

# California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



### COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ricardo Sanchez, Public Member, Chairperson Jason Weisz, Public Member, Vice Chairperson Ryan Brooks, Public Member Shirley Kim, Public Member Seung Oh, Licensee Member

The Communication and Public Education Committee will meet January 27, 2020. An update of the committee's work will be provided during the Board meeting.

# a. <u>Discussion and Consideration of Possible Changes to the Notice to Consumers</u> Poster/Display

## **Background**

Business and Professions Code (BPC) <u>section 4122</u> requires pharmacies to prominently post a notice provided by the Board to inform consumers about:

- the availability of prescription price information;
- the possibility of selecting generic drugs;
- the type of services provided by pharmacies; and
- a statement describing patients' rights pursuant to BPC <u>section 733</u>, which prohibits
  a licensee from obstructing a patient from obtaining a legally prescribed drug or
  device except in specific circumstances.

California Code of Regulations (CCR), title 16, <u>section 1707.6</u> requires pharmacies to post a "Notice to Consumers" poster or video screen that is conspicuous and readable by consumers. Section 1707.6(b) specifies the wording of the notice. Any changes to the current wording would require rulemaking to amend section 1707.6. and possible legislation to amend BPC sections.

Copies of the text of BPC sections 4122 and 733 and CCR section 1707.6 are in **Attachment** 1.

The Board provides English and Spanish versions of the poster that are 18-by-24 inches in size and versions in Chinese, Korean, Russian, Tagalog, and Vietnamese that are 11-by-14 inches. A copy of the English version is in **Attachment 1**.

The committee has asked staff to recommend ways to refresh the notice poster. At the January 2020 meeting, the committee directed staff to seek input from consumer groups on possible changes to the wording of the notice.

## Suggestions Regarding the Notice Wording and Design

Staff reached out to several groups and received feedback from three that were involved in developing the current poster: the California Alliance of Retired Americans (CARA), the California Pan-Ethnic Health Network (CPEHN), and Health Access California. Suggestions included:

- The poster should have larger type that can be read from a distance of 15 to 20 feet.
- The main headline should be "Know Your Rights!"
- Important consumer rights should be listed in a single column rather than two.
- The poster should have information about the right to have translated labels.
- The design should be updated with modern design standards. It should have more photos/illustrations to draw the viewer's attention.
- It's important that consumers can read their medication labels. Inform them they have a right to ask for easy-to-read print in 12-point font.
- Make sure people are aware 1) they can ask for interpretive services, and 2) interpretive services must be provided at no cost to the consumer.
- Use strong language.
- Make clear to consumers "If you have a complaint, contact the Board of Pharmacy" and provide Board's contact information.
- Do not make the notice a "catch all" for everything too much information to include on the poster.

In addition, staff solicited feedback from Board inspectors who observe pharmacy operations and interactions with consumers. Some key suggestions:

- Consumers no longer need to request 12-point font since it is now required by regulation.
- Emphasize the availability of interpreter services maybe also print in Spanish or other language.
- Tell consumers to check the label to verify the patient's name and the medication name and strength.
- Tell consumers to check the pills inside the bottle to be sure they match the physical description of the medication printed on the label.
- Tell consumers they can ask their prescriber to put the purpose for the medication on the prescription label.
- Use strong clear wording, underlined text, bold text, large type, and bullet points. Instead of saying "You have the right to ask for...", say "This pharmacy must provide...".
- Regarding consultation requirement:
  - Keep this as a priority in large type.
  - o Include other instances where the pharmacist must speak with consumer, not just when getting a new medication.
- Direct consumers to the "consumers" section of the Board's website for information.
- Add information about corresponding responsibility for patients filling controlled substance prescriptions.
- Add information about getting emergency refills during a declared disaster.

• Add information about drug take-back programs.

In addition to wording, staff notes that good design is critical to creating a poster that conveys information that is easy to read and understand. Most publications use clean, simple, visual elements such as photos, icons, or other graphics to illustrate text. Examples of DCA publications that use visual elements effectively are in **Attachment 1**.

## Staff Recommendation

The Notice to Consumers provides important information to the public about their rights and what to ask a pharmacist about their medications. However, the dense wording of the poster overloads consumers with too much information to process and understand. In addition, the text leaves less space for visual elements that convey information effectively.

Staff recommends the committee consider focusing on what are the most important things a consumer should know when visiting their pharmacy. The suggestions provided by consumer advocates and Board inspectors are useful as a starting point. It is worth noting that both groups have suggested pharmacist consultation and the right to free interpretive services are important messages for pharmacy consumers.

Staff welcomes suggestions and direction on possible wording or other matters regarding the Notice to Consumers poster.

