



California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Communication and Public Education Committee Report

Ken Schell, PharmD, Chair
Hank Hough, Board Member
Andrea Zinder, Board Member
Susan Ravnan, Board Member
Shirley Wheat, Board Member

There was no meeting of the Communication and
Public Education Committee this quarter.

There was a SB 472 Medication Label Subcommittee Meeting held April 12, 2008.
Minutes of this meeting are provided in **Attachment A**.

A. Report of the SB 472 Medication Label Subcommittee

Last fall, Governor Schwarzenegger signed SB 472 that directs the board to develop a patient-centered, standardized prescription container label for all medicine dispensed to California patients after January 1, 2011.

The board drafted the amendments that were ultimately enacted as SB 472, which requires the board to hold public meetings statewide that are separate from normally scheduled hearings to seek information from the public.

The timeline envisioned for this process was:

2008: conduct public hearings statewide – six meetings were envisioned
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

The Medication Label Subcommittee has been formed as a subcommittee of the Communication and Public Education Committee to work on the labeling requirements. President Powers appointed the following individuals to this committee:

Ken Schell, Chair
Bill Powers
Ruth Conroy
Rob Swart
Susan Ravnan
Shirley Wheat

The first meeting was held in Fremont on April 12. Senator Corbett asked that the first meeting be held in her district, and Senator Corbett attended the meeting to acknowledge the board's actions.

Minutes of the meeting are attached. The board used a number of methods to encourage participation; however, while there were about 40 people present, only 3 of these attendees could be considered public. The rest were affiliated with pharmacies or were sponsors of the bill. **Attachment 1** contains the information we mailed to community interest groups or the media about this meeting.

Staff is looking at alternative means to increase the participation of the public at future events.

The California Retailers Association and Kaiser Permanente provided samples of the diverse containers and labels in use in California pharmacies so the subcommittee and public could see the diversity of prescription containers that must be labeled.

In the future, the board will seek auxiliary labels that are used on containers to see an array of what is in use in California pharmacies.

B. Update Report on *The Script*

The next issue of *The Script* is planned for July publication. The issue will focus on application of laws and regulations. This issue will be mailed to pharmacies and wholesalers.

The California Pharmacy Foundation has advised the board that it is no longer able to find funding to mail the newsletter to all California pharmacists as it has done for the last four years. As such the board must either fund the mailing itself (\$50,000 - 60,000 per issue) or simply continue to distribute the newsletter as we have -- place notice on the board's Web site that it is available for downloading. It is important to note many of our licensees no longer pick up copies of the newsletter from the information booths we staff at association meetings because they have already obtained a copy from our Web site.

The board needs to express its gratitude to the California Pharmacy Foundation for mailing the newsletter to California pharmacists for the last few years. This has been a substantial workload and expense for them. It was a significant contribution

especially in the early 2000s because it helped the board during lean budget times when the board lost 10 staff positions along with the associated funding.

C. New Notice to Consumers Poster

In November, the Office of Administrative Law approved amendments to 16 CCR section 1707.2(g), creating additional requirements for a Notice to Consumers poster that present information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. This required notice must be posted in a pharmacy, or alternatively, printed on the back of customer receipts. The board prints these posters so they have a consistent look from pharmacy to pharmacy.

The final design has been selected and the board will print and mail the posters to all California pharmacies in July 2008. The estimated budget for this will be around \$80,000, twice what it cost to print the last Notice to Consumers two years ago when the board moved into its current office and the new address required a reprinting of the poster.

D. Update on Public Outreach Activities

From February through April 2008, the board provided five presentations to professional associations, five presentations at major conferences (including AphA's annual meeting and a drug company conference in Philadelphia), and staffed a booth at three public information fairs.

A detailed list of the board's public outreach activities this quarter is provided in **Attachment 2**.

Attachment 1

*Medication Label Subcommittee
Publicity*



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For immediate Release
March 12, 2008

Contact: Virginia Herold
916.574.7911

California State Board of Pharmacy Takes Steps to Make Prescription Container Labels Easier to Understand

Nearly half of Americans misunderstand prescription label instructions

(SACRAMENTO) – The California State Board of Pharmacy (Board) has begun work to develop standards to make prescription container labels more readable and easier to understand.

Recent studies have shown that 46% of American adults misunderstand the instructions on their prescription container labels, causing harm to at least 1.5 million people every year and costing close to \$1 billion annually.

The California Patient Medication Safety Act of 2007 requires the Board to develop regulations by 2011 that will standardize prescription drug labels and make them easier to understand.

“With few exceptions, most prescription container labels are not terribly user friendly,” said Board Executive Officer Virginia Herold. “Yet it’s crucial for patients to understand the information on them for the prescriptions to be effective.”

During the next several months, the Board will be holding a series of public meetings to gather information from both consumers and health care providers on ways to improve the readability of prescription labels. That information will then be used by the Board to develop new regulations.

- more -

California State Board of Pharmacy Takes Steps to Make Prescription Container Labels Easier to Understand

2-2-2

Among the things the Board will consider are:

- Medical literacy research that points to increased readability of labels;
- Improved directions for use;
- Improved font types and sizes;
- Placement of information that is patient-centered;
- The needs of patients with limited English proficiency; and
- The needs of senior citizens.

The first meeting will be held April 12, 2008 from 10:00 a.m. to 2:00 p.m. at the Wally Pond Irvington Community Center, 4188 Blacow Road in Fremont.

