



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ryan Brooks, Chairperson
Shirley Wheat, Public Member
Lavanza Butler, RPh
Ramon Castellblanch, Public Member
Albert Wong, PharmD

1. FOR DISCUSSION AND ACTION: Requests from California Pharmacies

The board has delegated to the Communication and Public Education Committee the authority to approve all requests for alternate formats or display methodologies of the Notice to Consumers Poster and/or the Notice of Interpreter Availability Poster. Staff has developed a request form that may be used by pharmacies requesting approval of an alternate format or display methodology. Use of the form is not required.

a. **“Notice of Interpreter Availability” Poster (16 Cal.Code Reg § 1707.6(e))
Walmart Request to Use an Alternate Format in all Walmart and Sam’s Club
Pharmacies**

Attachment 1

Board regulation at section 1707.6(c) requires every pharmacy to post or provide a **“point to your language”** notice so that consumers are aware that interpreter services will be provided to them at no cost. On this notice, the words *“Point to your language. Interpreter services will be provided to you upon request at no cost.”* are to appear in English and in twelve additional, specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese.

Walmart is requesting approval to use an alternate format of the board’s “Notice of Interpreter Availability” poster. When considered in October 2013, the committee denied the request because required “point to your language” verbiage was not consistent with the board’s regulation. Walmart has revised their notice to read as required by the regulation, and has also added a footer that the notice is required by the California State Board of Pharmacy to be posted. Walmart’s request and sample posters are provided in **Attachment 1** and are summarized below.

Scope: Walmart Stores, Inc. is requesting approval of the alternative format of the “point to your language” notice for all Walmart and Sam’s Club pharmacies currently licensed by the board, as well as for those that may be licensed by the board in the future.

As of December 24, 2013, the board has issued the following permits to Wal-Mart and Sam's Club pharmacies:

Wal-Mart: 248 pharmacies in California, 1 out-of-state pharmacy

Sam's Club: 30 pharmacies in California, no out-of-state pharmacies

Alternative Poster: The notices will be printed in color on 8 1/2"x 11" paper (samples provided).

Location of Poster: The notices will be placed at both the prescription drop-off and prescription pick-up counters, within reach of the consumer at all Walmart and all Sam's Club community pharmacies.

Languages: Walmart's "point to your language" poster contains the twelve languages specified in Board regulation, as well as four additional languages: Portuguese, Polish, French (Canadian), German and Italian. In addition, Walmart's notice also includes both "simplified" and "traditional" Cantonese and Mandarin. The languages specified on the notices reflect Walmart's nationwide demographic data.

**b. "Notice to Consumers" Poster (16 Cal.Code Reg § 1707.6(a))
Safeway Request for Approval to Use an Alternate Display Methodology**

Attachment 2

Board regulation at section 1707.6(a) requires every pharmacy to prominently post, in a place conspicuous to and readable by prescription drug consumers, a **Notice to Consumers** as made available by the board. The regulation allows a pharmacy to also or instead display the notice on a video screen that is 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 video images available on the board's website are two *PowerPoint* formats (slides) – one in English and one in Spanish.

Print images of the Notice to Consumers poster are also available for download from the board's website in the following languages: English, Spanish, Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese.

Request: Safeway is seeking approval to instead display the board's (PDF) "Notice to Consumer" poster in English on a 24" diagonal video screen, displayed for 60 seconds at a time, and where not more than five minutes will elapse between displays (as measured from the beginning of the display, to the time where the notice again displays). The screen will be oriented vertically (i.e., portrait). When mounted vertically, a 24" diagonal video screen has a display area of approximately 12 5/8" wide x 23 ½ inches high.

While Safeway/Von's/Pavillions will use the (.PDF) copy of the English Notice to Consumers poster re-sized to fit on the 24" diagonal video screen. In addition, Safeway anticipates they may also rotate in the Spanish poster (PDF) in areas that reflect a significant Hispanic population (based on Safeway's demographics); and where their demographics indicate other significant populations, Safeway may also rotate in the other language posters (PDF) that are available on the board's website.

When printed from the board's website, the eight non-English "Notice to Consumers" posters are approximately 11.5 inches x 15.3 inches. Safeway would re-size these posters to display on the full screen – approximately 12 5/8 wide x 23 ½ inches high.

A copy of Safeway's request and photos are provided in **Attachment 2**. James McCabe, RPh, Director of Patient Care Services for Safeway Inc. will be in attendance and available to answer questions from the committee.

Scope: Safeway Inc. is requesting approval to use an alternate display methodology of the Notice to Consumers poster for all currently licensed Safeway, Von's and Pavillions pharmacies, as well as those that may be licensed by the board in the future.

As of December 24, 2013, the board has issued 306 permits to Safeway pharmacies:

Safeway: 156 pharmacies in California, no out-of-state pharmacy
Von's: 127 pharmacies in California, no out-of-state pharmacies
Pavillions: 23 pharmacies in California, no out-of-state pharmacies

Location in the Pharmacy: As reflected in the pictures, the video screens will be mounted at the pharmacy counter, conspicuous to and readable by a prescription drug consumer. For pharmacies that do not yet have the video-mounted posters, the pharmacy will continue to utilize the printed poster provided by the board.

2. FOR INFORMATION: Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by 16 California Code of Regulations Section 1746

Attachment 3

Title 16, California Code of Regulations Section 1746 authorizes pharmacists to provide emergency contraception without a prescription to patients of any age. Pursuant to a protocol developed between this board and the Medical Board of California, a fact sheet is to be developed and made available to patients at the time of the pharmacist consultation.

In accordance with Business and Professions Code Section 4052.3(e), the board developed the standardized fact sheet that a pharmacist is required to provide a patient when dispensing emergency contraception. The board acquired bids to have this Fact Sheet translated into the following languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. The translations of the EC Fact Sheet are now available on the board's web site for download and are available upon request. Copies of the English, Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese fact sheets have been provided in **Attachment 3**.

3. FOR INFORMATION: Presentation and Discussion of a Research Project on Prescription Container Labels by Amir Zargarzadeh and Anandi Law

Attachment 4

In 2009-2010 when the board was developing parameters for patient-centered prescription container labels, Anandi Law attended several of the meetings and provided information about a research project she was working on to design patient-centered prescription labels. Recently, Dr. Anandi had a discussion with Board Member Gutierrez about the research she conducted that was published in March 2011. A copy related articles is provided in **Attachment 4**. Copies of labels developed by these researchers follow at the end of the attachment.

Dr. Anandi will provide a presentation on her findings during this meeting.

4. FOR REVIEW AND DISCUSSION: Assessment of California's Patient-Centered Labeling Requirements as Required by 16 California Code of Regulations Section 1707.5(e)

Attachments 5 and 6

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

The committee began a review of the regulations in April 2013. Materials used in these discussions are provided as **Attachment 5** as a reference to this document to reduce space.

The board started review and discussion of the committee's recommendations at the October 2013 Board Meeting, but lacked sufficient time to finish the process due to the many comments from the board and public present. The board directed the matter back to this committee for additional discussion and refinement. An excerpt of the minutes from the October 2013 Board Meeting is provided as **Attachment 6**.

Two items recommended by the committee were approved as amendments to the regulation by the board:

Board Approved Change 1:

1707.5(a)(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 10-point sans serif typeface or, if requested by the consumer, at least a 12-point 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 name of the manufacturer.
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

Board Approved Change 2:

1707.5(a)(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 10-point sans serif typeface or, if requested by the consumer,~~ 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 name of the manufacturer.
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

Additional Background for the Evaluation:

Business and Professions Code Section 4076.5 requires the board to consider the following factors when developing requirements for the patient-centered prescription label requirements:

- Medical literacy research that points to increased understandability of labels.
- Improved directions for use

- Improved font types and sizes
- Placement of information that is patient-centered
- The needs of patients with limited English proficiency
- The needs of senior citizens
- Technology requirements necessary to implement the standards.

Again, **Attachment 5** contains background used by the staff and committee in researching and evaluating California's the patient-centered labeling requirements. The requirements went into effect on January 1, 2011.

a. Additional Questions for Committee Discussion at this Meeting: Should 1707.5(a)(B) be modified?

Part 1: *Should changes be made to 1707.5(a)(1)(B) regarding the "name of the drug and strength of the drug"?*

Part 2: *Should the name of the manufacturer in the patient-centered portion of the label be removed?*

Part 3: *When a generic drug is dispensed, should the brand name of the generic equivalent be included on the label phrased as "generic for _____"?*

Text of regulation being discussed (non-bolded changes approved by the board at the last board meeting are shown as well):

1707.5(a)(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 10-point sans serif typeface or, if requested by the consumer,~~ 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 name of the manufacturer.**
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

At the last Communication and Public Education Committee meeting, the committee discussed the value of having the manufacturer's name as one of the patient-centered elements. During the October Board Meeting, considerable discussion was unable to result in a board action to conclude action on this item (in part because the draft language was not in written form for board review), and the matter was returned to the committee for additional discussion.

Recommendations provided in research relating this topic are as follows:

- USP suggests that the drug name be spelled out fully (brand AND the generic name) – no abbreviations.
- NABP suggests inclusion of suffixes (CD, SR, XL, XR, etc.) as part of the name.

It was the consensus of the committee in October that having both the trade/brand name and the generic name fully spelled out was needed. In addition, there was consensus that the suffixes referenced in the NABP recommendation were part of the drug name and should be used as part of the name of the drug.

- NABP suggests that if a prescription is written for a brand name and a generic drug is dispensed, then “generic for [brand name]” appear on the label.

The committee noted that it is already required that the manufacturer’s name appear somewhere on a prescription label, and that the committee’s discussion was solely whether or not it was to be included within the patient-centered cluster.

Public comments made at the committee meeting supported that “generic for” appear on the label when a generic drug is dispensed for a trade name drug – in support of the recommendation of the NABP. This is to avoid patient and/or caregiver confusion as to what medication to take, and to avoid adverse events caused by unintentional doubling up of a particular medication. As an example: when dispensing the generic drug hydrochlorothiazide for the brand name Hydrodiuril, a label would state “Hydrochlorothiazide (generic for Hydrodiuril).” Thus a patient who today receives the generic drug at the pharmacy, but has a previously dispensed container at home with the trade name, would be able to identify the two drugs as the same. This would not be possible unless both the generic and brand names appear on the label.

There were comments in support of retaining the *strength of the drug* on the container, as this is it is important to emergency personnel.

It was the consensus of the committee that the “suffixes” referenced in the research is a part of the drug name and should be on the label.

Committee Recommendation: Modify Section 1707.5(a)(1)(B) to:

1. Remove the requirement that the manufacturer’s name be listed in the patient-centered clustered area of the label when a generic is dispensed (the manufacturer’s name still must appear elsewhere on the label); and
2. Amend the language to require that when a generic is dispensed, to say “generic for _____” (the trade name).

Language developed at the board meeting to accomplish the Committee Recommendation above:

1707.5(a)(1)(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, if a generic is dispensed, or the generic name of the ~~manufacturer drug and a parenthetical containing “generic for”~~ and the trade name of the drug.

The committee should affirm this modification to bring to the board at the January 2014 Board Meeting

b. Additional Questions for Committee Discussion at this Meeting: Should Purpose or Condition be in the patient-centered clustered items? Should it be a required element for labels generally?

Currently the board’s regulation provides as one of the patient-centered elements: “The condition or purpose for which the drug is prescribed if the condition or purpose is indicated on the prescription.”

Mandating purpose on the label is a consideration the board deferred until this reevaluation of the regulation. The board has long-standing policy in supporting inclusion of purpose on the label as a key patient safety element. Knowing why a medication is being taken aids patient understanding about drug therapy, provides important information to patient caregivers, and can prevent medication errors when a pharmacy is dispensing a prescription.

There was wide consensus among the committee and the public during the October committee meeting that the purpose or condition should be on the prescription label within the clustered patient-centered items. Staff counsel commented that a statutory change may be needed, as Section 4076 states it is required to be on the label only if it is specified on the prescription.

Staff sought the committee’s input as to whether this should be a regulatory change, or perhaps a statutory change – noting that previous attempts to make a statutory change failed.

This item was not discussed during the October Board Meeting.

Committee Recommendation: Direct staff to work with legal counsel to draft language to amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

Possible approaches should be considered as to what a regulation requirement might look like versus a statutory modification.

c. Additional Questions for Committee Discussion at this Meeting: Should the existing requirements for “added emphasis” in the patient-centered area of 1707.5 be modified?

Current regulation at Section 1707.5(a)(2) states “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).”

The committee noted that not much research is available that addresses these items, however, there is a recommendation in the research that sentence casing be used to provide text on prescription containers and to avoid using all capital letters.

California’s label requirements seem to meet the existing recommendations for use of type font enhancers such as bolding, highlighting and white space. Staff was unable to suggest additional changes, and the committee did not recommend any changes to this requirement.

d. Additional Questions for Committee Discussion at this Meeting: Translations on Labels -- Translated directions for use are available on the board’s website. Should the board require use of them to aid patients with limited or no English proficiency understand the information on the prescription label? Should there be additional requirements?

There are a number of additional questions for the committee’s discussion.

The regulation requires that an oral interpreter be available to assist limited-English speaking patients. Is this sufficient?

- (i) Should the board support translations of labels?
- (ii) Should translations be only of directions for use or the whole patient-centered portion of the label?
- (iii) Should the board support translations of labels only if there is wider use of standardized directions for use?
- (iv) Should the board support translations of labels if there is also a requirement for an English version of the directions on the label as well. Should the English translation appear in the patient-centered dedicated area, or somewhere else on the label?
- (v) Should the board support translations of labels only if there is a liability exemption for pharmacies?

- (vi) Currently labels on all medication provided to patients in California have to be in the board's patient-centered format. Should all practitioners who dispense medication to patients be required to translate the labels if pharmacies are so required?

At the last committee meeting, the committee received public comment in support of translations on prescription labels. Ms. Sarah de Guia, CPEHN, expressed concern over the survey results that indicated that pharmacies were using on-line translation services, such as Google Translations, and she spoke in support of the professional field of translators that are certified to provide these services. She requested that as the board moves forward on its evaluations of the patient-centered labels, that it consider the use of such certified translators. She said CPEHN is concerned about the quality of translations that are being provided. She spoke in support of establishing standards for providing translations.