# b. <u>Discussion and Consideration of Requiring Pharmacies to Provide a Telephone Number on Prescription Labels</u>

### Background

At the November 2019 Board meeting, the Board adopted language to amend CCR section 1707.2 related to mail order pharmacy consultation. The regulation requires mail order pharmacies to provide a phone number for patients to receive consultation from a pharmacist.

During the Board's discussion, it was noted that <u>out-of-state</u> pharmacies must provide a toll-free number to facilitate communication between patients and pharmacists, and the number must be provided on the prescription label. However, there is no requirement for <u>in-state</u> pharmacies to provide any phone number on labels.

The Board directed the Communication and Public Education Committee to discuss and consider whether all pharmacies should be required to provide a phone number on prescription labels.

## For Discussion and Consideration

<u>BPC section 4076</u> and <u>CCR section 1707.5</u> provide requirements for patient-centered labels on prescriptions dispensed to patients in California. Neither section requires pharmacies to provide a phone number on the prescription label. Copies of BPC section 4076 and CCR section 1707.5 are in **Attachment 2.** 

For comparison, staff researched prescription label requirements in two neighboring states and two large states. A brief review of online sources indicates:

- Arizona does not require dispensers to provide a phone number on prescription labels, except mail order pharmacies must provide a toll-free number on a label affixed to each dispensed container.
- **Nevada** does not require pharmacies to provide a phone number on prescription labels
- New York does require prescription labels to include a pharmacy phone number.
- **Texas** requires prescription labels to include a pharmacy phone number.

Staff notes that BPC section 4076 and CCR section 1707.5 already require a lot of information to be printed on prescription labels, including the following items:

- Patient's name.
- Drug name and strength.
- Directions for use of the drug.
- The condition or purpose for the drug if the condition/purpose is indicated on the prescription.
- Prescriber's name.
- Date of issue.
- Pharmacy name and address and a prescription number.
- Drug quantity.
- Drug expiration date.

Should the committee and Board agree from a policy perspective the incorporation of the phone number is important, such a change would most likely need to be done either through statutory or regulation change. In addition, there could be a cost in requiring pharmacies to provide phone numbers on labels.

Staff welcomes discussion and direction on this matter.

# c. <u>Discussion and Consideration of Developing Information Materials about the Board of Pharmacy for Consumers</u>

The Board provides the public with important information about patient care, consumer protection, and regulatory issues through a variety of print and electronic materials. These materials include brochures about counterfeit prescription drugs, an online directory of drug take-back locations, and webpages with links to drug abuse prevention resources.

Staff is proposing to develop additional educational materials about the mission and work of the Board of Pharmacy. As an example, materials would provide basic information about the Board's membership – number of members, licensees and public members, Board committees, how to participate in meetings, etc.

Other information could explain the rulemaking process, how complaints are investigated, the disciplinary process, and other ways that the Board performs its consumer protection functions. In addition, educational materials could explain why consumers should talk to their pharmacists and what consumers should ask about their medications.

Information would be posted on the Board's website and also available to download, print and distribute. Hard copies would be available to disseminate to the public at Board meetings, training events, and public outreach activities.

These materials would increase general awareness of the Board and educate the public about the Board's role as a consumer protection agency. Staff welcomes suggestions regarding topics that should be included in information materials about the Board.

### d. Update on Communication and Public Education Activities by Staff

## 1. The Script

Articles planned for the next newsletter include new pharmacy laws for 2021, a reminder about new security prescription form requirements and CURES reporting requirements, and tips for completing a pharmacy technician application. Articles have been submitted for legal review. Publication is expected in January or February.

## 2. Board-Provided Training

Inspectors and staff provided CE training via WebEx on "Prescription Drug Abuse and Diversion – What a Pharmacist Needs to Know" on October 7 and December 16. A total of about 150 pharmacists participated in the events.

### 3. Staff Outreach

A list of staff outreach activities between October 1 and December 31, 2020, is in **Attachment 3**.

### 4. News Media

Staff responded to news media inquiries listed in **Attachment 4**.

#### e. Future Meeting Dates

Scheduled committee meetings in 2021 are:

- April 29.
- July 14.
- October 27.

## Adjournment

**Upon conclusion of business** 

# Attachment 1

- 1. Text of BPC section 4122, BPC section 733, and CCR section 1707.6
- 2. Notice to Consumers Poster
- 3. Three Samples of DCA Publications

# BUSINESS AND PROFESSIONS CODE - BPC DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

## CHAPTER 9. Pharmacy [4000 - 4427.8]

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

## **ARTICLE 7. Pharmacies [4110 - 4126.9]**

(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

### 4122.

- (a) In every pharmacy there shall be prominently posted in a place conspicuous to, and readable by, prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, the type of services provided by pharmacies, and a statement describing patients' rights relative to the requirements imposed on pharmacists pursuant to Section 733. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.
- (b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.
- (c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:
- (1) The request shall be in writing.
- (2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.
- (3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.
- (4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.
- (d) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.
- (e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:
- (1) Provide the price of any controlled substance in response to a telephone request.
- (2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester. (Amended by Stats. 2007, Ch. 130, Sec. 11. Effective January 1, 2008.)

