



Communication and Public Education Committee Report

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Shirley Wheat, Board Member
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Report of the Meeting Held September 26, 2011

a. FOR ACTION: Discussion and Possible Action to Initiate a Rulemaking to Repeal and Add New 16 California Code of Regulations Section 1746 Regarding the State's Emergency Contraception Protocol

Attachment 1

Earlier this year, the Board of Pharmacy initiated the process to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 California Code of Regulations section 1746. These sections authorize a pharmacist to initiate emergency contraception pursuant to a state protocol developed by the Medical Board of California and the Board of Pharmacy, and with the assistance of the American College of Obstetricians and Gynecologists, the California Pharmacists Association and other entities.

The existing state protocol was developed by the Medical Board in 2004 and then later adopted by the Board of Pharmacy as a regulation. Since the time of adoption, there have been changes in the availability of emergency contraception medication, the manufacturers who produce the medication, and there is a typo that needs correction (mcg instead of mg).

After the May Board Meeting, the executive officer compiled edits into a revised protocol from changes submitted from CPhA's representative (a women's health specialist pharmacist Katherine Besinque from USC, and two representatives of the American College of Obstetricians and Gynecologists (Shannon Smith Crowley and Phillip Diamond, MD).

At the July Board Meeting, the board reviewed the proposed changes. After this meeting, the executive officer attended the Medical Board of California's meeting to request their adoption of the updated protocol. With the EO was Dr.

Besinque and Ms. Smith Crowley. The Medical Board approved the protocol at their meeting.

At its September meeting, the Communication and Public Education Committee reviewed and recommended approval for action of the board at the October Board Meeting. If the board moves forward with the regulation changes, the regulation will be released for the formal 45 day comment period.

Once the rulemaking is underway, the board will need to update the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception.

Recommendation of the Communication and Public Education (with an adjustment by staff so a new motion is necessary):

Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR § 1746 to conform to the emergency contraceptive protocol approved by the Medical Board in July 2011; authorize the Executive Officer to make any non-substantive changes to the rulemaking package; and provide a 45-day public comment period.

If after the public comment period, no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1746 as described in the notice.

b. FOR ACTION: Addition to the Board's Web Site Translations of Directions for Use for Prescription Container Labels

Attachment 2

The California Endowment, to support ensuring quality labels for those who do not read English, funded a project with national PhD patient literacy researchers Stacy Bailey and Michael Wolf to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. The translations were vetted in local CA (and IL) communities with a survey of native speakers.

The board is fortunate that this funding and these researchers have been available to us in the development of these labeling requirements. As discussed early in the development of the regulation, the translations will be placed on the Web site with a disclaimer about board liability for use.

The regulation requires that the board place these translations on its Web site by October 2011.

Attachment 2 contains the translations that have been made in Spanish, Korean, Russian, Vietnamese and Chinese.

There are several differences from the directions for use in the regulation:

- There was no translation of “if you have pain, take ___ at a time. Wait at least ___ hours before taking again. Do not take more than ___.”
- They used the word pill in the translations, not “insert appropriate dosage form.”

The board has access to a translation service for its publications. Between now and the time of the board meeting, I will have these translations reviewed by this service.

Board Counsel Shellans may want to add a disclaimer to be added to the Web site.

c. FOR DISCUSSION AND POSSIBLE ACTION: Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels

The board’s requirements for patient-centered prescription drug container labels took effect on January 1, 2011, as required by statute. Since June 2010, when the board finalized its work on the regulation, the board has been publicizing its requirements to the board’s licensees. A copy of the regulation appears on the last page of this chair report.

The regulation’s requirements also contains several directives to the board:

1707.5:

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2011, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Regarding the board’s progress with respect to these requirements:

- Re: subdivision (b): Translations are available for addition to the Web site.
- Re: subdivision (c): The board already has examples of labels available on its Web site and has published these in its newsletter.

- Re: subdivision (e): The committee has begun discussions of the existing requirements to determine whether modifications to the requirements are needed.

During this meeting, board members will discuss enforcement options for compliance with the requirements. The board's inspectors have not done more than to encourage and probe about compliance with the labeling requirements. During a very near future Inspectors Meeting, the board's inspectors will discuss compliance issues for the labels, and the discussion from this meeting will be shared.

d. FOR INFORMATION: Review of USP's Guidance for Patient Prescription Container Labels

Attachment 3

Earlier this year, the United States Pharmacopeia completed its work on standards for prescription container labeling. The committee reviewed these standards at its September meeting.

A copy of the requirements is provided in **Attachment 3**. This guidance is a recommendation -- it does not carry the effect of law or regulation.

A comparison chart of the requirements has been developed which highlights the board's regulation with the USP's. USP's standards are markedly similar, which is not surprising since USP considered the board's draft requirements at an early state in the development of their standards.

	USP	Board Regulation
Organize label to emphasize patient info	X	X
• Patient's Name	X	X
• Drug Name & Strength	X	X
• Instructions in Clear & Simple Language	X	X
• Standardize order	O	X
• Dedicate 50% of label	O	X
• Require Purpose if on Rx	O	X
• Require Mfg if generic drug	O	X
Place all other required elements elsewhere so not as to interfere with the above	X	X
Use standardized pat-centered translations of directions for use "when appropriate"	X	X
Separate dose from timing of dose	X	X (in stnd. directions)
Use numeric, not alphabetic		

characters	X	X
Purpose for use if desired by patient and use simple terms	X	O
Purpose for use if written on Rx	O	X
Limit Auxiliary information/labels	X	O
Standardize terms & placement	X	O
Validate use of icons	X	O
Labels should be in language of Patient	X	Bd provided translations of directions In 5 additional lang.
or should have interpreter services available	X	X
Labels should be easy to read	X	X
Use high contrast ink	X	X
Simple uncondensed fonts	X	
Large Font size	X	
e.g., (not specified one type)		
12-point Times New Roman	X	O
11-point Arial	X	X
Use san serif (e.g, Arial) 10 point	O	X
Or 12 point if requested	O	X
No font smaller than 10 point	X	X
Use sentence case (not all caps)	X	O
Use Adequate white space	X	X
Use white space to separate directions from pharmacy info	X	X
Use horizontal text only	X	O
Minimize need to turn container to read	X	O
Do not truncate information	X	X
Use highlight, gold and typo cues to emphasize pt. centric or adherence (e.g., ordering)	X	X
Limit number of highlight colors	X	O

e. FOR DISCUSSION: Future Design of the New Notice to Consumers Posters

At the July 29, 2011 Board Meeting, the board completed its work on a new regulation to house all notice to consumer elements in one place.

The rulemaking file for this regulation has been compiled by board staff, and submitted to the Department of Consumer Affairs for review, then to the Office of Administrative Law. It will be approximately 6 months (perhaps a bit less) before the regulation would be in effect. A copy of the adopted text of the notice to consumers regulation is provided as **Attachment 4**.

The Communication and Public Education Committee has started work to redesign the new poster(s). Staff will take these recommendations and work with various graphic designers to develop prototypes for the new posters and bring these to the next committee meeting, which will be scheduled before the January Board Meeting.

Three major outcomes will result from the new notice to consumers requirements.

1. Proposed design elements
2. Concepts for the video display.
3. Concepts for interpreter services, which is likely a separate notice.

f. FOR DISCUSSION: Is there Value in Development of a Standardized Form for Pharmacies to Use to Request Refills from Prescribers?

Attachment 5

Recently the board received a proposal from Assembly Member Feuer that had been submitted to him by a constituent as a possible legislative proposal. The problem is that physicians receive numerous refill requests via fax daily from pharmacies that are not standardized, and there is potential for a medication error from the prescriber reviewing and approving such diverse refill requests daily. The proposal is to require use of a specific form.

The executive officer asked Cedars Sinai (where the MD constituent practices), the California Pharmacists Association and the California Retailers Association for their assessment of the need for such standardization. Several board inspectors also provided comments. No one was opposed, but no one was especially motivated either. Several thought that a pharmacy may need to seek different refill elements depending upon the patient, the medication or the medical condition, so standardization may not be achievable.

The committee did not believe there was a need to develop such a form. Ms. Veale discussed that she believes that requiring a specific form may create problems and may not create a lot of benefit overall. She discussed that each software program has its own format.

g. FOR INFORMATION: Assessment of the Board's Public Education Materials

Last year the committee determined that it wishes to assess its public education materials. A subcommittee of Board Members Castellblanch and Veale agreed to perform this function. After reviewing the number and diversity of materials, the committee decided first to focus on improving the Web site placement of these materials. However, all state agencies are being directed to transfer to a new state government web design, and the board will make the Web site changes when it migrates to the new web format.

In June, Board Associate Analyst Karen Abbe retired. Ms. Abbe was the board's public education and outreach staffer, but over the last year while the board had undergone a 15 percent operations cut and directed to reduce all unnecessary expenditures, she was reassigned to perform the reporting of board discipline taken against licensees to the HIPDB data bank.

Recently the board recruited a public information officer to aid the board in its public outreach, Web site maintenance, social media applications and in developing the new notice to consumers and education on patient-centered labels. We selected Kim Brown from the department's press office who previously assisted us with the development of the consumer education videos. She has been loaned to the board for three months, at which time we will reevaluate this assignment. Ms. Brown will be an asset to this committee in a number of ways including assessing the board's public education materials, and establishing social media channels for the board.

h. FOR INFORMATION: Update on *The Script*

The next issue of *The Script* is being written and will be released we hope in January. This will be a consolidated issue because the board was unable to complete a fall newsletter due to staffing issues in the Legal Office.

i. FOR INFORMATION: Update on Public Outreach Activities

A travel freeze was implemented in May pursuant to the Governor's executive order, suspending travel for all but the most essential and mandated purposes. In accordance with this mandate, the board reduced its public appearances. Nevertheless, the board was able to provide the following presentations, some of which were scheduled before the executive order.