Another issue related to translations is whether to require the English version of any non-English translated directions for use that appear on a label. The committee did not discuss this item, although there was concern expressed during the October Board Meeting that the existence of translated labels means that the board should reconsider what is included in the dedicated patient-centered area of the label.

The committee did not recommend any modifications to the current requirements at this time, nor did the board.

e. Additional Questions for Committee Discussion at this Meeting: Should the regulations retain the 50 percent dedicated area of the label exclusively for the patient-centered elements?

During the October Board Meeting, the board did discuss whether the 50 percent of the label being dedicated to the four patient-centered elements was too much. Several members were not certain this was the appropriate amount. The committee did not discuss this component of the labels in advance of the board meeting.

Staff notes that it is not aware of any problems with pharmacies being unable to comply with the labeling requirements with the 50 percent, and the standard is relatively easy to assess in a way another percent (say 37 percent) would not.

f. Additional Questions for Committee Discussion at this Meeting: Standardized Directions for use of the drug

There is support in the labeling recommendations of the NABP, USP, and in the NCPDP White Paper regarding emphasizing the use of the standardized directions for use. Standardized directions for use already are listed in the regulation, but are noted as "When applicable, directions for use shall use one of the following phrases."

Work may need to be done with the Medical Board and other prescribing boards to promote and secure the wider use of standardized directions. New research by Mike Wolf previously provided to the committee points to substantial improvement in patient comprehension of using such standardized directions

g. Additional Questions for Committee Discussion at this Meeting: Translated directions for use are available on the board's website. Should the board require use of them to aid patients with limited or no English proficiency understand the information on the prescription label?

The regulation requires that an oral interpreter be available to assist limited-English speaking patients. Is this sufficient?

- (i) Should the board support translations of labels?
- (ii) Should translations be only of directions for use or the whole patient-centered portion of the label?
- (vii) Should the board support translations of labels only if there is wider use of standardized directions for use?
- (viii) Should the board support translations of labels if there is also a requirement for an English version of the directions on the label as well. Should the English translation appear in the patient-centered dedicated area, or somewhere else on the label?
- (ix) Should the board support translations of labels only if there is a liability exemption for pharmacies?
- (x) Currently labels on all medication provided to patients in California have to be in the board's patient-centered format. Should all practitioners who dispense medication to patients be required to translate the labels if pharmacies are so required?

h. Additional Questions for Committee Discussion at this Meeting: Should the board consider technology standards to enhance the patient-centered requirement?

Are there technology impediments to improving prescription container labels?

For example, should the board emphasize the description of the medication on the label as another patient-centered element? Should the board require at some point in the future that a picture of any pill appear on the label as an alternative to a verbal description?

5. FOR INFORMATION: Update on the Committee's Goals for 2012-2017 to Fulfill the Board's Strategic Plan

Staff will bring to the committee meeting information related to setting Committee goals for the Board's Strategic Plan.

6. FOR INFORMATION: Update on *The Script*

The most recent issue of *The Script* was released in November. Work will soon begin on the next issue which will focus on new 2014 laws. We hope to finalize the issue for release sometime in February. In the interim, the board will add a feature to its website to present the text of new 2014 laws.

7. FOR INFORMATION: Discussion Regarding Public Outreach Activities to Address Prescription Drug Abuse

a. Public Continuing Education Training Session Provided by the California State Board of Pharmacy, the Los Angeles Field Division of the Drug Enforcement Administration and County of Orange Health Care Agency: January 22, 2014 in Brea, CA

This continuing education program for pharmacists is being held in conjunction with a new partner, the County of Orange Health Care Agency. The Los Angeles Office of the DEA and the board will provide its usual CE program which now features a strengthened component dealing with a pharmacist's corresponding responsibility.

b. Public Continuing Education Training Session by the California State Board of Pharmacy and Federal Drug Enforcement Administration Scheduled for January 31, 2014 in Sacramento

This six-hour CE presentation will feature Federal DEA Diversion Program Manager Joseph Rannazzisi and the board's strengthened corresponding responsibility component. It is the first time this presentation will be provided in Sacramento.

8. FOR INFORMATION: Public Outreach Activities Conducted by the Board

Staff will bring to the committee meeting information related to public outreach activities conducted during the months of October, November and December.

9. Public Comment for Items Not on the Agenda

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).

Attachment 1

Point to your language.

Interpreter services will be provided to you upon request at no cost.

ARABIC	اختر لغتك. يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة.	Նշեք ձեր լեզուն: Թարգմանչի ծառայություններն անվճար կտրամադրվեն ձեզ ըստ պահանջի:	ARMENIAN
CAMBODIAN	ចូរចង្អុលទៅកាន់ភាសារបស់អ្នក ។ មានផ្តល់សេវាកម្មបកប្រែភាសាដល់អ្នក តាមការស្នើសុំ ដោយឥតគិតថ្លៃ ។	廣州話 指向您的語言。 將根據您的要求免費為您提供翻譯服務。	CANTONESE
FARSI	زبان خود را مشخص کنید. خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.	Taw rau koj yam lus. Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi.	HIMONG
KOREAN	언어를 지정해 주십시오. 요청 시 통역 서비스를 무료로 제공해 드립니다.	指向您的语言。 官話 将根据您的要求免费为您提供翻译服务。	MANDARIN
RUSSIAN	Указать на ваш язык. Услуги переводчика будут бесплатно предоставлены Вам по требованию.	Indique su idioma. Se le proporcionarán servicios de intérprete sin costo si lo solicita.	SPANISH
TAGALOG	Ituro ang iyong wika. Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.	Xin hãy chỉ vào ngôn ngữ của quý vị. Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu.	VIETNAMESE

**Be aware and take care.
Talk to your pharmacist.**

California State Board of Pharmacy

Sign posted as required by the California State Board of Pharmacy

Walmart 
Pharmacy

LEP Signing | ©2013 Wal-Mart Stores, Inc. | 0000000



Point to your language.

Interpreter services will be provided to you upon request at no cost.

ARABIC	اختر لغتك. يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة.	Նշեք ձեր լեզուն: Թարգմանչի ծառայություններն անվճար կտրամադրվեն ձեզ՝ ըստ պահանջի:	ARMENIAN
CAMBODIAN	ចូរចង្អុលទៅកាន់ភាសារបស់អ្នក ។ មានផ្តល់សេវាកម្មបកប្រែភាសាដល់អ្នក តាមការស្នើសុំ ដោយឥតគិតថ្លៃ ។	廣州話 指向您的語言。 將根據您的要求免費為您提供翻譯服務。	CANTONESE
FARSI	زبان خود را مشخص کنید. خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.	Taw rau koj yam lus. Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi.	HIMONG
KOREAN	언어를 지정해 주십시오. 요청 시 통역 서비스를 무료로 제공해 드립니다.	指向您的语言。 官話 将根据您的要求免费为您提供翻译服务。	MANDARIN
RUSSIAN	Указать на ваш язык. Услуги переводчика будут бесплатно предоставлены Вам по требованию.	Indique su idioma. Se le proporcionarán servicios de intérprete sin costo si lo solicita.	SPANISH
TAGALOG	Ituro ang iyong wika. Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.	Xin hãy chỉ vào ngôn ngữ của quý vị. Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu.	VIETNAMESE

**Be aware and take care.
Talk to your pharmacist.**
California State Board of Pharmacy

Sign posted as required by the California State Board of Pharmacy



Sam's Club
Pharmacy

LEP Signage | ©2013 Sam's Club | 27016C13P



Attachment 2

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625N Market Blvd, N219
Sacramento, CA 95834
Virginia.Herold@dca.ca.gov

Dear Ms. Herold,

Thank you for the opportunity to discuss 1707.6 and the requirements for digital display of the Notice to Consumers. Safeway / Vons pharmacies would like to seek approval to display the poster format for 60 seconds at a time, repeated every 5 minutes on a 24" diagonal video screen.



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 to a nearby pharmacy.

BE AWARE AND TAKE CARE!
Talk to your pharmacist!
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(916) 374-7900 • www.pharmacy.ca.gov

Regards – James



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925 467 3389 Tel.
925 963 0710 Cell.
623 869 1628 Fax.
James.McCabe@Safeway.com

Ask Your Pharmacist!

Get the most out of your pharmacist by asking for help with your medicine. Here are 10 questions to ask your pharmacist.



You should ask your pharmacist:

1. What is this medicine for?

2. How should I take it?

3. How long will it take to work?

4. Are there any side effects?

5. Can I take this with other medicines?

6. Can I take this with food or alcohol?

7. What should I do if I miss a dose?

8. What should I do if I have a side effect?

9. How long can I take this medicine?

10. How should I store this medicine?

11. How should I dispose of this medicine?

12. How should I travel with this medicine?

13. How should I travel with this medicine?

14. How should I travel with this medicine?

15. How should I travel with this medicine?

16. How should I travel with this medicine?

17. How should I travel with this medicine?

18. How should I travel with this medicine?

19. How should I travel with this medicine?

20. How should I travel with this medicine?

pharmacy hours

mon-fri 9 am - 8 pm

saturday 9 am - 5 pm

sunday 9 am - 3 pm

tel: 292556-5344

Ask Your Pharmacist!

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

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.

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.



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¡Pregúntele a su farmacéutico!

La ley de California dicta que un farmacéutico debe hablar con usted cada vez que se le surte una **nueva receta**.

Usted tiene derecho a pedirle al farmacéutico:

Un tipo de letra que sea fácil de leer

Usted tiene derecho a solicitar y recibir en cualquier farmacia etiquetas de medicamentos recetados en un tipo de letra de 12 puntos.

Servicios de interpretación

Servicios de interpretación están disponibles para usted a petición y sin costo alguno.

Los precios de los medicamentos

Puede solicitar a esta farmacia información sobre los precios de medicamentos y el uso de medicamentos genéricos.

Antes de tomar su medicamento asegúrese de obtener la siguiente información:

- 1 El nombre del medicamento y para qué sirve.
- 2 Cómo y cuándo tomarlo, por cuánto tiempo y qué hacer si olvida tomar una dosis.
- 3 Los posibles efectos secundarios y lo que debe hacer si los tiene.
- 4 Si el nuevo medicamento funcionará de forma segura en combinación con otros medicamentos o suplementos.
- 5 Qué alimentos, bebidas o actividades debe evitar mientras toma el medicamento.

Hable con el farmacéutico si tiene alguna pregunta.

Esta farmacia debe proporcionarle cualquier medicamento o aparato que se le haya recetado de forma legal a menos que:

- No esté cubierto por su seguro.
- No pueda cubrir el costo.
- El farmacéutico determine que si lo hace sería contra la ley o potencialmente perjudicial para su salud.

Si algún medicamento o aparato no está disponible de inmediato, la farmacia colaborará con usted para ayudarlo a obtener su medicamento o aparato de manera oportuna.



BOARD OF PHARMACY
Publico con su farmacéutico
Elaborado por el Departamento de Salud Pública

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Attachment 3

Key Facts About Emergency Contraception



Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception (EC) if:

- You had unprotected sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of Emergency Contraceptive pills:

- Progestin-only pills (Plan B® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- High doses of regular oral contraceptive pills

Don't wait! Take EC as soon as possible.

- It is best to take EC as soon as possible; the sooner you take EC the more effective it is.
- It has been shown to be effective for up to 5 days.
- For more information talk to your pharmacist or doctor.

When taken as directed Emergency Contraception has been shown to be safe and effective.

- Emergency Contraception may reduce the risk of pregnancy by up to 89 percent.
- The effectiveness of EC varies based on the type used and when it is taken.
- EC is only recommended as a backup and should not be used as your primary method of birth control.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

What EC does:

- Emergency Contraceptive pills prevent pregnancy.
- Emergency Contraceptive pills are not effective after pregnancy has occurred and they will not harm the developing fetus.
- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Using Emergency Contraceptive pills will not affect a woman's ability to become pregnancy in the future.

Follow-up after taking Emergency Contraceptive pills:

- If you vomit after taking emergency contraception you may need to take another dose. Before you do, contact a pharmacist or healthcare provider immediately.
- If you do not get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic for a regular birth control method and information about preventing sexually transmitted infections.
- Medical providers or your pharmacist can provide Emergency Contraception for future use if needed.

In California, women and men may receive free family planning services through Family PACT based on income.

If you don't have a doctor or clinic, call (800) 942-1054 to find a Family PACT provider near you.

Under the Affordable Care Act (ACA), Emergency Contraception may be covered with a prescription.

Información básica sobre los anticonceptivos de emergencia



El anticonceptivo de emergencia (AE) constituye una manera segura y efectiva de prevenir un embarazo después de una relación sexual.

Considere usar el método anticonceptivo de emergencia (AE) si:

- Tuvo una relación sexual sin protección o
- Piensa que su método anticonceptivo falló.

¿Qué son las píldoras anticonceptivas de emergencia?

Las píldoras anticonceptivas de emergencia (también llamada “píldora del día después”) contienen el mismo medicamento que las píldoras anticonceptivas regulares y ayudan a prevenir un embarazo. Existen tres tipos básicos de píldoras anticonceptivas de emergencia:

- Píldoras de progestágeno solo (Plan B® One-Step, Next Choice®)
- Acetato de ulipristal (ella®)
- Altas dosis de las píldoras anticonceptivas orales habituales

¡No deje que el tiempo pase! Tome el anticonceptivo de emergencia lo antes posible.

- Se recomienda tomar el AE lo antes posible; cuanto más rápido toma el AE, más efectivo es.
- Se ha comprobado que su efectividad dura hasta 5 días.
- Para más información, hable con su farmacéutico o médico.

Cuando se toma según las instrucciones, se ha comprobado que el anticonceptivo de emergencia es seguro y efectivo.

- El anticonceptivo de emergencia podría reducir el riesgo de embarazo en hasta 89%.
- La efectividad del anticonceptivo de emergencia varía según el tipo que se utilice y el momento en que se tome.
- El anticonceptivo de emergencia solo se recomienda como método de respaldo y no debe utilizarse como el método principal para el control de la natalidad.
- Las píldoras anticonceptivas de emergencia no la protegen contra las infecciones de transmisión sexual, incluido el VIH/SIDA.

