



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## **Communication and Public Education Committee Report**

Ryan Brooks, Chair and Board Member  
Shirley Wheat, Board Member  
Stan Weisser, Board Member  
Rob Swart, Board Member

The Communication and Public Education Committee has not met since the July Board Meeting.

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### **A. ACTION: Initiate Rulemaking Process to Adopt Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

#### **Background:**

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

The timeline envisioned for this process was:

- 2008: conduct public hearings statewide
- 2009: develop regulations and adopt the requirements by the end of the year
- 2010: pharmacies implement requirements to be ready for 1/1/11 implementation
- 2011: requirements become effective and labels on prescription medicine are compliant

At the July and August 2009 Board Meetings, the board devoted time to development of the regulation requirements. In fact, the sole purpose of the August Board Meeting was to refine the regulation requirements.

At this October meeting, the board needs to refine the regulation requirements and direct the release of the regulation language for the required 45 days of public

comment. The board will then hold a regulation hearing at the January 2010 Board Meeting, and if necessary, modify the language for 15 days of public comment, and then adopt the regulation. This will allow pharmacies nearly 6- 9 months to implement the language, a bit less than the one year envisioned.

Here is overview of a timeline for adoption of the regulation:

October 22, 2009: Board initiates rulemaking and directs staff to release the language for 45 days

January 20 or 21, 2010: Board holds regulation hearing and either adopts or modifies language. If the board modifies language, the regulation will be re-noticed for 15 days of additional public comment. If the board adopts the language as initially noticed, staff will compile rulemaking file and submit to the Office of Administrative Law

February 2010 (if needed): Board adopts final language of the regulation at a Board Meeting specifically scheduled for this purpose

April 2010: Rulemaking file reviewed and approved by the Department of Consumer Affairs and submitted to the Office of Administrative Law

Mid-May 2010: Rulemaking approved; board releases requirements to all pharmacies

At the August Board Meeting, the board made some modifications to the draft regulation. Version 1 (**Attachment 1**) is the initial version of the regulation provided to the board in July and August 2009. Version 2 (**Attachment 2**) is the partially modified language developed by the board the August meeting. However, the board has not adopted either version of the regulation.

#### Focus of SB 472's Requirements

Senate Bill 472 directed the board to focus on five items in developing its patient-centered label regulation (4076.5(c)):

1. Medical literacy research that points to increased understandability of labels.
2. Improved directions for use
3. Improved font types and sizes
4. Placement of information that is patient-centered
5. The needs of patients with limited English proficiency
6. The needs of senior citizens
7. Technology requirements necessary to implement the standards

Here is how the proposed regulation addresses these components:

1. Medical literacy research that points to increased understandability of labels.  
*Since 2008,*

- *The board has reviewed numerous articles providing the state-of-the-art research in this area. This material was used to develop the regulation's requirements.*
  - *Speakers at the November 2008 PACT Summit dealing with patient-centered labels addressed the basic elements to emphasize improved comprehension of label information and the issues of patient literacy and why prescription container labels are important to patients.*
  - *Executive Officer Herold participated as a member of the National Association of Boards of Pharmacy (NABP) Task Force on Uniform Prescription Labeling Requirements. The guidelines developed by this task force are subsumed into the board's proposed regulation with only minor differences (**Attachment 3**)*
  - *The US Pharmacopeia is developing its own set of prescription labeling requirements for patient-centeredness. Although the project is still under development, USP staff believe their requirements will be similar to those of NABP.*
2. Improved directions for use.
    - *The board has used the directions for use developed by Michael Wolf, PhD, of the Medical School at Northwestern University. These requirements aim to be simple and prevent misunderstanding by patients, including those with low literacy. They have been vetted in consumer surveys.*
  3. Improved font types and sizes
    - *A sans serif font and 12 point type are documented throughout the literature as the best combination to make labels easy to read.*
    - *However, to ensure the containers are not excessively large, and to permit a diversity of packages and containers to be used, only the most important patient information components (patient name, drug name, strength, directions and, if specified, purpose) are identified as needing to be in a 12 point, sans serif font.*
  4. Placement of information that is patient-centered
    - *In version 2 of the regulation, the board has identified the order for the patient-centered elements – creating a template and standardization for all labels. The board further specifies that 50 percent of the label shall be dedicated to the the five most important patient-centered elements (patient name, drug name, strength, directions and, if specified, purpose), again ensuring these elements are among the largest elements on the label*
    - *The regulation also encourages the use of color, bold typeface and use of white space to emphasize the patient-centered elements on the label*
  5. The needs of patients with limited English proficiency
    - *The standardized directions for use currently listed in the proposed regulation, according to Dr. Wolf, will address about 90 percent of all directions in use. The California Endowment, in support of the board's regulation, is funding a project with Dr. Wolf to translate and field-test the directions for use into the five predominant non-English languages*

*in California. Once finalized, the translations will be made available for use via the board's Web site. However, it will be an estimated year before these translations are available.*

- *SB 853 (Escutia, Chapter 713, Statutes of 2003) requires insurers and HMOs to provide enrollees with limited English skills access to translated written material and oral interpreters (**Attachment 4**). Oral interpreters must be available at not cost of the pharmacy or enrollee.*
  - *Individual pharmacies may have additional solutions to ensure patients with limited English proficiency are provided with information; for example Kaiser Permanente recently advised its enrollees about the existence of "talking" pill bottles (**Attachment 5**).*
  - *There is non-English material provided to patients by pharmacies. Since 2006, materials currently distributed to patients with medicine dispensed by three large pharmacy chains operating in California are available in 11 non-English languages.*
6. The needs of senior citizens
- *The current versions of the regulation emphasize specific patient-centered components on a label be placed in a specific font size, with a standardized placement of this information on the label and with additional emphasis encouraged by way of bold or highlighted text or use of "white space..*
  - *Additionally, the requirement that 50 percent of the label be used for the five elements will aid in readability.*
  - *Inclusion of purpose for the medicine on the label will aid seniors and their caregivers in ensuring the proper drug is selected when the patient takes the medicine.*
7. Technology requirements necessary to implement the standards
- *By specifying requirements only for the most patient-centered elements, pharmacies will be able to use existing technology and standard containers already in use when developing their labels to conform with the regulation's requirements.*

***At this meeting:***

At this meeting, the board will continue to finalize the regulation. This will be the board's opportunity to discuss whether the proposed language based on these discussions and from national research on improved labels that has been shared with the board is ready to be released for public comment as a prospective regulation for 45 days, or whether more work and refinement is necessary.

Comments from the public will also be taken.

If the board believes the language as developed or amended during this meeting is sufficient to meet the requirements of SB 472, board action may be taken to initiate the rulemaking process. This would mean that the board could take action to adopt the regulation at the next board meeting (January 2010).

Additional information about this rulemaking is provided in **Attachment 6**.

**B. FOR INFORMATION: Update on The Script**

Work on the next of *The Script* is nearly completed. To save money, the board will be combining the July and January issues into one issue. The issue will focus on new legislative requirements involving pharmacy law, interpretations of pharmacy law and the Integrated Waste Management Board's Model Guidelines for drug-take back programs.