Information about the meeting, and about the Board's prescription readability initiative, can be found at www.pharmacy.ca.gov.

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March 20, 2008

To Interested Parties:

The most important aspect of taking a prescription medication is understanding and following the directions for its use, but approximately 46 percent of American adults cannot understand the instructions on the prescription container label. While current prescription container labels display important information about how to take the medicine, the directions are not always the easiest for patients to read and understand. Moreover, every pharmacy's prescription label is frequently formatted somewhat differently from other pharmacies.

To address this problem, the California Patient Medication Safety Act of 2007 was enacted to require the California State Board of Pharmacy to develop regulations requiring a standardized, patient-centered, prescription drug label to be used on all prescription medication dispensed to patients in California.

Because input from the public on this project is vital, the Board is hosting informal public hearings statewide, seeking information from patients about their ideas for improving prescription container labels. Improving the way information is presented on the labels can increase consumer protection and improve the health, safety, and well-being of consumers. The first meeting will be held from **10:00am to 2:00pm on April 12, 2008, at the Wally Pond Irvington Community Center, 41885 Blacow Road in Fremont**. The public is invited and strongly encouraged to attend and participate.

Please direct any questions related to the meeting to: Tina Thomas
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834
(916) 574-7941
Tina_Thomas@dca.ca.gov



Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

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

But patients have understood this to mean:

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

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

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

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

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

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

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

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

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

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Subscriber Alert:

The Board of Pharmacy today released the agenda for the first meeting of the Senate Bill 472 Medication Label Subcommittee. This subcommittee will hold a series of public hearings statewide over the next year to gather information from the public on how to make prescription container labels more patient-centered. Under SB 472 (Corbett, Chapter 470, Statutes of 2007), the Board of Pharmacy is required to develop standardized prescription container labels for all medicine dispensed to California patients by January 1, 2011.

This first meeting will be held April 12 in Fremont from 10 a.m. to 2 p.m. Attached is a link to the agenda.



08-04SB472 Agenda.DOT

Attachment 2

Public Outreach Activities



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Date: April 15, 2008

To: Communication and Public Education Committee

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the January report to the committee include:

- Board Member Goldenberg provided a presentation on the board's citation and fine program to pharmacists attending a USC continuing education program on January 26, 2008 in Ojai.
- Board Member Goldenberg presented information about the board's emergency response plans at a Kaiser Permanente CE Presentation on February 2.
- Board Member Schell provided information on the board's compounding requirements at CPhA's annual meeting in February 2008.
- Executive Officer Herold and President Powers presented information about medication errors at CPhA's annual meeting on February 10, 2008.
- Public Outreach Coordinator Karen Abbe staffed a booth at a DCA outreach event held February 23 at Cal Expo in Sacramento.
- Supervising Inspector Nurse provided information about e-pedigree law via teleconference to a Secure Pharmacy Conference in Philadelphia on February 26.
- Inspector Bob Kazebee provided information about Board of Pharmacy inspections to 50 pharmacists at a continuing education program held on March 7 through the USC School of Pharmacy.
- Inspector Ming provided information about pharmacy law to UCSF students on March 11.
- Executive Officer Herold provided a presentation along with FDA 's Ilisa Bernstein on counterfeit drugs at the American Pharmacists Association Annual Meeting in San Diego on March 17.
- Public Outreach Coordinator Karen Abbe attended a large public health fair at the Los Angeles Convention Center on April 12-13. Over 60,000 people attended. Board Inspector Simin Samari assisted part of one day.
- Board Member Graul provided information about the board's compounding regulations to a group of pharmacists, physicians and others in April.
- Executive Officer Herold provided information about Board of Pharmacy activities at a CSHP Board of Directors Meeting on April 19.

Future Activities

- Examination Coordinator Debbie Anderson will provide information about the board's pharmacist examination and licensure process to students at Loma Linda's School of Pharmacy on May 12.
- Board Members Conroy and Goldenberg will present information about the board and on pharmacy law to students at the University of the Pacific on May 17
- Executive Officer Herold will participate in a poster session held during NABP's annual meeting on May 18 describing the board's e-pedigree law.

Attachment A

*Minutes of the SB 472 Medication
Label Subcommittee Meeting of April
12, 2008*



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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SENATE BILL 472 (CHAPTER 470, STATUTES OF 2007)
PUBLIC FORUM
MINUTES**

DATE: April 12, 2008

LOCATION: Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA 94538

**BOARD MEMBERS
PRESENT:** William Powers, Public Member, President
Ruth M. Conroy, PharmD, Vice President
Kenneth H. Schell, PharmD
Susan L. Ravnan, PharmD

**BOARD MEMBERS
NOT PRESENT:** Robert Swart, PharmD
Shirley Wheat, Public Member

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Tina Thomas, Staff Analyst

**BOARD MEMBERS
IN AUDIENCE:** Stanley Goldenberg, RPh
Henry Hough, Public Member
James Burgard, Public Member

Dr. Schell called the meeting to order at 10:00a.m.

Invitation to Participate in the Redesign of Prescription Container Labels

Dr. Schell explained the purpose of the meeting. Dr. Schell stressed the importance of this law and the public forums the board will hold statewide. It is the Board of Pharmacy's goal to create a dynamic workable solution to standardize prescription labeling.