Cómo funciona el anticonceptivo de emergencia:

- Las píldoras anticonceptivas de emergencia previenen un embarazo.
- Las píldoras anticonceptivas de emergencia no son efectivas una vez que se produjo el embarazo y no lastimarán al feto en desarrollo.
- Las píldoras anticonceptivas de emergencia NO son lo mismo que RU-486 (píldora abortiva)
- El uso de píldoras anticonceptivas de emergencia no afectará la capacidad de una mujer de quedar embarazada en el futuro.

Seguimiento después de tomar la píldora anticonceptiva de emergencia

- Si vomita después de tomar el anticonceptivo de emergencia, es posible que deba tomar otra dosis. Antes de hacerlo, comuníquese con un farmacéutico o proveedor de servicios de atención médica de inmediato.
- Si no tiene un período normal al cabo de tres semanas, hágase una prueba de embarazo.
- Es importante que visite a su médico o clínica para obtener un método regular para el control de la natalidad e información sobre cómo prevenir infecciones de transmisión sexual.
- Los proveedores médicos o su farmacéutico pueden proporcionarle anticonceptivos de emergencia para su uso a futuro, si es necesario.

En California, hombres y mujeres pueden recibir servicios de planificación familiar en forma gratuita a través del programa Family PACT sobre la base de los ingresos.

Si no tiene un médico o clínica, llame al (800) 942-1054 para hallar un proveedor del programa Family PACT cercano a su domicilio.

Conforme a la Ley de Atención Asequible (Affordable Care Act, ACA), los anticonceptivos de emergencia pueden cubrirse con una receta médica.



INFÓRMESE Y CUÍDESE:
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Ключевые факты об экстренной контрацепции



Экстренная контрацепция (ЭК) является безопасным и эффективным способом предотвращения беременности после полового акта

Обратите внимание на экстренную контрацепцию (ЭК), если:

- У вас был незащищенный секс;
- Вы думаете, что ваше противозачаточное средство не сработало.

Что такое средства экстренной контрацепции?

Средства экстренной контрацепции содержат в себе такое же лекарственное вещество, как и обычные противозачаточные таблетки, и помогают предотвратить беременность. Существует три основных типа средств экстренной контрацепции:

- Прогестин-содержащий контрацептив (Plan B® One-Step, Next Choice®)
- Улипристала ацетат (ella®)
- Большие дозы обычных противозачаточных таблеток

Не ждите! Примите ЭК как можно скорее

- Лучше всего принять ЭК как можно скорее: чем раньше вы примите ЭК, тем сильнее будет эффект;
- Доказанная эффективность на протяжении 5 дней.
- Для получения дополнительной информации обратитесь к своему фармацевту или врачу.

Средства экстренной контрацепции, применяемые по назначению, доказали свою безопасность и эффективность.

- Средства экстренной контрацепции могут снизить риск беременности на 89%.
- Эффективность средств экстренной контрацепции зависит от их типа и времени приема.
- ЭК рекомендуется только как запасное средство и не должна использоваться в качестве регулярного противозачаточного средства.
- Средства экстренной контрацепции не защищают от инфекций, передаваемых половым путем, включая ВИЧ/СПИД.

Особенность ЭК:

- Средства экстренной контрацепции предупреждают беременность.

- Средства экстренной контрацепции не являются эффективным средством в случае возникновения беременности и не имеют никакого негативного влияния на развивающийся плод.
- Средства экстренной контрацепции ОТЛИЧАЮТСЯ от RU-486 (средства преждевременного прекращения беременности)
- Использование средств экстренной контрацепции никак не отражается на возможностях женщины забеременеть в будущем.

Действия после принятия средств экстренной контрацепции

- В случае рвоты после приема средств экстренной контрацепции, вам может понадобиться принять еще одну дозу. Но перед этим следует немедленно обратиться к фармацевту или лечащему врачу.
- При отсутствии обычного менструального цикла в течении трех недель, сделайте тест на беременность.
- Важно регулярно обследоваться у вашего врача или клинике по вопросам предотвращения беременности и получать информацию о предупреждении передачи инфекций половым путем.
- В случае необходимости, ваши лечащие врачи или фармацевты могут предоставить вам средства экстренной контрацепции для использования при необходимости в будущем.

В Калифорнии, благодаря программе Family Pact, мужчины и женщины с низким уровнем дохода могут бесплатно получать услуги, связанные с планированием семьи и рождаемости.

Если у вас еще нет лечащего врача или клиники, звоните по телефону (800) 942-1054 и мы поможем найти ближайшего к вам представителя программы Family Pact.

Согласно Программе Защиты Пациентов (ACA), средства экстренной контрацепции могут отпускаться по рецепту.



ПРИМИТЕ К СВЕДЕНИЮ ДАННУЮ ИНФОРМАЦИЮ И БЕРЕГИТЕ СЕБЯ:
Обратитесь к своему фармацевту!
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Mga Mahahalagang Katotohanan Tungkol sa Emerhensiyang Pamigil ng Pagbubuntis



Ang Emerhensiyang Pamigil ng Pagbubuntis (Emergency Contraception, EC) ay isang ligtas at epektibong paraan ng pagpigil ng pagbubuntis matapos ang pakikipagtalik.

Isaalang-alang ang paggamit ng Emerhensiyang Pamigil ng Pagbubuntis (Emergency Contraception, EC) kung:

- Nakipagtalik ka ng walang proteksiyon, o
- Sa iyong palagay ang iyong pamigil ng pagbubuntis ay hindi gumana.

Ano ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis?

Ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay naglalaman ng parehong mga gamot gaya ng sa mga pangkaraniwang pamigil ng pagbubuntis na tableta, at tumutulong na pigilan ang pagbubuntis. Mayroong tatlong uri ng mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis:

- Progestin-only pills (Plan B® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- Mataas na dosis ng mga karaniwang iniinom na pamigil ng pagbubuntis na tableta

Huwag ng maghintay! Uminom kaagad ng EC.

- Pinakamabuting uminom agad ng EC; mas mabisa ang pag-inom ng EC kung iinumun ito ng mas maagap.
- Naipakitang ito ay mabisa ng hanggang 5 araw.
- Para sa dagdag na impormasyon, makipag-usap sa iyong parmasyutiko o doktor.

Kapag ininom ng ayon sa tagubilin, ang Emerhensiyang Pamigil ng Pagbubuntis ay naipakitang ligtas at mabisa.

- Ang Emerhensiyang Pamigil ng Pagbubuntis ay maaaring magpababa ng peligro ng pagbubuntis ng hanggang 89 porsyento.
- Ang bisa ng EC ay nagbabago ayon sa uring ginamit at kung kailan ito ininom.
- Ang EC ang iminumungkahi lamang bilang backup at hindi dapat na gamitin bilang pangunahing paraan ng pagpigil ng pagbubuntis.
- Ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay hindi nagpoprotekta laban sa mga sakit na dulot ng pakikipagtalik, kabilang ang HIV/AIDS.

Ano ang ginagawa ng EC:

- Ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay pumipigil ng pagbubuntis.

- Ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay hindi mabisa matapos na magkaroon ng pagbubuntis at hindi nito mapipinsala ang nabubuong sanggol.
- Ang mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay hindi kapareho ng RU-486 (isang tableta na pampalaglag)
- Ang paggamit ng mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis ay hindi makakaapekto sa kakayahan ng isang babae na magbuntis sa hinaharap.

Mga gagawin matapos ang pag-inom ng mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis

- Kung ikaw ay sumuka matapos ang pag-inom ng mga tableta para sa Emerhensiyang Pamigil ng Pagbubuntis maaaring kailanganin mo na uminom ng isa pang dosis. Bago ka muling uminom, agad na makipag-ugnayan sa isang parmasyutiko o tagapagbigay ng pangangalaga ng kalusugan.
- Kung hindi ka magkaroon ng normal na regla sa loob ng tatlong linggo, magsagawa ng pagsuri sa pagbubuntis (pregnancy test).
- Mahalagang bumisita sa iyong doktor o klinika para sa karaniwang paraan ng pagpigil ng pagbubuntis at impormasyon tungkol sa mga impeksyon na dulot ng pakikipagtalik.
- Ang mga tagapagbigay ng medikal o ang iyong parmasyutiko ay makakapagbigay ng Emerhensiyang Pamigil ng Pagbubuntis para sa hinaharap kung kinakailangan. t

Sa California, ang mga babae at lalake ay maaaring makatanggap ng mga libreng serbisyo para sa pagpapalano ng pamilya sa pamamagitan ng Family PACT batay sa kinikita.

Kung ikaw ay walang doktor o klinika, tumawag sa (800) 942-1054 upang makahanap ng tagapagbigay ng Family PACT na malapit sa iyo.

Sa ilalaim ng Batas para sa Abot-Kayang Pangangalaga (Affordable Care Act, ACA), Ang Emerhensiyang Pamigil ng Pagbubuntis ay maaaring masaklaw kung may reseta.



ALAMIN AT MAG_INGAT:
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關於緊急避孕的一些重點



緊急避孕 (EC) 是性行為後避免懷孕的安全、有效方法。

如果以下情形發生，請考慮使用緊急避孕 (EC)：

- 您未使用防護措施，或者
- 您認為您的避孕措施不管用。

何謂緊急避孕藥？

緊急避孕藥為一般控制生育藥物，用途為避免懷孕。

目前有三種基本緊急避孕藥：

- 單一成份黃體素避孕藥 (Plan B® 一次性，Next Choice®)
- 醋酸烏利司他 (艾伊樂®)
- 高劑量的常規口服避孕藥

請勿延遲！立即採取緊急避孕。

- 建議立即採取緊急避孕；愈早使用緊急避孕愈有效。
- 經證實5日內皆有效。
- 請諮詢藥劑師或醫師，以獲取更多相關資訊。

經證實，按照指示採用緊急避孕不但安全而且有效。

- 緊急避孕可降低高達89%的懷孕風險。
- 緊急避孕的效果因種類及服用時間而定。
- 緊急避孕建議僅為補救辦法，而非用於生育控制的主要方法。
- 緊急避孕藥非用於保護HIV/AIDS等性行為傳染病。

緊急避孕用途：

- 緊急避孕藥可避免懷孕。
- 緊急避孕藥於懷孕後服用是無效的，但不會影響胎兒發育。
- 緊急避孕藥與RU-486 (墮胎藥) 不同。
- 服用緊急避孕藥不會影響女性未來懷孕的能力。

服用緊急避孕藥後續事宜：

- 若服用緊急避孕藥後嘔吐，需改用別種藥物。服用前，請立即與藥劑師或護理師聯繫。
- 若您三週內正常月事未至，請做懷孕測試。
- 定期看醫生或家庭醫師做生育控制及獲取有關預防性行為傳染病的資訊是很重要的。
- 藥物提供者或您的藥劑師可在您未來需要時提供緊急避孕藥。

在加州，每個人都可依其收入而經由家庭計劃 (Family PACT) 獲取免費家庭計劃服務。

若您無醫生或家庭醫師，請致電 (800)942-1054 查尋離您最近的家庭計劃 (Family PACT) 提供者。

根據平價醫療法案 (ACA)，緊急避孕藥為處方藥物。



務必注意及小心：
諮詢您的藥劑師！
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Những Điều Quan trọng Về Thuốc Ngừa thai Khẩn cấp



Thuốc Ngừa thai Khẩn cấp (EC) là một phương pháp hiệu quả và an toàn để ngừa thai sau khi quan hệ tình dục.

Cần nhắc sử dụng thuốc Ngừa thai Khẩn cấp (EC) nếu:

- Quý vị đã quan hệ tình dục không bảo vệ, hoặc
- Quý vị nghĩ phương pháp ngừa thai của mình không có tác dụng.

Thuốc Ngừa thai Khẩn cấp là gì?

Thuốc Ngừa thai Khẩn cấp chứa cùng loại thuốc như thuốc ngừa thai thông thường, và giúp ngừa thai. Có ba loại thuốc Ngừa thai Khẩn cấp cơ bản:

- Thuốc chỉ có Progestin (Plan B® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- Thuốc viên uống ngừa thai thông thường liều cao

Đừng chờ đợi! Uống EC sớm nhất có thể.

- Tốt nhất là uống EC sớm nhất có thể; quý vị càng uống EC sớm thì EC càng có hiệu quả.
- EC đã được chứng minh là có hiệu quả lên đến 5 ngày.
- Để biết thêm thông tin trao đổi với dược sĩ hoặc bác sĩ của quý vị.

Khi uống như chỉ dẫn thuốc Ngừa thai Khẩn cấp đã được chứng minh là an toàn và hiệu quả.

- Thuốc Ngừa thai Khẩn cấp có thể giảm nguy cơ mang thai đến 89 phần trăm.
- Hiệu quả của EC thay đổi tùy theo loại sử dụng và thời gian uống.
- Chỉ nên dùng EC như một phương án dự phòng và không nên được sử dụng làm phương pháp ngừa thai chủ yếu của quý vị.
- Thuốc Ngừa thai Khẩn cấp không bảo vệ chống lại các bệnh lây nhiễm qua đường tình dục, bao gồm HIV/AIDS.

EC làm gì:

- Thuốc Ngừa thai Khẩn cấp ngừa thai.
- Thuốc Ngừa thai Khẩn cấp không có tác dụng sau khi đã mang thai và sẽ không gây hại cho thai nhi đang phát triển.
- Thuốc Ngừa thai Khẩn cấp KHÔNG giống như RU-486 (thuốc phá thai)
- Dùng thuốc Ngừa thai Khẩn cấp sẽ không ảnh hưởng đến khả năng mang thai trong tương lai của phụ nữ.

Hành động Tiếp theo sau khi uống thuốc Ngừa thai Khẩn cấp

- Nếu quý vị nôn mửa sau khi uống thuốc ngừa thai khẩn cấp quý vị có thể cần uống thêm một liều nữa. Trước khi uống, liên lạc ngay với dược sĩ hoặc nhà cung cấp dịch vụ y tế.
- Nếu quý vị không có kinh bình thường trong vòng ba tuần, xét nghiệm thử thai.
- Điều rất quan trọng là phải đến bác sĩ hoặc phòng khám để có được một phương pháp ngừa thai thông thường và thông tin về cách phòng tránh bệnh lây nhiễm qua đường tình dục.
- Nhà cung cấp dịch vụ y tế hoặc dược sĩ của quý vị có thể cung cấp thuốc Ngừa thai Khẩn cấp để sử dụng trong tương lai nếu cần.