# BUSINESS AND PROFESSIONS CODE - BPC DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

## CHAPTER 1. General Provisions [500 - 865.2]

(Chapter 1 enacted by Stats. 1937, Ch. 399.)

## ARTICLE 10.5. Unprofessional Conduct [725 - 733]

(Article 10.5 added by Stats. 1979, Ch. 348.)

### 733.

- (a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.
- (b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:
- (1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.
- (2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:
- (A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.
- (B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.
- (C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.
- (3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the

prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (I) of Section 12940 of the Government Code.

- (c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.
- (d) This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives described in Section 4052.3.
- (e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.
- (f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

(Amended by Stats. 2013, Ch. 469, Sec. 1. (SB 493) Effective January 1, 2014.)

# § 1707.6. Notice to Consumers.

- (a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
- (b) The notice shall contain the following text:

### NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

*You* have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

*Point* to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance.

Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

# Ask Your Pharmacist!

You have the right to ask the pharmacist for:

# Easy-to-read type

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

# Interpreter services

Interpreter services are available to you upon request at no cost.

# **Drug pricing**

You may ask this pharmacy for information on drug pricing and use of generic drugs.

California law requires a pharmacist to speak with you every time you get a **new** prescription.

Before taking your medicine, be sure you know:

- 1 The name of the medicine and what it does.
- 2 How and when to take it, for how long, and what to do if you miss a dose.
- 3 Possible side effects and what you should do if they occur.
- 4 Whether the new medicine will work safely with other medicines or supplements.
- 5 What foods, drinks, or activities should be avoided while taking the medicine.

# Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless:

- It is not covered by your insurance;
- You are unable to pay the cost of a copayment;
- The pharmacist determines doing so would be against the law or potentially harmful to health.

If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.







# WELCOME.

To the Department of Consumer Affairs' "Expanding Earn and Learn Models in the California Health Care Industry" meeting

# **AGENDA**

1:30-1:45 p.m. Welcome & Opening Remarks

Dean R. Grafilo, Director Department of Consumer Affairs

Assemblymember Freddie Rodriguez District 52 – Pomona, Calif.

Eric Rood, Chief

Division of Apprenticeship Standards, Department of Industrial Relations

1:45-1:55 p.m. Committee Member Introductions

1:55-2:10 p.m. Presentation on

DCA's Implementation Efforts & Next Steps

Alana Bui, Workforce Development

and Policy Coordinator

Department of Consumer Affairs

2:10-2:20 p.m. Question & Answer

2:20-2:50 p.m. Guest Speaker

Robert Millay, R.N., MSN Ed. Professor/Director, Psychiatric Technicians Program, Napa Valley

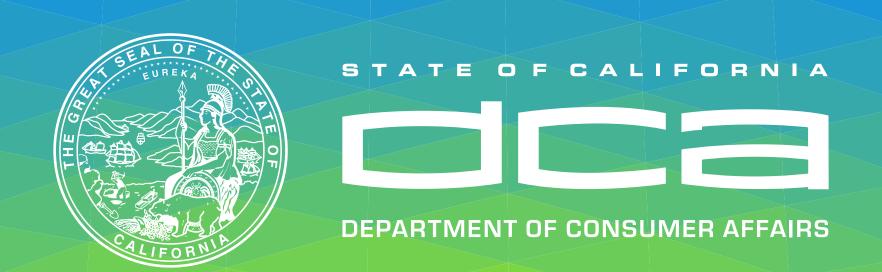
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2:50-3 p.m. Question & Answer

3 p.m. Closing Remarks

Dean R. Grafilo, Director Department of Consumer

Affairs



# ♥ H E A L T H

# **3 STEPS FOR SAFETY**

SLOW THE SPREAD OF THE CORONAVIRUS IN CALIFORNIA

### These three small steps will make a big difference:

- For our health—Save countless lives through m prevention.
- For our economy—Help businesses reopen, m and employees return to work.m
- For our future—Get our Golden State going m again.





# **WEAR A MASK**

FACE COVERINGS KEEP THE CORONAVIRUS FROM SPREADING.





# **WASH YOUR HANDS**

WASHING WITH SOAP AND WATER FOR 20 SECONDS KILLS THE CORONAVIRUS.





# **KEEP YOUR DISTANCE**

MAINTAIN 6 FEET BETWEEN YOURSELF AND OTHERS.