- July 8: Executive Officer Herold and President Weisser attend the CSHP's Board of Directors meeting in Sacramento to provide an update on board activities.
- August 18: Executive Officer Herold provides a Webinar on California's e-pedigree requirements to a conference hosted by the National Coalition of Pharmaceutical Distributors
- September 14: Executive Officer Herold attend a California Pharmacy Council Meeting to discuss pharmacist manpower today and in the future.

j. FOR INFORMATION: Minutes of the Meeting of September 26, 2011
Attachment 6

Attachment 6 contains a copy of the minutes from the meeting.

k. FOR INFORMATION: First Quarterly Report on Committee Goals for 2011/12
Attachment 7

Attachment 7 contains a copy of the first quarter's strategic plan update.

Attachment 1

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

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items 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 the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2011 the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Title 16. Board of Pharmacy Proposed Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

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Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One-Dose Regimen				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
Two-Dose Regimens				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

<u>Dedicated Approved Products for Emergency Contraception</u>			
<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<u>One Dose Regimen</u>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<u>Two Dose Regimen</u>			
<u>Next Choice™</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>Oral Contraceptive Pills</u>			
<u>Brand</u>	<u>Tablets per Dose (two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	<u>Levonorgestrel per dose (mg)*</u>
<u>Allesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

<u>Anti-Nausea Treatment Options For Use With Emergency Contraception</u>		
Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

Attachment 2

ENGLISH**SPANISH**

Take 1 pill at bedtime	Tome 1 pastilla a la hora de acostarse
Take 2 pills at bedtime	Tome 2 pastillas a la hora de acostarse
Take 3 pills at bedtime	Tome 3 pastillas a la hora de acostarse
Take 1 pill in the morning	Tome 1 pastilla por la mañana
Take 2 pills in the morning	Tome 2 pastillas por la mañana
Take 3 pills in the morning	Tome 3 pastillas por la mañana
Take 1 pill in the morning and 1 pill at bedtime	Tome 1 pastilla por la mañana y Tome 1 pastilla a la hora de acostarse
Take 2 pills in the morning and 2 pills at bedtime	Tome 2 pastillas por la mañana y Tome 2 pastillas a la hora de acostarse
Take 3 pills in the morning and 3 pills at bedtime	Tome 3 pastillas por la mañana y Tome 3 pastillas a la hora de acostarse
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Tome 1 pastilla por la mañana, 1 pastilla al mediodía y 1 pastilla al atardecer
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Tome 2 pastillas por la mañana, 2 pastillas al mediodía y 2 pastillas al atardecer
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Tome 3 pastillas por la mañana, 3 pastillas al mediodía y 3 pastillas al atardecer
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Tome 1 pastilla por la mañana, 1 pastilla al mediodía, 1 pastilla a la hora de acostarse
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Tome 2 pastillas por la mañana, 2 pastillas al mediodía, 2 pastillas a la hora de acostarse
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Tome 3 pastillas por la mañana, 3 pastillas al mediodía, 3 pastillas a la hora de acostarse

ENGLISH**KOREAN**

Take 1 pill at bedtime	취침 전 1 알을 복용하십시오
Take 2 pills at bedtime	취침 전 2 알을 복용하십시오
Take 3 pills at bedtime	취침 전 3 알을 복용하십시오
Take 1 pill in the morning	아침에 1 알을 복용하십시오
Take 2 pills in the morning	아침에 2 알을 복용하십시오
Take 3 pills in the morning	아침에 3 알을 복용하십시오
Take 1 pill in the morning and 1 pill at bedtime	아침에 1 알, 취침 전 1 알씩 복용하십시오
Take 2 pills in the morning and 2 pills at bedtime	아침에 2 알, 취침 전 2 알씩 복용하십시오
Take 3 pills in the morning and 3 pills at bedtime	아침에 3 알, 취침 전 3 알씩 복용하십시오
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	아침에 1 알, 정오에 1 알, 저녁에 1 알씩 복용하십시오
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	아침에 2 알, 정오에 2 알, 저녁에 2 알씩 복용하십시오
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	아침에 3 알, 정오에 3 알, 저녁에 3 알씩 복용하십시오
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	아침에 1 알, 정오에 1 알, 취침 전 1 알씩 복용하십시오
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	아침에 2 알, 정오에 2 알, 취침 전 2 알씩 복용하십시오
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	아침에 3 알, 정오에 3 알, 취침 전 3 알씩 복용하십시오

ENGLISH**RUSSIAN**

Take 1 pill at bedtime	Принимать по 1 таблетке перед сном
Take 2 pills at bedtime	Принимать по 2 таблетки перед сном
Take 3 pills at bedtime	Принимать по 3 таблетки перед сном
Take 1 pill in the morning	Принимать по 1 таблетке утром
Take 2 pills in the morning	Принимать по 2 таблетки утром
Take 3 pills in the morning	Принимать по 3 таблетки утром
Take 1 pill in the morning and 1 pill at bedtime	Принимать по 1 таблетке утром и по 1 таблетке перед сном
Take 2 pills in the morning and 2 pills at bedtime	Принимать по 2 таблетки утром и по 2 таблетки перед сном
Take 3 pills in the morning and 3 pills at bedtime	Принимать по 3 таблетки утром и по 3 таблетки перед сном
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Принимать по 1 таблетке утром, по 1 таблетке в полдень и по 1 таблетке вечером
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Принимать по 2 таблетки утром, по 2 таблетки в полдень и по 2 таблетки вечером
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Принимать по 3 таблетки утром, по 3 таблетки в полдень и по 3 таблетки вечером
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Принимать по 1 таблетке утром, по 1 таблетке в полдень, по 1 таблетке перед сном
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Принимать по 2 таблетки утром, по 2 таблетки в полдень, по 2 таблетки перед сном
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Принимать по 3 таблетки утром, по 3 таблетки в полдень, по 3 таблетки перед сном

ENGLISH**VIETNAMESE**

Take 1 pill at bedtime	Uống 1 viên trước khi đi ngủ
Take 2 pills at bedtime	Uống 2 viên trước khi đi ngủ
Take 3 pills at bedtime	Uống 3 viên trước khi đi ngủ
Take 1 pill in the morning	Uống 1 viên vào buổi sáng
Take 2 pills in the morning	Uống 2 viên vào buổi sáng
Take 3 pills in the morning	Uống 3 viên vào buổi sáng
Take 1 pill in the morning and 1 pill at bedtime	Uống 1 viên vào buổi sáng và 1 viên trước khi đi ngủ
Take 2 pills in the morning and 2 pills at bedtime	Uống 2 viên vào buổi sáng và 2 viên trước khi đi ngủ
Take 3 pills in the morning and 3 pills at bedtime	Uống 3 viên vào buổi sáng và 3 viên trước khi đi ngủ
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Uống 1 viên vào buổi sáng, 1 viên vào buổi trưa, và 1 viên vào buổi tối
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Uống 2 viên vào buổi sáng, 2 viên vào buổi trưa, và 2 viên vào buổi tối
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Uống 3 viên vào buổi sáng, 3 viên vào buổi trưa, và 3 viên vào buổi tối
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Uống 1 viên vào buổi sáng, 1 viên vào buổi trưa, và 1 viên trước khi đi ngủ

Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Uống 2 viên vào buổi sáng, 2 viên vào buổi trưa, và 2 viên trước khi đi ngủ
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Uống 3 viên vào buổi sáng, 3 viên vào buổi trưa, và 3 viên trước khi đi ngủ

ENGLISH**CHINESE**

Take 1 pill at bedtime	睡前服一粒藥丸
Take 2 pills at bedtime	睡前服兩粒藥丸
Take 3 pills at bedtime	睡前服三粒藥丸
Take 1 pill in the morning	早上服一粒藥丸
Take 2 pills in the morning	早上服兩粒藥丸
Take 3 pills in the morning	早上服三粒藥丸
Take 1 pill in the morning and 1 pill at bedtime	早上服一粒藥丸和 睡前服一粒藥丸
Take 2 pills in the morning and 2 pills at bedtime	早上服兩粒藥丸和 睡前服兩粒藥丸
Take 3 pills in the morning and 3 pills at bedtime	早上服三粒藥丸和 睡前服三粒藥丸
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	早上服一粒藥丸 中午服一粒藥丸和 傍晚服一粒藥丸
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	早上服兩粒藥丸 中午服兩粒藥丸和 傍晚服兩粒藥丸
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	早上服三粒藥丸 中午服三粒藥丸和 傍晚服三粒藥丸
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	早上服一粒藥丸 中午服一粒藥丸和 睡前服一粒藥丸
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	早上服兩粒藥丸 中午服兩粒藥丸和 睡前服兩粒藥丸
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	早上服三粒藥丸 中午服三粒藥丸和 睡前服三粒藥丸

Attachment 3

BRIEFING

(17) Prescription Container Labeling. This proposed new general test chapter provides information on prescription container labeling. 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. Those recommendations formed the basis of this general test chapter.

(NSL: S. Becker) RTS—C85490

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 (1). Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label (2–6). Although other written information and oral counseling sometimes may be available (2–4,6–13), 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 (2,3,13–15).

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread (2–12,14,16–18). Studies have found that 46% of patients misunderstood one or more dosage instructions (14), and 56% misunderstood one or more auxiliary warnings (17). The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy (2,3,5,6,8,9,12,15,17). In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels (17). However, even patients with adequate literacy often misunderstand common prescription directions and warnings (2,6,9,15,17). 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 (2,3,7,15,17,18). 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 versus explicit simplified language alone require further study (2–5,7,13–15,17–19).

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors (1–9,12,13,15,17,18,20).

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 (2–5,7,6,11,13,14,16,18,20–23).

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. Place at the top of the label the patient's name, drug name and strength, and explicit clear directions for use in simple language.