This is also the last issue that will be published and mailed to pharmacies and wholesalers. Future issues will be e-version, released to licensees and the public electronically.

**C. FOR INFORMATION: Update on Public Outreach Activities**

Public and licensee outreach activities performed during the first quarter of Fiscal Year 09/10 include:

- July 3, 2009 – Executive Officer Herold spoke at a Board of Directors Meeting of the California Society Of Health-Systems Pharmacists
- July 25, 2009 – President Schell volunteered in “Standdown” an event for homeless veterans in San Diego and dispensed prescriptions and counseled patient’s regarding their medications.
- July 31, 2009 – Executive Officer Herold made 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.
- September 12, 2009 – Board President Ken Schell made a presentation to the Indian Pharmacist Association about board activities.
- September 13, 2009 – Board Inspector Judi Nurse made a presentation to the California Pharmacist Association’s Long-Term Care members regarding the DEA and CURES compliance issues.
- September 21, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Logipharma, a group of drug manufacturers and distributors.
- September 23, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Specialty Pharma, an association of contract drug manufacturers.
- September 24, 2009 – Executive Officer Herold provided a law update to the Sacramento Valley Chapter of the California Society of Health Systems Pharmacists.
- October 1, 2009 – Executive Officer Herold provided an update about board activities to the Board of Directors of California Society of Health-System Pharmacists.
- October 2 and 3, 2009 – Board of Pharmacy staffed a booth at CSHP’s Annual Meeting, Seminar in San Diego.
- October 2, 2009 – Executive Officer Herold provided a presentation on 2009 pharmacy legislation at the CSHP Annual Meeting
- October 3, 2009 – Board President Schell provided a presentation on Board of Pharmacy activities at the CSHP Annual Meeting;.

**D. FOR INFORMATION: First Quarterly Report on the Communication and Public Education Committee Goals for 2009/10**

**Attachment 7**

# Attachment 1

*July 2009 Version of Proposed  
Section 1707.5*

**1707.5 Patient Centered-Labels on Medication Containers**

Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

- (a) Each of the following items shall be clustered into one area of the label, and shall be printed in at least 12-point, san serif typeface:
    - 1. Name of the patient
    - 2. Name of the drug, brand and/or generic  
(Manufacturer's trade name, or the generic name and name of the manufacturer)
    - 3. Strength of the drug
    - 4. Directions for use
    - 5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]
  - (b) For added emphasis, the label may also highlight in bold typeface or color items listed in subdivision (a).
  - (c) The remaining required elements for the label specified in Business and Professions Code section 4076 shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typefont.
- Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).
- (d) When applicable, directions for use shall use one of the following phrases:
    - 1. Take 1 tablet at bedtime
    - 2. Take 2 tablets at bedtime
    - 3. Take 3 tablets at bedtime
    - 4. Take 1 tablet in the morning
    - 5. Take 2 tablets in the morning
    - 6. Take 3 tablets in the morning
    - 7. Take 1 tablet in the morning, and Take 1 tablet at bedtime
    - 8. Take 2 tablets in the morning, and Take 2 tablets at bedtime
    - 9. Take 3 tablets in the morning, and Take 3 tablets at bedtime
    - 10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
    - 11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
    - 12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
    - 13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
    - 14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime

15. Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
16. Take 1 tablet as needed for pain. You should not take more than \_\_\_ tablets in one day
17. Take 2 tablets as needed for pain. You should not take more than \_\_\_ tablets in one day

- (e) By October 2010, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in (d) into at least five languages other than English, to facilitate use thereof by California pharmacies.
- (f) Beginning in October 2010 and thereafter, 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.
- (g) The board shall provide translations of the above-listed translations in at least the five most dominant non-English languages used in California. When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.
- (h) For patients who cannot read English but can read in another language, upon request, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient.

# Attachment 2

*August 2009 Version of Proposed  
Section 1707.5*

Version 2

August  
2009

### 1707.5 Patient Centered-Labels on Medication Containers

Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

- (a) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label, and shall be printed in at least a 12-point, san serif typeface, and listed in the following order:
1. Name of the patient
  2. Name of the drug, brand and/or generic  
(Manufacturer's trade name, or the generic name and name of the manufacturer)
  3. Strength of the drug
  4. Directions for use
  5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]
- (b) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to the set off the items listed in subdivision (a).
- (c) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typeface.
- ~~Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).~~
- (d) When applicable, directions for use shall use one of the following phrases:
1. Take 1 tablet at bedtime
  2. Take 2 tablets at bedtime
  3. Take 3 tablets at bedtime
  4. Take 1 tablet in the morning
  5. Take 2 tablets in the morning
  6. Take 3 tablets in the morning
  7. Take 1 tablet in the morning, and Take 1 tablet at bedtime
  8. Take 2 tablets in the morning, and Take 2 tablets at bedtime
  9. Take 3 tablets in the morning, and Take 3 tablets at bedtime
  10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening

11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
  12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
  13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
  14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
  15. Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
  16. Take 1 tablet as needed for pain. You should not take more than \_\_\_ tablets in one day
  17. Take 2 tablets as needed for pain. You should not take more than \_\_\_ tablets in one day
- (e) By October 2010, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (d) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (f) Beginning in October 2010 and thereafter, 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.
- (g) ~~The board shall provide translations of the above-listed translations in at least the five most dominant non-English languages used in California.~~
- When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.
- (h) For patients who cannot read English but can read in another language, upon request, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient.

# Attachment 3

## *NABP Task Force Report on Elements of a Patient-Centered Prescription Container Label*

## Updated Model Act Addresses Quality and Safety in Patient Care

NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to further protect the public during the dispensing of prescription drugs and improve quality and safety in patient care. These changes were incorporated as a result of the Executive Committee-approved recommendations of the Task Force on Uniform Prescription Labeling Requirements, the Task Force on Standardized Pharmacy Technician Education and Training, the Task Force on Medication Collection Programs, and the Committee on Law Enforcement/Legislation, as well as from Resolution 105-03-09, entitled Valid Patient-Practitioner Relationships, which was passed by the voting delegates at the NABP 105<sup>th</sup> Annual Meeting.

### Task Force on Uniform Prescription Labeling Requirements

Amendments recommended by the Task Force on Uniform Prescription Labeling Requirements include a completely revised labeling subsection that consciously removed some data elements historically included on prescription labels to make room for the most critical patient information. Information is designated as either critical or important to ensure prescription labels are organized in a patient-centered manner and mandate that the following summarized data elements appear on the prescription label:

1. Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif (such as “arial”), minimum 12-point font,

and in “sentence case.” Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated.

- a. Patient name
  - b. Directions for use
  - c. Drug name
  - d. Drug strength
  - e. “Use by” date
2. Important Information for Patients – Must appear on the label but should not supersede Critical Information for Patients.
    - a. Pharmacy name
    - b. Pharmacy telephone number
    - c. Prescriber name
    - d. “Fill date”
    - e. Prescription number
    - f. Drug quantity
    - g. Number of refills
    - h. Product description
    - i. Auxiliary information

Additionally several comments were added to clarify certain informa-

Download the updated Model Act in the Publications section of the NABP Web site at [www.nabp.net](http://www.nabp.net).

tion, such as if a physician instructs a patient to “take as directed,” that this should not be used in lieu of patient counseling. Other comments concerned record-keeping requirements, phone numbers, “fill date” and “discard after date,” and auxiliary information. Examples of suggested labeling formats are below.

