdoses. If a patient has a prescription issued in the brand name and then refilled in the generic name, the patient may not be aware that the two bottles contain the same medication. This could cause them to take double or triple the dose in error. Additionally, according to the United States Census Bureau, in 2011 approximately 8.7 million California residents had little or no English proficiency. This means that approximately 8.7 million California residents are unable to read and understand the prescription label and may rely on non-medically trained individuals to translate the information. The Board determined that pharmacies need to have policies and procedures in place to provide translation services in order to better educate and serve those patients with limited or no English proficiency.

Underlying Data

1. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held April 1, 2014 (Pages 2-7).
2. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held September 18, 2014 (Pages 6-7).
3. Relevant Meeting Minutes from Board of Pharmacy Meeting held October 28-29, 2014 (Pages 56-57).
4. Relevant Meeting Minutes from Board of Pharmacy Meeting held January 27-28, 2015 (Pages 16-17).
5. U.S. Census Bureau, *Language Use in the United States: 2011*. Issued August 2013 (<https://www.census.gov/prod/2013pubs/acs-22.pdf>).

Business Impact

The Board of Pharmacy has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the proposed text, and are consistent with patient-centered label for prescription drug requirements meeting national and industry standards.

The proposed amendment is intended to protect the people of California by ensuring consumers receive their prescription drugs with respective labels that are centered around the consumers' needs so that each consumer is able to understand the prescription drug is for them, the name of the prescription drug (and the brand name if a generic drug is dispensed), the directions for use of the prescription drug, and the condition or purpose for which the prescription drug was prescribed is indicated on their prescription. Additionally, the proposed regulation would require pharmacies to have policies and procedures in place to respond to patients with limited or no English proficiency will ensure that pharmacies have the ability provide accurate information regarding prescription drugs in a language appropriate for the patient.

As a result, there may be a one-time cost to implement these regulations; however, the Board does not anticipate a statewide adverse economic impact directly affecting businesses. The Board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the State of California because the proposed regulation amends and clarifies the existing patient-centered label requirements. Existing law requires the following items to comprise at least 50 percent of the label: name of the patient; name of the drug and strength of the drug; the directions for the use of the drug; and the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. This proposal clarifies the meaning of “name of the drug” to include the brand name when dispensing generic drugs. Additionally, existing law requires the pharmacies have policies and procedures in place for interpretive services. This proposal amends this requirement to include translation services.

It will not create new business or eliminate businesses within the State of California because the proposed regulation amends and clarifies the existing patient-centered label requirements. Existing law requires the following items to comprise at least 50 percent of the label: name of the patient; name of the drug and strength of the drug; the directions for the use of the drug; and the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. This proposal clarifies the meaning of “name of the drug” to include the brand name when dispensing generic drugs. Additionally, existing law requires that pharmacies have policies and procedures in place for interpretive services. This proposal amends this requirement to include translation services.

It will not affect the expansion of businesses currently doing business within the State of California because the proposed regulation amends and clarifies the existing patient-centered label requirements. Existing law requires the following items to comprise at least 50 percent of the label: name of the patient; name of the drug and strength of the drug; the directions for the use of the drug; and the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. This proposal clarifies the meaning of “name of the drug” to include the brand name when dispensing generic drugs. Additionally, existing law requires that pharmacies have policies and procedures in place for interpretive services. This proposal amends this requirement to include translation services.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation will further educate Californians as to the generic and brand names of their prescription drugs. This education may prevent accidental drug overdoses by alerting Californians that the drugs are the same when taking multiple prescriptions for the same medical issue. This will result in improved health for Californians. Additionally, by requiring policies and procedures to be in place for translation services, more Californians will have access to prescription translations by a medical professional.

This regulatory proposal benefits worker safety because the proposed regulation will further educate Californians as to the generic and brand names of their prescription drugs. This education may prevent accidental drug overdoses by alerting Californians that the drugs are the same when taking multiple prescriptions for the same medical issue. Additionally, by requiring policies and procedures to be in place for translation services, more Californians will have access to prescription translations by a medical professional. On-the-job accidents may decrease if

employees and/or co-workers are better educated about their prescription drugs and are taking them as prescribed by their physician.

The regulatory proposal does not affect the state's environment because the proposed regulation amends and clarifies the existing patient-centered label requirements. Existing law requires the following items to comprise at least 50 percent of the label: name of the patient; name of the drug and strength of the drug; the directions for the use of the drug; and the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. This proposal clarifies the meaning of "name of the drug" to include the brand name when dispensing generic drugs. Additionally, existing law requires that pharmacies have policies and procedures in place for interpretive services. This proposal amends this requirement to include translation services.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

The only alternative would be to not require that the brand name be listed with the generic name and not require pharmacies to have policies and procedures in place for translation services. This is not reasonable as it would not mitigate accidental overdoses as a result of prescription confusion and it will not address the needs of the 8.7 million people who have limited or no English proficiency.