Presentations of SCR 49 findings, and need for patients to understand their drug therapy as a source of reducing prescription errors.

Mike Negrete with the Pharmacy Foundation of California spoke on behalf the Medication Error Committee resulting from SCR 49, and shared their findings.

Dr. Negrete reviewed the definition of medication error. He also reviewed the background of SCR49, the panel's focus on outpatient setting and need for patient-centered prescription labels. The committee reviewed key systems, which included healthcare training and licensure, healthcare provider payments and incentives, transcription and transmission of prescriptions, and education to the consumer. Dr. Negrete reviewed the seven goals identified by the panel, as well as their eleven recommendations (3 directly related to consumer education) with relation to prescription errors. Dr. Negrete discussed those consumer education related goals, where communication improvements are needed. He noted the issue of poor communication between prescribers, pharmacists and patients whereas such poor communication causes patient on-adherence. Dr. Negrete gave examples of pictographs developed by the USP and the lack of clarity of the pictures and text even among those with high health literacy. Dr. Negrete invited the audience to review the full report of the panel's research on their web site.

Joan Lee (Gray Panthers) commented that patients frequently waive consultations, or patients are placed in the situation of signing a waiver to consultation because they are given an option. Dr. Negrete replied that this issue was a big discussion for the panel. He noted that the panel considered that the only person allowing the patient to waive the consult must be a pharmacist.

Ms. Herold pointed out that if a pharmacist fails to initiate a consultation when required, it is a violation of law. She stressed that the board does not want to put the burden solely on the patient to determine whether a consultation is needed. The Board of Pharmacy provided the Notice to Consumers poster to every pharmacy, which includes five questions that every patient should read. These questions are aimed at improving patient understanding of their drug therapy through patient consultation.

Ms. Lee noted that Gray Panthers is creating a survey that relates to the consultation process in pharmacies.

Stephen Rosati commented that owners and directors of pharmacy chains should get the information on that screening for consultation violates California law.

Joshua Room asked whether Dr. Negrete is aware of any compilation of all the various label sizes and space needed on the labels. Dr. Negrete responded that he could not find any such information. Mr. Room noted that typically board regulations are developed based on a set of minimums previously defined.

Ms. Herold stated the request to hear from the public and what works for them on the label. She referenced the more than 50 different sizes and shapes of pharmacy containers displayed for the subcommittee and stated that the corresponding labels for these containers would be similarly diverse.

Michael Villaire (Institute for Healthcare Advancement) referenced a recent study where the findings indicated the pharmacy's logo, address, and phone number as the largest items on the label.

Mr. Rosati noted to be cautious with compression ability, and that some things can be compressed, but not others. Mr. Rosati suggested an 8 point font, to avoid compressing the important information (i.e., sig.)

Ms. Lee shared a piece of paper with small point font, and voiced her opinion that it's too small. Ms. Lee requested that the size of the font be in relation to the importance of the material, and that the sig and warnings be kept larger

Steve Gray (Kaiser Permanente) pointed that it is virtually impossible to accomplish all of the goals mentioned so far. Dr. Gray shared the results of their internal studies, which included the issue of portability when patients travel with their prescriptions. He also pointed out the other types of prescription containers, and discussed auxiliary labels. Dr. Gray mentioned the issue of gaining consensus from the various physicians, nurses and pharmacists on how dosages. Dr. Gray reiterated the concern over how much can be accomplished, and would like to see us go back to the basics of what we want to accomplish. Mr. Room asked Dr. Gray about any studies showing any difference in prescription errors with the verbal description mandate. He shared that they did notice a slight decrease in dispensing errors.

Mr. Rosati provided a rough estimate of 75 cents per prescription, if all prescriptions had pictures placed on labels. Mr. Rosati suggested a picture be added to the label instead of the currently required description of the pill.

Ms. Herold asked Dr. Gray who makes the decision on which container the medicine will go into. Dr. Gray stated that it some factors include what sizes of containers a pharmacy chooses to stock, automated filling systems are used, and the patients' requests for portability.

Cookie Quandt (Longs Drugs) commented that some pharmacies do use automation, thus technology determines the size of the bottle.

Dr. Gray and Dr. Negrete noted issues with placing pills into multiple bottles due to large quantities or for travel purposes. Patients often will not carry large containers and so will place medicine dispensed in a large container into unlabeled smaller containers.

Mr. Room made the suggestion of multiple labels being dispensed to patients with medicine so patient-selected containers chosen for convenience could also have a label applied by patients.

Ms. Quandt commented on the concern of patients' mixing pills into one container.

Requests for Public Comment on the Following: What works on prescription container labels? What does not?

Ramon Castellblanch (San Francisco State University) stated that based on his research and the materials for this meeting, there is a consensus on what contents and formatting of labels should be. The labels should be patient friendly, with relation to indication, benefits of the prescription, duration, and the adverse effects. He listed other components needed relating to format, font, terminology and the need for written inserts. Mr. Castellblanch shared the current development being conducted to create a universal medication schedule based on time of day (morning and evening or breakfast, lunch, dinner, and bedtime).

Dr. Schell asked the audience for one specific item that is currently helping them to take their medications.

Ms. Lee noted the confusion over generic names being listed on the label, and would rather have the purpose of the pill listed than a chemical name that has little value to her. Ms. Lee stated that the directions for use is the one thing that is most crucial to her.