Ở California, phụ nữ và nam giới có thể nhận dịch vụ kế hoạch hóa gia đình miễn phí thông qua Family PACT dựa trên thu nhập.

Nếu quý vị chưa có bác sĩ hoặc phòng khám, gọi (800) 942-1054 để tìm một nhà cung cấp Family PACT gần quý vị.

Theo Đạo luật Chăm sóc y tế với giá Phải chăng (ACA), thuốc Ngừa thai Khẩn cấp có thể được chi trả với bảo hiểm thuốc theo toa.



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응급 피임제에 관한 핵심 사항



**응급 피임제(EC)는 성관계 후 임신을 방지하는
안전하고 효과적인 방법입니다.**

**다음과 같은 경우 응급 피임제의 사용을
고려하십시오.**

- 무방비 상태에서 성관계를 한 경우, 또는
- 피임약이 듣지 않는다고 생각될 경우.

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응급 피임제에는 보통의 경구 피임약과 마찬가지로의 약물이 포함되어 있으며, 임신을 방지하는데 도움을 줍니다. 응급 피임제에는 세 가지 기본 유형이 있습니다.

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- 보통의 경구 피임제의 고용량 처방

기다리지 마세요! 즉시 EC를 복용하세요.

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- 최장 5일까지 효과가 있는 것으로 나타났습니다.
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- 응급 피임제를 복용한 후에 구토를 할 경우 추가로 복용해야 할 수도 있습니다. 추가 복용을 하기 전에 약사나 의사에게 즉시 문의하십시오.
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- 필요할 경우 의사나 약사가 나중에 위해 응급 피임제를 처방할 수도 있습니다.

캘리포니아주에서는 소득을 기반으로 한 패밀리 팩트 (Family PACT)를 통하여 무료 가족 계획 서비스를 받을 수도 있습니다.

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경제적인 의료보험법(Affordable Care Act, ACA)하에서 응급 피임제는 처방약으로 취급될 수 있습니다.



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Attachment 4

Design and test of preference for a new prescription medication label

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Abstract *Objective* This study measured preference for newly designed prescription labels in comparison with two existing labels from the perspective of patients, pharmacists and physicians, based on three parameters: content, convenience and cosmetic appearance. *Setting* Participants were interviewed at pharmacies (patients) and at professional meetings (physicians and pharmacists) regarding their preference for the labels. *Method* Two new labels (A and B) were designed using Publisher[®] Software version 2007 based on literature and results from our previous study. New features focusing on content, convenience and cosmetic appearance (3Cs) included a time table for medication administration, indication of medication and warnings, on a redesigned label. These labels were initially tested on a small sample and then revised. A survey instrument was developed to compare currently used labels and modified labels A and B, on the 3Cs. *Main outcome measure* The preference of three groups of stakeholders (patients, pharmacists and physicians) were measured for newly designed labels in comparison with two existing labels. *Results* Complete data obtained with 444 patients,

115 pharmacists and 69 physicians indicated that the median age range of participants was between 51 and 64 years. The patient and physician samples consisted of a higher percentage of women. Pharmacists working in chain pharmacies and family practitioners comprised majority of our sample in professional groups. Mean years of experience in pharmacy and physician groups was 18.2 and 26.8 years, respectively. Most patients (94.4%) in the sample had at least high school education. Majority of patients (82.8%) preferred new labels over existing ones and 55.2% preferred label B on all three parameters. Close to two thirds of pharmacists (76.4%) and physicians (75.3%) preferred new labels with 55.3 and 57.9% preferring label B, respectively. Participants cited all the added modifications as reasons for their preference. *Conclusion* New prescription labels were favored over existing labels by all stakeholders, for content, convenience and cosmetic appearance. The results may help in making labels more user-friendly and addressing problem areas in labels.

Keywords Label preference · Label design · Label layout · United States · Prescription drug label

Amir H. Zargarzadeh was an Outcomes Research Fellow at Western University of Health Sciences when this study was conducted.

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Impact of findings on practice

- Changes may be in order to make labels more patient friendly. Specific areas that could be changed include adding indications to the label, creating a time table of medication administration and creating a box for warnings.
- Change in design of labels in addition to content may be welcomed by patients. These include font size increase and changes in placement and white space.

Introduction

Prescription labels are an immediate and important source of medication information for patients. Currently available labels and amber-cast pharmacy pill bottles have been in existence in the US since World War II without much change [1]. Recently, however, labels have been a subject of interest in the literature given the focus on health literacy and its impact on healthcare utilization and outcomes. Published studies cite variability of label formats and instructions among US pharmacies as a possible source of difficulty in reading and understanding labels and auxiliary labels. This is especially true for vulnerable populations such as the elderly, those with low literacy skills and low English proficiency (LEP) [2–10]. In addition, complex labeling language, unclear administration times, confusing label layout, and small font size are cited as contributing factors to the difficulty in reading and understanding labels [8, 11–13]. Misunderstanding of labels can become the source of patient initiated errors in medication use such as inadvertent misuse of medications and under or over dosing, it also has the potential to cause emergency room visits, hospital admissions, unnecessary adverse drug reactions, mortality, and morbidity [3, 14–16]. Considering that up to 63% of patients misunderstand one or more dosage instructions (on the prescription label) and up to 12% of emergency room visits are drug related, identifying and addressing new ways to improve readability and understandability of prescription labels is a matter of patient safety [9, 17].

As expected, countries around the world have different rules and regulations on prescription labels. A review of Board websites and personal communications with Boards of some countries on these regulations revealed that they run the gamut from having no particulars on the content or format of these labels to having some general regulations leaving most parameters to the professional judgment of the pharmacist to decide what needs to be included on the label [18–21]. While some countries (Canada, New Zealand, UK) may have requirements on label components, there is no specification for wording of directions aimed at any particular group (such as low health literacy), nor is there evidence on required label formats. Further, there is no published literature on problems or issues resulting from labeling, outside of the US.

Given the recent evidence, the California Senate in 2007 passed Bill 472 mandating the California Board of Pharmacy to promulgate regulations for a standardized, patient-centered, label to go into effect by January 2011 [18]. The mandate's primary objective was creation of a label that caused less confusion and was more useful to patients.

Results of our recent study with labels found that patients desire better organization of labels, and use of bigger fonts, color backgrounds, as well as inclusion of indication and

precautions on the labels [22]. These studies as well as the CA bill served as an impetus to design a new label. Recommendations by the Institute of Medicine and the American College of Physicians on standardizing medication labels served as the basis for the new label design [23].

Label redesign

Our label redesign was based on the premise of minimizing add-on costs by retaining the current size of label to fit a 13 dram size bottle that is most commonly used by pharmacies in California. The content of label was based on 2008 California State law requirements for prescription drug labels (section 4076) [24]. The framework that we developed and used for label redesign was categorized as content, cosmetic appearance, and convenience. Three new labels were designed to improve content by using simple language for directions intended for 5th grade reading skills (age range 10–11 years), inserting a table for times of administration and adding indication to the instructions. Color backgrounds and white space were manipulated to improve the cosmetic appearance of label. Bigger font size (larger font size used for patient name, medication name and dosage and directions in comparison to other components of the label) and a box for warnings and precautions were incorporated to improve convenience of finding information on the label. Two widely used existing labels in California were selected to create generic templates as "control" labels. The new labels with 2¼" × 3¾" (5.715 × 9.525 cm) dimensions were designed using Publisher® Software version 2007 and the content of labels were based on California State law requirements for prescription container labels in 2008 (section 4076) [24]. Medication usage directions, table for times of administration, indication for use and common side effects were the main changes incorporated on to the new labels.

Aim of the study

The objective of this study was to measure preference for the redesigned (new) labels in comparison with two existing labels on parameters of content, cosmetic appearance, and convenience from the perspective of three groups of stakeholders most closely associated with labels: patients, pharmacists and physicians; and to identify factors that correlated with preference for a specific label.

Methods

Initially, a ten member panel comprising of four pharmacists, two physicians and four nonprofessionals (patients)

examined the new labels. Their suggestions were reviewed by the research team in order to make any necessary modifications to the new labels.

Preference for labels

Study design

The study used a structured interview design.

Target sample and sampling design

The target sample was patients, pharmacists and physicians. (An initial sample size was estimated based on proportional sampling taking into account the number of patients, physicians and pharmacists in CA. These numbers were large given that CA population is roughly 36 M. In addition, there were several constraints; chiefly funding for recruitment and data collection; as well as time to gather sufficient evidence to present to the CA Board of Pharmacy prior to their decision on label modification. Hence convenience sampling was used as a solution for this exploratory study, in order to provide a base for evidence on label modifications before a controlled study was planned.). Since this was an initial study in testing label design, a convenience sampling technique was used. Patients were drawn from 20 community pharmacies and two hospital outpatient pharmacy departments that served as experiential sites for our Pharm D students. The sample of pharmacists and physicians was drawn from professional association meetings or similar venues held in California.

Data collection instrument

A survey was developed by the authors to test preference for the labels. The survey was divided into two sections: section one was devoted to questions about the cosmetic appearance, content and convenience of labels and section two dealt with demographic information on participants. Questions focusing on the cosmetic appearance were about the ease of label on the eyes and ease of readability of label. The following questions dealt with the content of labels: understandability of instructions, warnings and side effects, and of the indication. Convenience was addressed by ease of finding information and helpfulness of directions in taking medications. Section two included questions on age, gender, level of education, ethnicity and whether English was the primary language for patients. Section one was identical for the three participant groups and section two changed slightly among three groups to account for specific demographic characteristics of each sample, for example, physician and pharmacist surveys included questions about practice site, years of experience and type

of specialty. The survey also included open-ended questions regarding reasons for preferring one label over another and suggested modifications to improve the preferred label.

The research protocol and instruments were approved as expedited review by the institutional review board at the authors' institution.

Data collection

Label preparation

The existing labels (D and E) and new labels (A, B and C) were prepared for Lipitor 20 mg tablets with the direction stating, "Take 1 tablet by mouth once every night for cholesterol."

Existing labels from two major chain pharmacies in California were selected and after de-identifying the logo, name, address and telephone number of pharmacy, were placed on same size prescription bottles as were used for the new labels. Labels were affixed on prescription bottles without using tape so as to reduce the impact of illumination glare of the surroundings on the visual acuity of participants.

Pilot testing

The study was pilot tested on a small group (10) of stakeholders including patients, pharmacists and physicians. After being presented with three new labels, the sample was asked for their preference and to compare the preferred label with one of two randomly selected existing labels commonly used in community pharmacies. One of the new labels (C) was discarded based on comments from the panel that it did not appear to have any advantage over A or B. Appropriate changes were made to the survey form and the new labels for the final study.

Testing the label for preference

Student pharmacists were trained on how to conduct the survey and observed by the authors while conducting the first interview. A written sheet of instructions was also handed to students to reinforce their training. Rotation students at the 20 experiential sites were also trained by the authors.

Pharmacy patrons receiving a new and/or refilling an existing prescription and willing to give a verbal consent (as approved by the IRB), were recruited at the community and outpatient sites by fourth year pharmacy students on rotation. A minimum of 30 patients were recruited per site. Patients were interviewed while waiting for their prescriptions to be filled. Patients were excluded from the

study if they did not speak or read English or had difficulty reading the labels due to vision impairment. Physicians and pharmacists were approached by the students at professional meetings and informed about the study. Verbal consent was obtained before they were enrolled.

Following verbal consent from the participants, the two bottles with new label designs (A and B) were presented and participants were asked for their preference and reasons for it. Then the preferred new label was compared with one of the two randomly selected existing labels (D or E). The intent was to establish preference between the new labels first and then compare with existing labels as the “control.” The interview ended with demographic and open-ended questions. Participant suggestions on improvement of the preferred label were recorded.

Data analysis

Data collected from the interviews were entered into SPSS for Windows version 15.0 [25]. Analysis was predominantly descriptive in nature and also included correlational analysis to test for correlations between the three parameters and overall preference. Further, chi-square analysis was conducted to test for associations between sample characteristics (education, ethnicity, age, gender, type of specialty, practice site and years of experience) and dependent variable (label of preference). Preference was compared between the three respondent groups. All analyses were conducted at the 95% significance level.

Responses to open ended questions were independently coded and categorized by two judges. Agreements were recorded and any differences were resolved by discussion.

Results

Description of the three groups of samples

A total of 501 patients were approached, of whom 444 consented to participate in the study and completed the interview (88.6%). The response rates for pharmacists and physicians were 91.2% (115 out of 126) and 82.1% (69 out of 84), respectively. As seen in Table 1, the common age range for the participants was 51–64 years, except for the pharmacist group. There were more females in the patient and physician sample. The sample also had a predominance of Caucasians in all three groups. Employees of chain pharmacies formed a large percentage of pharmacists and likewise family practitioners featured often among physicians in the sample. Mean (SD) number of years of experience for pharmacists and physicians was 18.2 (12.5) and 26.8 (11.0), respectively. Majority of respondents in the patient sample had at least some

college education and reported English as their primary language.

Label preference

The majority of patients, 366 (82.8%) preferred new labels over existing ones. Label B was picked by 244 (55.2%) of patients, majority stating more space for directions as the main reason for their preference over label A (Fig. 1). Also, format of label B allowed the table of administration times to be in the field of view without having to turn the bottle. As seen in Fig. 2, similar patterns of preference were reported for other two groups. More than two thirds of pharmacists, 87 (77.7%), and physicians, 52 (75.4%), preferred new labels with 63 (56.3%) and 40 (57.9%) preferring label B, respectively. These two groups also cited similar reasons as patients for their preference for label B over label A. Sixty eight (15.3%) patients, 17 (14.8%) pharmacists, and 12 (17.4%) physicians preferred label D and 8 (1.8%) patients, 8 (7.0%) pharmacists and 5 (7.2%) physicians preferred label E. For those who picked a certain new label, the likelihood of preferring that same label in all parameters was high. However, even when the label picked was D, preference seemed to be divided with label B in several parameters. A subgroup analysis showed preference for labels among patients was based on their age, language skills and education (Table 2). In all three groups, label B was preferred more over other labels. Two patients and three pharmacists could not make up their minds in selecting one label over another.

Correlational analysis

Content, convenience, and cosmetic appearance were significantly correlated ($P < 0.05$) with preference for labels (Table 3). These three parameters were also significantly correlated with each other (Table 3). No statistically significant correlations were found between demographic characteristics and preference for labels in any of the professional groups.

