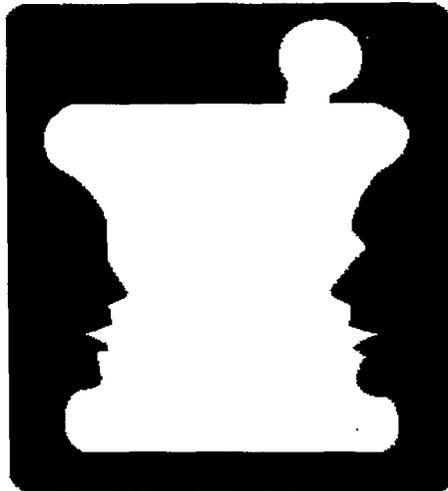


State of California
Board of Pharmacy
Report to the Legislature



Prescription Drugs: Labeling Requirements
January 2010

Arnold Schwarzenegger, Governor
Kenneth H. Schell, PharmD, President, Board of Pharmacy
Virginia Herold, Executive Officer, Board of Pharmacy

Summary

The California Patient Medication Safety Act (Chapter 470, Statutes 2007) requires the Board of Pharmacy 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. This Act further requires the board to report to the Legislature by January 1, 2010, on its progress in implementing these regulations.

This report summarizes the Board of Pharmacy's efforts to establish a standardized, patient-centered prescription drug label.

After approximately 18 months of public discussion regarding a standardized, patient-centered prescription label and gathering information at public forums, hearings, board and committee meetings, and conducting patient surveys, the board issued on November 20, 2009 proposed regulatory text to add section 1707.5 to Title 16 of the California Code of Regulations. This proposed section contains California's requirements for patient-centered prescription labels. The board will take action on this proposed regulation at its next scheduled meeting scheduled in January of 2010.

Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a multidisciplinary panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. As required, that panel prepared and submitted to specific legislative committees a final report (referenced as the SCR 49 Report) containing its conclusions and recommendations. The report reflected improvements, additions or changes which would reduce errors associated with the delivery of prescription and over-the-counter medications to consumers.

One bill was pursued based on the recommendations of the SCR 49 panel's report. Senator Ellen Corbett authored SB 472, resulting in enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007), Business and Professions Code section 4076.5. Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which could increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature mandated that the Board of Pharmacy adopt regulations to implement a standardized, “patient-centered” prescription drug container label in California.

SB 472 Medication Label Subcommittee

Legislation required that the board initiate public hearings to collect information from the public to facilitate the development of a regulatory proposal. The Board of Pharmacy president appointed a SB 472 Medication Label Subcommittee in January of 2008 to conduct public forums and to work with organizations and individuals to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label.

The SB 472 Medication Label Subcommittee held public forums on the following dates, apart from regularly-scheduled board meetings.

April 12, 2008

January 27, 2009

November 20, 2008

March 12, 2009

Agendas for these meetings are provided in Attachment 1.

At these public forums and at other board and board sub-committee meetings, as directed by the SB 472 Label Subcommittee, the board considered testimony and information provided from the public, the pharmaceutical industry, pharmacy professionals and literacy subject matter experts on medical literacy research, improved directions for use, improved font types and sizes, the 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 developed. Board members were also provided with research

articles on designing patient-centered labels. The information and data received helped frame draft regulatory text to implement the provisions of SB 472.

Public and Community Outreach / Survey

Responding to minimal public input regarding the public's concerns about the current medication prescription labels that are used, the board developed a survey (Attachment 2) that could be provided and/or conducted one-on-one with participants at public outreach events, such as health fairs, where the board provides consumer information. This survey was provided in English and in Spanish. The survey was posted on the board's public Web site from May 2008 through November 2009. Survey questions were open-ended, allowing participants to provide as little or as much information as desired, but the questions did not direct participants to pre-defined responses. Survey results were provided to the board at SB 472 Subcommittee meetings, and also at regularly-scheduled board meetings.

Attachment 3 lists those organizations and individuals to which the survey was distributed to solicit input. Attachment 3 also contains a list of public outreach events at which board staff interviewed consumers and provided printed surveys to solicit input.