Remarks from the Honorable Ellen Corbett, California Senator, District 10

Senator Corbett, the author of Senate Bill 472, addressed the audience. Senator Corbett thanked everyone attending the forum for their advocacy of SB 472. Senator Corbett gave a brief history of the bill and the reason for its creation. She also gave specific thanks to those heavily involved in the development of the bill. She pointed out the issue of language access and visual impairment, make it difficult for some consumers to understand the medicine they take.

Continuation of discussion on what is currently most crucial piece of label to forum members.

Mr. Rosati felt that the sig text in bold printing and all caps was crucial. He also suggested that pharmacies tape labels with transparent tape to avoid ruboff.

Vanessa Cajino (Latino Coalition) commented that translation of directions is necessary for non-English speaking patients.

Dr. Gray stated that the name of the pharmacy and a prescription order number is crucial in order to easily request refills.

Ms. Lee added that the expiration date of the medication is important, for those prescriptions who are not used as often.

Mr. Castellblanch suggested the importance of the indication of each type of prescription, dosing, schedule, and adverse effects.

Dr. Negrete commented on the importance of communicating adverse effects in an effective way. He gave the example of "2%" vs. "some", and the concern over leaving the terminology of "some". The concern over leaving terminology of "some" as too open and infers for more frequent problems than 2 percent would indicate, making patients overly concerned.

Ernie Tom (Ralphs Pharmacies) stated that everything on the label right now "works," because it is all needed information.

Mr. Villaire pointed out the loss of control once the prescription goes home with a patient. Mr. Villaire stated that even consultations may be later forgotten by patients after they leave (or have questions later). Mr. Villaire suggested a phone number that goes directly to a pharmacy for consultations or questions relating to their prescription. He suggested a second set of inserts written at a lower reading level, as well as a follow-up survey with patients to determine proper use of medications. Mr. Villaire also suggested text messages to patients to remind them to take their prescriptions, as well as follow-up phone calls to see how a prescription is working for patient. He also suggested additional focus groups to get more information from public. Mr. Villaire urged the board to go out to the public for more input.

Mr. Room asked if there is anything on labels now that is unnecessary. He suggested the name of the drug manufacturer as an example.

Dr. Negrete brought up the issue of a need for that information in the case of a recall. Mr. Room pointed out that the pharmacy will initiate a recall and knows this information.

Ms. Lee commented that knowing where a drug is manufactured these days may be important to some consumers, due to the current degree of concern over imported drugs. Mr. Lee suggested putting the origin of the label on inserts.

Dr. Tom noted that he has had consumers indicate an allergic reaction to drugs from certain manufacturers, so the name of the manufacturer is important.

The comment was made that, in the event of an allergic reaction, most consumers will contact their pharmacy in order to find out what manufacturer the drug came from.

A discussion ensued regarding providing a manufacturer code, as opposed to the manufacturer's name (on the label).

Mr. Rosati noted excessive phone numbers and addresses of the patient on some pharmacy labels, and suggested placing an auxiliary label on the side.

Mr. Rosati commented that the bar code should be only thing placed vertically on the bottle.

President Powers asked about the source of funding for the insert, as it needs to be geared towards benefiting the patient, not the manufacturer. He also asked if there is information on the studies in Canada on the effectiveness on auxiliary labels.

Mr. Castellblanch shared the success of standardized (patient-friendly) risk and benefit leaflets required by the manufacturers there. He suggested the ability for us to utilize their leaflets here in the US.

Dr. Quandt noted that most chain pharmacies use information provided by First Data Bank, and is not funded by the manufacturer.

A discussion ensued on additional inserts currently provided, First Data Bank and MedGuide.

Dr. Negrete noted that First Data Bank has launched the World Free of Medication Errors campaign, with a conference occurring in a couple of weeks. It was suggested to ask a representative to come to a Forum and speak on how the campaign is being applied to their processes. Dr. Negrete also commented on the previous discussion of manufacturer information provided. He stated that some patients are very particular about having the right medications from the right manufacturer, and that changes to that can have a physiological affect on them. He also commented that we must be careful on providing too much information to a patient, and ensuring that we only place information on the label that is crucial to the patient.

Ms. Lee requested that colored fonts be avoided with regard to warning labels. She suggested larger font as crucial.

Mr. Castellblanch shared a suggestion of a label on the back side of the bottle for the warning labels.

Dr. Negrete noted the importance of being careful not to go overboard on warnings. He stated that this can cause the patient to be overly concerned and possibly choose not to take their medicine.

Discussion ensued regarding the indication being placed on the label.

Mr. Room referenced the idea of the universal medical schedule. He raised the question of how to determine the language for medications where the directions are NOT to be taken during meal time. Mr. Castellblanch responded that 72% of prescriptions would be satisfied with a breakfast/lunch/supper/bedtime schedule. The directions of "take as needed" or "take as directed" brings the total up to 85% of all prescriptions.

Mr. Room stated that he understood the survey conducted only referred to directions that involved medication being taken certain times of day (and not whether or not it was to be taken with food).

Toni Jette (Kaiser Permanente) stated her concerned about the take with meals schedule idea. She conducted a survey among a small group, and determined that some patients skip meals and others have several meals a day. She noted that economics is also an issue, as patients will skip doses because they can't afford to take all daily doses.

Mr. Villaire noted the universal schedule as a first step, and that it does minimally address the issue of health literacy.