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, product 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 (2–6,11–16,18).

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 unclarified medical jargon.

Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used. Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. The principles established by Doak, Doak, and Root for maintaining simple language can facilitate the simplification process (24). Consumer feedback also should be sought (2–6,9,12–15,17,18,25,26–28).

Give explicit instructions: Instructions for use shall 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 and evening or at breakfast and dinner). Instructions should use numeric rather than alphabetic characters for numbers (e.g., 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" or "Take 1 tablet at breakfast and 1 tablet at dinner" 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.) are more easily understood than implicit vague instructions, dosing by precise hours of the day is less readily understood and may present greater adherence issues than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime.

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 (2–4,6,12–15,29).

Include purpose for use: Determine what the patient prefers, and include the purpose of the medication on the label unless the patient prefers that it not appear. Confidentiality and FDA approval for intended use (e.g.,

labeled versus 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”) (2–4,13,14).

Limit auxiliary information: Auxiliary information on the prescription container label should be evidence-based on 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 evidence that they improve patient understanding about correct use. Because of the limited space on the container, use only those icons shown in consumer testing to improve understanding beyond simple explicit text alone. 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 (2–6,13–15,17–19).

Address limited English proficiency: Whenever possible, prescription container labeling should be provided in an individual’s preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, that could lead to medication errors and adverse health outcomes.

Translations of prescription medication labels should be produced using a high-quality translation process. If a high-quality translation process cannot be provided, labels should be printed in English and translated by

trained interpreter services 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 hazardous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency (2,3,30,31).

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 versus sans serif typefaces, so simple uncondensed fonts of either type can be used (2–4,20,22,2–37).

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 two 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 often experience declines in visual acuity.

- 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 versus pharmacy information.
- Horizontal text only.

Other measures that can also improve readability include the following:

- If possible, minimize the need to turn the container in order to read lines of text.
- Never truncate 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).

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**Recommendations to the Safe Medication Use Expert Committee
by the Health Literacy and
Prescription Container Labeling Advisory Panel
May and November 2009**

Posted April 2010

Background

Inadequate understanding of prescription medication directions for use and auxiliary information on dispensed containers is widespread among patients and is a major concern affecting safe and effective use. Lack of universal standards and formal oversight for dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and even medication errors. On May 18, 2007 the Safe Medication Use Expert Committee established the Health Literacy and Prescription Container Labeling Advisory Panel (HL AP) to examine ways to improve prescription drug container labeling and, if possible, to recommend ways to standardize this labeling. In December 2008 the HL AP held its first meeting. During 2009 the HL AP wrote a series of recommendations for standards development and requested that USP develop patient-centered label standards for the format, appearance content, and language of prescription medication instructions to promote patient understanding.

The following recommendations for patient-centered prescription label standards are for the format, appearance, content, and language of prescription medication containers to promote patient understanding. These recommendations are evidence-based and address optimal understanding, adherence, and safe and effective use of medications by patients. These recommendations emanated from the May 16, 2009 and November 4, 2009 meetings of the HL AP. Pursuant to these recommendations, the HL AP is developing a proposed General Chapter <17> *Prescription Container Labeling* that will be forwarded into the *Pharmacopeial Forum* public review and comment process. The General Chapter also will be pre-posted on the USP Web site to enable broad public comment.

Recommendations

Organize the Prescription Label in a Patient-centered Manner

Patient-directed information must 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 critical patient information needed for safe and effective understanding and use.

Patient-directed instructional content will be at the top of the label, and other less critical content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, product description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information can be placed e.g., at the bottom of the label or another less prominent location. Drug name and directions for use (e.g., specific dosage/usage/administration instructions) should be displayed with greatest prominence.

Simplify Language

To improve patient understanding and safe and effective prescription medication use, language on the label should be clear, simplified, concise, and standardized. Only common terms and sentences should be used. Use of unfamiliar words (including Latin terms; see below) and unclear medical jargon should be avoided.

Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used. 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 stated on the container label.

Readability formulas and software are not recommended for short excerpts of text like that on prescription labels. The principles established by Doak, Doak, and Root for maintaining simple language can facilitate the simplification process.¹ Consumer feedback should also be sought.

Use Explicit Text to Describe Dosage/Interval Instructions

Dosage/usage/administration instructions must clearly separate dose from interval and must provide the explicit frequency of drug administration (e.g., "Take 4 tablets each day. Take 2 tablets in the morning and 2 tablets in the evening" is better than "Take two tablets by mouth twice daily"). Use numeric rather than alphabetic characters for numbers.

Include Purpose for Use

Confidentiality and FDA approval for intended use (e.g., labeled vs off-label use) may limit inclusion of indications on drug product labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms. Therefore, the prescriber's intended purpose of use/indication should be included on the prescription medication label whenever possible and should be stated in clear, simple, patient-centered language. When such use conflicts with unit-of-use commercial packaging information, the patient should receive appropriate counseling to clarify the intended purpose of the medication vs. what is stated in commercial labeling.

Improve Readability

Critical information for patients must appear on the prescription label in an uncondensed, simple, familiar, minimum 12-point, sans serif font (e.g., Arial) that is in sentence case (i.e., punctuated like a normal sentence in English: initial capital followed by lower-case letters except for proper nouns, acronyms, etc.). Field size and font size may be increased in the best interest of patient care. Critical information should never be truncated.

The following several general rules can improve readability:

- Optimize typography
- Optimize white space (use adequate space between lines of text; use wide letter spacing; and use white space to distinguish sections on the label such as directions for use vs pharmacy information)
- Use numeric rather than alpha representation (e.g., for dose information)
- Use horizontal text only
- If possible, minimize need to turn the container in order to read lines of text.

Highlighting, bolding, and other typographical cues should preserve readability (e.g., contrast, light color for highlighting), and should emphasize patient-centric information or information that facilitates patient adherence.

Provide Labeling in Patient's Preferred Language Whenever possible, prescription container labeling should be provided in a patient's preferred language. Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process includes the following four elements:

¹ by the Suitability Assessment of Materials by Doak, Doak, and Root

- Initial translation by a trained and competent translator (e.g., a translator with documented proficiency in both English and the other language and knowledge in both languages of terminology and concepts relevant to prescription medication)
- Review of the translation by another trained and competent translator and reconciliation of differences
- Review of the translation by a pharmacist or other medical professional who is a native speaker of the target language and reconciliation of differences
- Testing of comprehension with target audiences.

If a high-quality translation process cannot be provided, labels should be printed in English.

Include Supplemental Information

Auxiliary information on the prescription container should be minimized and should be limited to evidence-based critical information regarding safe. The information should be presented in a standardized manner and should be necessary for patient understanding. This is necessary because of the extensive variability in the content and application of supplemental information, the lack of scientific evidence for these labels, and potential ambiguity and failure to address specific patient needs.

Auxiliary information should be critical to the medicine's safe and appropriate use and should be evidence-based, should clarify instructions for use, and should enhance understanding. Use of icons should be limited to those for which evidence demonstrates enhancement of interpretation and clarity about use. The inclusion of auxiliary information on the patient prescription medication label (e.g., warnings and critical administration alerts) should be minimized and limited to critical information that is evidence based, standardized, and complementary to the patient prescription medication label.

Standardize Directions to Patients

In recognition of the nation's move toward e-prescribing, the HL AP recommends that standards should be developed for prescribing directions to patients (SIGs). This would lead to consistency of language and use across all health care professionals and systems. An important element is the elimination of Latin abbreviations (BID, QID, PRN, etc.), which are often misunderstood and susceptible to variation in translation.

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Attachment 4

Board of Pharmacy

California Code of Regulations

Add § 1707.6. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.6. Notice to Consumers.

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

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

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

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

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

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

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

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

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

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

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

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

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

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

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

Attachment 5

Alan W. Weinberger, M.D.
8631 West Third Street, Suite 540-E
Los Angeles, California 90048
Diplomate American Board of Medicine

Facsimile (310) 657-4769
Telephone (310) 854-7224
Fellow American College of Rheumatology

July 22, 2011

Assembly Member Mike Feuer
9200 Sunset Blvd. Suite 1212
West Hollywood, CA 90069

Re: Pharmacy Forms

Dear Representative Feuer:

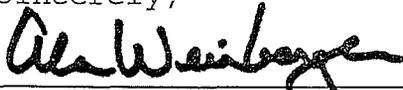
I am a physician at Cedars-Sinai. Every day I sign faxed prescription forms from a variety of pharmacies, often as many as 30.

The problem is that every pharmacy uses a different format, and the potential for making a mistake is much bigger than it needs to be because of this variation.

I think that the State should mandate that pharmacies use a standard prescription refill facsimile form, one approved by the State, so that all pharmacies use the same standard form and doctors don't have to study each form to be sure they fill it out correctly.

I would love if you made a bill or something to set this in motion, and I would be more than happy to discuss it or help.

Sincerely,



Alan W. Weinberger, M.D.

AWW:mc



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

September 6, 2011

The Honorable Mike Feuer
Member, California State Assembly
9200 Sunset Boulevard, Suite 1212
West Hollywood, CA 90069

RE: July 22, 2011 Letter from Alan Weinberger, M.D.

Dear Assembly Member Feuer:

I am responding to a letter forwarded to the board from your office in late July from Dr. Weinberger (copy attached). Dr. Weinberger suggests the introduction of legislation to require pharmacies to use a state-mandated form when requesting refill authorization from a prescriber. I apologize for the delay in responding to this inquiry.

As background to this inquiry: pharmacies fairly routinely seek refill authorizations on behalf of patients for their prescription medication. This authorization is often done by fax, although telephone authorization and less often electronic requests (e-prescribing) from the pharmacy to the prescriber's office are used to secure this refill approval. There is no standardized refill request form to do this; instead only certain information is required to authorize a refill between a pharmacy and a prescriber.

