

**Board of Pharmacy**  
**Final Statement of Reasons**

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

**Title 16 Sections Affected:** Amend 16 Cal. Code Reg. § 1707.5

**Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the Board of Pharmacy’s (board) position regarding the adoption of the above section, and is updated to include the following information.

The Board of Pharmacy is clarifying the following information in the Final Statement of Reasons. The Initial Statement of Reasons referenced Relevant Meeting Materials and Minutes from the Board of Pharmacy Legislation and Regulation Committee Meetings held July 30, 2013, as underlying data when in fact this data was not used. The board determined this typing error to be non-substantive pursuant to Government Code Section 11346.8. As the board is unable to correct the typographical error in the Initial Statement of Reasons, the board notes the error in the Final Statement of Reasons. The reference has been removed from the Table of Contents and Underlying Data in this rulemaking file.

The board did not intend to conduct a Regulation Hearing on the matter, unless requested. On May 9, 2014, the board received a request for a regulation hearing from Paige Talley of RPT Consulting on behalf of the California Council for the Advancement of Pharmacy. At the request of Ms. Talley, the board notified all interested persons that a regulation hearing was scheduled for May 27, 2014, at 9:30 a.m. in the El Dorado Room located at 1625 N. Market Blvd., Suite N219, Sacramento, CA. 95834. The board conducted a regulation hearing on May 27, 2014.

At its public board meeting held June 26, 2014, the board considered the comments received during the 45-day public comment period and at the regulation hearing. The board’s responses to the comment received are detailed under “Summary of Comments Received during the 45-Day Comment Period and Regulation Hearing.”

After reviewing the comments received during the 45-day comment period and regulation hearing, the board directed staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative

Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1707.5 as noticed on April 11, 2014.

**Local Mandate:**

None

**School District Mandate:**

None

**Business Impact:**

This regulation will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. The following types of businesses would be affected by this regulation: pharmacies, non-resident pharmacies, and clinics. This determination was based on the minimal amount and content of comments received by the board during the 45-day comment period and testimony indicating adverse economic impact regarding this rulemaking proposal as well as other factors including the following:

- Senate Bill (SB) 472(Corbett, Statutes of 2007, Chapter 470) was approved by the Legislature as the California Patient Medication Safety Act. SB 472 was signed and approved by the Governor. A review of the bill analyses did not indicate an economic impact on the creation or eliminations of jobs within the state; the creation of new business or elimination of existing business within the state; nor the expansion of business currently doing business within the state.
- According to the United States Bureau of Labor Statistics' May 2012 National Occupational Employment and Wage Estimates, the annual average salary for a pharmacist in California is \$125,800 and the national annual average salary is \$114,950. Pursuant to Business and Professions Code section 4116, a pharmacist must be present in an area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. In order for a pharmacy to be open, a pharmacist is required to be present and the labor for one pharmacist annually represents approximately \$114,950-\$125,800 based on geographic location.

In 2009 when the board initiated the original rulemaking file, the board received testimony from an independent pharmacist indicating that changing requirements to the labels

would require a one-time programming cost. For purposes of estimation, the board estimated this to be a one-time cost of approximately \$1,000 in 2009. Accounting for inflation, the board estimates the 2014 cost to be approximately \$1,500. The Board estimates that 5% of pharmacies and clinics may be in violation of current law and would require minor computer programming to accommodate the 12 point sans serif typeface. If 490 pharmacies and clinics (5%) are required to make this change at an estimated \$1,500, the total estimated statewide economic impact would be \$735,000. The one-time cost associated to pharmacies and clinics in violation of current prescription drug container requirements represents making required prescription labels software updates represents less than 2 percent of the labor cost associated to the required pharmacist, or approximately \$1,500 as a one-time cost.

- When the Governor and Legislature enacted the California Patient Medication Safety Act (Senate Bill (SB) 472 – Corbett, Statutes of 2007, Chapter 470), the Legislature found and declared the following outlining costs associated with medication errors:
  - (a) Health care costs and spending in California are rising dramatically and are expected to continue to increase.
  - (b) In California, prescription drug spending totaled over \$188 billion in 2004, a \$14 billion dollar per year spending increase from 1984.
  - (c) Prescription drug cost continues to be among the most significant cost factors in California’s overall spending on health care.
  - (d) According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people every year.
  - (e) Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.
  - (f) Approximately 46 percent of American adults cannot understand the label on their prescription medications.
  - (g) Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications.
  - (h) Nearly six out of 10 adults in the United States have taken prescription medications incorrectly.
  - (i) The people of California recognize the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling, which can increase consumer protection and improve the health, safety, and well-being of consumers.
  - (j) The Legislature affirms the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels.