Open ended responses

Patients found the new features of the redesigned labels more appealing. About 40% of respondents reported the table of times for administration and indication (27.9%) as advantages of the new labels. Bigger font size and easiness to read were other most preferred features with 27.2 and 19.8% of responses, respectively. Pharmacists and physicians had similar responses on the reasons for their preference for new labels, stating in order, inclusion of table for times of administration, indication and the warnings section in the new label as most common reasons. Some of the

Table 1 Demographic characteristics of participants

Stakeholder	Category	Frequency (%)		
		Patient <i>n</i> = 444	Pharmacist <i>n</i> = 115	Physician <i>n</i> = 69
Age in years	18–34	79(18.0)	26(22.8)	0(0)
	35–50	117(26.7)	42(36.8)	17(24.6)
	51–64	136(31.0)	36(31.6)	37(53.8)
	65–79	84(19.1)	10(8.8)	13(18.8)
	>80	23(5.2)	0(0)	2(2.9)
Gender	Female	253(57.9)	49(42.6)	60(87)
	Male	183(41.9)	65(56.5)	9(13)
Ethnicity	Caucasian	221(50.5)	56(49.6)	52(75.4)
	Hispanic	83(18.9)	5(4.4)	1(1.4)
	Asian	56(12.8)	48(42.5)	9(13)
	Black	38(8.7)	1(0.9)	3(4.3)
	Other	40(9.1)	3(2.7)	4(5.8)
Practice site ^a or specialty ^b			44(38.6) Chain store	25(37.9) Family practice
			30(26.3) Independent	11(16.7) Internal medicine
			14(12.3) Inpatient	4(6.1) Pediatrics
			5(4.4) Academia	6(9.1) Ob-Gyn
		Other	21(18.4)	20(30.3)
Work experience	Mean (SD) years		18.2(12.5)	26.8(11.0)
English primary language	Yes	391(89.7)		
	No	45(10.3)		
Education	Some school	24(5.6)		
	High school	109(25.3)		
	Some college	165(38.3)		
	College degree	133(30.9)		

Missing data in categories that numbers do not add up to total

^a Practice site for pharmacists

^b Specialty for physicians

improvements suggested by all three groups on the new label was bigger font size, increasing visibility of the check mark used in the table of administration times and a few reformatting suggestions.

Discussion

To the best of our knowledge, this is the first study that has examined the preference of three groups of stakeholders for a newly designed label in comparison to existing labels. The results from this study showed that majority of our participants in all three groups preferred new labels over existing labels in spite of familiarity with existing label formats. The content, convenience and cosmetic appearance changes we implemented appeared to influence preference for redesigned labels. Further, there appeared to be a tendency to reduce cognitive dissonance, (i.e., once a certain label was preferred, it was likely respondents held to that preference in all parameters) [26].

Most of the research published on design and format of labeling has dealt with OTC medication labels, consumer

medication information leaflets and package inserts [8]. Bernardini et al. have shown that font size of at least 10 point, using certain color print for certain sections and better layout could all lead into better readability of patient package leaflets in Italian patients [27]. Font sizes on redesigned labels varied from 4 to 12 based on importance of information to patients. Due to paucity of literature on prescription drug labels, a direct comparison of our results with similar research is not possible.

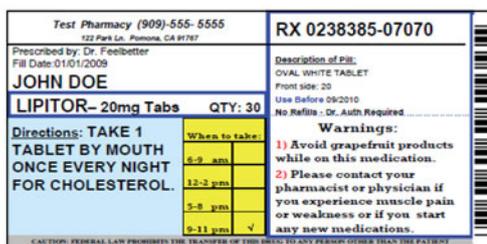
To take the results of this research one step further, we would like to test the usefulness of the new label B in a real world setting by having patients use them for a period of time such as 3 months and report their opinions (cognitive interviewing). However, a longer time span is needed to test the impact of the label on health outcomes such as adherence and safety. Recently, two articles have been published on the impact of better labeling (Target Clear-Rx[®] labels) on adherence and rate of outpatient and inpatient health services use and emergency room visits. Although both studies had limitations such as exclusion of elderly, uninsured and beneficiaries of Medicaid in their sample study, overall, neither study demonstrated a

Fig. 1 Labels A, B, D and E



Label A

Label D



Label B



Label E

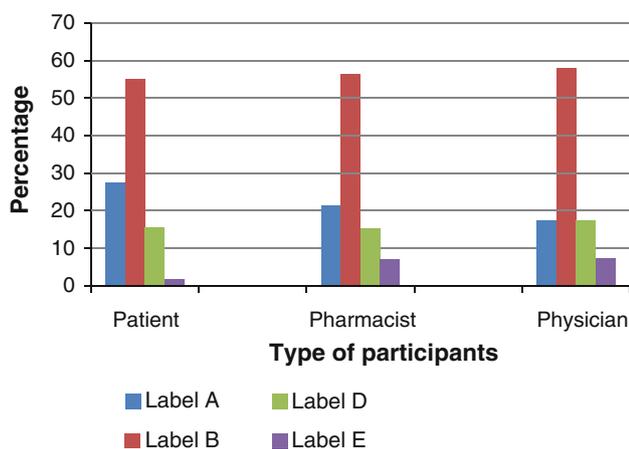


Fig. 2 Label preference. Two patients and three pharmacists could not determine their label of preference

Table 2 Label preference in subgroups of patients (no. %)

Patients characteristics	Label A	Label B	Label D	Label E
Age				
<65 years old	87 (19.9)	189 (43.3)	49 (11.2)	6 (1.4)
≥65 years old	33 (7.6)	54 (12.4)	18 (4.1)	1 (0.2)
Language skills				
English as primary language	102 (23.5)	221(50.9)	59 (13.6)	7 (1.6)
English as second language	16 (3.7)	21 (4.8)	8 (1.8)	0 (0)
Education				
Some school	9 (2.1)	12 (2.8)	3 (0.7)	0 (0)
Completed high school	30 (6.9)	61 (14.2)	16 (3.7)	1 (0.2)
Some college	53 (12.4)	81 (18.9)	28 (6.5)	2 (0.4)
College degree	27 (6.3)	82 (19.1)	20 (4.7)	4 (0.9)

significant impact of labels on adherence or outcomes [28, 29]. Other studies including vulnerable groups of patients and differing levels of health literacy should be performed to confirm these results.

In an earlier study that we conducted [22], we found that the average patient found their (own) prescription labels generally easy to read, understand and useful; a variation from previous studies in the literature that have used hypothetical labels and found label readability and understandability to be low among vulnerable populations. We posited that our findings were partially due to familiarity with existing label formats. We had concluded that changes in labels were probably needed for specific vulnerable

populations. However, the results from the current study show that improvements could be made that may help all patients. These changes need to be tested for usefulness in general and in vulnerable populations for conclusive evidence.

While prescription drug labels are undoubtedly an important part of increasing patients' understanding of their medications, improved labels are necessary but not sufficient to induce changes in patient medication taking behavior. Also, determining preference may not necessarily correspond to usefulness in practice but it provides an indirect examination of usefulness because if the

Table 3 Correlations between content, cosmetic appearance, convenience and overall label preference for the three groups

Correlations	Patients	Pharmacists	Physicians
Cosmetic appearance × content	0.585–0.785 ^a	0.280–0.906	0.606–0.868
Content × convenience	0.776–0.846	0.885–0.957	0.880–0.959
Convenience × cosmetic appearance	0.801–0.928	0.357–0.966	0.732–0.959
Cosmetic appearance × preference	0.815–0.835	0.852–0.880	0.878–0.885
Content × preference	0.717–0.789	0.832–0.843	0.832–0.840
Convenience × preference	0.833	0.873	0.879

All correlations were statistically significant at $P < 0.001$

^a The ranges provided are for various inter item correlations of each parameter

stakeholders prefer a label, it is more likely to be useful to them. We would like to restate the caveat, that while there may be evidence that misunderstanding labels could lead to poor patient outcomes, there is no current evidence that improving labels will lead to better outcomes [9, 28, 29].

Given that California is poised to move to a standardized, user-friendly label, the extension of the current research appears imperative. At the time of writing this manuscript, State Bill SB470 has been signed to allow indication on the label if the condition or purpose is indicated on the prescription.

Study limitations

We used a convenience sampling, as a result generalizability and representativeness may be limited. Also, our study did not include significant numbers of low English proficient individuals or patients with low literacy skills; therefore, the study needs to be extended to these populations.

Study strengths

This is the first study of its kind which examines preference of key stakeholders on changes in prescription labels. It showed that despite differences in education and skills, preferences did not differ among the groups. Further, this study adds value because it may generate further interest on redesigning labels to make them more useful to patients.

Conclusion

This study found that redesigned prescription labels were preferred over existing labels in terms of content, convenience and cosmetic appearance. These labels need to be tested for usefulness to patients in real life applications. Additional research needs to be done to measure impact of the new label on patient outcomes.

Acknowledgments We would like to thank our students Meeta Goel, Deborah Kheradyar and Nirav Rathod for their contribution to design of and data collection of this research.

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Conflicts of interest We hereby declare that no conflict of interest exists with any aspect of this study.

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Test Pharmacy (909)-555-5555 123 Main Street, Anytown, USA 11111	RX 0238385-07070
JANE SMITH 456 MAIN STREET ANYTOWN, USA 11111	<u>Round red tablet</u> Front side: 10 Prescribed by: Dr. C. JONES Fill Date: 01/23/2013
Simvastatin 20 mg (Generic for: Zocor)	Use Before: 01/23/2014
QTY: 30 tablets 3 Refills	Warnings: 1) Avoid grapefruit products. 2) Contact your pharmacist or physician if you experience muscle pain or weakness. 3) Avoid pregnancy or breast-feeding.
Directions: Take 1 tablet by mouth in the evening for lowering cholesterol.	
When to take medication:	
6-9 pm √	
<small>CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT</small>	

Test Pharmacy (800)-555-5555 123 Main Street, Anytown USA, 11111	RX 0238385-07071
JANE SMITH 456 MAIN STREET ANYTOWN, USA 11111	<u>Round white tablet</u> Front side: 20 Prescribed by: Dr. C. JONES Fill Date: 01/21/2013
Metformin 500 mg (Generic for: Glucophage)	Use Before: 01/21/2014
QTY: 90 tablets 4 Refills	Warnings: 1) Avoid drinking alcohol while taking this medication. 2) Contact your pharmacist or physician if you develop nausea, vomiting, abdominal pain, rapid breathing.
Directions: Take 1 tablet by mouth with breakfast, and 1 tablet with dinner for lowering blood sugar.	
When to take medication:	
6-12 am √	
12-6 pm	
6-9 pm √	
<small>CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT</small>	

Test Pharmacy (800)-555-5555 123 Main Street, Anytown USA, 11111	RX 0238385-07072
JANE SMITH 456 MAIN STREET ANYTOWN, USA 11111	<u>Round white tablet</u> Front side: 30 Prescribed by: Dr. C. JONES Fill Date: 01/19/2013
Glipizide 5 mg (Generic for: Glucotrol)	Use Before: 01/19/2014
QTY: 30 tablets 0 Refills	Warnings: 1) Watch out for symptoms of low blood sugar (e.g. sweating, nervousness, dizziness) 2) May cause dizziness. Avoid physical and mental activities that require alertness.
Directions: Take 1 tablet by mouth 30 minutes before breakfast for lowering blood sugar.	
When to take medication:	
6-12 am √	
<small>CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT</small>	

Test Pharmacy (800)-555-5555 123 Main Street, Anytown USA, 11111		RX 0238385-07074	
JANE SMITH 456 MAIN STREET ANYTOWN, USA 11111		<u>Round red tablet</u> Front side: 40 Prescribed by: Dr. C. JONES Fill Date: 01/17/2013	
Lisinopril 20 mg (Generic for: Prinivil)		Use Before: 01/17/2014	
QTY: 30 tablets 3 Refills			
Directions: Take 1 tablet by mouth in the morning for lowering blood pressure.		Warnings: 1) Do not take extra salt substitute supplement. 2) Avoid pregnancy or breast-feeding while taking this medication.	
When to take medication:			
6-12 am	<input checked="" type="checkbox"/>		
<small>CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT</small>			

Test Pharmacy (800)-555-5555 123 Main Street, Anytown USA, 11111		RX 0060023-08291 ©	
JANE SMITH 456 MAIN STREET ANYTOWN, USA 11111		<u>Round white tablet</u> Front side: 50 Prescribed by: Dr. C. JONES Fill Date: 01/15/2013	
Hydrocodone/Acetaminophen 5/500mg (Generic for: Lortab 5/500)		Use Before: 01/15/2014	
QTY: 30 tablets 0 Refills			
Directions: Take 1 tablet by mouth every 4 to 6 hours as needed for pain. Wait at least 4 hours before taking again. Do not take more than 6 tablets in a day.		Warnings: 1) May cause dizziness, avoid activities that require alertness. 2) Avoid drinking alcohol. Liver damage may happen.	
<small>CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT</small>			

Effect of Focused Education on Functional Health Literacy and Prescription Label Comprehension: A Randomized Controlled Trial

Objectives:

1) To assess change in functional health literacy (FHL) and prescription (Rx) label comprehension of English-speaking older adults after a focused educational intervention, 2) to examine the correlation between FHL and Rx label comprehension, and 3) to examine factors that may predict FHL and Rx label comprehension.

Methods:

A randomized, controlled, single-blinded trial was conducted at 3 senior centers. Inclusion criteria were: English-speaking older adults, 55 years of age or above; currently taking 2 or more Rx medications; and with no visual, hearing, or cognitive impairment. The 107 recruited individuals were randomized to control (N=47) or intervention group (N=60). Pre- and post-intervention FHL levels were measured by a validated and widely used instrument, STOFHLA. Rx label comprehension levels were measured using a 25-item instrument (with established face and content validity), based on labels for 4 common chronic conditions. Intervention group received focused education (individual counseling and printed material) on Rx labels during the 1-month study period. Data were analyzed using IBM SPSS Version 21.