At public outreach events and at board and committee meetings, the public was provided with fact sheets entitled "Do you understand the directions on your Rx medicine label?" (Attachment 4) and demonstrated samples of faux prescription labels serving as visual aids.

The board also worked with the Pharmacy Foundation of California to develop a multi-choice survey of four questions that were available via a radio-sponsored survey. The goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels. The survey was conducted via Entercom Broadcasting and was made available in January 2009 on radio station Web sites that stream their audio. Results of this survey were provided to the SB 472 Medication Label Subcommittee at its meeting held March 12, 2009.

Proposed Regulatory Text

To implement the provisions of Business and Professions Code section 4076.5 (the California Medical Safety Practice Act) the board proposed text to add section 1707.5 to Title 16 of the California Code of Regulations (Attachment 5).

By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California.

Specifically, the regulatory language proposed on November 20, 2009, specifies the following:

- What components of a prescription label are considered “patient-centered”
- The font type, font size, wording and placement of specified components of a prescription label
- The Board will publish on its Web site by October 2011 translations of specified directions for use into at least five (5) languages other than English
- The Board will publish on its Web site by October 2010 examples of prescription labels that conform to the requirements of the regulation
- A pharmacy, upon request of a patient, shall provide oral interpretive services of the “patient-centered” elements of the prescription label, and
- The Board will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with the California Patient Medication Safety Act (Business and Professions Code section 4076.5)

Contained within the provisions of the proposed regulation, the board will publish on its Web site by October 2011 translations of the “directions for use” as specified in the proposed regulations, into at least five (5) languages other than English. The board will work with research health care advocates to develop these translations.

To assist those with limited English proficiency, and upon request by a patient, the proposed regulations will require a pharmacy to provide an oral language translation of the “patient-

centered” components of a prescription label, as specified in the proposed regulatory language.

At its board meeting held October 20, 2009, representatives from chain and retail pharmacy representatives stated that their existing oral language translation services provided to insured patients would be extended to cover all non-English speaking patients, if requested, with no further economic impact on their industry. The board commends the pharmacy industry for recognizing this significant component of delivering prescription drugs, and for meeting the needs of these patients.

Finally, the board included in its proposed regulations a requirement that it will re-evaluate the requirements of the regulations by December 2013 to ensure the effectiveness of the regulation in light of the factors contained in the California Patient Safety Medication Act (e.g., new developments in technology).

Regulation Schedule

The board issued proposed regulatory text on November 20, 2009. A 45-day comment period will close on January 4, 2010.

In addition, the board has scheduled a regulation hearing for January 20, 2010, in Sacramento. At that time, the board will accept written and verbal testimony and comments concerning the draft proposal. This hearing will be conducted prior to its regularly scheduled public Board Meeting that

same day and the board, at that time, may take action to adopt, amend, or to not move forward with the proposed regulation.

The board also scheduled a public Board Meeting for February 17, 2010, in anticipation of the need for a 15-day comment period of modified text following the regulation hearing and Board Meeting.

The board believes this regulation schedule will allow industry approximately ten months to prepare for the implementation of new regulatory requirements. The board also believes its current Board Meeting schedule will allow it to address the needs of industry and the public, and provide for the required reviews prior to implementing a regulation by the January 2011 mandate contained in SB 472.



California State Board of Pharmacy
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Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting April 12, 2008

Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA

10 a.m. – 2 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

10 a.m.

1. Invitation to Participate in the Redesign of Prescription Container Labels
Committee Chair Ken Schell, PharmD
2. Opening Remarks
The Honorable Ellen Corbett, California Senator, District 10
3. Presentation of SCR 49 findings, and the need for patients to understand their drug therapy as a source of reducing medication errors.
Michael Negrete, PharmD
4. Requests for Public Comment on the Following: What works on prescription container labels? What does not? How can prescription container labels be improved to make them patient-centered?
5. Timeline for Project
6. Future Meeting Dates

Adjournment

2 p.m.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF PUBLIC BOARD MEETING OF THE CALIFORNIA STATE BOARD OF PHARMACY

FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS

November 20, 2008
1:30 p.m. - 4:30 p.m.

The Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

Contact: Virginia Herold
(916) 574-7911

This forum is hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being. The public is invited to attend.

This meeting is open to the public (no pre-registration is required) and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Gallagher at (916) 574-7912, at least five working days prior to the meeting. Opportunities are provided to the public to address the board on each open agenda item. Action may be taken on any item on the agenda by the Board of Pharmacy. All times are approximate and subject to change.

-
1. **Welcoming Remarks** 1:30 p.m.
Kenneth Schell, PharmD, President, California State Board of Pharmacy
 2. **Improving Prescription Container Labels – What is the Status of the Research**
Michael S. Wolf, PhD, MPH, Feinberg School of Medicine, Northwestern University
Stacy Cooper Bailey, MPH, Feinberg School of Medicine, Northwestern University
 3. **Patient Health Literacy in the U.S. and its Impact on Health**
Michael Villaire, MSLM, Director Programs and Operations, Institute for Healthcare Advancement
 4. **Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling**
Vanessa Cajina, Director, Regional Networks Coordinator, Latino Coalition for a Healthy California
 5. **Perspective of California's Seniors to Improve Prescription Container Labeling**
 6. **Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy**
Virginia Herold, Executive Officer, California State Board of Pharmacy
 7. **Next Steps**
 8. **Public Comments for Items Not on the Agenda**
 9. **Adjournment** 4:30 p.m.



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Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
January 27, 2009

Sheraton Hotel - Mission Valley
1433 Camino Del Rio South
San Diego, CA, 92108
(619) 260-0111

1 – 5 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

1 p.m.

1. Welcoming Remarks
Subcommittee Chair Ken Schell, PharmD
2. Review of Consumer Surveys Conducted by the Board of Pharmacy
3. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy
4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076)
5. Timelines for Project Deliverables
6. Public Comment
7. Future Meeting Dates

Adjournment

5 p.m.



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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting

March 12, 2009

Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7900
6 - 9 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

6 p.m.

1. Welcoming Remarks
2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels
3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance
4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472
6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
7. Legislative Proposal to Add "Purpose" to Prescription Container Labels
8. Public Comment for Items Not on the Agenda
(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment

9 p.m.



CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.

What information on the label is most important to you?

Do you understand the directions?

What would you change on the label?

What would make the label easier to read?

Other suggestions:

City: _____ Date: _____



Examples of warning labels



Printed information in different colors



Examples of different container shapes and sizes requiring different types of labels



Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834



CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ Fecha: _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834



CONSUMIDORES – ¡Queremos oír de usted!

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Ciudad: _____ Fecha: _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

RESULTS: A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (224 of 1,207 responses = 18.6%)

Name of drug; if generic, state generic name AND brand name (222 of 1,207 responses = 18.4%)

Dosage prescribed (213 of 1,207 responses = 17.6%)

Side effects/warnings/interactions/contraindications (122 of 1,207 responses = 10.1%)

Purpose of drug – state what condition medication is prescribed to treat (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (170 of 568 responses = 30%)

Nothing needs to be changed on the label (139 of 568 responses = 24.5%)

Include purpose of drug – state what condition medication is intended to treat (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (314 of 522 responses = 60%)