This is also typical for how drugs are initially ordered for patients by prescribers: there is no standardized prescription order form that prescribers must use, only required elements for what must appear on the prescription blank (see California Business and Professions Code section 4076). For the most highly regulated prescribed medication, controlled substances, again there is not a standardized prescription form, although California law has: (1) a separate set of required elements for the security prescription form, (2) requirements that only state-approved printers can print security prescription forms to prescribe from, and (3) mandates that specialized security features appear on the prescription documents (see California Health and Safety Code sections 11161.5, 11162.1).

Dr. Weinberger suggests that it would benefit prescribers if pharmacies used a standardized form for refill authorizations. We appreciate the opportunity to respond. The board has no policy in this area. I have contacted both the California Pharmacists Association and Cedars Sinai with whom Dr. Weinberger is associated to respond. No one I have spoken with is especially eager to establish a law that requires a specialized form, although no one specifically opposed it.

So that the board may provide its input to your inquiry, I will add this suggestion to the agenda of the board's Communication and Public Education Committee meeting on

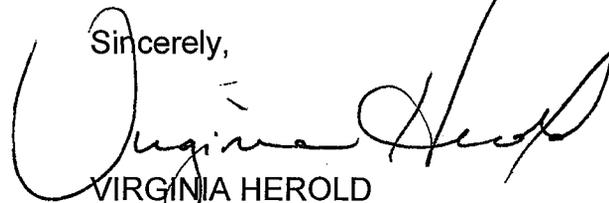
The Honorable Mike Feuer
September 6, 2011
Page Two

September 26. This will provide the committee, and perhaps later the board, with the opportunity to provide comments.

We will provide you with a more specific response after the committee discusses the proposal.

Should you have questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold". The signature is fluid and cursive, with a large initial "V" and a long, sweeping tail.

VIRGINIA HEROLD
Executive Officer

Enclosure

Alan W. Weinberger, M.D.
8631 West Third Street, No. 540-E
Los Angeles, California 90048

RECEIVED BY CLERK
BOARD OF PHARMACY
2011 SEP 15 PM 1:11

Telephone (310) 854-7224
Fax (310) 652-2499

Diplomate of American Board of Internal Medicine

Fellow of the American College of Rheumatology

September 9, 2011

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, California 95834

Re: Pharmacy Faxed Refill

Dear Ms. Herold:

I am taking the liberty of communicating directly with you regarding a suggestion I made to the Honorable Mike Feuer regarding the faxed refill forms pharmacies routinely fax to physician offices to get refills.

By way of background, I have been involved in various quality control measures at Cedars-Sinai for many years, and one of the things we try hardest to prevent is medication errors.

I easily do as many as 20 of these faxed refill forms a day. And it seems some days that there are as many as 20 different formats, each pharmacy using its own proprietary form.

A simple truism in processes is that unnecessary variation promotes errors. As a busy physician, it's difficult and time consuming to study each new form to see who the patient is, what medicine they want, how many refills are requested, what the directions are, whether generic is ok, etc. It's especially confusing when more than one medicine is listed on the form.

My idea of standardizing this form was not to make life easier for physicians, although it would. Rather, it is simply to eliminate the additional opportunity for medication errors that having a large variety of refill forms creates. I have no special interest in the format, only that it should be the same format every time.

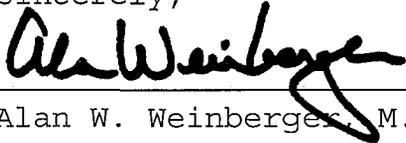
Re: Pharmacy Faxed Refill
September 9, 2011
Page 2

The Pharmacy Board could certainly create such a form, with appropriate input from pharmacists, and implement it at a cost that would be essentially zero.

The need for phone calls for clarification, the number of inadvertant medication errors, and the time spent filling out those forms would be significantly reduced.

Thanks for considering this suggestion, and for presenting it to the Board's Communication and Public Education Committee meeting this September 26th.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Weinberger". The signature is written in a cursive style and is positioned above a horizontal line.

Alan W. Weinberger, M.D.

AWW:mc

Attachment 6



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING
MINUTES**

DATE: September 26, 2011

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Ryan Brooks, Public Member, Chair
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

COMMITTEE MEMBERS

NOT PRESENT: Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Office
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Ryan Brooks called the meeting to order at 1:31 p.m.

A roll call was conducted. Committee Members Brooks, Hackworth and Veale were present.

President Stanley Weisser was in attendance in the audience.

1. Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels

Chair Report

Chair Brooks provided that the board's requirements for patient-centered prescription drug container labels took effect on January 1, 2011, as required by statute. He stated that since June 2010, when the board finalized its work on the regulation, the board has been publicizing its requirements to the board's licensees. A copy of the regulation is attached, following this meeting summary.

Chair Brooks provided that in addition to the actual text of the requirements, the regulation also contains several directives to the board. He reviewed the following directives from Section 1707.5:

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2011, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Chair Brooks reviewed the following discussion items with respect to each directive.

- Re: subdivision (b): Translations are available for addition to the Web site.
- Re: subdivision (c): The board already has examples of labels available on its Web site and has published these in its newsletter.
- Re: subdivision (e): The committee may want to begin discussions of the existing requirements to determine whether modifications to the requirements are needed.

Discussion

Executive Officer Virginia Herold reported that the translations will be posted on the board's Web site in advance of the October 2011 deadline. She indicated that the translations were developed and vetted by the California Endowment.

Committee Member Deborah Veale suggested that the board discuss the existing requirements in about six months after all requirements are in place.

Chair Brooks spoke in support of this suggestion and indicated that this will allow for comments and feedback to be submitted by the public.

Public Comment

Steve Gray, representing Kaiser Permanente, expressed concern regarding delaying the discussion of the requirements. He stated that several unintended consequences have been identified as a result of the labeling requirements including noncompliance by out-of-state pharmacies. Dr. Gray discussed other unintended consequences and indicated that generic names are being truncated and the size of the description of the medication and other important information is being significantly reduced in order to comply with the requirement that certain information be clustered into one area of the label. Dr. Gray urged the board to address these issues.

Committee Member Ramón Castellblanch arrived at 1:41 p.m.

Ms. Herold stated that the board has not been notified of these issues. She urged Dr. Gray and any other individuals aware of such problems to file a complaint with the board.

Dr. Gray provided comment regarding the increase in generic products on the market. He stated that pharmacies use the label as a mechanism to indicate generic substitution. Dr. Gray indicated that the labeling requirements are limiting the ability of pharmacies to put this information on the label.

The committee discussed these issues and the required report to the Legislature on the implementation of the patient-centered labels by January 1, 2013. It was the consensus of the committee to review all issues comprehensively in preparation for the report.

Chair Brooks indicated that additional comments and feedback can be submitted to Executive Officer Herold.

2. Review of USP's Guidance for Patient Prescription Container Labels

Chair Report

Chair Brooks provided that earlier this year, the United States Pharmacopeia (USP) completed its work on standards for prescription container labeling.

Chair Brooks reviewed the following comparison chart of the requirements which highlights the board's regulation with the USP standards. He stated that USP considered the board's initial draft requirements at an early stage in the development of their standards.

	USP	Board Regulation
Organize label to emphasize patient info	X	X
• Patient's Name	X	X
• Drug Name & Strength	X	X
• Instructions in Clear & Simple Language	X	X
• Standardize order	O	X
• Dedicate 50% of label	O	X
• Require Purpose if on Rx	O	X
• Require Mfg if generic drug	O	X
Place all other required elements elsewhere so not as to interfere with the above	X	X
Use standardized pat-centered translations of directions for use "when appropriate"	X	X
Separate dose from timing of dose	X	X (in stnd. directions)
Use numeric, not alphabetic characters	X	X
Purpose for use if desired by patient and use simple terms	X	O
Purpose for use if written on Rx	O	X
Limit Auxiliary information/labels	X	O
Standardize terms & placement	X	O
Validate use of icons	X	O
Labels should be in language of Patient	X	Bd provided translations of directions In 5 additional lang.
or should have interpreter services available	X	X
Labels should be easy to read	X	X
Use high contrast ink	X	X
Simple uncondensed fonts	X	
Large Font size	X	
e.g., (not specified one type)		
12-point Times New Roman	X	O
11-point Arial	X	X
Use san serif (e.g, Arial) 10 point	O	X
Or 12 point if requested	O	X
No font smaller than 10 point	X	X
Use sentence case (not all caps)	X	O

Use Adequate white space	X	X
Use white space to separate directions from pharmacy info	X	X
Use horizontal text only	X	O
Minimize need to turn container to read	X	O
Do not truncate information	X	X
Use highlight, gold and typo cues to emphasize pt. centric or adherence (e.g., ordering)	X	X
Limit number of highlight colors	X	O

Discussion

Chair Brooks provided comment in support of the guidelines but discussed that some are not needed and may be too prescriptive.

Dr. Castellblanch sought clarification regarding the standardized directions for use provided in Section 1707.5. He asked why pharmacies are not being required to use these on prescription labels.

Ms. Herold clarified that the regulations specifies that these directions are to be used “when applicable.”

DCA Staff Counsel Kristy Shellans indicated that a statutory change would be needed in order to require use of the standardized directions for use on the label. She provided background on this issue and indicated that the board had discussed whether it wanted to control the judgment and discretion of pharmacists to use the directions and the consensus was to provide flexibility in this area. Ms. Shellans discussed that if questioned by the board, pharmacists will have to provide justification for why they are not using the directions provided in the regulation.

Ms. Herold stated that the board’s inspection team can open investigations based on questionable labels. She stated that findings from these investigations can be reported back to the board to be addressed for the report to the Legislature due in 2013.

Chair Brooks reminded the committee that these issues should be addressed in a comprehensive manner.

Ms. Veale asked whether a pharmacist is permitted to change directions for use as indicated by the physician to the standardized directions provided in the regulation.

