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

Communication and Public Education Committee Report

Shirley Wheat, Chair and Board Member
Ken Schell, President and Board Member
Ryan Brooks, Board Member

The Communication and Public Education Committee has held no meeting since the October Board Meeting. However, the board's SB 472 Medication Label Subcommittee met in an evening meeting on March 12 in Sacramento.

A. FOR INFORMATION: Report of the SB 472 Medication Label Subcommittee Held March 12, 2009

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 is also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels.

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 first special public forum was held at a community center in Fremont on April 12, 2008. Approximately 40 people attended, though most attendees were from the pharmaceutical industry.

The board has also convened special meetings of the subcommittee on November 20, 2008 at the Professionals Achieving Consumer Trust Summit in Los Angeles, on January 27, 2009 in San Diego, and in the evening of March 12 in Sacramento.

Three attendees at the initial forum were "public" participants. The vast majority of attendees at the next three meetings have not been consumers per se, but representatives of consumer groups or pharmacy stakeholders. Early on, it became apparent that the board would need to find alternative venues to increase participation from consumers.

1. FOR INFORMATION: Consumer Surveys Conducted by the Board of Pharmacy

In May 2008, board staff developed a prescription label survey for distribution at public outreach events. The survey is available in English and Spanish, and a copy is provided in **Attachment 1**.

Since late May, 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. In October 2008, pharmacist and pharmacy associations agreed to share the surveys with their members to aid the board in data collection.

The survey can be completed and submitted electronically on the board's Web site at https://app.dca.ca.gov/pharmacy/survey_sb472.asp. It is also available on the board's Web site in Spanish. In addition, AARP invited consumers to "Put in Your Two Cents on Prescription Labeling" in the AARP September 2008 newsletter.

The board has also provided consumers with one-page fact sheets entitled, "Do you understand the directions on your Rx medicine label?" The fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

A total of 646 consumers completed board surveys as of April 21, 2009, 2009. **Attachment 2** contains the results of the board's consumer surveys. 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
(324 of 541 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black
(62 of 541 responses = 11.5%)

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

- Print should be larger or darker
(177 of 583 responses = 30.4%)
- No changes should be made to label – references were made to Target, Raley's, CVS and Kaiser labels
(143 of 583 responses = 24.5%)
- Include purpose of the drug – state what condition the medication is intended to treat
(70 of 583 responses = 12.0%)

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

- Directions for use
(233 of 1,1,256 responses = 18.6%)
- Name of drug; if generic, brand name and generic
(233 of 1,256 responses = 18.6%)
- Dosage prescribed
(223 of 1,256 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
(25 of 146 responses = 17.1%)
- Include purpose of the drug – state what condition the medication is intended to treat
(19 of 146 responses = 13%)

This year, the board is sponsoring legislation to add the purpose of the drug to the label if requested by the patient. This bill is SB 470 and the author is again Senator Corbett. Having the purpose of the drug listed on the label was stated as a response to the following three questions:

What information is most important to you:
86 of 1,256 responses = 6.9 percent
or 86 of 646 individuals submitting surveys (13.3 percent)

What would you change on the label:
70 of 583 responses = 12.0 percent
or 70 of 646 individuals submitting surveys (10.8 percent)

Other suggestions for improving the label:
19 of 146 responses = 13 percent
or 19 of 646 individuals submitting surveys (2.9 percent)

2. FOR INFORMATION: Review of Results from a Joint Survey Developed by the Pharmacy Foundation of California and the Board of Pharmacy

Additionally, the board worked with the Pharmacy Foundation of California to develop a multiple choice survey of four questions that were available via a radio-sponsored survey. The goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels.

The survey was conducted via Entercom Broadcasting – and was made available during January 2009 on radio station Web sites that stream their audio. There were 1,357 responses to the following questions:

1. How often do you read the label on your prescription containers?
2. When you need to obtain information from the label, what do you have the most trouble with?
3. Which parts of the label are most important to you?
4. What would you change on the prescription label?

A full explanation of the results and basic demographics about the survey submitters is provided in **Attachment 3**.

Key results:

1. How often do you read the label on your prescription containers?
 - a. Every time I take the drug 30.9 percent
 - b. Once in a while 16.7 percent
 - c. Only the first time I take it 42.8 percent
 - d. Almost never 12.5 percent
2. When you need to obtain information from the label, what do you have the most trouble with?
 - a. Finding it 44.3 percent
 - b. Reading it –too small 37.5 percent
 - c. Reading it –style hard to read 11.3 percent
 - d. Understanding it – too technical 26.5 percent
 - e. Understanding it – wrong lang. 5.8 percent
3. Which parts of the label are most important to you?
Directions: 64.5 percent

Exp. Date: 34.6 percent
Strength: 31.2 percent
Brand name: 24.9 percent
Refill number: 21.3 percent
Generic name: 19.7 percent
Purpose: 17.2 percent
Plus other responses

4. What would you change on the prescription label to improve it?

Bigger print size for drug names & directions

Clarity in directions

Purpose placed on label

Side effects/interactions on labels versus "sticker"

"Chunking" info into identifiable sections

3. FOR INFORMATION: Presentation on the Requirements of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance

In 2003, California enacted provisions that require health care service plans to ensure access of their enrollees to language assistance services when obtaining health care services. A copy of this law is provided in **Attachment 4**.

At the committee meeting, Marty Martinez provided a presentation on the requirements of this law. Mr. Martinez will attend this Board Meeting to provide a similar presentation to the board.

4. FOR INFORMATION AND POSSIBLE ACTION: Patient-Focused Elements of Prescription Container Labels

The board is directed by SB 472 to develop patient-centered prescription labels. At the January 27, 2009 committee meeting, the committee reviewed each prescription label requirement specified in California Business and Professions Code section 4076 and selected those with the greatest importance to consumers.