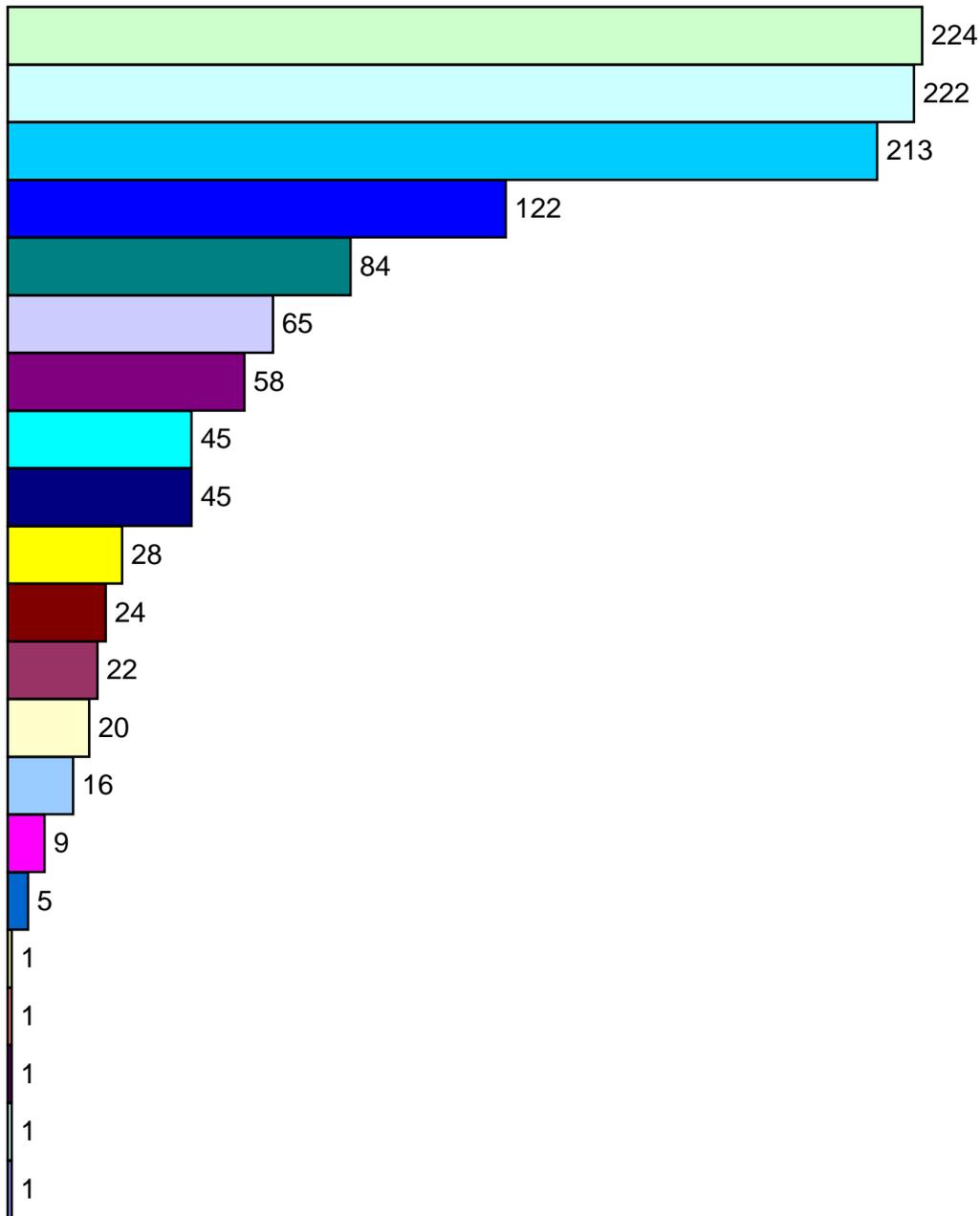
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 134 responses = 14.9%)

Include purpose of drug - state what condition medication is intended to treat (17 of 134 responses = 12.7%)