Caroline Lee noted that some pharmacies serving specific populations write directly on the labels what the prescription is for, what it's treating, how many times a day, plus the actual times. This makes the directions time oriented, not meal oriented. Ms. Lee feels that it's a good idea to have the label state what the medicine is used for to be on the label.

Mr. Castellblanch noted that the universal schedule is only a proposal at this point, and that the author of the schedule had attempted the time oriented approach, but had less success with it. He also noted that the author included a field for addressing critical issues in relation to how the medication should be taken.

Ms. Joan Lee noted her concern as a patient of how to break out the total time within a 24-hour day for taking her doses of medication.

Dr. Conroy noted the concern over having to pick times for patients to take medication, because people go to bed and wake up at different times, for example. Dr. Conroy brought up the awareness of pharmacies not using certain terminology on labels that are beyond a 5th grade reading level (i.e., "sparingly"). She also mentioned the varying opinions on whether "daily" and "once daily" have the same meaning.

Dr. Gray discussed the issue of "as directed" and what means to pharmacists. There was significant discrepancy in what the sig codes really mean to different pharmacists.

Dr. Negrete suggested the need for a consult between prescriber and pharmacist, to clarify the understanding of the sig as listed.

Mr. Castellblanch reiterated the concern over differences in verbiage, and pointed out that the universal schedule concept would assist in resolving that.

Dr. Gray discussed the reduction of patient wait time due to technology and e-prescribing. He noted that, if we ask for patient input on a label, it may increase patient wait time again.

How can prescription container labels be improved to make them patient-centered?

Dr. Schell began the discussion on literacy versus comprehension, and what we can for those people with people with low health literacy.

Dr. Negrete indicated that the SCR 49 panel discussed encouraging consumers to seek out pharmacies that share their language and culture. The panel also discussed increasing awareness in the pharmacies on the need for translators. They did not address the issues of visually impaired patients.

Mr. Villaire stressed the use of the “teach back method,” where patients state back what they understood. Mr. Villaire suggested the “teach back method” be used at consultations.

Dr. Schell asked the group if that is being done.

Dr. Gray stated that consultation competitions for pharmacy school students, the “teach back method” is within pharmacy practices. Dr. Gray suggested that this may be because patients respond defensively to that method, so pharmacists get discouraged. Dr. Gray also raised the issue of retention, as well as the issue of caregivers who are not English-speaking. He stated that many pharmacists may not know that they are legally required to provide translation services, as well as accommodations for the visually impaired.

Mr. Room and Ms. Herold initiated a discussion and display of pictograms and the confusion and lack of clarity over what the pictures are supposed to indicate.

Vanessa Cajina (Latino Coalition for a Healthy California) shared that there is research coming out from UCSF and Fresno and the use of pictograms. Ms. Cajina offered to share the information on that research from those interested.

Ms. Joan Lee stated that she wants to mention the importance of visually impaired patients and would like to ensure that the topic isn’t left out of further discussions. Ms. Lee also reiterated the importance of colored labels for those with vision issues.

Dr. Schell pointed out that comprehension changes as you age, and that we may have to consider different languages that are age-appropriate.

Dr. Gray noted that the visually impaired accommodations are already spelled out in the ADA, and questioned whether we should even need to address this when it is already in the federal law. Dr. Gray indicated that there is a service in Oregon that provide a Braille package insert of a prescription within 48 hours. Ms. Herold suggested that Dr. Gray write an article regarding this for the July newsletter.

Ms. Jette referenced the talking vial for those who are visually impaired.

Dr. Schell began a discussion on what should be done next, and who is going to pay for all this.

Dr. Gray commented that we should wait until we get more input from different parts of state before moving forward. He also stated that we should consider a “test” process.

Mr. Room asked if it might be possible to get software vendors who can participate and give their perspective on labeling space and what’s feasible.

Dr. Gray stated that there are key pharmacy organizations that have computer systems and tools who will sell them. He referenced McKesson’s work in this area and First Data Bank.

Mr. Castellblanch responded to the comment of testing language or pictograms, and stated that if other entities are already working on this, we should use their research findings rather than recreating the wheel.

Ms. Herold reviewed the purpose of this forum and the intent to engage the public. She asked how many public individuals are here, there were only a few. Ms. Herold stated that two press releases were issued, letters of invitation were sent to a number of community service agencies in the area and use of mailing

lists of the bill's sponsors did not result in desired public participation. She noted that the SB 472 committee is trying to elicit and encourage conversation on this topic. Ms. Herold stated that the board is asking those attending the forum to help bring in their constituencies. She reminded the group of the agreement with Senator Corbett, the bill's author, to hold six public forums independent of board meetings to get the public involved. She also noted that the Director of the Department of Consumer Affairs is planning to hold a board meeting once a year with all of the boards and bureaus present. The date is in November and will include the Medical Board and Nursing Board. Ms. Herold would suggest that the experts attend that meeting to present their research, as it will follow the opportunity to have a few more public forums. Ms. Herold also asked for input on how the future forums should be structured.

Mr. Room shared concern over those organizations. (i.e., Target, CVS) who have developed their own labeling systems that may have intellectual property rights attached. He encouraged us to make sure those companies are included in the discussions. Ms. Herold responded that both the organizations mentioned were contacted at the time the legislation was pending. They are being represented today by an association member.