Along the same line, the Committee on Law Enforcement/Legislation added a definition for *fill date*, which “means the actual date a new or refilled prescription is dispensed but not necessarily delivered to a patient from a pharmacy.” The committee also advised that bar codes, the pharmacy address, and ‘2) store number may appear on the prescription label as additional information for patients.

### Sample Labels

Pharmacy Name: Phone: <b>Purpose:</b> <b>Patient Q. Name</b> Prescriber: <b>Take 1 tablet in the morning and 2 tablets at bedtime.</b> <b>Drug Name and Strength</b> <b>Generic for:</b> <b>Use by: MM/DD/YY</b> Qty: Refills:	Date Filled: MM/DD/YY Rx No.: Cautions:  Description:	Pharmacy Name: Phone: <b>Patient Q. Name</b> Rx No.: Date Filled: MM/DD/YY Prescriber: <b>Drug Name and Strength</b> <b>Generic for:</b> Qty: Refills: <b>Use by: MM/DD/YY</b>	<b>Purpose:</b>  Take 1 tablet in the morning and 2 tablets at bedtime. Cautions:  Description:
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The recommendations from the Task Force on Uniform Prescription Labeling Requirements to completely revise the labeling subsection of the Model Act were approved by the Executive Committee. These updates remove some data elements historically included on the labels to make room for the most critical patient information.

# Attachment 4

*Senate Bill 853 (Escutia, Statutes  
of 2003)*



**BE AWARE & TAKE CARE:**  
Talk to your pharmacist!

# The Script

CALIFORNIA BOARD OF PHARMACY SEPTEMBER 2009

## Senate Bill 853: Interpreted and Translated Healthcare Services for Insured Californians

Senate Bill 853 (Escutia) Chapter 713, Statutes of 2003, became effective January 1, 2004, and included requirements that the Department of Managed Health Care (DMHC) and Department of Insurance (DOI) adopt regulations to implement its provisions by 2006. This bill requires all health care service plans, including dental and vision plans, (e.g., Blue Cross, Healthnet, PacifiCare, etc.) and specified health insurers to provide, free of charge, language assistance programs that give enrollees with limited English skills access to translated written material and oral interpreters. Regulations adopted by the DMHC and DOI require those language assistance programs to be in place by January 1, 2009, and April 1, 2009, respectively.

Language assistance programs will include a survey by the insurer to determine which of their enrollees have language assistance needs, and in what language, and subsequently provide them with appropriately translated documentation regarding

their insured benefits. Additionally, the health plan must provide a system whereby an insured with limited English proficiency would have the services of an interpreter at every "point of contact," which is defined as "an instance in which an insured (or enrollee) accesses the services covered under a health insurer's policy (or plan contract), including administrative and clinical services, telephonic and in-person contacts." (Title 28 California Code of Regulations [CCR] 1300.76.04 and Title 10 CCR 2538.2)

Pharmacy services, doctor and lab visits can be included among the insureds' points of contact, and it is important to understand that it is the responsibility of the insurer, not the pharmacy or the doctor, to develop and provide access to translators and interpreters for the insured patients at the points of contact.

## July 1 was deadline for completion of updated Self-Assessment forms

The pharmacist-in-charge (PIC) of a community or outpatient hospital pharmacy is required to complete a "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment" on Form 17M-13 (Rev 10/08) before July 1 of every odd-numbered year and within 30 days when a new pharmacy permit has been issued, or when there is a new PIC. The same rules apply for an inpatient hospital PIC, who must complete the "Hospital Pharmacy and Self-Assessment" on Form 17M-14 (Rev 10/08). (Title 16, California Code of Regulations [16 CCR] section 1715)

Updated forms may be downloaded from  
[www.pharmacy.ca.gov/forms/app\\_forms.shtml](http://www.pharmacy.ca.gov/forms/app_forms.shtml)

A wholesaler's designated representative-in-charge must complete the "Wholesaler Dangerous Drugs & Devices Self-Assessment" on Form 17M-26 (Rev 10/08) before July 1 of every odd-numbered year and within 30 days when a new wholesale permit has been issued, when there is a new designated representative-in-charge or when there is a change in the licensed location of a wholesaler to a new address. (16 CCR section 1784)

All completed self-assessment forms must be retained and easily retrievable in the pharmacy or wholesale premises for three years.

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# Attachment 5

## *Talking Pill Bottles*

## "talking" pill bottle helps reduce medication errors

Taking the wrong medication, or the wrong dose, can be dangerous. But what if you can't see the label clearly or can't read it?

"Now you can order your Kaiser Permanente prescription medications in 'talking' pill bottles," says area pharmacy director Karen Tokunaga, PharmD. "The talking pill bottle empowers those with limited vision or reading impairments to feel confident about taking medications correctly."

The bottle has a computer chip that lets a pharmacist record verbal instructions: medication name, how much and how often to take it, warnings, and refill information. Pressing a button on the side of the bottle activates the message.

"Our goal is to provide all our members with the same high-quality medication information," says Tokunaga. "We want

to make sure our patients understand how and when to take their medications."

Talk to your doctor if you think a talking pill bottle would benefit you or a family member. There's no extra charge. You can ask for one when the medication is being prescribed, from your pharmacist, or when you request a refill.

### More resources for the visually impaired:

- Sign up to receive *Partners in Health* in audio format. Provide your name, medical record number, and address to Virginia Lam at [Virginia.w.lam@kp.org](mailto:Virginia.w.lam@kp.org) or call (510) 268-4491.
- Our *Healthwise Handbook* is available in eight Braille volumes. Other informational booklets and pamphlets are also available in audio formats. Call the Member or Customer Service number on your ID card.

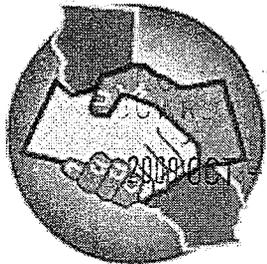
Source: Partners in Health

Fall 2009

Kaiser - Permanente

# Attachment 6

## *Additional Material on Patient-Centered Labels*



**California Labor Federation**

**AFL-CIO**

[www.workingcalifornia.org](http://www.workingcalifornia.org)

2009 OCT 1 6 AM 9:03

Headquarters: 600 Grand Ave  
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October 1, 2009

Mr. Kenneth H. Schell, PharmD  
President, California Board of Pharmacy  
1625 N. Market Boulevard, N219  
Sacramento, CA 95834

**RE: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

Dear Dr. Schell and Members of the California Board of Pharmacy:

On behalf of the two million working families of the California Labor Federation, I am writing to urge the Board of Pharmacy to adopt draft regulations implementing SB 472 without delay. Any appropriate concerns about the draft regulations can be adequately addressed during the formal rulemaking process. Further delays are unnecessary and put the health of Californians at risk.

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The Board had a chance to fulfill its obligation under the law at its August 2009 meeting by adopting the draft regulations recommended by staff. The Board instead opted to further delay adopting the regulations.