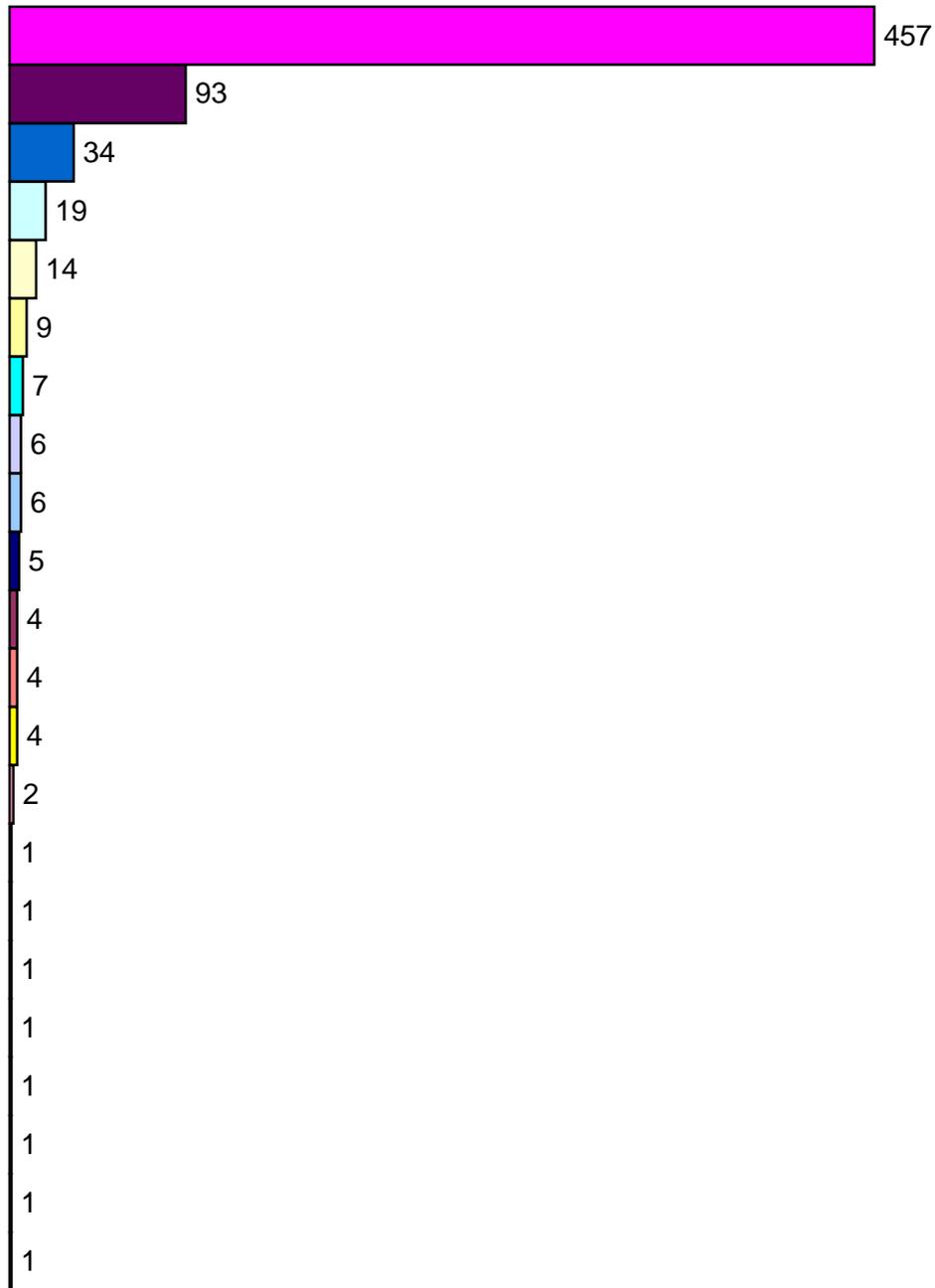
CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

QUESTION #1: What information on the label is most important to you?
622 surveys returned (1,207 responses to Question #1) as of March 3, 2009



- Directions for use
- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Phone numbers (NOT printed in close proximity to each other)
- Prescribing doctor's name
- Description of pill (shape/color)
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- With a large family, keep all prescriptions in the same place
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