IN THE SPOTLIGHT

# **COVID-19 REMINDERS**

## **SAFETY TIPS**

The California Department of Public Health recommends the following steps to prevent the spread of all respiratory viruses:



# WASH. YOUR. HANDS.

WASH YOUR HANDS WITH SOAP AND WATER REGULARLY.





# **KEEP YOUR DISTANCE**

AVOID CLOSE CONTACT WITH PEOPLE WHO ARE SICK.



# **COVER A COUGH OR SNEEZE**

COVER YOUR COUGH OR SNEEZE WITH YOUR SLEEVE OR DISPOSABLE TISSUE.



# **STAY HOME**

IF YOU EXPERIENCE RESPIRATORY SYMPTOMS LIKE A FEVER OR COUGH, STAY HOME.



# **DON'T TOUCH**

AVOID TOUCHING EYES, NOSE, OR MOUTH WITH UNWASHED HANDS.



# **GET HELP**

IF YOU EXPERIENCE SYMPTOMS OF COVID-19, CALL YOUR HEALTH CARE PROVIDER.

## **MORE INFORMATION**

Get the latest news and data from the California Department of Public Health—www.cdph.ca.gov or follow @capublichealth—or visit www.covid19.ca.gov.



# **Attachment 2**

- 1. BPC Section 4076.
- 2. CCR Section 1707.5.

# BUSINESS AND PROFESSIONS CODE - BPC DIVISION 2. HEALING ARTS [500 - 4999.129]

(Division 2 enacted by Stats. 1937, Ch. 399.)

## **CHAPTER 9. Pharmacy [4000 - 4427.8]**

(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)

## ARTICLE 4. Requirements for Prescriptions [4070 - 4079]

(Article 4 added by Stats. 1996, Ch. 890, Sec. 3.)

### 4076.

- (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
- (1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
- (2) The directions for the use of the drug.
- (3) The name of the patient or patients.
- (4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.
- (5) The date of issue.
- (6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
- (7) The strength of the drug or drugs dispensed.
- (8) The quantity of the drug or drugs dispensed.
- (9) The expiration date of the effectiveness of the drug dispensed.
- (10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

- (11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
- (i) Prescriptions dispensed by a veterinarian.
- (ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
- (iii) Dispensed medications for which no physical description exists in any commercially available database.
- (B) This paragraph applies to outpatient pharmacies only.
- (C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
- (D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.
- (b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.
- (c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.
- (d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.
- (e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

(Amended by Stats. 2015, Ch. 784, Sec. 1. (AB 1073) Effective January 1, 2016.)

## 16 CCR § 1707.5

# § 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
- (1) Each of the following items, and only these four 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 of the drug, or the generic name and the statement "generic for \_\_\_\_\_" where the brand name is inserted and the name of the manufacturer. In the professional judgment of the pharmacist:
- (i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and
- (ii) The manufacturer's name may be listed outside of the patient-centered area.
- (C) The directions for the use of the drug.
- (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
- (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 [insert appropriate dosage form] at bedtime
- (B) Take 2 [insert appropriate dosage form] at bedtime
- (C) Take 3 [insert appropriate dosage form] at bedtime
- (D) Take 1 [insert appropriate dosage form] in the morning

- (E) Take 2 [insert appropriate dosage form] in the morning
- (F) Take 3 [insert appropriate dosage form] in the morning
- (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and I [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take \_\_ [insert appropriate dosage form] at a time. Wait at least \_\_ hours before taking again. Do not take more than \_\_ [appropriate dosage form] 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) 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) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
- (e) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

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

# **Attachment 3**

**Staff Outreach** 

#### Staff Outreach

Staff participated in the following outreach activities between October 1 and December 31, 2020:

- October 21: Executive Officer Anne Sodergren participated in a panel discussion "Pharmacy, Government, and Emergency Preparedness: the COVID-19 Pandemic and Beyond" hosted by CSHP.
- October 22: Executive Officer Anne Sodergren provided a Board of Pharmacy Law and Update presentation hosted by CSHP.
- October 27: Executive Officer Anne Sodergren presented and participated in a Q&A session at the FDA's 2020 Virtual Intergovernmental Working Meeting on Drug Compounding, highlighting the Board's approach to the regulation of sterile compounding pharmacies and outsourcing facilities during the COVID-19 pandemic.
- October 31: Executive Officer Anne Sodergren a Board of Pharmacy Law and Update presentation hosted by CPhA.

# **Attachment 4**

**News Media Inquiries** 

## **News Media Inquiries**

Board staff responded to the following recent news media inquiries:

- October 30, 2020: Jeff Burdick, Sacto Politico, regarding stipulated settlement with wholesaler AmerisourceBergen effective February 21, 2020.
- January 12, 2021: Paul Sisson, San Diego Union-Tribune, regarding expired "vaccination certificates" for pharmacists providing COVID-19 vaccinations.