(k) It is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by the California State Board of Pharmacy for use on any prescription drug dispensed to a patient in California.

In an effort to increase patient safety and medication compliance, the board's proposal provides for a prescription drug label that allows for the consumers of California to easily read the pertinent information specific to the prescription.

**Specific Technologies or Equipment:**

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

**Consideration of Alternatives:**

No reasonable alternative which was considered would be more effective in carrying out the purpose for which the regulation was proposed, would be as effective as and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The supporting information considered was determined based on the minimal amount and content of comments received by the board during the 45-day comment period and testimony indicating adverse economic impact regarding this rulemaking proposal.

**Summary of Comments Received During the 45-Day Comment Period and at the Regulation Hearing Held May 27, 2014 (Objections or Recommendations/Responses):**

**Written Comments by Mr. Corey Whitney, Pacific West Pharmacy**

Mr. Whitney does not specify any one amendment to the regulation that he opposes. For purposes of response, the board assumes that he is opposed to all of the amendments, and also to the existing statutory and regulatory requirements regarding the format and font size requirements of prescription labels on drugs dispensed to patients from a pharmacy.

Mr. Whitney states his pharmacy is a "closed door" pharmacy and that he services the needs of a skilled nursing facility. Mr. Whitney references a "packager" in a skilled nursing facility, and cites his investment in automated dispensing. For purposes of the board's response, the board assumes Mr. Whitney is talking about an automated drug delivery system in the skilled nursing facility that is owned by the pharmacy, which would be consistent with the authority provided in section 4119.1 of the Business & Professions Code, and utilized in a manner that meets the requirements of Health and Safety Code section 1261.6.

A "closed door" pharmacy is not defined in pharmacy law (Division 2 of Chapter 9 of the Business and Professions Code). While not specifically defined, a "closed door" pharmacy is commonly referred to as a licensed pharmacy that serves specific client(s) – often times, skilled nursing facilities, long term care facilities, etc. These types of pharmacies typically are not open to the public, though they are not precluded from serving the public in addition to health care

facilities. The following definitions are provided in support of the board's response to this comment.

Pharmacy (defined at B&PC 4037). An application for a "Community Pharmacy" allows the applicant to specify the type(s) of pharmacy practice that is provided by the pharmacy. The application indicates: Retail, Home Health Care, Nuclear, Mail Order, Skilled Nursing Facility, and Board and Care. The requirements for a pharmacy are the same irrespective of the type(s) of practice of the pharmacy, to include the labeling of dangerous drugs dispensed to patients.

Nonresident Pharmacy. A nonresident pharmacy is the same as a "pharmacy" except that it is a pharmacy that is outside of California and dispenses drugs to California patients.

Hospital Pharmacy (defined at B&PC 4029). A hospital pharmacy is one that serves inpatients of an acute care hospital that is licensed by the Department of Public Health. A Hospital pharmacy does not serve outpatients. It is common for acute care hospitals to have both an inpatient pharmacy (that which serves patients registered for care at the facility), as well as an outpatient pharmac(ies) (that which serves patients who are not registered / admitted for overnight care).

"Dispensing" is the furnishing of a drug or device to a patient upon the prescription of an authorized prescriber. (See B&PC 4024)

Also, Business and Professions Code section 4119.1 allows a pharmacy to provide pharmacy services to a health care facility, as defined, through the use of an automated drug delivery system. These provisions were enacted in 1997 (c. 549, Sec. 72, Statutes 1997; Senate Bill 1606 Lewis) and became effective on January 1, 1998. That bill also added Health and Safety Code section 1261.6. This section (1261.6) specifies requirements for the use, dispensing, and stocking of the automated drug delivery system. Subdivision (i) of Section 1261.6 specifies that drugs dispensed from an automated drug delivery system that meets the requirements of the section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code ... if the drugs ... are in unit dose packaging or unit of use and if the information required by Section 4076 ... is available at the time of drug administration.