Results:

Majority of the sample (mean age of 76.7 years) was female (59.8%), Caucasian (56.1%), completed some college education or above (63.6%), with annual household income less than \$50000 (58.9%). No significant differences were found between the intervention and control groups in demographics, baseline FHL and Rx label comprehension levels. Reliability (internal consistency) of the label instrument scale was at Cronbach's alpha of 0.87. Significant improvement was seen in STOFHLA (27.5 to 31.4) and label comprehension scores (22.8 to 24.0) from baseline (both $p < 0.01$), compared to the control group. STOFHLA and label instrument scores were significantly correlated ($r = 0.628$, $p < 0.01$). Age and education level were significant predictors for both measures.

Implications/Conclusions:

A significant improvement in FHL and Rx label comprehension was observed after educational intervention. Improving Rx label comprehension may be an avenue for improving FHL.

Attachment 5

Background and Research on Patient-Centered Prescription Container Labels

The following information has been presented to the committee and board multiple times. In the interests of providing it as a ready reference, it is being provided as an attachment to the committee meeting materials.

a. United States Pharmacopeia Guidelines for Prescription Drug Labels

In November 2012, the U.S. Pharmacopeial Convention (USP) published guidelines for prescription container labeling (**Attachment 5a**). The guidelines provide a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacies. Review of the material in USP's guidelines would be one source of information useful for comparison of the board's regulations with guidelines for premium presentation and focus on patient needs. It is important to note that USP's guidelines already closely resemble the board's existing regulation requirements for patient-centered prescription container labels, specifically:

- Organize the prescription label in a patient-centered way. Feature the information patients most often seek out or need to understand about taking the medication safely.
 - Emphasize: directions
 - At the top of the label place: patient's name
 - Drug name (spell out full brand AND generic name)
 - Strength
 - Explicit and clear directions for use in simple language
- Prescription directions should follow a standard format so the patient can expect where to find information.
- Less critical information can be placed elsewhere and in a matter where it will not "supersede" critical patient information, and away from where it can be confused with dosing instructions
- Use language that is clear, simplified, concise and familiar, and in a standardized manner. Use common terms and full sentences. Do not use unfamiliar words, Latin terms or medical jargon
- Use simplified, standardized sentences that have been developed to ensure ease understanding the directions (by seeking comment from diverse consumers)
- Separate dose from the timing of each dose to clearly explain how many pills to take and specify if there is an appropriate time to take them (morning, noon, evening, bedtime).
- Do not use alphabetic characters for numbers (not in CA's) e.g., "nine" instead of "9".
- Use standardized directions whenever possible.
- Avoid ambiguous terms such as "take as directed" (not in CA's) unless clear and unambiguous supplemental instructions and counseling are provided

- Include purpose on the label unless patient does not want it, and if used, use “purpose for use” language such as for blood pressure rather than hypertension.
- Limit auxiliary information, and only if evidence based. (not in CA’s)
- Use icons only if vetted with the general public (not in CA’s)
- Address limited English proficiency.
- Labels should be designed so they are easy to read. Optimize typography by using:
 - High contrast print (black print on white background)
 - Large font sizes in simple, uncondensed fonts in at least 11 point if Arial, or 12 point if Times New Roman)
 - Optimize use of white space between lines (25-30 percent of font size)
 - Horizontal placement of lettering only
 - Sentence case
 - Highlighting, bolding and other typographical cues should enhance patient-centered information, but limit the number of colors used for highlighting
- Address visual impairment (not in CA’s)

Regarding addressing limited English speaking/reading patients, USP encourages directions for use in the patient’s language as well as in English. Translations should be developed using high quality translation processes (CA’s translated directions would fit this criterion).

b. Medical Literacy Research

The National Council for Prescription Drug Programs developed the “Universal Medication Schedule White Paper” (draft April 2013, **Attachment 5b**). This document supports the standardized directions in the board’s regulation at 16 CCR Section 1707.5. The goal of the universal medication schedule is to increase patient understanding and adherence to medication instructions by standardizing the phrasing of directions, thereby improving health outcomes.

The hope is to secure the use of directions for use in a Universal Medication Schedule into e-prescribing systems. Staff will continue to identify additional medical literacy research for the committee’s consideration.

c. Surveys

The board has conducted surveys to assess California’s patient-centered label requirements. Survey results are provided in **Attachment 5c**.

1. Survey of Patient-Centered Labels in Use in California Pharmacies

The first survey was conducted in 2012 and was used to measure pharmacies' compliance with the patient-centered label requirements. It included components related to the 10- and 12-point fonts used on labels and how pharmacies have been complying with the interpreter requirements. Over the course of approximately seven months, board inspectors collected prescription labels used in California 767 pharmacies to determine compliance with the patient-centered label requirements. In general, nearly 70 percent of the labels in use as found by the board's inspectors are printed in 12-point font; 15 percent use both 10 and 12 point font on the labels; and about 15 percent are printed in 10 point.

2. Survey of Pharmacies' Compliance with Interpreter Availability

During the inspections described in the above survey in item 1, the board's inspectors also inquired how pharmacies are complying with the requirements for the availability of interpreters to provide services to limited English speaking patients. Most rely upon telephone services to provide the wide array of languages that could be needed in a language diverse state such as California. Often, staff was available to translate in communities where a language other than English is principally spoken.

3. Consumer Satisfaction with Prescription Labels

The board conducted a survey in 2012 to determine if consumers were satisfied with their prescription labels and how they could be improved. Several consumer groups including AARP, Consumers Union, and California Pan Ethnic Health Network (CPEHN) distributed the survey electronically. The survey was also translated into Chinese and Spanish by the board and distributed by CPEHN to the appropriate audiences. Further, surveys were distributed and collected in person at local Senior Scam Stopper seminars (public protection fairs) sponsored by the Contractors State License Board. The board received a total of 1204 completed surveys.

4. Survey of Pharmacies that Translate Labels

The board has surveyed pharmacies to determine if they are providing consumers with translated labels, and if they are using the translated "directions for use" that are on the board's website. A copy of the survey questions are provided in **Attachment 5d**.

Attachment 5a



FOR IMMEDIATE RELEASE

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First Universal Standards Guiding Content, Appearance of Prescription Container Labels to Promote Patient Understanding of Medication Instructions

Nearly Half of Patients Misunderstand One or More Dosage Instructions Pharmacies Across the Country Urged to Adopt "Patient-Centered" Labels

Rockville, Md., October 9, 2012 — With medication misuse resulting in more than one million adverse drug events per year in the United States, new standards released today by the U.S. Pharmacopeial Convention (USP) for the first time provide a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists. Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a "patient-centered" manner that best reflects how most patients seek out and understand medication instructions.

"Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, non-adherence and medication errors," said Joanne G. Schwartzberg, M.D., director, aging and community health for the American Medical Association and a member of the USP Nomenclature, Safety and Labeling Expert Committee, the group of independent experts responsible for the new standard. "With an aging and increasingly diverse population, and people utilizing a growing number of medications, the risks are more pronounced today than ever. These USP standards will promote patient understanding of their medication instructions, which is absolutely essential to preventing potentially dangerous mistakes and helping to ensure patient health and safety."

Studies have found that 46 percent of patients misunderstood one or more dosage instructions on prescription labels. The problem is particularly troublesome in patients with low or marginal literacy (one study showed patients with low literacy were 34 times more likely to misinterpret prescription warning labels), and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, non-standardized time periods. However, even patients with adequate literacy often misunderstand common prescription directions and warnings.

The USP effort to create these new standards developed from an Institute of Medicine (IOM)-led initiative to improve health literacy, which is defined as the degree to which people can obtain, process and understand the basic health information and services they need to make appropriate health decisions. According to IOM, 77 million Americans have limited health literacy, and a majority of Americans have difficulty understanding and using currently available health information and services.

Elements of the new USP standards, contained in General Chapter <17> *Prescription Container Labeling*, of the *United States Pharmacopeia* and the *National Formulary*, include:

- **Emphasize instructions and other information important to patients.** Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the

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label specify patient name, drug name (spell out full nonproprietary and brand name) and strength, and clear directions for use in simple language. Less critical information (e.g., pharmacy name, drug quantity) should not supersede critical information and should be placed away from dosing instructions.

- **Improve readability.** Labels should be designed and formatted so they are easy to read. Typography should be optimized by using high contrast print; adequate white space between lines of text (i.e., 25-30 percent of the point size); simple uncondensed familiar fonts (Times Roman or Arial are specifically recommended); and large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Older adults, in particular, have difficulty reading small print.
- **Give explicit instructions.** Instructions for use should clearly separate the dose itself from the timing of each dose. Do not use alphabetic characters for numbers. For example, write, “Take 2 tablets in the morning and 2 tablets in the evening” rather than “Take 2 tablets twice daily.” Dosing intervals such as “twice daily,” “3 times daily,” or hourly intervals such as “every 12 hours” should be avoided because such instructions are implicit rather than explicit, may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions worded in terms of specific hourly times (e.g., 8 a.m. and 10 p.m.) may be assumed to be more easily understood, in actual use they are less readily understood and may present greater adherence issues due to individual lifestyle patterns (e.g., shift work) than general timeframes such as “in the morning” or “after breakfast.” Ambiguous directions such as “take as directed” should be avoided without clear supplemental information.
- **Include purpose for use.** If the purpose of the medication is included on the prescription, it should be included on the label unless a patient prefers that it not appear. Confidentiality and FDA approval for intended use (i.e., labeled vs. off-label use) may cause some to constrain its inclusion on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms, e.g., “for high blood pressure” rather than “for hypertension.”
- **Address limited English proficiency.** Whenever possible, the directions for use on a prescription container label should be provided in the patient’s preferred language. The drug name shall be in English as well so that emergency personnel can have quick access to the information. Translations should be produced using a high-quality translation process; an example is provided in the standard.
- **Address visual impairment.** Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics or assistive technology).

“Patients’ best—and often only—source of information regarding the medications they have been prescribed is on the prescription container label,” Dr. Schwartzberg noted. Although other written information and oral counseling may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

USP issued a draft version of this standard for public review and comment by all interested stakeholders—including healthcare practitioners, retailers, software vendors, consumers and others—in December 2011. The final standard will be published in November 2012, and incorporates multiple additions based on comments received, including more detail on producing high-quality translations,



the visual impairment section, and the direction to include both brand and nonproprietary names on labels.

Enforcement of the standard will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations—similar to USP standards for sterile and nonsterile pharmaceutical compounding, both of which are widely recognized by states. At its 2012 annual meeting, the National Association of Boards of Pharmacy passed a resolution supporting state boards in requiring a standardized prescription container label.

Examples of prescription container labels that comply with the new USP standard are available at <http://uspgo.to/prescription-container-labeling>. Media inquiries may be directed to mediarelations@usp.org.

###

USP – Advancing Public Health Since 1820

The United States Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are relied upon and used worldwide. For more information about USP visit <http://www.usp.org>. FY1317

Add the following:

◀(17) PRESCRIPTION CONTAINER LABELING

INTRODUCTION

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States. Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label. Although other written information and oral counseling sometimes may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread. Studies have found that 46% of patients misunderstood one or more dosage instructions, and 56% misunderstood one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, nonstandardized time periods. In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels. However, even patients with adequate literacy often misunderstand common prescription directions and warnings. In addition, there is great variability in the actual auxiliary warning and supplemental instructional information applied by individual practitioners to the same prescription. The specific evidence to support a given auxiliary statement often is unclear, and patients often ignore such information. The essential need for, and benefit of, auxiliary label information (both text and icons) in improving patient understanding about safe and appropriate use of their medications vs. explicit simplified language alone require further study.

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors. On May 18, 2007, the USP Safe Medication Use Expert Committee established an Advisory Panel to: 1) determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions and 2) create universal prescription label standards for format/appearance and content/language.

In November 2009, the Health Literacy and Prescription Container Labeling Advisory Panel presented its recommendations to the Safe Medication Use Expert Committee, which then requested that USP develop patient-centered label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding. These recommendations form the basis of this general chapter.

Note—These standards do not apply when a prescription drug will be administered to a patient by licensed personnel who are acting within their scope of practice.

PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING

Organize the prescription label in a patient-centered manner: Information shall be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use.

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the label specify the patient's name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.

The prescription directions should follow a standard format so the patient can expect that each element will be in a regimented order each time a prescription is received.

Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding.

Simplify language: Language on the label should be clear, simplified, concise, and familiar, and should be used in a standardized manner. Only common terms and sentences should be used. Do not use unfamiliar words (including Latin terms) or medical jargon.

Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. Instead, use simplified, standardized sentences that have been developed to ensure ease of understanding the instructions correctly (by seeking feedback from samples of diverse consumers).

Give explicit instructions: Instructions for use (i.e., the SIG or signatur) should clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning, noon, evening, and bedtime). Instructions shall include specifics on time periods. Do not use alphabetic characters for numbers. For example, write "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily".

Whenever available, use standardized directions (e.g., write "Take 1 tablet in the morning and 1 tablet in the evening" if the prescription reads b.i.d.). Vague instructions based on dosing intervals such as twice daily or 3 times daily, or hourly intervals such as every 12 hours, generally should be avoided because such instructions are implicit rather than explicit, they may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions that use specific hourly times (e.g., 8 a.m. and 10 p.m.) may seem to be more easily understood than implicit vague instructions, recommending dosing by precise hours of the day is less readily understood and may present greater adherence issues due to individual lifestyle patterns, e.g., shift work, than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime. Consistent use of the same terms should help avoid patient confusion.

Ambiguous directions such as "take as directed" should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be included on the container label.

Include purpose for use: If the purpose of the medication is included on the prescription, it should be included on the prescription container label unless the patient prefers that it not appear. Always ask patients their preference when prescriptions are submitted for filling. Confidentiality and FDA approval for intended use (e.g., labeled vs. off-label use) may limit inclusion of the purpose on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., "for high blood pressure" rather than "for hypertension").

Limit auxiliary information: Auxiliary information on the prescription container label should be evidence-based in simple explicit language that is minimized to avoid distracting patients with nonessential information. Most patients, particularly those with low literacy, pay little attention to auxiliary information. The information should be presented in a standardized manner and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts). Icons are frequently misunderstood by patients. In addition, icons that provide abstract imagery for messages that are difficult to visually depict may be ineffective at improving understanding compared with simplified text alone. Use only icons for which there is adequate evidence, through consumer testing, that they improve patient understanding about correct use. Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice.