Heidi Barsuglia (California Retailers Association) shared that those would be involved once we are further in the process.

Mr. Castellblanch stated that he wasn't aware of CARA (California Alliance of Retired Americans) having been invited to the forums, but would get them involved.

Mr. Villaire suggested the Board go to where people are for other purposes and events, and have board representatives schedule some of these meetings in conjunction with events.

A member of the audience suggested creating posters in pharmacies to advise the public when a meeting will be held in the area.

Dr. Negrete pointed out that SB472 is not on the radar screen for average people right now, which is why they are not attending the forum. Dr. Negrete also referred back to the question of maximum capacity on a label. He calculated that, at 10pt font for all text, you can fit 216 characters which is 36 words on a label (if fully covered with text).

Ms. Lee stated that she is a community member organizer. She said that they do have community forums, which includes groups of seniors who are passionate about having patient-centered labels. She stated that it is just a matter of finding the venues to get the information out.

Dr. Gray discussed getting the insurance companies involved in the forums as well.

Ms. Herold suggested that the pharmacists simply ask their patients on an individual basis.

Dr. Negrete asked about where the National Association of Boards of Pharmacy is on this issue. Ms. Herold stated that we are ahead of their progress, and that they will be putting out a resolution a year from now.

Ms. Herold stated that the panel will need to make some serious decisions in terms of the direction we go. Ms. Herold pointed out that they are not set up to alter what is currently required on the label, and will not be changing the law. She reiterated Mr. Room's concern with regards to Target/CVS and the requirement of a standardized format.

Mr. Room stated that we cannot necessary capture intellectual property rights without agreement by the party who holds it.

Ms. Herold opened the discussion on future meeting dates. She commented that she would like to reach Southern California, and could consider joining with a consumer outreach event. Ms. Herold requested setting a date for May or June, based on the issue of a state budget delay and the lack of funds at that point.

Dr. Gray suggested avoiding downtown governmental areas, because consumers will avoid them. Dr. Gray suggested put the forums in the suburbs or other neutral area.

Mr. Cajina suggested clinics in the Los Angeles area that may be willing to host an event.

Dr. Schell asked if there are any schedule conflicts with large events in the Los Angeles area. Ms. Cajina could not think of any events and will check on Health Fairs, etc. that may be going on. Dr. Schell asked the audience members to review the calendars and upcoming events and respond back to the board with potential opportunities.

Mr. Castellblanch commented that CARA has large meetings, and would be a good venue to present. Ms. Herold asked Mr. Castellblanch to contact her with the information.

The meeting was adjourned at 1:20 p.m.

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"> 1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. <ul style="list-style-type: none"> <i>Sept. 2006: Committee begins review of consumer outreach.</i> <i>Dec. 2006: 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>Jan. 2007: Drafts of board informational brochure and complaint process brochures are updated; brochures will undergo review.</i> <i>April 2007: Drafts of board informational brochure and complaint process brochures are provided to the Department of Consumer Affairs for review.</i> <i>June 2007: Committee reviews Department of Consumer Affairs prepared brochures and recommends board produce its own versions.</i> <i>Sept. 2007: Board publishes new board brochure and complaint brochure.</i> <i>Jan. 2008: Reformatted complaint brochure.</i> 2. Restructure the board's Web site to make it more user friendly. <ul style="list-style-type: none"> <i>July 2006: Web site modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.</i> <i>March 2007: Web site modified by adding 14 links to obtain various information regarding Medication Safety and Drug Interactions.</i> <i>Web site modified by adding 7 links to obtain information from FDA regarding Medications and Medical Devices.</i> <i>March 2007: Work initiated on the latest State Web site design to be in place by November 2007.</i> <i>June 2007: Work progressing for timely completion by November 1, 2007.</i> <i>Oct. 2007: Work nearly completed on Website.</i> <i>Nov. 2007: New Website design completed.</i> <i>Jan. 2008: Web page created consolidating all information on e-pedigree.</i> 3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. <ul style="list-style-type: none"> <i>Sept. 2006: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.</i> <i>April 2007: Summary provided of the Fall 2006 campaign to raise awareness about breast cancer screening and prostate cancer screening. No recent meetings of the partnership have occurred.</i>

4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics.
 - Sept. 2006:* 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.
 - April 2007:* Four draft fact sheets are still under review and the committee receives three new fact sheets. 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.
 - Sept. 2007:* Discussion with UCSF lead to request for funding to continue project. Meanwhile board seeks to establish intern projects with other schools of pharmacy.
 - Oct. 2007:* Board agrees to offer intern fact sheet program to all California schools of pharmacy.
 - Jan. 2008:* Committee prepares scope for program.
5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies.
 - Sept. 2006:* Governor signs AB 2583.
 - Oct. 2006:* 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.
 - Jan. 2007:* 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.
 - April 2007:* Board reviews comments submitted in rulemaking process to adopt this regulation change, and plans to renotice amended language for a new rulemaking process.
 - July 2007:* New "Notice to Consumers" approved by board; rulemaking file submitted to Administration for approval.
 - Nov. 2007:* Office of Administrative Law approves "Notice to Consumers" rulemaking. Work on drafting new poster design initiated by board staff at DCA design staff.
 - Jan. 2008:* Committee reviews draft concepts for new poster: additional work by board staff and the Office of State Publishing artists will continue to generate concept designs for the poster.
 - March 2008:* New design and layout for two Notice to Consumer posters are selected.
6. Evaluate the practice of pill splitting as a consumer protection issue.
 - Jan. 2007:* Board holds discussion of pill splitting issues during Board Meeting.
 - March 2007:* Legislation and Regulation Committee and Communication and Public Education Committee continue discussion of pill splitting.
 - April 2007:* Board hears discussion of pill splitting.
 - June 2007:* Communication and Public Education Committee discussed proposed consumer fact sheet on pill splitting.
 - July 2007:* The Script newsletter contains an article for pharmacists on pill splitting.
 - Sept. 2007:* Consumer Fact Sheet completed.