The staff of the Board of Pharmacy spent the last year researching the issues at hand, holding public hearings, conducting surveys, and consulting experts in order to draft regulations. The regulations recommended by the staff draw on their extensive information-gathering and should be adopted at the next Board meeting to begin this formal rulemaking process.

We urge the Board of Pharmacy to adopt draft regulations immediately in order to protect the public from the risk of injury, inappropriate care or even death from prescription drugs. California's policymakers have determined that standardized, accessible, translated prescription labels are a vital element in appropriate health care delivery. Patients have a right to these labels and the Board must not be a barrier to that right.

Thank you for your attention to this matter.

Sincerely,

Sara Flocks  
Public Policy Coordinator  
SF: sm  
OPEIU 3 AFL CIO (31)

Cc: California Board of Pharmacy

# Educating Patients About Their Medications: The Potential And Limitations Of Written Drug Information

No consumer-information standards have been implemented for drugs, the most potentially hazardous products regulated by the FDA.

by William H. Shrank and Jerry Avorn

**ABSTRACT:** Drug information on labels and inserts is a major source of knowledge for patients as they attempt to balance the risks and benefits of drugs and administer them safely. Yet this information is often inconsistent, incomplete, and difficult for patients to read and understand. We reviewed the numerous sources of written prescription drug information, the regulations that govern their content and format and the lack of oversight in the process, and the history that led to this system. We suggest that oversight and standards are needed so that written drug information can serve as a coherent and organized system to educate patients. [*Health Affairs* 26, no. 3 (2007): 731-740; 10.1377/hlthaff.26.3.731]

**T**O MAKE THOUGHTFUL DECISIONS about using medications and to take them safely and appropriately, patients must have at least a basic understanding about the risks and benefits of their prescribed drugs and how to administer them. Recent safety problems associated with commonly prescribed and aggressively advertised medications such as the COX-2 inhibitors and antidepressants have increased awareness about the importance of considering medication risks. In its 2006 report, *Preventing Medication Errors*, the Institute of Medicine (IOM) highlighted the pervasive problem of poor medication safety.<sup>1</sup> Ideally, patients should receive counseling about risks, benefits, and safe administration of medications from their physicians and pharmacists. Surveys indicate that most patients prefer to receive this information from their physicians, as learned intermediaries.<sup>2</sup> However, there is considerable evidence that such discussions occur infrequently and are often quite limited.<sup>3</sup> A recent study evaluated audiotaped office visits and found major shortfalls in the quality of information communicated to patients about their prescribed medicines; physicians explained adverse effects

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and duration of therapy in only about a third of the discussions and provided patients with instructions for use in only 55 percent of the discussions.<sup>4</sup> Communication with pharmacists is also inadequate.<sup>5</sup> As a result, many patients rely on written information, either on labels or in package inserts.

Even among those who do receive information from clinicians, many likely will not remember this information shortly after the visit and will look to labels and associated written information for ongoing guidance.<sup>6</sup> Written information has also been shown to augment patients' knowledge about prescription drugs, even when oral communication does occur.<sup>7</sup> Although efforts to improve oral communication about medications must persist, improving written medication information is one straightforward way to help patients safely and appropriately administer their medications. Evaluation of the quality of that information and policy options to improve it will benefit patients.

### **Patients' Understanding Of Written Medication Information**

■ **Health literacy.** About half of Americans have difficulty reading and using health information; poor health literacy is a critical barrier to adequate care.<sup>8</sup> These problems are especially important concerning medication information.<sup>9</sup> In a recent multisite study of primary care patients, nearly half were unable to understand one or more of the label instructions on five common prescription drugs.<sup>10</sup> Another study evaluated low-literacy patients' ability to interpret warning stickers (usually colorful stickers often indiscriminately placed on the backs of prescription bottles) and found profound deficits in their understanding.<sup>11</sup> Elderly patients have particular difficulty reading and understanding drug labeling.<sup>12</sup> In a survey of older hospitalized patients prior to discharge, only 40 percent reported no problems in reading their drug labels, and even fewer reported that they had a clear understanding of the instructions. Another survey of geriatric patients found that they frequently did not understand how to time their dosing in relation to meals.<sup>13</sup> In younger populations, an evaluation of parents' ability to comprehend drug labels for their children and calculate appropriate doses found that 77 percent of the adults studied were unable to correctly administer oral rehydration therapy, 56 percent were unable to calculate appropriate doses of cough syrup, and 68 percent planned therapy schedules that led to incorrect dosing.<sup>14</sup>

■ **Medication errors.** These limitations likely contribute to the high rates of medication error seen in the outpatient setting. In its report on medication errors, the IOM estimates that 1.5 million medication errors occur annually in the United States. A large proportion of these occur in the outpatient setting, generating costs of more than \$3.5 billion.<sup>15</sup> Poor labeling was identified as a critical source of those errors. Similarly, U.S. Pharmacopoeia reports that about a third of errors it evaluates are attributable at least in part to inadequate labeling.<sup>16</sup> Poor understanding of medication instructions might also inhibit a patient's ability to adhere to therapy as prescribed.

## Sources Of Written Prescription Drug Information

■ **Container labels and CMI leaflets.** Patients have several sources of written information about prescription drugs. The container label provides basic drug information such as the drug name, dose, instructions, pharmacy, and patient's name. The container also sometimes includes auxiliary stickers to communicate additional warnings and administration directions. Supplementary leaflets often accompany prescriptions filled, referred to as "consumer medication information" (CMI).<sup>17</sup> These have more surface area than the container label and are used to communicate additional information about medication directions, risks, and benefits.

■ **Package inserts.** Some drugs are dispensed with a package insert, a document approved by the Food and Drug Administration (FDA) that contains scientific information about pharmacokinetics, pharmacodynamics, molecular structure, indications, risks, and benefits. Despite recent formatting changes to simplify readability, this document uses technical language aimed at physicians but is frequently delivered to patients via single-dose containers packaged by the manufacturer.<sup>18</sup>

■ **Medication Guides.** In addition, federal regulations require that some drugs be accompanied by a Medication Guide, providing more detailed risk information. The FDA requires Medication Guides for drugs that represent a "significant public health concern," such as Accutane (isotretinoin) in women of child-bearing ages or, more recently, all nonsteroidal anti-inflammatory drugs (NSAIDs) and selective serotonin reuptake inhibitors (SSRIs), to provide warnings for cardiovascular risks and suicide, respectively.<sup>19</sup> Only forty-four active ingredients now require Medication Guides; they range from commonly prescribed medications with formulations available over the counter to rarely used biologics to treat metastatic cancer.<sup>20</sup> Rarely, manufacturers prepare a patient-oriented document called a patient package insert, required for oral contraceptives and inhaled isoproterenol, that must be approved by the FDA and can be packaged with the drug.<sup>21</sup> The use of these ancillary materials is variable, however. Even mandated Medication Guides frequently are not provided, and an underfunded FDA lacks the capacity to police its regulations.<sup>22</sup> Thus, patients may receive any number of combinations of these information sources with their drug, or just the container label.