Address limited English proficiency: Whenever possible, the directions for use on a prescription container label should be provided in the patient's preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, which could lead to medication errors and adverse health outcomes. Additionally, whenever possible, directions for use should appear in English as well, to facilitate counseling; the drug name shall be in English so that emergency personnel and other intermediaries can have quick access to the information.

Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process is:

- Translation by a trained translator who is a native speaker of the target language
- Review of the translation by a second trained translator and reconciliation of any differences
- Review of the translation by a pharmacist who is a native speaker of the target language and reconciliation of any differences
- Testing of comprehension with target audience

If a high-quality translation process cannot be provided, labels should be printed in English and trained interpreter services used whenever possible to ensure patient comprehension. The use of computer-generated translations should be limited to programs with demonstrated quality because dosage instructions can be inconsistent and potentially hazard-

ous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency.

Improve readability: Labels should be designed and formatted so they are easy to read. Currently no strong evidence supports the superiority in legibility of serif vs. sans serif typefaces, so simple uncondensed fonts of either type can be used.

Optimize typography by using the following techniques:

- High-contrast print (e.g., black print on white background).
 - Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
 - Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns).
 - Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Note that point size is not the actual size of the letter, so 2 fonts with the same nominal point size can have different actual letter sizes. X-height, the height of the lower-case x in typeface, has been used as a more accurate indicator of apparent size than point size. For example, for a given point size, the x-height and apparent size of Arial are actually bigger than those for Times Roman. Do not use type smaller than 10-point Times Roman or equivalent size of another font. Older adults, in particular, have difficulty reading small print.
 - Adequate white space between lines of text (25%–30% of the point size).
 - White space to distinguish sections on the label such as directions for use vs. pharmacy information.
 - Horizontal text only.
- Other measures that can also improve readability:
- If possible, minimize the need to turn the container in order to read lines of text.

- Never truncate or abbreviate critical information.
- Highlighting, bolding, and other typographical cues should preserve readability (e.g., high-contrast print and light color for highlighting) and should emphasize patient-centric information or information that facilitates adherence (e.g., refill ordering).
- Limit the number of colors used for highlighting (e.g., no more than one or two).
- Use of separate lines to distinguish when each dose should be taken.

Address visual impairment:

- Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics of assistive technology).

Attachment 5b

The National Council for Prescription Drug Programs developed the “Universal Medication Schedule White Paper” (draft April 2013). This document supports the standardized directions in the board’s regulation at 16 CCR Section 1707.5. The goal of the universal medication schedule is to increase patient understanding and adherence to medication instructions by standardizing the phrasing of directions, thereby improving health outcomes.

A link to the “Universal Medication Schedule White Paper” is provided below.

<http://www.drugstorenews.com/sites/drugstorenews.com/files/NCPDP.pdf>

Attachment 5c

Summary

Patient-Centered Labeling Inspections

DATE: April - August 2012

This survey is intended to be used during inspections of all pharmacies. Unless otherwise indicated, please use tally marks. Sections 1-4 should always be completed. Section 5 will only be used if the pharmacy is compliant and indicated as such in section 4.

1	Number of Inspections	767
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2	Patient-Centered Label (B&P 4076[a] & CCR 1707.5[a][1][A] - [D])			
		Chain Store	Community	Clinic
	Compliant	355	339	1
	Noncompliant	13	67	7
	Corrections issued	13	49	7

3	The label is usually printed in...	Chain Store	Community	Clinic
	10-point font is the default	40	73	0
	12-point font is the default	280	161	1
	Both 10-point & 12-point font appear on the label	47	138	0

Please tally the number in sections 2 and 3 of the survey. This survey is designed to measure compliance with the patient-centered labeling requirements (section 2). Section 3 is designed to identify if pharmacies are defaulting to the larger or smaller font, or using a combination of sizes on the patient-centered elements.

4	Interpretative Services (CCR 1707.5[d])			
		Chain Store	Community	Clinic
	Compliant (all 12 languages available)	349	253	0
	Noncompliant	23	150	1
	Corrections issued	23	146	1

5	If compliant, interpretative services provided by	Chain Store	Community	Clinic
	Staff only	17	2	0
	Telephone (e.g. language line)	68	51	0
	Combination of staff and telephone	260	199	43
	Other, please specify	0	1	0

Please tally the number of pharmacies compliant and non-compliant in Section 4. Complete Section 5 section only if the pharmacy is compliant with the interpretative services provisions.

Other: Internal system with video conference - UC Davis

**California State Board of Pharmacy
Patient-Centered Prescription Label Survey**

Objective

To secure public comments from California consumers regarding the new patient-centered prescription labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007).

Methodology

The consumer survey soliciting feedback regarding the readability of the new prescription drug container labels was widely distributed. An electronic version of the survey was sent to several consumer groups, who in turn distributed the survey to their ListServe contacts. The survey was also translated into Chinese and Spanish and distributed by The California Pan Ethnic Health Network (CPEHN) to the appropriate audiences. Surveys have also been collected at local Senior Scam Stopper seminars sponsored by the Contractors State Licensing Board.

Results

A total of 1204 surveys were received. Respondents did not always provide answers to all of the questions. Results are summarized below:

Responses to Yes/No Questions

English: 1142 Surveys Received	YES	NO
1. Are your prescription container labels easy to read?	693	502
2. Are the directions for taking the medicine easy to understand?	245	959
3. Do you know why you take each of your medicines?	1049	149
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	963	232

Chinese: 46 Surveys Received	YES	NO
1. Are your prescription container labels easy to read?	40	5
2. Are the directions for taking the medicine easy to understand?	45	1
3. Do you know why you take each of your medicines?	42	4
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	30	4

Spanish: 16 Surveys Received	YES	NO
1. Are your prescription container labels easy to read?	6	10
2. Are the directions for taking the medicine easy to understand?	7	9
3. Do you know why you take each of your medicines?	7	9
4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)?	16	0

Top responses to open-ended questions:

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

1. Directions for use/clear dosing instructions: 539 of 1098 responses = 49%
2. Name of drug (including generic and brand name): 403 of 1098 responses = 36%
3. Side effects/warnings/interactions/contraindications: 68 of 1098 responses = 6%

When asked what changes would make the labels better, the top responses were:

1. Larger font: 318 of 1180 responses = 26%
2. State purpose for taking med: 84 of 1180 responses 7%
3. Include brand name as well as generic name: 52 of 1180 responses = 4%

When asked how the information could be improved:

1. Include clear directions/dosing instructions: 123 of 574 responses = 21%
2. Larger font: 43 of 574 = 7%
3. Include purpose for taking the med: 27 of 574 = 4%

Attachment 5d

Survey Questions Regarding Translated Labels:

1. Do you provide prescription container labels with translated directions?
 - a) Yes
 - b) No (if no, go to question 4)

2. How do you provide the translation of the directions for use?
 - a) Pharmacy staff translates the labels
 - b) The pharmacy uses the Board of Pharmacy's online translated directions for use
 - c) The pharmacy uses computer software or online programs
 - d) The pharmacy uses other means of providing translations (describe):

3. If you translate the labels, do you also provide the English language equivalent on the label?
 - a) Yes
 - b) No

4. If you do not provide translated directions on the label, why?
 - a) The pharmacy has no requests for translated labels
 - b) The pharmacy has too many patients with diverse language needs
 - c) The pharmacy's software will not print in foreign language fonts
 - d) The pharmacy is concerned that errors on the label will go undetected
 - e) Other: _____

5. How does the pharmacy comply with the interpreter requirements?
 - a) Uses pharmacy staff at this or other pharmacies to interpret
 - b) Uses a telephone language service
 - c) Is not compliant with current requirements to have access to an interpreter

Inspector: _____ Date _____

Pharmacy: _____

Survey Results Regarding Pharmacy Compliance with Translated Labels and Interpreter Availability

A total of 239 surveys were collected by Board inspectors. The results are as follows:

1. Do you provide prescription container labels with translated directions?

a) Yes 185 (77.4%) b) No 54 (22.6%)

Individual Comments:

Limited Spanish

No occasion has arisen

Spanish/French Canadian on label and as counseling information

Spanish

Spanish only

2. How do you provide the translation of the directions for use?

a) Pharmacy staff translates the labels: 69 (37.3%)

Individual Comment: Spanish Only

b) The pharmacy uses the Board of Pharmacy's online translated directions for use: 5 (2.7%)

c) The pharmacy uses computer software or online programs: 151 (81.67%)

Comments: Spanish only; by Sigs only; no free-form Sigs can be translated on label.

d) The pharmacy uses other means of providing translations (describe): 12 (6.5%)

Individual Responses:

1. Third party Language Line, although the occasion has never arisen

2. Language Line

3. Store employees (Spanish only). No other language translations have ever come up

3. If you translate the labels, do you also provide the English language equivalent on the label?

a) Yes 47 (26%) b) No 134 (74%)

Individual Comments:

Optional

If the software is used correctly an additional leaflet prints in English, with label information and medication information

No room/space for both

Hard copy is in English

RPh translates based on Spanish experience

Some prescribers write both English and the foreign language, so the pharmacy puts both on the label

Has never come up

Don't use often

Don't know if label provides English translation.

4. If you do not provide translated directions on the label, why?

a) The pharmacy has no requests for translated labels 28 (51.9%)

b) The pharmacy has too many patients with diverse language needs 4 (7.4%)

c) The pharmacy's software will not print in foreign language fonts 18 (33.3%)

d) The pharmacy is concerned that errors on the label will go undetected 14 (25.9%)

e) Other:

Individual Responses:

Pharmacy has not contracted with any software vendor to provide labels yet (new pharmacy).

Pharmacy has no prescription processing software at this time (new pharmacy).

5. How does the pharmacy comply with the interpreter requirements?

- a) Uses pharmacy staff at this or other pharmacies to interpret 138 (57.7%)
- b) Uses a telephone language service 190 (77.5%)
- c) Is not compliant with current requirements to have access to an interpreter 15 (6.3%)

Individual Comments:

Is not in full compliance. Only has Spanish-speaking staff.

Both staff and rarely Language Line

Attachment 6

EXCERPT OF THE MINUTES FROM THE OCTOBER 2013 BOARD MEETING

XVI. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

In Chairperson Brooks' absence, President Weisser provided a report on the Communication and Public Education Committee meeting that was held on October 7, 2013

1. Report of the Communication and Public Education Committee Meeting Held October 7, 2013

a. Review and Discussion of the 42nd Annual Report of the Research Advisory Panel of California

President Weisser reported that Patrick R. Finley, Pharm.D., is the board's appointment to the seven member advisory panel. Mr. Weisser referenced the copy of the 42nd Annual Report of the Research Advisory Panel of California (July, 2012) provided with the meeting materials. The committee recommended that Dr. Finley come to a future meeting of the committee or board to tell them more about the Advisory Panel's activities and to share additional information on studies that may be of interest to the board or related to the pharmacy profession.

Discussion

There were no comments from the board or from the public

b. Discussion on Requests from California Pharmacies for Exemption from Title 16 California Code of Regulations Section 1707.6(e) to Use Alternate Notice of Interpreter Availability Posters

President Weisser provided that existing board regulations require pharmacies to prominently post the "Notice to Consumers" required by 16 CCR Section 1707.6. In addition, Section 1707.6(c) requires every pharmacy to post or provide a "point to your language" notice so that consumers are aware that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the board unless the pharmacy has received prior approval of another format or display methodology. The board has delegated to the Communication and Public Education Committee the authority to act on all requests to use another format or display methodology of these posters.

At the October 7, 2013 meeting, the committee considered and denied two requests to use an alternate format notice of interpreter availability. One request was from Costco, and the other from Walmart Stores (for both Walmart and Sams Club pharmacies). While each request specified additional languages (in addition to the 12 mandated by board regulation), neither contained the specific language/phrasing that is required by 16 California Code of Regulations

Section 1707.6(c): “Point to your language. Interpreter services will be provided to you upon request at no cost.” Copies of the alternate format notices considered by the committee are provided in Attachment 2.

The committee concluded that it would like to see any alternate format notice submitted for the committee’s approval to include the statement “This notice is required to be posted by the California Board of Pharmacy.”

Board staff drafted a form that can be used for future waiver requests for the committee’s consideration. Staff will add to that request form a reminder that any alternative format notice must contain the language required by 1707.6(c).

Discussion

There were no comments from the board or from the public.

c. Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by Title 16, California Code of Regulations Section 1707.5(e)

President Weisser reported that staff is in the process of securing bids to have the emergency contraception fact sheet (required by 16 CCR Section 1746(b)) translated into six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. These are the same six languages that the board makes available for its “Notice to Consumers” posters. When available, the fact sheets will be available upon request, and will also be available for download from the board’s web site. A copy of the updated emergency contraception fact sheet (English version) was provided in the meeting materials.

Discussion

There were no comments from the board or from the public.

d. Results of Assessment of California’s Patient-Centered Labeling Requirements as Required by Title 16 California Code of Regulations Section 1707.5(e)

Background

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

Since April 2013, the committee has initiated review of the components in the current regulatory requirements. President Weisser noted that the USP guidelines for prescription container labeling published in November 2012 had a close resemblance to the board’s requirements.

Ms. Herold stated that staff continues to search for medical literacy research regarding standardized directions for use, noting the goal of such a schedule is to increase patient understanding, adherence to medication instructions and improving health outcomes. Board staff has been trying to build support among groups by highlighting the benefits of using standardized directions for use, and that there may be educational opportunities to work with the other prescribing boards to this end.

One of the recommendations in the NCPDP's White Paper is to implement the use of universal medication instructions in an effort to help standardize e-prescribing directions for use. In its various surveys regarding components of the patient-centered labels, the board has looked at the use of font sizes, how interpretive services requirements are being implemented, and patient satisfaction with labels – noting they want larger font, and the purpose on the label.

At the October 7, 2013 committee meeting, the committee discussed the distribution of the surveys, noting that CPEHN distributed the board-translated surveys among limited English and other groups to secure their input.

Board Meeting Discussion

President Weisser reported that at the October 7, 2013 committee meeting, the committee discussed what should be considered “patient-centered.” Regulations currently require that “patient-centered” items (listed below) shall be clustered into one area of the label that comprises at least 50 percent of the label:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

The committee discussed and recommended that these four items, and specifically only these four items, remain clustered into the one area of the label that comprises at least 50 percent of the label in at least 10 point font (or 12 point if requested).

