

Board of Pharmacy
Initial Statement of Reasons

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

Sections Affected: Amend § 1707.5 of Article 2 of Division 17 of Title 16 Cal.Code Reg.

Specific Problems Addressed

The Board of Pharmacy (“Board”) proposes to amend Sections 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 section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Stats. 2007, Chapter 470) and to make specific the prescription drug container label requirements found in Business and Professions Code section 4076, the Board of Pharmacy has proposed to amend Section 1707.5 to Title 16 of the California Code of Regulations.

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). Business and Professions Code Section 4076.5 required the Board to consider the following factors when developing requirements for the patient-centered prescription label requirements:

- 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.

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 Business and Professions Code Section 4076.5.

The patient-centered label requirements went into effect on January 1, 2011, and since that time the Board has worked to secure compliance by educating licensees, conducting surveys, distributing notices, and reviewing pharmacies’ compliance with requirements. Accomplishments include conducting surveys of pharmacies for compliance with label requirements.

This proposal further specifies the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, and placement of words.

As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy 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.

Purpose of the Proposed and Rationales of Changes

Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations specifies requirements related to the patient-centered labels for prescription drug container requirements. The board's proposal requires the items that shall be clustered into one area of the label and comprises at least 50 percent of the label as well as require the size and typeface of the prescription label to be at least 12-point sans serif typeface. The board's proposal is 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.

The proposed changes align with the results of the board's consumer survey soliciting feedback regarding the readability of the new prescription drug container labels. Additionally, the board's proposal harmonizes with the U.S. Pharmacopeial Convention (USP), November 2012, published guidelines for prescription container labeling. The USP guidelines provide a universal approach to the format, appearance, content, and language of instructions for medicines in containers dispensed by pharmacies and resemble the board's existing and proposed regulation requirements for patient-centered prescription container labels. Finally, the board's proposal corresponds with the National Council for Prescription Drug Programs' "Universal Medication Schedule White Paper" (draft April 2013). This document supports the standardized directions in the board's proposed regulations. The goal of the universal medication schedule is to increase patient understanding and adherence to medication instructions by standardizing the phrasing of directions, thereby improving health outcomes. The hope is to secure the use of directions for use in a Universal Medication Schedule into e-prescribing systems.

Factual Basis

Business and Professions Code 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 Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4076 specifies information that is required to be placed on a prescription drug container label dispensed to a patient in California.

Business and Professions Code 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 of Pharmacy 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.

As a result of the regulations promulgated by the board January 1, 2011, as required Business and Professions Code section 4076.5, the board added subdivision (e) to Section 1707.5 of the California Code of Regulations requiring re-evaluation of the section. The board's proposed amendments are a result of this re-evaluation.

Economic Impact Assessment

The board conducted an Economic Impact Assessment and has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed changes will help protect the public health and are consistent with patient-centered labels for prescription drug containers requirements in industry.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony and also applies to pharmacies located in California, pharmacies outside of California that provide prescription drug products to California patients, and clinics.

Existing law implemented January 1, 2011, requires pharmacies and clinics to provide the prescription label in at least 10-point sans serif typeface, or 12-point sans serif typeface if requested by the consumer. Additionally, 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.

During the rulemaking process in 2009-2010 for implementation January 1, 2011, one industry member testified that they may incur one-time costs to configure the labeling of that pharmacy's prescription drug label – resulting in a one-time approximate cost of \$1,000.

The board's proposal requires the use of only 12-point sans serif typeface. Given existing law implemented January 1, 2011, pharmacies are required to have this font option available for consumers. The board's proposal requires the above-mentioned four items to be the only items comprising 50 percent of the prescription label rather than allowing other items to be added. Essentially, pharmacies are required to have the capability to allow for these requirements. Additionally, there has been no evidence supporting significant statewide adverse economic impact directly affecting business since the implementation of the initial requirements in January 1, 2011.

Technical, Theoretical, and/or Empirical Study, Report, or Documents

The Board of Pharmacy relied on Chapter 17 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) as well as the National Council for Prescription Drug Programs' April 2013 draft of "Universal Medication Schedule White Paper, Version 1.0." as indicated in the Underlying Data.

Benefits

Business and Professions Code section 4005 states that "the board may adopt rules and regulations....pertaining to the practice of pharmacy...." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The board believes the regulatory changes as described in the Notice will serve to protect the public health by ensuring the board's regulations regarding requirements for patient-centered labels for prescription drug products are aligned with the national standards as outlined in Chapter 17 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) as well as the National Council for Prescription Drug Programs' April 2013 draft of "Universal Medication Schedule White Paper, Version 1.0."

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that no reasonable alternative to adopting or amending the regulations would lessen any adverse impact on small business.

The Board of Pharmacy has made an initial determination that no alternatives proposed as less burdensome and equally effective in achieving the purposes of the regulation in a manner that achieves the purposes of the regulation.

Specific Technologies or Equipment

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

Underlying Data

1. Senate Bill 472 (Corbett, Statutes of 2007, Chapter 470.)
2. Chapter 17 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013).
3. California State Board of Pharmacy Patient-Centered Prescription Label Survey
4. California State Board of Pharmacy Summary Patient-Centered Labeling Inspections, April – August 2012
5. “Universal Medication Schedule White Paper, Version 1.0,” National Council for Prescription Drug Programs, April 2013 draft.
6. Relevant Meeting Materials and Minutes from the Board of Pharmacy Communication and Public Education Committee Meetings held April 12, 2013; July 16, 2013; and January 6, 2014.
7. Relevant Meeting Materials and Minutes from the Board of Pharmacy Legislation and Regulation Committee Meetings held July 30, 2013; and January 29, 2014.
8. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meetings held February 5-6, 2013; April 24-25, 2013; July 30-31, 2013; October 29-30, 2013; and January 29-30, 2014.
9. Economic Impact Assessment