## Fragmentation In Creating And Regulating Drug Information

The development and presentation of these various types of written materials occurs in a fragmented and disorganized way, with numerous organizations participating in their development (Exhibit 1). The content of container labels is regulated jointly by the FDA and state boards of pharmacy. The FDA requires several items to be included on all prescription drug container labels, including the name and address of the pharmacy, serial number of the prescription, prescriber, patient's name, name and dose of the drug, and directions for use.<sup>23</sup> State pharmacy boards then specify their own requirements. The FDA has no regulations and state pharmacy boards have few regulations concerning the format of container labels,

## EXHIBIT 1 Types And Regulation Of Commonly Dispensed Written Prescription Drug Information For Patients

Type of written drug information	Purpose of information	Type and source of regulation
Container label	Provide succinct information about drug name, directions for use, and warnings	Content regulated by the FDA and by state boards of pharmacy; <sup>a</sup> format is unregulated
Consumer medication information (CMI)	Provide more thorough information about medication risks, benefits, and appropriate administration	Content and format: guidelines are provided by the FDA, but private firms ultimately determine both <sup>b</sup>
Package insert	Provide physicians with indications for use and offer detailed information about the medication	Content and format: strict guidelines from the FDA; package inserts are created by manufacturers and approved by the FDA <sup>c</sup>
Medication Guide	Additional information about medication risks for drugs that the FDA determines are a "serious public health concern"	Content and format: strict guidelines from the FDA; Medication Guides are created by manufacturers and approved by the FDA <sup>d</sup>

**SOURCES:** See below.

**NOTE:** FDA is Food and Drug Administration.

<sup>a</sup> Section 503(b)(2) of the Food, Drug, and Cosmetic Act (21 U.S. Code, sec. 353[b][2]).

<sup>b</sup> Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information*, December 1996, <http://www.keystone.org/spp/documents/FinalActionplan.pdf> (accessed 14 March 2007).

<sup>c</sup> U.S. Government Accountability Office, "Drug Safety: Improvement Needed in FDA's Postmarket Decision-Making Process," March 2006, <http://www.gao.gov/highlights/d06402high.pdf> (accessed 15 February 2007).

<sup>d</sup> *Omnibus Consolidated Appropriations Act, 1997*, P.L. 104-180, Title VI, Sec. 601, "Effective Medication Guides," 110 Stat. 1593.

which are determined by the dispensing pharmacy and its software vendor.

Although the government has established guidelines concerning CMI, its content and format are ultimately determined by a few private firms that compile and sell libraries of medication monographs to pharmacies. First DataBank and Medispan constitute the majority of this market.<sup>24</sup> The format of CMI is determined by local pharmacies and their software vendors. By contrast, the content and format of the package insert and mandated guides are strictly regulated by the FDA.<sup>25</sup>

These written sources offer patients a complex menu from which to identify information about their medications, with no single source responsible for oversight of how these components fit together to provide patients with useful, comprehensive drug information.

### History Of Efforts To Regulate CMI

The FDA has long struggled to establish its role in regulating CMI—one particular component of written medication information (Exhibit 2). In the 1970s, the agency identified CMI as an important adjunct to medication counseling and in 1979 proposed regulations requiring educational leaflets to accompany all prescriptions filled. By 1980, at the end of the Carter administration, regulations were finalized requiring manufacturers to prepare such information, for a limited number of medication classes at first. However, these regulations were revoked early in

## EXHIBIT 2 History Of Efforts To Regulate Consumer Medication Information (CMI)

1979	The FDA proposed regulations to require educational leaflets to accompany all prescription drugs (to be phased in) <sup>a,b</sup>
1982	The FDA withdrew these regulations and determined that the private sector would provide written information <sup>c</sup>
1995	The FDA proposed regulations to require manufacturers to produce educational leaflets <sup>d</sup> A task force of stakeholders was convened to develop and implement the Keystone Guidelines, the <i>Action Plan for the Provision of Useful Prescription Medicine Information</i> , setting quality and distribution guidelines for the private sector to prepare medication leaflets <sup>e</sup>
1996	Medication Guide law was passed requiring standardized, FDA-approved leaflets for medications that the FDA deems pose a serious and significant public health concern <sup>f</sup>
2000	The FDA assessed the distribution and quality of CMI delivered in a sample of pharmacies; distribution guidelines were met but the quality was found to be substandard <sup>g</sup>
2007	Distribution and quality of CMI will again be assessed <sup>f</sup>

**SOURCES:** See below.

**NOTE:** FDA is Food and Drug Administration.

<sup>a</sup> *Federal Register* 44, no. 131, Pt. 2 (1979): 40016–40041.

<sup>b</sup> *Federal Register* 45, no. 179, Pt. 2 (1980): 60754–60784.

<sup>c</sup> *Federal Register* 47, no. 173 (1982): 39147–39165.

<sup>d</sup> *Federal Register* 60, no. 164 (1995): 44182.

<sup>e</sup> Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information*, December 1996, <http://www.keystone.org/spp/documents/FinalActionplan.pdf> (accessed 14 March 2007).

<sup>f</sup> *Omnibus Consolidated Appropriations Act, 1997*, P.L. 104-180, Title VI, Sec. 601, "Effective Medication Guides," 110 Stat. 1593.

<sup>g</sup> B.L. Svarsted et al., "Evaluation of Written Prescription Information Provided in Community Pharmacies: A Study in Eight States," *Journal of the American Pharmacists Association* 43, no. 3 (2003): 383–393.

the Reagan administration, which determined that the private sector should provide all necessary written information that patients required.

This did not prove to be the case. By 1995, the FDA, dissatisfied with progress in the provision of written information to consumers, again proposed regulations to require manufacturers to produce and distribute standardized consumer leaflets and specified guidelines for their content and quality. In August 1995, despite strong support from consumer groups such as Public Citizen, the agency was blocked by a consortium of stakeholders including pharmacists, drug manufacturers, and the American Medical Association (AMA). Pharmacists and physicians expressed concerns about government intrusion into clinical practice and the importance of clinical autonomy. Manufacturers expressed similar concerns and were intent on keeping the physician in the role of learned intermediary, protecting manufacturers from additional liability.

■ **Action Plan.** Instead, the FDA convened a task force to develop and implement a long-range *Action Plan for the Provision of Useful Prescription Medicine Information*. It stated that by 2000, 75 percent of new prescriptions would be accompanied by CMI, and 95 percent by 2006.<sup>26</sup> Eight quality criteria were established, ranging from

scientific accuracy to legible formatting. These criteria were to be only guidelines; the FDA received no power to regulate content or format and continued to rely on the private sector to create the material. With enactment of the Medication Guide rule in 1996, the FDA secured authority over information leaflets only for those drugs they judged to raise a “serious and significant public health concern.”<sup>27</sup>

■ **Measuring progress.** In 2000, the FDA sought to measure how well the private sector was meeting the interim goals of the Action Plan. A nationwide study was performed by Bonnie Svarstadt and colleagues, who sent trained shoppers to fill 918 new prescriptions at 306 randomly selected pharmacies in 8 states to evaluate the CMI received.<sup>28</sup> The study found that distribution guidelines were exceeded, with 87 percent of prescriptions accompanied by CMI. However, the CMI quality was quite poor, with its contents, length, and quality varying greatly by pharmacy. Fewer than half of the materials presented acceptable information about how to take the medication, receive maximal benefit, and interpret benefits. Only about a quarter included acceptable information about medication precautions and how to avoid adverse reactions, and fewer than a fifth contained acceptable information about contraindications and what to do in case of a contraindication. In 2007, the FDA is due to assess whether the final goals set out in the Action Plan have been met. Despite decades-long efforts to improve medication leaflets, the FDA still has no regulatory control over this material.