Ms. Shellans provided that a pharmacist should use his or her professional judgment and consult with the physician.

Ms. Herold suggested that this issue be discussed with the Medical Board and also be addressed in *The Script*.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed that the regulation conflicts with Section 1716 which states that a “pharmacist shall not deviate from the requirements of a prescription.” He stated that this conflict creates confusion and the requirements of Section 1716 should be changed to allow a pharmacist to utilize his or her professional judgment.

Dr. Gray also provided comment on e-prescribing and indicated that the information inputted by the prescriber is what will print out on the label. He suggested that in addition to modifying Section 1716, the board should also pursue regulatory change to require that the purpose of a medication be included on the label.

Michael Negrete, representing the Pharmacy Foundation of California, suggested that in addition to discussing this issue with the Medical Board, the board should also hold discussions with organized medicine. He provided comment on Cal eConnect and the development of standards for E-prescribing systems.

A member of the public provided comment on Script Your Future, a national campaign to raise awareness about medication adherence. She encouraged the board to involve consumers, pharmacists and physicians to promote language that is understandable for patients.

Chair Brooks discussed the importance of consumers to be actively involved in identifying and solving problems in this area.

The committee discussed differences between the board’s requirements and the standards established by USP (refer to items indicated with an “O” in the chart provided above). The committee encouraged additional feedback in order to address improvements for the 2013 report to the Legislature.

3. Review and Discussion Surrounding the Developed Translations of Directions for Use for Patient Medication as Specified in 16 California Code of Regulations Section 1707.5

Chair Report

Chair Brooks provided that the California Endowment, to support ensuring quality labels for those who do not read English, funded a project with national PhD patient literacy researchers Stacy Bailey and Michael Wolf to develop and vet translations of the standardized directions for use that are contained in the board’s patient-centered label requirements. He stated that the translations were vetted in CA (and IL) communities with a survey of native speakers.

Chair Brooks provided that the regulation requires that the board place these translations on its Web site by October 2011. He advised that they will be posted by this deadline.

Chair Brooks provided that the translations have been made in Spanish, Korean, Russian, Vietnamese and Chinese.

Discussion

Dr. Castellblanch discussed that at least one major chain currently has a system to provide translations. He stated that the system allows the pharmacist to see both the label in English and in the translated language.

Chair Brooks discussed that there are errors that can be made when utilizing a translation service. He encouraged licensees to utilize the vetted translations that will be available on the board's Web site.

Public Comment

Missy Johnson, representing the California Retailers Association (CRA), confirmed that there is a major chain that is currently providing translations. She discussed that this chain has built a verification element into their system and has devoted resources to ensure the validity of the system.

Sarah Mercer, California Pan-Ethnic Health Network (CPEHN), encouraged the board to work with CPEHN to solicit feedback from community groups on the translations. She asked how pharmacies will be notified once the translations are posted on the board's Web site.

Ms. Herold suggested that all labeling information dealing with patient-centered labels, including the translations, be posted on the board's Web site in one central location.

Dr. Castellblanch provided comment in support of Ms. Herold's suggestion.

A member of the public provided comment regarding the importance of providing translations to ensure that patients understand how to take their medication.

4. Discussion Regarding the Future Design of New Notice to Consumers Posters (Pending 16 California Code of Regulations Section 1707.6)

Chair Report

Ms. Herold provided that at the July 29, 2011 Board Meeting, the board completed its work on a new regulation to house all notice to consumer elements in one place. She discussed that while waiting for the regulation to take effect, the committee can begin to discuss the design for the new poster(s), concepts for the video display, and concepts for interpreter services (likely a separate poster).

Ms. Herold provided that Kim Brown from the department's press office has been assigned to work with the board to develop concepts and prototypes for the new posters.

Discussion

The committee discussed the required notice language in Section 1707.6 and how best to design the poster so that important information is emphasized. Consideration was given to a concern regarding the volume of language required and ensuring that important information is communicated effectively to consumers.

Ms. Veale recommended that the committee review the new notice language and identify important information that should be emphasized. She provided that she believes the information regarding patient education and what a patient should know before taking their medication is the most important information and should be emphasized. Ms. Veale also suggested that the following language be used as a header for this information:

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

Chair Brooks suggested that important information be displayed with the use of bullet points, bolding, or underlining.

Dr. Castellblanch discussed that the language regarding the availability of interpreter services is important and should be emphasized.

Ms. Veale provided that information regarding interpreter services can be provided on a separate notice as the regulation requires that this information be provided on a handout or flyer or on a video screen that is positioned so that a consumer can easily point to their language. She discussed that the Notice to Consumers should focus on patient safety and medication adherence.

Ms. Veale and Committee Member Rosalyn Hackworth expressed that the remaining notice language is important but is of lesser importance than the information regarding what a patient should know about taking prescription medication.

Dr. Castellblanch provided that he believes the information regarding the patient's right to labels in 12-point font is the second most important piece of information.

Chair Brooks suggested that the committee direct board staff to develop a poster based on the committee's discussion that promotes consumer protection to be reviewed by the committee at a future meeting.

Ms. Veale asked whether the committee has the same priority for the video screen display of the notice.

It was the consensus of the committee that the paper form and video screen display notices will have the same priority for important information to be emphasized.

Public Comment

Michael Negrete, representing the Pharmacy Foundation of California, reviewed information submitted to the board by Beccah Rothschild, MPA, Director of Health Literacy Projects at the University of California, Berkeley, regarding health literacy, readability, and consumer testing to assess usability of consumer notices.

Ms. Herold indicated that Ms. Rothschild has indicated an interest to work with the board to conduct consumer testing for the new notices.

Sarah Mercer, California Pan-Ethnic Health Network (CPEHN), provided comment in support of providing information regarding interpreter services on a separate notice. She asked whether the Notice to Consumers will be translated into different languages.

Ms. Herold provided that the notice will be available in other languages and will be provided in a smaller size like the current translated notices.

Ms. Mercer indicated that CPEHN is interested in working with the board to perform a focus group testing to solicit feedback on the new notices. She asked how noncompliance or failure to utilize the interpreter service notice will be addressed by the board.

Dr. Castellblanch provided that consumers should report noncompliance to the board.

Ms. Herold discussed that the board will educate all licensees regarding this requirement during inspections, in *The Script*, and via subscriber alerts.

Chair Brooks asked for an anticipated timeline for completion of the sample posters.

Ms. Brown indicated that the sample posters should be completed within the next 2-3 months.

5. Proposal to Review and Recommend Approval of an Update of the Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746)

Chair Report

Chair Brooks provided an overview of the revised protocol for pharmacists furnishing emergency contraception. A copy of the protocol is attached, following this meeting summary.

Discussion

Ms. Herold discussed that the protocol has been revised to reflect changes submitted from CPhA's representatives (a women's health specialist, Pharmacist Katherine Besinque from USC, and two representatives of the American College of Obstetricians and Gynecologists (Shannon Smith Crowley and Phillip Diamond, MD) regarding changes in the availability of emergency contraception medication, the manufacturers who produce the medication, and to correct a typo (mcg instead of mg).

Ms. Herold provided that after the board reviewed the proposed changes at the July 2011 Board Meeting, the revisions were subsequently reviewed and approved by the Medical Board. She stated that the Board of Pharmacy will now need to proceed with a rulemaking to update the requirements as a regulation.

Ms. Veale asked whether the revisions address a concern that was raised at the July 2011 Board Meeting regarding inconsistencies with the use of the terms "patient," "man," and "woman."

Ms. Herold provided that the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception, will be modified to address this issue.

Dr. Castellblanch left the meeting room at 3:14.

Mr. Brooks offered a proposal to recommend that the board approve the updated protocol. He advised that if the board moves forward with the regulation changes, the regulation will be released for the formal 45-day comment period.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to repeal and amend 16 California Code of Regulations Section 1746 to be consistent with the proposed update of Emergency Contraception Protocol Regulation.

M/S: Brooks/Hackworth

Approve: 3 Oppose: 0 Abstain: 0

6. Discussion Surrounding a Proposal to Develop a Standardized Form for Pharmacies to Use to Request Refills

Chair Report

Chair Brooks provided that the board recently received a proposal from Assembly Member Feuer that had been submitted to him by a constituent as a possible legislative proposal. He stated that the problem is that physicians receive numerous refill requests via fax daily from pharmacies that are not standardized, and there is potential for a physician to make an error when reviewing and approving such diverse refill requests daily that could impact patient safety. Chair Brooks indicated that the proposal is to require use of a specific form.

Discussion

Ms. Veale discussed that she believes that requiring a specific form may create problems and may not create a lot of benefit overall. She discussed that each software program has its own format.

Dr. Castellblanch returned to the meeting room at 3:17 p.m.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that this proposal comes from the prescriber's point of view. He stated that developing a standardized format would be a lengthy process and would require a lot of changes for pharmacies. Dr. Gray discussed that this proposal would detract from efforts by the National Council for Prescription Drug Program (NCPDP) and Cal eConnect regarding electronic health information exchange.

Ms. Herold provided that she brought the proposal and sought the reaction or need from Cedars Sinai (where the MD constituent practices), from the California Pharmacists Association and the California Retailers Association, and various board inspectors. She indicated that no one was opposed, but no one was especially motivated either. Ms. Herold advised that the prescription document is currently not standardized.

7. Update on an Assessment of the Board's Public Education Materials

Report

Ms. Veale reported that she and Committee Member Castellblanch have been working to improve the board's Web site design and placement of its public education materials. She reviewed the following categories that have been identified to improve the current layout of the Web site:

1. Public Information
2. Professional Information
3. Applicant Information
4. Board Information
5. Regulation Information

Dr. Castellblanch provided that these changes will be implemented when the board's Web site migrates to the new state government web design.

There was no committee discussion or public comment.