President Weisser provided that the committee also discussed if changes should be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug.” The committee recommended that Section 1707.5(a)(1)(B) be modified to remove the requirement that the manufacturer be in the “patient-centered” clustered items. They also recommended amending the language where a generic is dispensed to say “generic for” (the trade name). Staff worked with counsel to develop the following language. Laura add the language here.

At the October 7, 2013 committee meeting, the committee also discussed if purpose or condition should be on the patient-centered portion of the label. President Weisser reported that there was strong consensus among the committee and the public at the meeting that the

purpose or condition should be on the prescription label within the clustered patient-centered items. Currently the purpose is only required to be on the label if it is specified on the prescription. The committee directed staff to work with legal counsel to draft language to amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

Acknowledging the Governor's recent veto of legislation (SB 205) that sought to mandate a 12-point font on prescription labels, the board discussed the current font requirements in the regulation.

President Weisser reported that staff summarized surveys which indicated that pharmacies, by a wide preponderance, are currently using 12 point font as the primary font on prescription labels. It was the consensus of the committee that the regulation should be modified to require a minimum 12 point font. The committee recommended modifying Section 1707.5(a)(1) to read as follows:

(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 10-point sans serif typeface or, if requested by the consumer,~~ at least a 12-point sans serif typeface, and listed in the following order:

There was substantial discussion of this and other elements of the patient-centered regulations by the board and the public. President Weisser and staff counsel asked that each of the committee recommendations be discussed and voted on separately.

Ms. Herold noted that in the Governor's veto message for SB 205 he stated that rather than mandate a statutory change to establish a minimum font size on prescription labels, he would wait for the Board of Pharmacy to finish its review of its patient-centered label regulations.

Ms. Veale commented that she has no issue with the 12 point font, however she expressed concern that requiring the patient-centered portion to be 50 percent of the label would not leave enough room for other information such as number of refills. President Weisser commented that in the surveys he did not see that there was a concern with refills being printed in too small a font. Ms. Herold added that she does recall anyone saying the four items that are considered "patient centered" are not the most important information for patients and caregivers. The goal has been to keep the portion of the label containing those four items as uncluttered as possible. Ms. Herold added that overall the feedback received by the board mainly focused on making the font for the patient-centered items as large as possible.

Mr. Lippe commented that an issue that had been previously discussed is what to do if the directions for use are very long. He asked if that had been resolved. Ms. Herold responded that Board Member Wong brought in samples of labels he uses in his pharmacy which have long directions for use, where he was able to make fit this fit within the 50 percent space.

Ms. Wheat commented that she is opposed to the committee recommendation because the sample size that of the surveys received was so small that the board should not take action based on the results. Ms. Wheat added that she does not feel the board needs to change the law to require 12 point font as patients are able to get 12 point font if they request it.

Mr. Law commented he is uncertain if the board really needs to assign a specific percentage requirement for the patient-centered area of the label.

Dr. Castellblanch and Ms. Shellans again asked that the board discuss and vote on each recommendation separately to avoid confusion.

Dr. Wong commented that the market will regulate itself so the board does not have to create regulations that may perhaps be unnecessary.

Ms. Herold stated that this regulation was very controversial from the beginning and that is why the board agreed to review the regulation in two years. The public *strongly* requested 12 point font. Ms. Herold added that the board does not have to decide on everything at this meeting, if additional items need to be considered such as the 50 percent requirement, it can be placed on a future agenda.

Ms. Wheat commented that the law is working as it is, people are asking 12 point font and they are getting it. She does not feel that the board needs to change it just because people ask.

President Weisser reminded the board and the public that the board will take each committee recommendation for discussion and voting.

Amend Section 1707.5(a)(1) to read as follows, to specify that only the four items listed in that paragraph are to be within the patient-centered clustered area.

(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 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Mandy Lee, from the California Retailer's Association, commented that the board seemed to be discussing multiple recommendations at once and asked for clarification on what the board was voting to change. President Weisser responded that currently the board is voting on adding the phrase "and only those four items" to the regulation. Ms. Shellans noted that there would not

be any adoption at this meeting, the board would just be deciding if they want to move in that direction and possibly initiate the rulemaking.

Dr. Castellblanch stated that he thought that if the board voted on the committee recommendations it would move to rulemaking today. He added that many people have shown up to this meeting specifically to give comments on patient-centered labels.

Mandy Lee, from the California Retailers Association, commented that prescription bottle labels are one of the most over regulated pieces in pharmacy and she cautioned the board from adding additional requirements.

Committee Recommendation: Amend Section 1707.5(a)(1) to read as follows, to specify that only the four items listed in that paragraph are to be within the patient-centered clustered area.

- 1707.5(a)(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 10-point sans serif typeface or, if requested by the consumer, at least a 12-point 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 name of the manufacturer.
 - C. The directions for use
 - D. The condition or purpose, if it is indicated on the prescription.

Support: 10 Oppose: 1 Abstain: 0

President Weisser moved the discussion to the next committee recommendation which was the removal of the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amending the language where a generic is dispensed to say “generic for” (the trade name).

Ms. Herold commented that at a previous meeting someone gave a very clear example of a patient who had been given a brand name drug and they already had a generic at home. The patient did not realize it was the same medication and took both. The proposed amendment would address this issue, and help prevent such a mistake.

Mr. Room pointed out that the language that was given to the board did not include the “generic for” section, so it would need to be added before a vote could be taken.

Mr. Zee commented that due to some of the language being missing he would like to table the motion until the board could receive complete language clearly showing what was being added and removed.

Dr. Castellblanch asked if Mr. Zee wanted to table just this particular committee recommendation or the entire patient centered label discussion. Mr. Zee responded that he would like to table the entire patient centered discussion for a future meeting.

Dr. Castellblanch commented that the board noticed to the public that the patient-centered labels would be discussed at this meeting. He expressed his opinion that it is the board's responsibility to take action on items that have been properly noticed.

Mandy Lee commented that she would support Mr. Zee's motion to table the entire discussion.

Carrie Sanders, from the Pan Ethnic Health Network, commented she had traveled to the meeting from the Bay Area specifically for the patient-centered label discussion.

Donna Hernandez, from the California Alliance of Retired Americans, commented that many of their members traveled a long way to be at the meeting and she asked the board to continue their discussion.

Jonathan Nelson, from the California Society of Health System Pharmacists, supported Mr. Zee's motion.

Dr. Castellblanch again expressed his desire for the board to continue with the discussion rather than tabling it for future meetings.

Ms. Wheat added that she supported Mr. Zee's motion to table the entire patient-centered label discussion until proper language could be provided at a future meeting.

Motion: Table the discussion regarding the entire patient centered label regulation because of the problems and inconsistencies in the language provided to the board.

M/S: Zee/Wheat

Support: 4 Oppose: 7 Abstain: 0

As the motion to table the discussion failed, Mr. Room reported that he had been able to create language for the board and public to view on the projector screen. While the language was being put on the projector he recommended that the board move to the next committee recommendation – 12 point font.

President Weisser moved the discussion to the next committee recommendation: Each item shall be printed in 12-point sans serif typeface.

Dr. Castellblanch commented that the U.S. Pharmacopeia has recommended a national standard of 12 point font and the public has been very vocal in their support of 12 point font.

Ms. Wheat commented that she feels the law currently allows for flexibility in choosing whether to use 10 or 12 point font and she would not support the motion to require 12 point font only.

Ms. Don Braun Seema, from the California Alliance for Retired Americans, expressed her support for requiring 12 point font.

Ms. Pat Stanyo, from the California Alliance for Retired Americans, commented that she supports the committee recommendation to require 12 point font as many people do not realize that currently they have to request it if they need it.

Donna Hernandez, from the California Alliance for Retired Americans, expressed her support for 12 point font as well as having the purpose on the label.

Lorenzo Reals, from California Alliance for Retired Americans, commented that some of his friends have gone to pharmacies that refuse to provide larger font, so the 12 point requirement is necessary. President Weisser responded that any time someone goes into a pharmacy and finds that they are violating pharmacy law, the patient should file a complaint so the board can investigate.

A representative from Peoples Pharmacy commented that fitting all the ingredients for a compounded medication in 12 point font would be nearly impossible.

Sharron Nacamoto, from California Alliance for Retired Americans, commented that she supports the 12 point font.

Al Carter, from Walgreens, asked if the “generic for” would need to be in 12 point font. Ms. Herold responded that it would.

Carrie Sanders, from the Pan Ethnic Health Network, stated that the network strongly supports the use of 12 point font.

Mandy Lee, from the California Retailers Association, asked the board to consider allowing a year or two time period for all of their members to get in compliance with the 12 point font requirement if it passed today. Mr. Zee asked how long the members would need. Ms. Lee commented that they would need a year or two. Ms. Herold responded that even if the board finalized the regulation today the earliest they get the regulation in place would be at least a year, if not longer.

Committee Recommendation: Modify Section 1707.5(a)(1) to read as follows:

1707.5(a)(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 10-point sans serif typeface or, if requested by the consumer,~~ 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 name of the manufacturer.
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

Support: 10

Oppose: 1

Abstain: 0

Dr. Gutierrez thanked the public for attending the meeting and providing feedback.

President Weisser indicated that the board would now move back to the previous committee recommendation to modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name).

Mr. Room had been able to finalize the language on the “generic for” section of the language. The language Mr. Room created was displayed on the projector screen so the board and the public could view it. The language was displayed as follows:

1707.5(a)(1)(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, if a generic is dispensed, or the generic name of the ~~manufacturer~~ drug and a parenthetical containing “generic for” and the trade name of the drug.

Mr. Lippe commented that the pharmacy he goes to already does this.

Ms. Veale expressed her opinion that the manufacturer is a very important piece of information asked that the public provide feedback if the removal of the manufacturer from the patient-centered label would be a problem.

Dr. Gutierrez clarified that the manufacturer would still be on the label, it would just not be in the patient-centered portion.

Dr. Wong commented that he feels the manufacturer should remain in the patient-centered section of the label, right next to the drug name.

Donna Hernandez, from the California Alliance for Retired Americans, asked to clarify if “manufacturer” means the company who making the drug not the generic name of the drug. Mr. Room confirmed this. Ms. Hernandez replied that she does not think manufacturer is important enough to be in the patient-centered portion of the label as long as the generic name was there.

Lorenzo Reals, from California Alliance for Retired Americans, commented that he does not feel the language needs to be changed at all.

Dennis McAllister, from Express Scripts, agreed with Mr. Reals that the current language is good enough.

Carrie Sanders, from the Pan Ethnic Health Network, expressed her support of listing both the brand name and generic name.

Al Carter, from Walgreens, stated that manufacturer should remain in the same location on the label.

Megan Harwood, from San Gabriel Medical Pharmacy, commented that listing the manufacturer right next to the drug name may actually confuse the public.

Mr. Room clarified that this committee recommendation would actually accomplish two things. First it would require that you provide the trade name of the drug if you are substituting a generic. The second is it eliminates the requirement for the manufacturer’s name to be included in the cluster on the patient-centered portion of the label. The manufacture’s name would still be provided in another location of the label. President Weisser added that the “generic for” information *would* be in the patient centered portion of the label.

Ms. Wheat asked to clarify if the law currently requires the use of both the manufacturer name and the generic name. Mr. Room responded that currently if you use a generic, you have to list the manufacturer; if you do not use a generic you, do not have to list the manufacturer. Ms. Wheat asked if currently you have to list the brand name if you use a generic. Mr. Room responded that currently you are *not* required to list both the brand name and generic name.

Dr. Wong asked if a doctor writes the prescription for the generic, does the label need to list both the brand name and generic name? Mr. Room responded that the proposed language would require both to be listed.

Dr. Wong asked whether a pharmacist could list the manufacturer's name as well as the generic and brand name. Mr. Room replied that the manufacturer's name could not be in the patient centered portion of the label, it would have to be provided in another section of the label.

Dr. Wong asked why it is a problem to list the manufacturer in the patient centered portion of the label. Mr. Room responded that as the board moved toward requiring 12 point font the idea was to eliminate any information that was not needed to avoid cluttering the patient centered portion. Ms. Herold added that the board also considered the value of the information to the patient, often time the manufacturer's name is abbreviated and the patient has trouble understanding what the abbreviation means.

Jonathan Nelson, from the California Society for Health System Pharmacists, commented that the board should return this item to the committee to allow for further comments from the public.

Mandy Lee, from the California Retailers Association, agreed with Mr. Nelson's comments and again asked the board to allow for a one year buffer period once the rulemaking is finalized.

Ms. Veale asked to table this specific motion and to allow time for more comments from stakeholders. Ms. Herold provided that the regulation cannot move forward until the board votes on this item.

Dr. Gutierrez commented that it makes sense for the entire regulation to be modified and implemented at one time.

Motion: Table the motion to modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the "patient-centered" clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say "generic for" (the trade name).

M/S: Veale/Hackworth

Support: 8

Oppose: 3

Abstain: 0

Mr. Zee asked if the all of the changes to 1707.5 would be in one regulation package. Ms. Herold confirmed that all of the changes should be handled in one regulation.

Upon Mr. Lippe's request, Ms. Herold provided the board with an overview of the regulation process. Mr. Lippe commented that Mandy Lee's request for a one year buffer period after the regulation is finalized to allow time for implementation seemed reasonable and asked for a motion to be made to allow for it. Ms. Shellans responded that until the board has a *complete* regulation package and agrees to adopt the regulation they should not make any motion to allow for implementation time.

President Weisser clarified that in light of the motion being tabled the recommendation to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name) would be sent back to the committee.

Mr. Room recommended that the committee recommendation to amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items also be sent back to the committee. President Weisser agreed that this item would be sent back to the committee.

e. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5

As a result of the board’s discussion, the board will not be initiating a rulemaking to amend Title 16 California Code of Regulations Section 1707.5.

f. Update on *The Script*

President Weisser reported that the next issue of *The Script* is being finalized and prepared for being posted online. Staff leaves of absences and other issues have delayed the publication, but it should be available by the end of the October.

g. Public Outreach Activities Conducted by the Board

President Weisser encouraged the board and the public to review the public outreach activities provided in the meeting materials.

h. Update on the Development of Committee Goals for 2012-2017 to Fulfill the Board’s Strategic Plan

President Weisser noted that staff has suggested that at a future meeting, the committee augment its goals for the Strategic Plan.

The board recessed for break at 11:42 p.m. and resumed at 12:00 p.m.