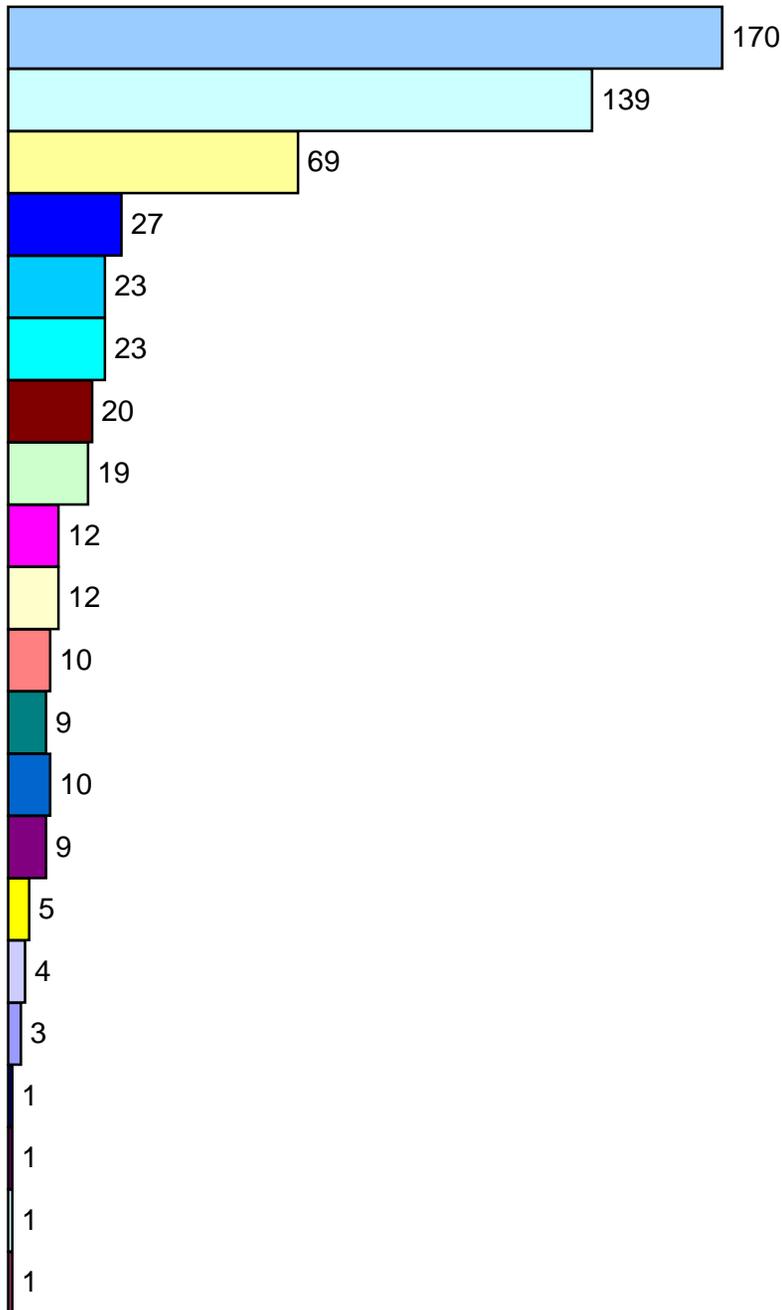
QUESTION #2: Do you understand the directions on the prescription label?
622 surveys returned (672 responses to Question #2) as of March 3, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