	<p>7. Evaluate the SCR 49 Medication Errors Report for implementation. <i>March 2007: Communication and Public Education Committee reviews SCR 49 report.</i> <i>April 2007: Board presentation of the SCR 49 report by former board member Sandra Bauer.</i> <i>Oct. 2007: SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.</i></p> <p>8. Develop patient-centered standardized prescription container labels by 2011 pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007). <i>Oct. 2007: Board president appoints members to subcommittee.</i> <i>Jan 2008: Board readies plans for six public hearings statewide during 2008</i> <i>April 2008: First meeting in Fremont on April 12. Approximately 40 people attend.</i></p>
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Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="354 216 1520 546"> <p>1. Publish The Script two times annually.</p> <p><i>Sept. 2006: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>Jan. 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>July 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>Jan 2008: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <li data-bbox="354 546 1520 1957"> <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>1st Qtr 06/07: Board supervising inspectors present five CE programs on pharmacy law and the Board of Pharmacy to pharmacist associations statewide.</i></p> <p><i>Sept. 2006: Supervising Inspector Ming provides information on pharmacy law to 80 pharmacists and pharmacy technicians at a San Mateo Pharmacist Association.</i></p> <p><i>Supervising Inspector Ratcliff provides information on pharmacy law to the Sacramento Valley Society of Health System Pharmacists.</i></p> <p><i>Oct. 2006: Interim Executive Officer Herold presents Legislation and Regulation update at CSHP's Annual Seminar. Board also staffs information booth for licensees.</i></p> <p><i>Nov. 2006: Board Member Goldenberg speaks at the California Association of Health Facilities Convention in Palm Springs.</i></p> <p><i>Supervising Inspector Ming provides information on pharmacy law to UCSD students.</i></p> <p><i>Jan. 2007: Supervising Inspector Ming provides information on pharmacy law to the Indian Pharmacist Association.</i></p> <p><i>Feb. 2007: Executive Officer Herold provides information about the board at the CPhA's annual meeting.</i></p> <p><i>Feb. 2007: Board Member Hiura provides information about pharmacy law to pharmacists at a Korean pharmacist association meeting.</i></p> <p><i>March 2007: Supervising Inspector Nurse presents California's Electronic Pedigree requirements to the Generic Pharmaceutical Manufacturers Association annual meeting in Phoenix.</i></p> <p><i>March 2007: Supervising Inspector Ratcliff provides information about pharmacy law and the board to 80 UCSF students.</i></p> <p><i>March 2007: Former Board Member John Jones provides a law update to Western University students.</i></p> <p><i>April 2007: Supervising inspectors and board members provide information about pharmacy law and board programs to pharmacists at Anaheim Memorial Hospital, to the Diablo Valley Pharmacists Association Meeting and the San Diego Pharmacists Association.</i></p> <p><i>May 2007: Staff and board members provide information about pharmacy law and board programs to Loma Linda and University of the Pacific School of Pharmacy graduating students, and to Sutter Hospitals' pharmacists.</i></p> <p><i>June 2007: Board member provides information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley.</i></p>

- Aug. 2007: Staff provide information about the Veterinary Food Animal Drug Retailer program to a group of food animal veterinarians.*
- Sept. 2007: Supervising Inspector Ming provides information about pharmacy law to the Indian Pharmacists Association.*
- Dec. 2007: Supervising Inspector Ratcliff provided information about pharmacy law in a CE presentation to the Sacramento Valley Society of Health-System Pharmacists.*

3. Maintain important and timely licensee information on Web site.

- 1st Qtr 06/07: 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.
Posted board and committee meeting agendas and materials.
Sent out subscriber alert notifications to the board's e-mail notification list, including two drug recalls.*
- 2nd Qtr 06/07: Unveiled new Web site 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.
Updated listing of 50 year pharmacists.
Added frequently asked questions on emerging contraception.
Updated listing of enforcement actions taken.
Reviewed and updated board member biographies.
Made corrections to the board's online lawbook.
Added all agendas, meeting packets and minutes for board and committee meetings.
Sent out nine subscriber alerts for important information added to the board's Web site.*
- 3rd Qtr 06/07: Completed updates to website to comply with SB 796.
Updated copyright year.
Updated links referring to California's and the governor's web pages.
Added information about the denial of a registration or license.
Added information about the new CPJE vendor.
Added inspector and supervising inspector exam information.
Revised information on our Contact Us page.
Updated applications on the website to include mandatory reporting information.
Updated public disclosure through Web Lookup to include discipline taken after January 2002.
Updated listing of 50-year pharmacists.
Added enforcement actions for effective dates between January 1 and March 30, 2007.
Posted board and committee meeting agendas and materials.
Sent out 19 subscriber alert notifications to the board's e-mail notification list.*