### **Information Quality And Variability**

A growing body of data indicates that instead of the marketplace producing an ever more useful portfolio of information resources, the lack of regulation of such information has led to the proliferation of products that are patient-unfriendly and of poor quality. Information is often presented in an excessively complex manner, even though many Americans (especially those over age sixty-five) read at a sixth-grade level or below.<sup>29</sup> In addition to Svarstadt and colleagues’ work, studies have demonstrated that CMI, patient package inserts, and Medication Guides are often presented in a type size smaller than 10 point (too small for many older patients to see) and written at a tenth-grade level or greater (a challenge for those with poor health literacy).<sup>30</sup>

Although Svarstadt and colleagues’ analysis documented great variability of CMI, no published studies to date have thoroughly evaluated the level of variability in container labels. But even a casual observation of those labels reveals striking variability in the content and format of information presented.

Thus, the FDA applies quite different levels of scrutiny to risk information for different audiences. The agency pays very close attention to each indication and side effect listed on material aimed at physicians and the format of that information but plays no role in identifying the content most relevant to patients (except for the small number of Medication Guides) and only offers unenforced guidelines on formatting.

## Improving The Communication Of Drug Information

Efforts are needed to provide patients with an integrated, coherent information system about their prescription drugs rather than the redundant, uncoordinated, and hard-to-read pieces of information they receive now. We suggest a new approach in which information is presented legibly and hierarchically. We should require a standardized container label that is easy to read, that does not rely on vague and indiscriminate warning stickers, and that clearly delineates administration directions and key warnings. A single well-organized and standardized leaflet would present more complete information about risks and benefits and augment the information on container labels. To do this, centralized oversight of the development of labeling components with minimum standards is needed. More research is also needed to evaluate the optimal ways to communicate written information to patients to create a system that best educates patients about medications.

■ **Value of standardization.** Better oversight of the labeling process would offer several key improvements. A standardized container label could use evidence-based techniques to optimize formatting. Larger type sizes, a schematic organization of drug information, and judicious use of white space represent basic formatting techniques shown to improve readability and understanding.<sup>31</sup>

Consistency of formatting between pharmacies could simplify the search for information. Better oversight would also present an opportunity to require information for patients who do not speak English, those with poor vision, or those with low reading levels. Such information might help reduce medication errors caused by patients' poor health literacy and could provide more-equitable care.

New standards for written drug information could also help ensure consistency in the content of information. To do this, it will be necessary to identify the specific risks and instructions that should be included for each drug. In this approach, all container labels for a given drug (such as ibuprofen) would include the same administration instructions (for example, take with milk or food) and warnings (for example, if you develop stomach upset or black, tarry stools, contact your physician). Less variability could reduce the likelihood that medication errors or adverse-event rates will vary depending on the pharmacy chosen.

■ **Successful standardization for other products.** It is instructive to compare the different ways that the FDA has managed the standardization of labeling formats for other products under its jurisdiction. Consumers who buy food at a grocery store know where to find nutrition information on the FDA's standardized "Nutrition Facts" label. People who purchase over-the-counter medications can use uniform "Drug Facts" labels to help find administration directions or risk information. Yet no such standards have been implemented for prescription drugs, arguably the most complex and potentially hazardous of the products regulated by the FDA.

■ **Regulatory limitations and options.** We propose that the FDA develop and require minimum standards for the content and format of both container labels and CMI.<sup>32</sup> Although labels have traditionally been under state control, the FDA has re-

cently taken the controversial position that its statements about drug risk should preempt any differing opinions held at the state level.<sup>33</sup> If this is true, then the agency should be equally comfortable preempting state variation in the presentation of information on medication containers. If considerations of federalism turn out to limit the FDA's authority to regulate container labels at the state level, partnerships could nonetheless be developed between state pharmacy boards and the FDA to develop and implement improved patient information standards.

■ **Examples from other countries.** Standards have been implemented in the European Union for manufacturers to develop written materials that must adhere to strict guidelines and must be approved by the European Medicines Agency.<sup>34</sup> However, medication there is generally dispensed in individual-use packaging, which simplifies the delivery of materials created by manufacturers. Most U.S. pharmacies purchase medications in bulk and repackage prior to dispensing. In Canada, where bulk purchasing is also common, manufacturers are required to develop a dedicated patient leaflet for all new drugs as part of the federally approved product labeling, but little is known about the frequency with which these leaflets are delivered to patients at pharmacies.<sup>35</sup> A discussion about the best party to create written materials (manufacturers; private companies that contract with pharmacies; a government agency; or a nonprofit agency) is needed and warrants thorough exploration.

### **The Right Time For Change**

Growing concerns about the quality and safety of prescription drugs have helped open a political window for action on written prescription drug information. With implementation of Medicare Part D in 2006, the federal government has become the nation's largest purchaser of prescription drugs. This investment confers even greater responsibility to ensure that patients take their medications safely, maximizing the return on the government's investment.

The recent IOM report highlighting the high frequency and costs associated with medication errors, citing poor labeling as an important cause of this problem, adds fuel to the argument to improve written information. A growing awareness of the problems associated with poor health literacy adds additional support, and physician groups such as the AMA now strongly support initiatives to improve health literacy and seem unlikely to oppose such efforts. Greater public concern over medication safety might force prescription drug manufacturers, who previously opposed CMI standardization, to be amenable to these efforts. Consumer groups such as Public Citizen and the Center for Medical Consumers have expressed a keen interest in change.<sup>36</sup> All of these stakeholders would no doubt be eager to participate in a dialogue about requiring standards for written drug information. Doing so could provide patients with an information system that could improve their understanding and use of prescription drugs.

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## **Consumer Surveys Conducted by the Board of Pharmacy**

Since May 2008, the board has been distributing a patient survey for distribution at public outreach events. The survey is available in English and Spanish.

Board staff has been using the survey to interview attendees at public events. Consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. This method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. Board staff attending the community events has also reported positive feedback when discussing this initiative with the public.

A total of 695 consumer surveys were completed as of July 2009. Some results of the board's consumer surveys are provided below. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions. Many consumers gave the same response (i.e., larger font) to more than one question.

Trends have been identified in the answers provided thus far. Many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print  
(347 of 578 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black  
(65 of 578 responses = 11.3%)

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

- Print should be larger or darker  
(194 of 616 responses = 31.5%)
- No changes should be made to label – references were made to Target, Raley's, CVS and Kaiser labels  
(148 of 616 responses = 24.0%)
- Include purpose of the drug – state what condition the medication is intended to treat  
(71 of 616 responses = 11.5%)

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

- Directions for use  
(257 of 1,361 responses = 18.9%)
- Name of drug; if generic, brand name and generic  
(253 of 1,361 responses = 18.6%)
- Dosage prescribed  
(242 of 1,361 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors  
(30 of 158 responses = 19.0%)
- Include purpose of the drug – state what condition the medication is intended to treat  
(22 of 158 responses = 13.9%)



**SB 472 Regulation Requirements  
for Patient-Centered Labels**

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Virginia Herold  
Executive Officer  
California State Board of Pharmacy

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**B & P Code Section 4076.5(a)**

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- o SB 472, enacted in 2007 as Business and Professions Code section 4076.5, requires the board to develop a standardized, patient prescription label to be in use for all patients receiving medication in California.