8. Update on The Script

Chair Report

Chair Brooks provided that the next issue of *The Script* has been written and has been with legal for review for a while. He indicated that work on the January issue has begun and will focus on new laws.

There was no committee discussion or public comment.

9. Public Outreach Activities Conducted by the Board

Chair Report

Chair Brooks referenced the following public and licensee outreach activities performed during the first quarter of Fiscal Year 2011/12:

- July 8: Executive Officer Herold and President Weisser attend the CSHP's Board of Directors Meeting in Sacramento to provide an update on board activities.
- August 18: Executive Officer Herold provides a Webinar on California's e-pedigree requirements to a conference hosted by the National Coalition of Pharmaceutical Distributors (NCPD).
- September 14: Executive Officer Herold attend a California Pharmacy Council Meeting to discuss pharmacist manpower today and in the future.

NOTE: Since late spring, state government has been subject to a travel freeze that restricts all but the most essential travel. Moreover, the Department of Consumer Affairs has to preapprove all travel where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach.

There was no committee discussion or public comment.

10. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 3:29 p.m.

Attachment 7

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="367 428 1524 716"> <p>1. Assess the effectiveness of the board’s educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired.</p> <p><i>2006-2007: Staff conducts assessment of the board’s consumer outreach written materials. Material is identified for revision and update, future development, or evaluation for continued need.</i></p> <p><i>2007-2008: Board publishes new board brochure and complaint brochure, and redesigns several board brochures into new single-page, format.</i></p> <li data-bbox="367 716 1524 1493"> <p>2. Restructure the board’s website to make it more user friendly.</p> <p><i>2006-2007: Website modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.</i></p> <p><i>Links added to obtain various information regarding medication safety, and drug interactions, and information from FDA regarding Medications and Medical Devices.</i></p> <p><i>Work Initiated on new website design to meet new state design standards.</i></p> <p><i>2007-2008: New website design completed in November 2007.</i></p> <p><i>Web page created consolidating all information on e-pedigree into one place.</i></p> <p><i>1st Qtr 09/10: Regulation section of the board’s Web site updated to improve presentation and readability.</i></p> <p><i>Status of board licensees on probation changed from “active” to “disciplined”.</i></p> <p><i>3rd Qtr 09/10: Updated website template to conform with new directive from Governor.</i></p> <p><i>3rd Qtr 10/11: Committee begins project to redesign how board publications are listed on website. Changes to be made when state agencies shift to new website design approved by the Governor’s office.</i></p> <p><i>Meeting held with Webmaster, two Board Members, and Executive Officer regarding making the forms/publications page of website more user friendly.</i></p> <li data-bbox="367 1493 1524 1719"> <p>3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics.</p> <p><i>2006-2007: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.</i></p> <p><i>No additional meetings scheduled after January 2007.</i></p>

4. Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics.

2006-2007: *Nine previously developed fact sheets are sent to a translation service to develop Spanish, Chinese, and Vietnamese versions of these materials. Four new fact sheets developed and undergoing review by the board.*

2007-2008: *The committee determines that the board will expand the project beyond the Center for Consumer Self Care to include students from other Schools of Pharmacy.*

Meanwhile discussion with UCSF lead to request for funding to continue project.

Meanwhile board seeks to establish intern projects with other schools of pharmacy.

1st Qtr 08/09: *Letter to Deans of California's pharmacy schools mailed.*

1st Qtr 09/10: *Staff prepare to initiate program using intern coordinators at school of pharmacy campuses in California.*

4th Qtr 09/10: *UCSD submits fact sheets for board consideration.*

Western, USC and California North State all anticipate programs beginning in fall 2010.

2nd Qtr 10/11: *Fact sheets received from UOP and UCSD, additional editing needed.*

5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies.

2006-2007: *Governor signs AB 2583.*

Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster.

Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.

2007-2008: *New "Notice to Consumers" approved by board and later by the Office of Administrative Law.*

New design and layout for two new Notice to Consumer posters are selected.

1st Qtr 08/09: *New posters are mailed to California pharmacies.*

2nd Qtr 08/09: *Posters are translated into several languages and made available on the board's website.*

6. Evaluate the practice of pill splitting as a consumer protection issue.

2006-2007: *Board holds discussion of pill splitting issues during January and April 2007 Board Meetings.*

2007-2008: *The Script newsletter contains an article for pharmacists on pill splitting and a Fact Sheet for consumers is completed.*

7. Evaluate the SCR 49 Medication Errors Report for implementation.

2006-2007: *Communication and Public Education Committee reviews SCR 49 report and board has presentation of the SCR 49 report.*

2007-2008: *SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.*

Feb. 2009: *SB 470 introduced to add "purpose" to the prescription container's label.*

Sept. 2009: *SB 470 is enrolled and sent to the Governor.*

- 8. Develop patient-centered standardized prescription container labels by 2011 pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007).**
- Oct. 2007: Board president appoints members to subcommittee.*
- Jan. 2008: Board readies plans for six public hearings statewide during 2008*
- April 2008: First meeting in Fremont on April 12. Approximately 40 people attend.*
- Apr. - Jul. 08: Board attends health fairs and interviews patients for information on how to improve prescription labels. Survey available on board's website. 123 surveys completed.*
- July 2008: Board Inspector Bayley and Associate Analysts Durst and Abbe staff a resource table at the Lotus Festival in Los Angeles and interview attendees about their prescription labels as part of the board's initiative to implement a patient-centered prescription label.*
- Aug. 2008: Associate Analysts Durst and Abbe and Assistant Executive Officer Sodergren staff the department's booth at the State Fair and distribute brochures, respond to public questions and elicit suggestions to improve the labeling on prescription labels.*
- Oct. 2008: Board Member Powers provides information and conducted labeling surveys of those attending CARA's annual meeting. Publications Coordinator Abbe attends Celebrando Nuestra Salud to conduct labeling surveys of those in attendance.*
- Nov. 2008: Board sponsors public forum on health literacy and designing patient-centered labels. National experts provide information.*
- Dec. 2008: Board Executive Officer participates on National Association of Boards of Pharmacy task force to develop national standards for patient-centered labels. Board and CPhA develop joint survey for administration via listeners of radio stations on patient medication labels.*
- Jan. 2009: Over 600 consumer surveys submitted; SB 472 Subcommittee meets to begin developing regulations. Radio surveys add 1,800 additional survey responses. Subcommittee holds afternoon meeting in San Diego.*
- March 2009: Evening meeting held on SB 472 task force draws a few more public attendees. Ongoing surveys from consumers continues.*
- July 2009: Draft regulation language discussed by board.*
- Aug. 2009: Draft regulation language discussed by board.*
- 2nd Qtr 09/10: Board holds informational hearing, finalizes language and releases regulation for 45-day comment period.*
- Dec. 2009: Board submits required report to Legislature on implementation to date of SB 472's provisions.*
- Jan. 2010: Board holds regulation hearing and make text changes to be released for 15-day comment period.*
- Feb. 2010: Board meets and deliberates on proposed modified text. Text released for 15-day comment period after meeting from February 22 - March 10, 2010.*
- April 2010: Board meets and discusses the more than 1,200 comments received.*
- June 2010: Board adopts regulation as noticed on February 22, 2010.*
- Nov. 2010: Office of Administrative Law approves regulation.*
- Jan. 2011: Regulation takes effect.*

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| | <p>9. Address and promote licensee and public education on minimizing prescription errors.</p> <p><i>July 2008:</i> Forum on medication errors held as part of board meeting. Michael Cohen, Institute of Safe Medical Practices, John Keats, California Patient Action Coalition, and Lorian deMartini, California Department of Public Health, talk about activities of their organizations to prevent errors. Board Inspector Orlandella represented the board on a panel to a group of seniors in Roseville, California.</p> <p><i>Jan. 2009:</i> Board publishes medication errors segment in its newsletter, <u>The Script</u>, describing several medication errors investigated by the board.</p> <p><i>June 2009:</i> Enforcement Committee hears presentation on board investigations of medication errors during 2008/2009.</p> <p><i>June 2010:</i> Executive Officer attends meeting, convened by the California Pharmacy Foundation, discussing ways to reduce medication errors in pharmacies.</p> <p><i>April 2011:</i> The Board of Pharmacy and Drug Enforcement Administration host a day-long seminar on Diversion of Controlled Substances "What every pharmacist should know to prevent diversion" in Los Angeles. Executive Officer Herold provides an update on board activities to senior executive members of the Healthcare Distribution Management Association in a Sacramento meeting.</p> <p>10. Educate consumers about steps they can take to prevent receiving a medication error.</p> <p><i>2nd Qtr 09/10:</i> Develops and distributes 3-minute video tape on how patients can prevent receiving a medication error. Video placed on the board's Website.</p> |
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Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1479 695"> <p>1. Publish <i>The Script</i> two times annually.</p> <p><i>Jul. 2008:</i> <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>Apr. 2009:</i> "February" issue of <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>Jul. 2009:</i> "July" issue of <i>The Script</i> written and undergoing review.</p> <p><i>Jan. 2010:</i> "July" issue of <i>The Script</i>, now finalized.</p> <p><i>March 2010:</i> Titled as "February 2010" board newsletter published and released. Future issues will be released online.</p> <p><i>Sept. 2010:</i> "September" issue released online only; this is the first issue not printed and mailed.</p> <p><i>Feb. 2011:</i> Articles developed and submitted to DCA for review.</p> <p><i>Sept. 2010:</i> "July" issue of <i>The Script</i> released online.</p> <li data-bbox="370 695 1479 1503"> <p>2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.</p> <p><i>2006-2007:</i> The board's members, supervising inspector and executive officer provide 22 CE and licensee educational seminars during the year.</p> <p><i>2007-2008:</i> The board's members, supervising inspector and executive officer provide at least 10 CE and licensee educational seminars during the year.</p> <p><i>1st Qtr 08/09:</i> Board Member Goldenberg provides information about pharmacy law to medical staff at the Jewish Home Hospital in Los Angeles. President Schell speaks on requirements regarding conscience provisions in California law at Loma Linda University.</p> <p><i>2nd Qtr 08/09:</i> Executive Officer Herold speaks to the CSHP's Board of Directors about the board's heparin inspections. Executive Officer Herold speaks to CSHP's Seminar on Board legislative and regulation activities. Assistant Executive Officer Sodergren and Supervising Inspector Ratcliff staff an informational booth at CSHP's Seminar. Executive Officer Herold speaks to CSHP's Seminar on the heparin inspections conducted with the California Department of Public Health in California Hospitals. Executive Officer Herold speaks to CSHP's Seminar on California's e-pedigree requirements.</p>