*4th Qtr 06/07: Created a page dedicated to drug alerts and recalls.
Updated exam information to reflect the new vendor.
Added the new self-assessment forms for Community and Hospital Pharmacies.
Added the self-assessment form for Wholesalers.
Updated the lawbook with an updated, book marked version for easier usability.
Updated DEA links.
Added enforcement actions for the effective dates between April 1 and June 30, 2007.
Posted board and committee meeting agendas and materials.
Sent out 20 subscriber alert notifications to the board's email notification list.*

*1st Qtr 07/08: Added information about NAPLEX being suspended.
Added the latest issue of The Script.
Added information about Heat Preparedness.
Updated fingerprint fees.
Updated regrade information.
Updated information about the release of CPJE results.
Added information about pill-splitting.
Updated information on our Contact Us page.
Sent out 8 subscriber alert notifications to the board's e-mail notification list.
Posted board and committee meeting agendas and materials.
Verified that minutes are included for each of the past meetings listed on the website.*

*2nd Qtr 07/08: Website reflecting the New State Redesign launched.
Updated applications and application information to reflect the Board's new application fees.
Updated the fee schedule page to reflect the Board's new application and renewal fees.
Updated pages which include fingerprint fees to reflect new costs.
Sent out three disaster response subscriber alerts regarding the Southern California wildfires to the board's e-mail notification list.
Updated number of current licenses by license types.
Added enforcement actions for the effective dates between October 1 and December 31, 2007.
Posted board and committee meeting agendas and materials.
Sent out nine subscriber alert notifications to the board's e-mail notification list.*

	<p><i>3rd Qtr 07/08: Created a page dedicated to E-Pedigree information and laws. Updated to the 2008 lawbook. Updated the instruction sheet on all board applications. Added a quick-hit link to access the Enforcement Actions page. Added enforcement actions for the effective dates between January 1 and March 30, 2008. Added information about pill-splitting. Posted board and committee meeting agendas and materials. Sent out 14 subscriber alert notifications to the board's email notification list.</i></p>
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Objective 4.3	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	<p>1. Participate in forums, conferences and educational fairs.</p> <p><i>Sept. 2006: Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Logi-Pharma's Annual Convention in Austin TX.</i></p> <p><i>Oct. 2006: Board hosts the three-day NABP Districts 7 & 8 Meeting. Topics include the FDA's pedigree requirements, the DEA's pseudoephedrine requirements, divergent intern requirements from state to state, and development of ethics programs for health professionals.</i></p> <p><i>Supervising Inspector Nurse provides presentations to national EPCglobal Convention (a standards setting organization) in Los Angeles on California's e-pedigree requirements for prescription drugs.</i></p> <p><i>Board staffs information booth at San Mateo Senior Fest where 600 people attend.</i></p> <p><i>Dec. 2006: Inspector Barnard and Public and Licensee Education Analyst Abbe staff information booth at the Sacramento AARP-sponsored Ask A Pharmacist event.</i></p> <p><i>Jan. 2007: Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Secure Pharma 2007, the supply chain security conference in Philadelphia.</i></p> <p><i>Feb. 2007: The board hosts an information booth for two days at CPhA's annual meeting.</i></p> <p><i>March 2007: Inspector Wong and Analyst Abbe staff information booth at the 2007 Consumer Protection Day forum in San Diego.</i></p> <p><i>April 2007: Presentation on being a pharmacist at a career day presentation in Southern California.</i></p> <p><i>May 2007: The board staffed a public information booth at the Family Safety and Health Expo at Safetyville in Sacramento, at the Sacramento Chapter of the American Diabetes Association Health Fair. Also provided information about California's electronic pedigree requirements for prescription medicine to a full session at the National Association of Boards of Pharmacy annual meeting.</i></p> <p><i>June 2007: Board Member participated in panel discussion that will be released as a web cast on prescription errors with Lyle Bootman and Michael Cohen hosted by Drug Topics.</i></p> <p><i>July 2007: Staff met with visiting dignitaries from Australia who were interested in learning about California's controlled substances requirements.</i></p> <p><i>Aug. 2007: The board staffed a public information booth at the California State Fair.</i></p> <p><i>Sept. 2007: Major presentation made on California's standards to LogiPharma in Philadelphia.</i></p> <p><i>The board staffed a public information booth at the Senior Fraud Fest event.</i></p> <p><i>The board staffed a public information booth at the Siskiyou County Fairgrounds.</i></p> <p><i>Major presentation made on California's standards at HDMA's conference in Berkeley.</i></p>

	<p><i>Oct. 2007: Executive Officer Herold and Supervising Inspector Nurse speak at EPCglobal's annual U.S. Exposition on California's pedigree requirements. Executive Officer Herold and Supervising Inspector Nurse speak about California's electronic pedigree requirements at CSHP's Seminar. President Powers speaks to the Renaissance Society about pedigree issues, purchasing drugs online and other consumer issues involving pharmacy. The board staffed a public information booth at the Annual Marin County Senior Information Fair and at the CSHP's Seminar.</i></p> <p><i>Nov. 2007: Executive Officer Herold provides information about the board's emergency response activities at CPhA's Synergy Conference. Executive Officer Herold and Supervising Inspector Nurse speak at the NACDS/HDMA conference on California's e-pedigree requirements.</i></p>
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