622 surveys returned (568 responses to Question #3) as of March 3, 2009



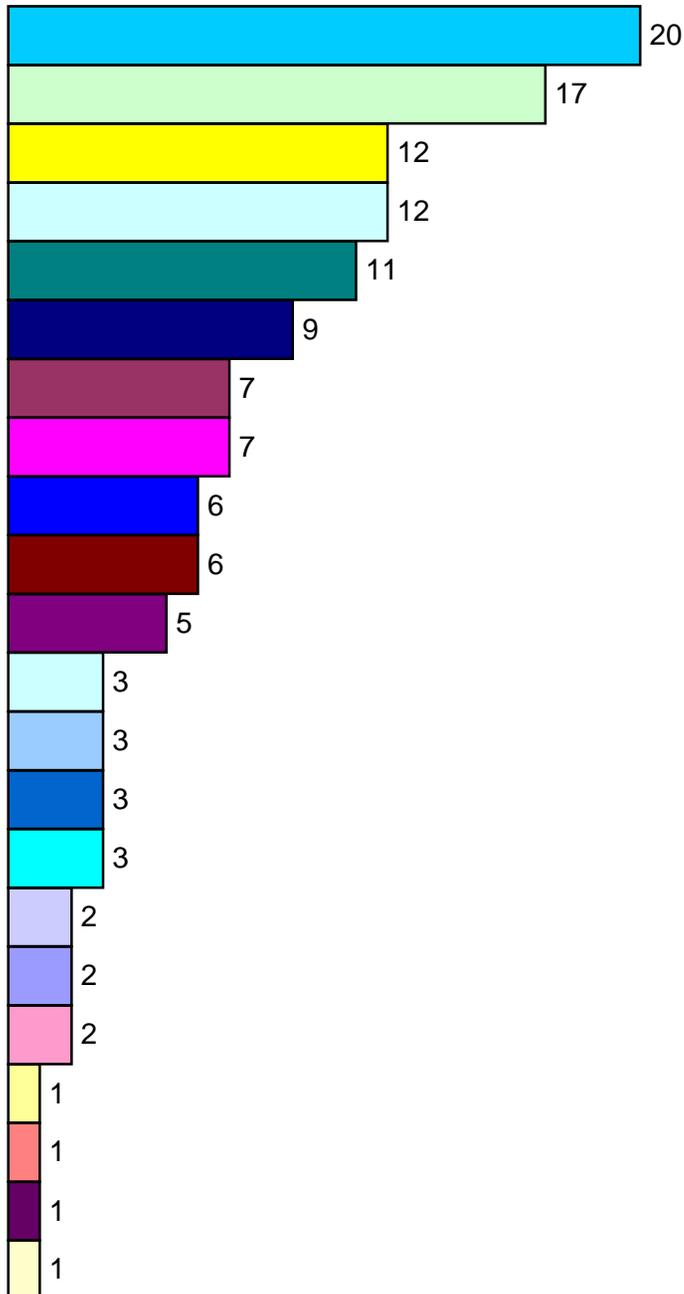
- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?
622 surveys returned (522 responses to Question #4) as of March 3, 2009



QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via pharmacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

**COMMUNITY ORGANIZATIONS AND OTHER ENTITIES
PROVIDED WITH BOP PRESCRIPTION LABEL SURVEYS 2008/09**

The organizations and individual entities listed below were provided with English and Spanish versions of the California State Board of Pharmacy Prescription Label Survey during 2008/09.

- | | |
|--|---|
| <p>1. Casey Young
AARP State Legislative Director
1415 L Street, #960
Sacramento, CA 95814
(916) 556-3018
cyoung@aarp.org</p> | <p>7. Sandra Fitzpatrick, Director
California Commission on Aging
1300 National Drive, Suite #173
Sacramento, CA 95834
(916) 419-7591
sfitzpatrick@ccoa.ca.gov</p> |
| <p>2. Sam Totah
Kaiser Permanente
10990 San Diego Mission Road
San Diego, CA 92108
sammy.r.totah@kp.org</p> | <p>8. Steve Blackledge
CalPIRG
1107 9th Street, Suite #601
Sacramento, CA 95814
(916) 448-4516
Sblackledge@calpirg.org</p> |
| <p>3. Vanessa Cajina
Latino Coalition for a Healthy California
1225 8th Street, Suite 500
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(916) 448-3234
vcajina@lchc.org</p> | <p>9. Betty Williams, Executive Director
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| <p>4. Nancy Kawahara, PharmD
Associate Professor of Pharmaceutical
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11262 Campus St, West Hall, Room 1334
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19. Lavender Seniors of the East Bay
1395 Bancroft Avenue
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20. East Bay Services for the Developmentally
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797 Montague Ave.
San Leandro, CA 94577
21. Evergreen Senior Program/Wisdom Path
985 Suerro Street
Hayward, CA 94541
22. Hayward Area Senior Center
22325 N. 3rd Street
Hayward, CA 94546-6969
23. Kenneth Aitken Senior & Community
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Castro Valley, CA 94546
24. Ralph & Mary Ruggieri Senior Center
33997 Alvarado-Niles Road
Union City, CA 94587
25. Newark Senior Center
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26. Fremont Multi-Service Senior Center
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**PUBLIC OUTREACH EVENTS WHERE BOP STAFF INTERVIEWED ATTENDEES AND
COMPLETED BOP PRESCRIPTION LABEL SURVEYS**