3rd Qtr 08/09: Executive Officer Herold and Board President Schell provide three presentations at the California Pharmacists Association's Outlook on the Board of Pharmacy, major issues before the board and medication errors. Supervising Inspector Ratcliff provides a presentation about pharmacy law to 70 students at Loma Linda's School of Pharmacy. President Schell provides a presentation on Board of Pharmacy issues to the San Diego CPhA meeting. Supervising Inspector Ratcliff presents information on "How to Survive a Board Inspection" to 80 pharmacists at a Vietnamese Pharmacist Association. Board President Schell provides a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy. Executive Officer Herold and President Schell present a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting. Supervising Inspector Ratcliff and Assistant Executive Officer Sodergren staff a booth at the CPhA's annual meeting answering pharmacy law and licensing questions. Executive Officer Herold and President Schell discuss the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting. Executive Officer Herold provides presentation to UCSF and UCSD students in a first year pharmacy school law class. President Schell provides a presentation to students at the USC School of Pharmacy.

4th Qtr 08/09: Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Town hall meeting at Loma Linda for 80 pharmacists. Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a CSHP Town hall meeting at UOP for 60 pharmacists.

1st Qtr 09/10: Executive Officer Herold presented at CSHP Board of Directors Meeting. Supervising Inspector Nurse presented at CPhA's Long Term Care Board Meeting. Executive Officer Herold presented at CSHP Sacramento Valley Chapter Meeting.

3rd Qtr 09/10: Board inspectors provided five continuing education sessions on pharmacy law or inspections. Additionally the board staffed an information booth at CPhA's annual meeting. Executive Officer Herold provided an update on 2010 pharmacy law changes, and Executive Officer Herold and President Schell provided an update on Board of Pharmacy activities underway and during 2009.

4thQtr 09/10: Executive Officer Herold and Supervising Inspector Ratcliff presented information about the Board of Pharmacy and answered questions about pharmacy law to 60 Costco Northern California pharmacy managers.

1st Qtr 10/11: Inspector Wong provided information about Board of Pharmacy enforcement activities to students at California Northstate School of Pharmacy.

2nd Qtr 10/11: Executive Officer Herold presented information about the 2010 legislative year at Seminar 2010, the annual meeting of the California Society of Health System Pharmacists (CSHP) in San Francisco.
 Executive Officer Herold and Inspector Hokana staffed the board's public information booth at CSHP's Seminar 2010.
 Executive Officer Herold presented information on e-prescribing and e-prescribing of controlled drugs to attendees of a CalERx Conference in Oakland.
 Executive Officer Herold provided a presentation on California's patient-centered prescription container label requirements at a quarterly meeting of the California Hospital Association's Medication Safety Committee.

3rd Qtr 10/11: Supervising Inspector Nurse provides information to students at Loma Linda's School of Pharmacy.
 Supervising Nurse provides training regarding the board's investigations and regulatory jurisdiction at Orange County Med Board and Drug Officer training.
 Board staffs a booth at CPhA's annual meeting, Outlook.
 Board President Weisser and Executive Officer Herold provided an update about Board of Pharmacy activities and a Town Hall for questions and answers at Outlook. The two presentations comprised three hours of contact time.
 Executive Officer Herold provides a presentation on California's e-pedigree requirements via video conference to FDA's Track and Trace Workshop.
 Executive Officer Herold provides a presentation at a statewide annual meeting of California district and city attorney's offices that handle consumer protection cases about the types of cases investigated by the board including California's serious drug diversion and prescription abuse issues.
 Executive Officer Herold participates as a trainer in the day-long DCA Board Member Orientation and Training.
 Supervising Inspector Ratcliff provides training about the board, clinics and Title X in Orange County.
 Executive Officer Herold provides a presentation about California's identification of the heparin recall failures in 2008 and participates in a two-day workshop hosted by the PEW Trust in Washington DC.
 Supervising Inspector Ratcliff provides a webinar to Providence Hospital pharmacists.
 Supervising Inspector Dang gave a presentation on "Surviving as the Pharmacist-in-Charge" at Western University.
 Inspector Bailey provides information on "How to Survive a Board Inspection" to the Korean Pharmacists Association.

4th Qtr 10/11: Executive Officer Herold provides a presentation to UCSF students about Board of Pharmacy activities.
 Executive Officer Herold meets with a delegation from Japan regarding California's e-pedigree requirements.
 The Board of Pharmacy and Drug Enforcement Administration host a day-long seminar on Diversion of Controlled Substances "What every pharmacist should know to prevent diversion" in Los Angeles.
 Assistant Executive Officer Sodergren provides an update to the CSHP Board of Directors about Board of Pharmacy activities.
 Executive Officer Herold, Supervising Inspector Nurse and Inspector Sakamura provide information to the consumer law attorneys of Southern California District and City Attorneys about the board's investigations and regulatory jurisdiction.
 Supervising Inspector Dang provides a CE presentation on new pharmacy laws to over 70 pharmacists at an association meeting in Los Angeles.
 Executive Officer Herold provides a presentation on California's patient-centered labeling requirements to over 100 individuals at the annual Ralphs manager meeting in Orange County.
 Executive Officer Herold provides a presentation to over 100 attendees on the board's citation and fine and enforcement programs at the CPhA Celebrate Pharmacy Conference in Oakland. Board Inspector Hunt provides a presentation on responsibilities on how to survive a board inspection and the roles of a PIC at the same conference. New Supervising Inspector Young also provides a presentation on addressing prescription drug abuse.
 Executive Officer Herold participates in the mandatory DCA day-long training for new board members in Los Angeles on the roles of the executive officer, roles of a board member, and the components of the state enforcement, legislative and budget programs in operation at the boards.
 Executive Officer Herold provides a Webinar-like presentation at an Axway conference in New Jersey on California's e-pedigree requirements.
 Executive Officer Herold participates in a conference call of western states' pharmacy board directors hosted by the NABP. This call was initiated at Ms. Herold's request to allow discussion of regulatory issues involving neighboring states.
 Executive Officer Herold tapes a "postscript blog" with Community Catalyst in Washington DC on the security of the pharmaceutical supply chain and the issues identified in California surrounding the 2008 heparin recalls. This is part of the PEW Trust's forthcoming report on the 2008 heparin contamination which affected the supply of heparin in the US.

1st Qtr 11/12: Executive Officer Herold and President Weisser attend the CSHP's Board of Directors meeting in Sacramento to provide an update on board activities.
 Executive Officer Herold provides a Webinar on California's e-pedigree requirements to a conference hosted by the National Coalition of Pharmaceutical Distributors.
 Executive Officer Herold attend a California Pharmacy Council Meeting to discuss pharmacist manpower today and in the future.

3. Maintain important and timely licensee information on website.

2006-2007: *Added 50-year pharmacist recognition pages as a special feature.
Updated license totals.
Added enforcement actions for effective dates between April 1 and June 30, 2005.
Changed definitions on license lookup to clarify license status.
Sent out more than 50 subscriber alert notifications to the board's e-mail notification list.
Unveiled new website of the board, and created new web links.
Revised and added new fax and contact information to speed communication with appropriate enforcement and licensing staff.
Added frequently asked questions on emerging contraception.
Updated the board's online lawbook.
Created a page dedicated to drug alerts and recalls.
Sent out three disaster response subscriber alerts regarding the Southern California wildfires to the board's e-mail notification list.
Created a page dedicated to e-pedigree information and laws.
Updated the 2008 lawbook.
Added two sets of comments submitted to the FDA in support of a unique identifier and on promising technologies for prescription drug identification, validation, track and trace or authentication to e-pedigree page.
Added survey of patients for prescription container labels.
Added page for subscription to board mailing list.*

1st Qtr 08/09: *Updated information regarding release of exam results.
Added enforcement actions for the effective dates between July 1 and September 30, 2008.
Added two recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 24 subscriber alert notifications to the board's email notification list.*

2nd Qtr 08/09: *Updated online renewal forms for individual licenses.
Created information on CURES page.
Created a survey page for public opinion on how to improve prescription labels (SB 472) in English and Spanish.
Added three recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 20 subscriber alert notifications to the board's email notification list.*

3rd Qtr 08/09: *Began process of making all PDFs on board's website accessible for the visually impaired.
Added four recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 27 subscriber alert notifications to the board's email notification list.
Posted latest edition of The Script.
Board mails letter pursuant to SJR 19 (Ridley-Thomas, Statutes of 2008) regarding prohibition of healing arts licensees not to engage in torture.*