**Comment #1:** Mr. Whitney speaks of limiting drug supplies to skilled nursing facilities or post-acute facility settings, as well as drug waste associated with these types of facilities.

Response to Comment #1: Mr. Whitney's comment is not within the scope of the board's regulatory proposal and, as such, the comment is rejected.

**Comment #2:** Mr. Whitney speaks of the labeling of drugs dispensed to patients through an automated drug delivery system. He comments on the efficiency of packaging multiple medications together (that are given at the same time).

Response to Comment #2: Existing law at Health and Safety Code section 1261.6 specifies the requirements for use of these automated drug delivery system (ADDS) that is used within a

health facility licensed pursuant to section 1250(c), 1250(d) or 1250(k) – and specifies in subdivision (i) that drugs dispensed from an ADDS are not subject to the labeling requirements of 4076, if the administration of these drugs comply with the requirements found in 1261.1. Thus, the board disagrees that the proposed changes to section 1707.5 will negatively impact the technology, and that there is no reduction in the efficiency of these systems where the pharmacy is complying with existing provisions of the Health and Safety Code. For these reasons, the board rejects Mr. Whitney’s comment.

**Comment #3:** Mr. Whitney comments that the proposed changes to the regulation will have no benefit to his practice setting.

Response to Comment #3: The board disagrees with this comment. Where Mr. Whitney utilizes automated delivery systems in a health care facility that is licensed pursuant to section 1250 of the Health and Safety Code, as specified; the board believes that the proposal will have a benefit to his practice. For example, should his pharmacy dispense medications to a facility’s patient that is going on a weekend pass from the facility and needs his or her medications, those “weekend pass” medications would be required to be labeled in accordance with the provisions of the proposal, providing the patient with the benefits of the “patient-centered” labeling components and in a minimum 12 point sans serif font size. For this reason, the board rejects Mr. Whitney’s comment.

**Comment #4:** Mr. Whitney comments that the proposed changes will negatively impact his current and future business.

Response to Comment #4: See the board’s response to Comment #2.

**Written comments from Barry Solomon, R.Ph, M.Ed**

**Comment #5:** Mr. Solomon suggests that certain instructions be added to the regulation.

Response to Comment #5: Existing law at Section 4040(a) of the Business and professions code specifies items that are required to be included in a prescription, to include the directions for use. Existing law Section 4076(a)(2) of the Business and Professions Code requires a pharmacist to include the directions for use on the prescription label of a drug that is dispensed. The board’s regulation contains standardized directions for use that are to be used “if applicable.” Thus, if the prescriber indicates on the prescription document that if the patient is not asleep after 1 hour to take a second tablet – the pharmacist must include this direction for use on the prescription label. If the directions for use, as specified by the prescriber, are not consistent with the standardized directions for use that are specified in the board’s regulation – then the pharmacist would have to use the directions for use as specified on the prescription document.

The board did not propose any modifications to the standardized directions for use specified in the board’s regulation. When promulgating this regulation (2009/2010) the board utilized subject matter experts, white papers and other underlying data and determined that the standardized directions for use were appropriate. When revising the requirements of the

regulation prior to the promulgation of the proposed amendments, the board reviewed the directions for use and determined that no changes would be proposed at this time. Thus, the board finds the comment to be irrelevant to the proposed amendments and rejects the comment.

**Written Comment by Anandi V. Law, B.Pharma., MS, PHd, FAACP, FAPhA**

**Comment #6:** Pharmacist Law recommends that a table of administration times be added to the regulation.

Response to Comment #6: The board's existing regulation at 1707.5 specifies standardized directions for use (see section 1707.5(a)(4)). The directions for use are required "when applicable." Thus, a pharmacy would be required to use these directions for use when the directions coincide with the prescriber's instructions. The board did not propose any modifications to the directions for use. When promulgating this regulation (2009/2010) the board utilized underlying data, subject matter experts, white papers and other underlying data and determined that the standardized directions for use were appropriate. When revising the requirements of the regulation prior to the promulgation of the proposed amendments, the board reviewed the directions for use and determined that no changes would be proposed at this time. Thus, the board finds the comment to be irrelevant to the proposed amendments and rejects the comment.