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**Patient-Centered Label**

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- o A patient centered label is one that emphasizes information of most importance to patients.

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**B & P Code Section 4076.5(b)**

- o The board shall hold public meetings statewide that are separate from its normally scheduled meetings to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

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**B & P Code Section 4076.5(c)**

- o In developing requirements for labels, the board shall consider:
  - Medical literacy research that points to increased understandability of labels.
  - Improved directions for use.
  - Improved font types and sizes.

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**B & P 4076.5(c) (continued)**

- o The board shall consider:
  - Placement of information that is patient-centered.
  - The needs of patients with limited English proficiency.
  - The needs of senior citizens.
  - Technology requirements necessary to implement the standards

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**B & P Code Section 4076.5(d)**

- o The board shall report to the Legislature on January 1, 2010, about its progress in implementing the standards. The board shall report to the Legislature the status of implementation by January 1, 2013.

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**The Label Serves a Number of Purposes**

- o To Patients (and their caregivers):
  - main source of information on how to take the drug outside a health care setting.
- o To Pharmacy:
  - what is in container, tracking and reference elements for state and federal laws, also advertising where drugs were obtained.
- o To Regulators:
  - conformance with requirements, contents, tracking.

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***NABP Policy***

- o The National Association of Boards of Pharmacy states:
  - *The purpose of the label is to provide critical information to the patient so that he or she may use medication appropriately and comply with the medication regimen.*
  - *The label should not be used as an audit mechanism by third-party payers, nor should it be used for promotional purposes by dispensing pharmacies.*

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**NABP Policy (continued)**

- o *The label should not be used as a sole means to determine compliance with pharmacy laws and regulations by pharmacy regulators.*
- o *The prescription label cannot and should not replace critical pharmacist care responsibilities, such as appropriately identifying the patient at the time of dispensing and providing patient counseling.*

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**Logistic Issues in Developing this Regulation:**

- o 350 million prescriptions were dispensed in outpatient settings to California consumers in 2008.
- o Diversity of containers in use makes it unrealistic to require a single label of specified format.

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**If the Container is Too Large**

- o Storage takes too much space in pharmacies, in homes, in purses, etc.
- o Patients remove drugs from containers, separating the label from the drugs.
- o Refill pharmacies can use only certain container sizes; nonconforming labels would negate the use of automation in these specialized pharmacies.

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**A Container Could Be Too Small for the Standardized Label**

- o If the container is smaller than the label:
  - How to attach label so it is readable?  
Typically the label is folded onto itself.
- o Space is limited since most labels are 2 inches by 4 inches

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**Result on Regulation:**

- o Allow flexibility in size of label to fit diverse containers and packages. Instead focus on standardization of patient-information on label in a minimized font size, with emphasis on the identified patient-centered text using:
  - sans serif font,
  - minimum of 12 point typeface,
  - highlighting or bolding for emphasis, and
  - "chunking" or clustering of patient-centered elements into one area of the label.

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**Directions for use**

- o Today, phrasing of directions on a container's label will differ from pharmacy to pharmacy. This can be confusing to patients, who are dispensed multiple medications with different directions that essentially mean the same thing. (e.g., "take two times daily" vs. "take one pill in the morning, one in the evening")

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**Directions for use**

- Standardization of directions for administration instructions can deal with 90 percent of all labels' directions (*Michael Wolf, 2009*)
- Research by those involved in optimal label design has developed phrasing for directions that are most understandable by patients.

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**Standardizing Directions for Use**

- Will allow pharmacies or even the board to develop translations of these directions for use.
- Will assure that patients who can read a language other than English will still be able to read the important directions for use on the label.

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**General rules:**

- Text in sans serif font, 12 point, not in all capital letters
- Use numerals, not text, for numbers (e.g., 3 versus three)
- Cluster patient-centered information in one area of the label
- OK to use highlighting and bold to emphasize patient-centered text.

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**General Rules:**

- Standardized directions for use, which will increase consistency for patients when taking medication, developed specifically to maximize comprehension in the greatest number of people, and will allow translations.

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**Question:**

- Should the board specify the minimum size of the area for the clustered patient-centered elements on a label?

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**Question:**

- Should the board develop translations in the top five languages for directions for use?

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**Question:**

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- o How shall the board deal with labels for the remaining 10 percent of directions for use that are not in the standardized list? Should the pharmacy be required to translate these directions if necessary?

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**Question:**

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- o What about the requirements of the physical description of the contents of a medication container that is required on the label by B& P 4076(a)(11)(A) – should the board require these be translated into diverse languages, or should a picture of the pill be considered as complying with the directions?

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**Question:**

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- o If the board translates the directions for use -- how to deal with translating other patient-centered items on the label?

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**Question:**

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- o NABP also identified expiration date as patient-centered. Does the board wish to reclassify this component?

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**Question:**

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- o What about auxiliary labels – how should the board deal with these? They are not standardized, they are not translated. They are confusing because patients can receive two completely different labels providing the same warning.

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**Reevaluation:**

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- o The board needs to periodically review the requirements of this regulation. At least after the first 4 years and then periodically thereafter.
- o Issues for consideration: universal medication instructions, other directions for use.

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**Questions:**

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- o How does the board want to deal with the description of the pill (mandate that it be translated or allow a picture)?

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# Attachment 7

*First Quarterly Update of the  
Communication and Public  
Education Committee  
2009-10*

# 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="365 457 1485 745"> <p>1. <b>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.</b>  <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>  <i>2007-2008: Board publishes new board brochure and complaint brochure, and redesigns several board brochures into new single-page, format.</i></p> </li> <li data-bbox="365 745 1485 1123"> <p>2. <b>Restructure the board’s website to make it more user friendly.</b>  <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. Links added to obtain various information regarding medication safety, and drug interactions, and information from FDA regarding Medications and Medical Devices. Work Initiated on new website design to meet new state design standards.</i>  <i>2007-2008: New website design completed in November 2007. Web page created consolidating all information on e-pedigree into one place.</i></p> </li> <li data-bbox="365 1123 1485 1344"> <p>3. <b>Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics.</b>  <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. No additional meetings scheduled after January 2007.</i></p> </li> <li data-bbox="365 1344 1485 1894"> <p>4. <b>Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics.</b>  <i>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.</i>  <i>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.</i>  <i>1st Qtr. 08/09: Letter to Deans of California's pharmacy schools mailed.</i>  <i>1st Qtr. 09/10: Staff prepare to initiate program using intern coordinators at school of pharmacy campuses in California.</i></p> </li> </ol>