1. Meet The Pharmacist – San Diego – May 2008
2. Senior Day in The Park – Elk Grove – May 2008
3. Better Business Bureau Community Alliance Day – Merced – June 2008
4. Eddie Smith Senior Center – Riverside – June 2008
5. Safetyville Family Safety Expo – Sacramento – June 2008
6. Lotus Festival – Los Angeles – July 2008
7. California State Fair – Sacramento – August 2008
8. Celebrando Nuestra Salud – Sacramento – October 2008
9. Evans Community Adult School Consumer Fair – Los Angeles – March 2009

Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

CALIFORNIA STATE
BOARD OF PHARMACY



A prescription label says to "Take two tablets by mouth twice daily." Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be "Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to \$1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD.
SUITE N-219
SACRAMENTO, CA 95834



sample prescription labels

OUS/pharmacy #0000 Ph: 555-555-5555 PC

000 WEST AVE
DAVIS, CA 95618

SODERGREN, ANNE
1625 N MARKET BLVD
Sacramento, CA 95834

PRESCRIBER:
Perez, Victor

Rx: 000000

**USE INTRAMUSCULARLY
LATERAL THIGH AS NEEDED
FOR SEVERE ALLERGIC
REACTION**

EPIPEN 0.15 MG/2-PAK AUTO-IDEY
PHARM FARM

Refillable 3 times before 01-03-2008

HAGEN, VERONICA
Date filled: 01-03-2007 Orig Date: 01/03/2007 Discard After:

KENNETH'S PHARMACY

Refill Phone:
(555) 555-5555
www.AP.com

DESSERT MEDICAL/030
1025 North Market Blvd., Suite N-219
Sacramento, CA 95834
(555) 555-5555

Cannot Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

Rx# 554484100

Perez, Victor I 11/12/07 PXA
TAKE 1 TABLE SPOON THREE TIMES A DAY AS NEEDED FOR
COUGH

PROMETHAZINE/CODEINE SYRUP
QTY: 480ML Mfr: PHARM FARM
CLEAR, PURPLE-RED, PEACH-MINT, SYRUP.

Discard: _____
(FOR: PHENERGAN/CODEINE)

Please call 48 hrs in advance for refills.

Linda's Drugs TAKE MEDICATION WITH FOOD

Store # 1025 N MARKET
SACRAMENTO, CA 95834
0000 24 HOUR PHONE (555) 555-5555

Perez, Victor MD
Rx: 000000 01/07/2008 HAH
Durst, Sue

TAKE 1 CAPSULE TWICE A DAY

Generic for ACTIGALL
URSODIOL 300 MG CAPSULE
60 (PHARM FARM) J35L11Y

WHITE, OBLONG CAPSULE
Front: PHARM Back: 0000

NO REFILLS

Title 16. Board of Pharmacy Proposed Language

To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5 Patient Centered-Labels on Medication Containers

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.
- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:
- (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.
- (2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 tablet at bedtime
 - (B) Take 2 tablets at bedtime
 - (C) Take 3 tablets at bedtime
 - (D) Take 1 tablet in the morning
 - (E) Take 2 tablets in the morning
 - (F) Take 3 tablets in the morning
 - (G) Take 1 tablet in the morning, and Take 1 tablet at bedtime

- (H) Take 2 tablets in the morning, and Take 2 tablets at bedtime
 - (I) Take 3 tablets in the morning, and Take 3 tablets at bedtime
 - (J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
 - (K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
 - (L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
 - (M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
 - (N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
 - (O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
 - (P) Take 1 tablet as needed for pain. You should not take more than ___ tablets in one day
 - (Q) Take 2 tablets as needed for pain. You should not take more than ___ tablets in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
- (d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.
- (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.