**Written Comment from Fred S. Mayer, R.Ph, MPH**

Comment #7: Mr. Mayer requested information about the regulation, information about publishing an article, and clarification on current law.

Response to Comment #7: Mr. Mayer did not object to or voice concerns with any of the proposed regulatory amendments. He asked for clarification of current laws and commented on his interest in publishing an article. The board appreciates Mr. Mayer's comments; however, they are deemed irrelevant because they were not specifically directed at the board's proposed action, or the scope of the regulation. For these reasons, the board rejects the comment.

**Oral Testimony at the Regulation Hearing: Mr. Corey Whitney, Pacific West Pharmacy**

**Comment #8:** Mr. Whitney stated that the language states that the board may exempt the requirements if a licensed health care professional was the person administering the medication. Mr. Whitney requested clarification if the board has exempted that.

Response to Comment #8: The board believes that Mr. Whitney is referring to Section 1261.6. See the board's response to Comment #2.

**Comment #9:** Mr. Whitney stated that, in essence, by increasing the font size, his pharmacy would not be able to put 2-3 prescriptions in a packet which would limit the use of this technology in a care facility.

Response to Comment #9: See the board's response to Comments #2 and #3.

**Oral Testimony at the Regulation Hearing: Mr. Art Whitney, Pacific West Pharmacy**

**Comment #10:** Mr. Whitney stated he was seeking a board exemption to the labeling requirements, as the drugs dispensed in the health care facility do not go home with the patient.

Response to Comment #9: See the board's response to Comment #2.

**Comment #11:** Mr. Whitney clarified that his comment (#10, above) was for patients in home settings – in that the pharmacy would not be able to provide the unit of use packaging for those particular patients.

Response to Comment #11: Please see the board's response to Comment #2. Also, the provisions of the Health and Safety Code section 1261.6 apply to automated dispensing machines that are within a health facility that is licensed pursuant to Health and Safety Code section 1250, as specified (i.e., those which are administered to patients in specified facilities). The provisions of Health and Safety Code section 1261.6 do not apply to automated dispensing machines that are utilized in a community pharmacy, which may be used to dispense dangerous drugs to patients (that are not in a health care facility, as discussed above). Business and Professions Code section 4076.5(e) authorizes the board to exempt from the requirements of the regulation certain prescriptions, and specifies the criteria that must be met in order for the board to consider such a request. Any request for exemption would be heard by the board in a public meeting and acted on accordingly. The board's authority is separate from the regulatory proposal. The board finds that to repeat the statutory exemption language within the regulation would be duplicative; thus, the board rejects the comment.

**Oral Testimony at the Regulation Hearing: Ms. Paige Talley, California Council for the Advancement of Pharmacy**

**Comment #12:** Ms. Talley offered clarification to the comments made regarding institutional meds with packets; specifically, the multi-unit dose packages. She stated these medications would not get into the patient's hands because they are labeled at the time of dispensing through a specific machine. She stated that as technology advances, there would be lots of changes and that it may be challenging to come back to the board with an exemption request as changes occur.

Response to Comment #12: Regarding the board's authority to approve any exemptions sought under Business and Professions Code section 4076.5(e), please see the response to Comment #11.

**Oral Testimony at the Regulation Hearing: Valerie Wiebe, University of California, Davis – Veterinary Medical Teaching Hospital**

**Comment #13:** Ms. Weibe stated she has concerns and issues with the labeling of veterinary medications when they are dispensed by a regular pharmacy, but she did not expand on or specify what those concerns or issues might be.

Response to Comment #13: The board's proposed regulation applies to prescription drugs that are dispensed to patients. If a community pharmacy dispenses a dangerous drug, the prescription container would need to be labeled in accordance with the board's regulation. For the dispensing of controlled substances (to an animal), the California Health and Safety Code section 11241 also requires that a prescription written by a veterinarian shall state the kind of animal for which the drug was ordered, and the name and address of the owner or person having custody of the animal. Absent any objection to the proposed regulation, or specificity of concerns, the board is not able to address the 'issues' that Ms. Weibe states she has. The board believes that the owner of the animal for which a prescription is acquired would benefit from the proposed regulation, because the owner would have the benefit of a prescription label that is consistent with the format they may be accustomed to (as an individual) and would have the information in a font size that is clear and readable. For these reasons, the board rejects the comment.