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|  | <p>5. <b>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.</b></p> <p><i>2006-2007: Governor signs AB 2583.<br/>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.<br/>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.</i></p> <p><i>2007-2008: New "Notice to Consumers" approved by board and later by the Office of Administrative Law.<br/>New design and layout for two new Notice to Consumer posters are selected.</i></p> <p><i>1st Qtr. 08/09: New posters are mailed to California pharmacies.</i></p> <p><i>2nd Qtr. 08/09: Posters are translated into several languages and made available on the board's website.</i></p> <p>6. <b>Evaluate the practice of pill splitting as a consumer protection issue.</b></p> <p><i>2006-2007: Board holds discussion of pill splitting issues during January and April 2007 Board Meetings.</i></p> <p><i>2007-2008: <u>The Script</u> newsletter contains an article for pharmacists on pill splitting and a Fact Sheet for consumers is completed.</i></p> <p>7. <b>Evaluate the SCR 49 Medication Errors Report for implementation.</b></p> <p><i>2006-2007: Communication and Public Education Committee reviews SCR 49 report and board has presentation of the SCR 49 report.</i></p> <p><i>2007-2008: SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.</i></p> <p><i>Feb. 2009: SB 470 introduced to add "purpose" to the prescription container's label.</i></p> <p><i>Sept. 2009: SB 470 is enrolled and sent to the Governor.</i></p> |
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- 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.*
- 9. Address and promote licensee and public education on minimizing prescription errors.**
- July 2008: 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.*
- Jan. 2009: Board publishes medication errors segment in its newsletter, The Script, describing several medication errors investigated by the board.*
- June 2009: Enforcement Committee hears presentation on board investigations of medication errors during 2008/2009.*

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 1487 436"> <p>1. Publish <i>The Script</i> two times annually.</p> <p><i>July 2008:</i> <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>April 2009:</i> "February" issue of <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>July 2009:</i> "July" issue of <i>The Script</i> written and undergoing review.</p> </li> <li data-bbox="370 443 1487 1239"> <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> </li> </ol>

**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. 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.

**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.

**2007-2008:** Added information about NAPLEX being suspended.  
 Added information about Heat Preparedness.  
 Added information about pill-splitting.  
 Sent out more than 55 subscriber alert notifications to the board's e-mail notification list.  
 Website reflecting the New State Redesign launched in November 2007.  
 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.

**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.

	4. Jan 2009: Board mails letter pursuant to SJR 19 (Ridley-Thomas, Statutes of 2008) regarding prohibition of healing arts licensees not to engage in torture.
<b>Objective 4.3</b>	Participate in 12 forums, conferences and public education events annually.
<b>Measure:</b>	Number of forums participated.
<b>Tasks:</b>	<p>1. Participate in forums, conferences and educational fairs.</p> <p><i>July 2008:</i> Board Member Goldenberg provides information about pharmacy law to medical staff at the Jewish Home Hospital. Board Inspector Orlandella represents the board to a group of seniors and provided general information and responded to questions in Roseville, CA Executive Officer Herold provides a presentation to a group of 150 individuals and agencies regarding California law and drug take back programs in communities. Board staff attend the Lotus Festival in Bakersfield, CA and distribute consumer brochures and interview attendees about their prescription labels as part of the board's initiative to implement a patient-centered prescription label.</p> <p><i>Aug. 2008:</i> 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. Executive Officer Herold provides a presentation at a conference sponsored by the California Integrated Waste Management Board on the board's concerns with drug take back programs and sharps container returns.</p> <p><i>Sept. 2008:</i> Executive Officer Herold provides a presentation to AstraZeniga's government relations staff on SB 1307. Executive Officer Herold provides a presentation at the Generic Pharmaceutical Association's annual meeting on SB 1307. Executive Officer Herold participates in a web cast on California's pedigree requirements and SB 1307 (Ridley-Thomas) hosted by software provider SAP. Board President Schell and Executive Officer Herold make a presentation at a national meeting held in Sacramento regarding California's pharmacy law and the requirements barring needles and syringes being inappropriately discarded in landfills and other locations.</p> <p><i>Oct. 2008:</i> Executive Officer Herold speaks at CSHP Seminar providing three major presentations: 2008 Laws and Regulations, the 2008 Heparin Inspections, and an e-pedigree update.</p> <p><i>Nov. 2008:</i> Executive Officer Herold and Assistant Executive Officer Sodergren attend Synergy 2009, an event sponsored by the California Pharmacists Association.</p> <p><i>Nov. 2008:</i> Board hosts two major forums on public policy. The board's forum on e-prescribing brings in national and state experts in a session designed for healing arts boards. The forum on designing patient-centered labels has national experts and health literacy advocates.</p> <p><i>Dec. 2008:</i> Board President Schell serves on a National Association of Boards of Pharmacy Task Force on the take back of drugs from the public.</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. President Schell provides a presentation on prescription drug safety at the California Science Center in Los Angeles.

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 provides an update on board activities to the California Society of Health-Systems Pharmacists Board of Directors.

Board President Schell provides a presentation to undergraduate students of UCSD on career paths in pharmacy.

Supervising Inspector Ratcliff provides a presentation to the South Bay Pharmacists Association on "Surviving an Inspection."

Executive Officer Herold presents at the Pharmacy Foundation of California's Award Ceremony honoring a patient education advocate.

Executive Officer Herold and President Schell present a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting.

Executive Officer Herold serves as one of three judges for patient education videos produced by students as part of the CPhA's annual meeting. The winning videos will be promoted by the board.

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.

President Schell spoke at an Eagle Scout ceremony in Sacramento.

**4th Qtr 08/09:** Executive Officer Herold attends annual National Association of Boards of Pharmacy meeting.  
 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.  
 Assistant Executive Officer Sodergren provided a legislative update to the CSHP Board of Director's meeting.  
 Board Member Swart participated in an accreditation review by the national Accreditation Council for Pharmacy Education of the California North State School of Pharmacy.  
 Executive Officer Herold presented information about California's e-pedigree requirements via web cast at the RFID Journal Annual Technology Conference in Florida.  
 Executive Officer Herold presented via web cast to the Center for Business Intelligence Annual Drug Security Conference in Philadelphia information about California's e-Pedigree requirements.  
 Executive Officer Herold presented information about the board's six sponsored bills at CSHP Legislation Day.  
 Licensing Manager Debbie Anderson provided a presentation to students at Loma Linda University on becoming licensed as pharmacists in California.  
 Board Member Swart provided a presentation to students at the University of the Pacific on pharmacy law and the board.  
 Board President Schell made a presentation to UC San Diego students regarding intern hour requirements.

**1st Qtr 09/10:** Board President Schell volunteered in "Standdown" an event for homeless veterans in San Diego and dispensed prescriptions and counseled patient's regarding their medications.  
 Executive Officer Herold made 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 made a presentation to the Indian Pharmacist Association about board activities.  
 Supervising Inspector Nurse made a presentation to the California Pharmacists Associations Long Term Care Board regarding DEA and CURES compliance issues.  
 Executive Officer Herold made a presentation on California e-pedigree requirements to Logipharma to a group of manufacturers.  
 Executive Officer Herold made a presentation on California e-pedigree requirements to Specialty Pharma to group of contract drug manufacturers.