- 4th Qtr 08/09:** Continued making all PDFs on board's website accessible for the visually impaired.
Updated lawbook to 2009 edition.
Added four recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 26 subscriber alert notifications to the board's email notification list.
- 1st Qtr 09/10:** Updated information regarding release of exam results.
Added enforcement actions and accusations for the effective dates between July 1 and September 30, 2009.
Made Pending Regulations page more user friendly.
Posted board and committee meeting agendas and materials.
Sent out 16 subscriber alert notifications to the board's email notification list.
- 2nd Qtr 09/10:** Added enforcement actions and accusations for the effective dates between Oct 1 through Dec 31, 2009.
Posted board and committee agendas and materials.
Sent out 28 subscriber alert notifications to the Board's email subscriber list.
Migrated subscriber list to new software program and created an additional subscriber list for emergency compounding.
- 3rd Qtr 09/10:** Added enforcement actions and accusations for the effective dates between January 1 through March 31, 2010.
Updated lawbook to 2009 edition.
Posted board and committee agendas and materials.
Sent out 17 subscriber alert notifications to the Board's email subscriber list.
Created online Change of Address form.
- 4th Qtr 09/10:** Added enforcement actions and accusations for the effective dates between April 1 through June 30, 2010.
Posted board and committee agendas and materials.
Sent out 16 subscriber alert notifications to the Board's email subscriber list.
- 1st Qtr 10/11:** Added enforcement actions and accusations for the effective dates between July 1 and September 30, 2010.
Updated information regarding release of exam results.
Continued making all PDFs on board's website accessible for the visually impaired.
Updated lawbook to 2010 edition.
Added 2 recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 24 subscriber alert notifications to the board's email notification list.
Posted latest edition of The Script.
- 2nd Qtr 10/11:** Added enforcement actions and accusations for the effective dates between October 1 and December 31, 2010.
Updated information regarding release of exam results.
Continued making all PDFs on board's website accessible for the visually impaired.
Added 30 recall notifications to FDA recall page.
Posted board and committee meeting agendas and materials.
Sent out 53 subscriber alert notifications to the board's email notification list.

	<p>3rd Qtr 10/11: <i>Added enforcement actions and accusations for the effective dates between January 1 and Marcy 31, 2011.</i> <i>Updated information regarding release of exam results.</i> <i>Continued making all PDFs on board's website accessible for the visually impaired.</i> <i>Posted board and committee meeting agendas and materials.</i> <i>Sent out 78 subscriber alert notifications, of which 67 were recall notices, to the board's email notification list.</i></p> <p>4th Qtr 10/11: <i>Added enforcement actions and accusations for the effective dates between April 1 and June 30, 2011.</i> <i>Updated information regarding release of exam results.</i> <i>Continued making all PDFs on board's website accessible for the visually impaired.</i> <i>Posted board and committee meeting agendas and materials.</i> <i>Sent out 51 subscriber alert notifications, of which 28 were recall notices, to the board's email notification list.</i></p> <p>1st Qtr 11/12: <i>Added enforcement actions and accusations for the effective dates between July 1 and September 30, 2011.</i> <i>Updated information regarding release of exam results.</i> <i>Posted board and committee meeting agendas and materials.</i> <i>Sent out 81 subscriber alert notifications, of which 62 were recall notices, to the board's email notification list.</i></p>
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Objective 4.3	Develop communication venues for other health care professionals (e.g., physicians, nurses).
Measure:	Number of communication venues developed to other health care professionals.
Tasks:	<i>2nd Qtr 10/11: Worked with Medical Board to produce guidance document for pharmacies and prescribers on the DEA's requirements for e-prescribing controlled drugs.</i>

Objective 4.4	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	<p>1. Participate in forums, conferences and educational fairs.</p> <p>1st Qtr 09/10: Board President Schell volunteers in "Standdown" an event for homeless veterans in San Diego and dispensed prescriptions and counseled patient's regarding their medications. Executive Officer Herold makes a presentation on patient-centered medication labels during a "Women in Government Conference" in San Diego. The group was comprised of female legislators representing the western United States. Board President Schell makes a presentation to the Indian Pharmacist Association about board activities. Supervising Inspector Nurse makes a presentation to the California Pharmacists Associations Long Term Care Board regarding DEA and CURES compliance issues. Executive Officer Herold makes a presentation on California e-pedigree requirements to Logipharma to a group of manufacturers. Executive Officer Herold makes a presentation on California e-pedigree requirements to Specialty Pharma to a group of contract drug manufacturers.</p> <p>2nd Qtr 09/10: Executive Officer Herold presents information on e-pedigree requirements to Healthcare Distributors Management Association's Track and Trace Conference. Executive Officer Herold provides CE presentation on medication errors as part of a day long conference at California Northstate College of Pharmacy. Executive Officer Herold provides a presentation on "take back" drugs to 20 rural California County Governments. Executive Officer Herold provides CE presentation on activities of the board the Sacramento Valley Society of Health Systems Pharmacists. Supervising Inspector Dang provides a CE presentation to a group of pharmacists in Orange County. Executive Officer Herold provides information about the board's patient-centered label requirements to CPhA's Long Term Care Committee. Executive Officer Herold and President Schell attended California Hospital Association's Hospital Drug Distribution Meeting in Sacramento.</p>

3rd Qtr 09/10: Executive Officer Herold did a Webinar on California's e-pedigree requirements hosted by IBS.
Executive Officer Herold and Assistant Executive Officer Sodergren did a presentation to 200 California NorthState School of Pharmacy students on the board's enforcement program.
Supervising Inspector Nurse provided information to 50 consumers about medication discount plans, Internet purchase of drugs, counterfeit drugs and obtaining medication safety.
President Schell provided information at UCSF about pharmacy at Career Day.
Supervising Inspector Nurse provided a presentation on pharmacy law to Loma Linda students.
President Schell provided a presentation on the future of pharmacy to 200 students at CAL.

4th Qtr 09/10: Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Board of Directors Meeting in Sacramento.
Executive Officer Herold and Supervising Inspector Ratcliff presented information about the Board of Pharmacy and answered questions about pharmacy law to 60 Costco Northern California pharmacy managers.
Board Member Kajioka provided presentations to students at the University of the Pacific about new pharmacy law and projects at the Board of Pharmacy.
Supervising Inspector Nurse made a presentation about drug thefts and robberies from pharmacies at a day-long San Diego Pharmacy Conference hosted by the federal Drug Enforcement Administration. Over 100 pharmacy representatives attended.
Board President Schell and Executive Officer Herold hosted a booth at the annual National Association of Boards of Pharmacy Meeting in Orange County.
Inspector Toevs provided a presentation about lowering drug costs at a community meeting hosted by Senator Liu in Los Angeles
Executive Officer Herold presented information about the board's compounding requirements and other key board issues to a meeting of the Bay Area Pharmacy Directors at Stanford.
Executive Officer Herold attended a conference hosted by the California Endowment on Building Quality and Equitable Health Care Systems in Los Angeles.
Board Member Schell and Executive Officer Herold participated in a High Risk Drug Task Force Meeting, hosted by the California Hospital Association.
Executive Officer Herold attended a Medication Safe Alliance Conference in San Francisco hosted by the Pharmacy Foundation of California.
Executive Officer Herold presented information on the role of the executive officer at the Department of Consumer Affairs Board Member Orientation in Sacramento.

1st Qtr 10/11: *Executive Officer Herold presented information about preventing medication errors, the Board of Pharmacy's mandate and ongoing projects at a DCA-hosted meeting of consumers in Sacramento. The FDA also provided information during event.*

Executive Officer Herold provided information about the CIWMB's drug take back guidelines at a CalRecycle Hearing focusing on a draft report to the Legislature (the board also submitted written comments following this hearing).

Executive Officer Herold provided comments on a hospital repopulation policy developed by the California Hospital Association with the Department of Public Health via conference call. (This document was finalized in October.)

Executive Officer Herold provided information about the board's ongoing activities at the NACDs Technology Meeting in San Diego.

Executive Officer Herold attended an invitation only conference at UCSF on pharmacy leadership, which focused on inpatient facilities.

President Weisser and Board Member Veale hosted a board information booth at the Indian Pharmacist Annual Meeting in Orange County.

Executive Officer Herold provided a presentation to 300 attendees on California's e-pedigree requirements to pharmaceutical company compliance staff at the 2010 PDMA Sharing Conference in San Diego.

Executive Officer Herold participated as a member of the National Association of Pharmacy Board's Task Force on Recommended Revisions to the federal Controlled Substances Act. Participation was via telephone call because out of state travel would have been required to physically attend the meeting.

Executive Officer Herold and Board Liaison Joshua Room provided information about California's e-pedigree requirements at the GS1 workshop conference in San Francisco.

Executive Officer Herold presented information about preventing medication errors, the Board of Pharmacy's mandate and ongoing projects at a DCA-hosted meeting of consumers in Sacramento. The FDA also provided information during event.

Executive Officer Herold provided information about the CIWMB's drug take back guidelines at a CalRecycle Hearing focusing on a draft report to the Legislature (the board also submitted written comments following this hearing).

Executive Officer Herold provided comments on a hospital repopulation policy developed by the California Hospital Association with the Department of Public Health via conference call. (This document was finalized in October.)

Executive Officer Herold provided information about the board's ongoing activities at the NACDs Technology Meeting in San Diego.

Executive Officer Herold provided information about the board's Intern Fact Sheet Project to students at the University of the Pacific who are working on fact sheets for the board.

	<p>2nd Qtr 10/11: Board Vice President Kajioka provided information about the board's consumer materials to a group of 150 consumers at a consumer education event in Assemblymember Hayashi's district.</p> <p>Executive Officer Herold attended an invitation only conference at UCSF on pharmacy leadership, which focused on inpatient facilities.</p> <p>President Weisser and Board Member Veale hosted a board information booth at the Indian Pharmacist Annual Meeting in Orange County.</p> <p>3rd Qtr 10/11: Executive Officer Herold provides a presentation on California's e-pedigree requirements via video conference to FDA's Track and Trace Workshop.</p> <p>DEA and board cohost day-long conference for pharmacies of controlled substances. Due to interest and success, more conferences planned.</p> <p>Executive Officer Herold provides a presentation about California's identification of the heparin recall failures in 2008 and participates in a two-day workshop hosted by the PEW Trust in Washington DC.</p>
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