The committee generated a basic list that identified three key items of most importance to a patient using a medication and the container's label:

- trade name/ generic name,
- directions
- strength

The complete assessment/list is provided in **Attachment 5**.

Concurrently, the board's executive officer has participated as a member of a National Association of Boards of Pharmacy (NABP) task force in developing model guidelines for patient-centered labels for all states. The report of this task force will be given at the NABP Annual Meeting in May 2009. However, the NABP has recently released the list of key prescription label requirements from a patient's

perspective in advance of their May meeting. This list, which is provided in a basic background article about the task force report, is provided in **Attachment 5**. Also included is the full task force report.

The key recommendations of the task force report with respect to patient-centered labels are that: (page 49):

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- patient name
- directions for use and, if included on the prescription drug order, the purpose/indication
- drug name and strength
- date by which the medication should be used

In developing California's regulation, the board will need to consider the general format of prescription container labels to maximize value to patients, and yet consider the diversity of containers in use by pharmacies. The NABP task force report on pages 4 and 5 show two sample labels that highlight essential consumer information and minimize other information. The board's staff also developed sample labels based on the elements identified as most important for consumers at the January meeting. These labels were shared at the March subcommittee meeting and are provided at the back of **Attachment 5**.

5. FOR INFORMATION: Directions for Use on Prescription Labels

The board's staff has collected information about research in standardizing directions for use on prescription labels. This will be important for securing translations of the directions into key languages used in California.

One list of standardized directions is provided in **Attachment 6**. This list was developed by researcher Michael Wolf, PhD, who is an expert in the area of label design. Dr. Wolf states that about 90 percent of all directions for use will fit into one of these statements.

Dr. Wolf has agreed to be available during this meeting via telephone to discuss research in standardizing directions for use on prescription container labels.

6. FOR INFORMATION: Meeting Summary of the Meeting of March 12, 2009

A meeting summary of the SB 472 Medication Label Subcommittee is provided in **Attachment 7**.

Information on the Communication and Public Education Committee's Activities

B. FOR INFORMATION: Update on The Script

The February 2009 issue of *The Script* was actually distributed in early April.

Work is now centered on the July issue. The issue will focus issues involving pharmacy law and emerging new federal polices for pharmacies. There will also be an article on the Model Guidelines of the California Integrated Waste Management Board on drug-take back programs.

C. FOR INFORMATION: Update on Public Outreach Activities

Public and licensee outreach activities performed during the third quarter of Fiscal Year 08/09 include:

- January 5, 2009: Board President Schell provided a presentation to UCSD School of Pharmacy on careers paths in pharmacy.
- January 22, 2009: Board President Schell provided a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy.
- January 23, 2009: EO Herold provided an update on board activities to the California Society of Health-Systems Pharmacists Board of Directors.
- January 27, 2009: Board President Schell provided a presentation to undergraduate students of UCSD on career paths in pharmacy.
- February 5, 2009: Supervising Inspector Ratcliff provided a presentation to the South Bay Pharmacists Association on "Surviving and Inspection."
- February 7, 2009: Board President Schell provided a presentation at the California Science Museum.
- February 20, 2009: EO Herold made a presentation at the Pharmacy Foundation of California's Award Ceremony honoring a patient education advocate.
- February 21, 2009: EO Herold and President Schell presented a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting.
- February 21, 2009: EO Herold served as one of three judged for patient education videos produced by students as part of the CPhA's annual meeting. The winning videos will be promoted by the board.
- February 20 – 21, 2009: SI Ratcliff and AEO Sodergren staffed a booth at the CPhA's annual meeting answering pharmacy law and licensing questions.
- February 22, 2009: EO Herold and President Schell discussed the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting.
- February 24, 2009: EO Herold made a presentation to UCSF and UCSD students in a first year pharmacy school law class.
- February 25, 2009: President Schell made a presentation to students at the USC School of Pharmacy.

- March 14, 2009 - President Schell spoke at an Eagle Scout ceremony in Sacramento.
- March 19, 2009 - SI Ratcliff did a CE presentation on board inspections to 80 pharmacists at a Vietnamese Pharmacist Association.

D. FOR INFORMATION: Third Quarterly Report on the Communication and Public Education Committee Goals for 2008/09

Attachment 8 contains the third quarter's report of the Communication and Public Education Committee Goals for 2008/09.

Attachment 1

SB 472 Consumer Surveys



CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.



Examples of warning labels



Examples of different container shapes and sizes requiring different types of labels

What information on the label is most important to you?

Do you understand the directions?

What would you change on the label?

What would make the label easier to read?

Other suggestions:

City: _____ **Date:** _____



Printed information in different colors



Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834



CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Gracias por su reacción. Vuelva por favor su forma completada a:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

Attachment 2

Results of SB 472 Consumer Surveys

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

RESULTS: A total of 646 surveys were received as of April 21, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

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

Directions for use (233 of 1,256 responses = 18.6%)

Name of drug; if generic, state generic name AND brand name (233 of 1,256 responses = 18.6%)

Dosage prescribed (223 of 1,256 responses = 17.8%)

Side effects/warnings/interactions/contraindications (127 of 1,256 responses = 10.1%)

Purpose of drug – state what condition medication is prescribed to treat (86 of 1,256 responses = 6.9%)

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

Print should be larger or darker (177 of 583 responses = 30.4%)

Nothing needs to be changed on the label (143 of 583 responses = 24.5%)

Include purpose of drug – state what condition medication is intended to treat (70 of 583 responses = 12%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (324 of 541 responses = 60%)

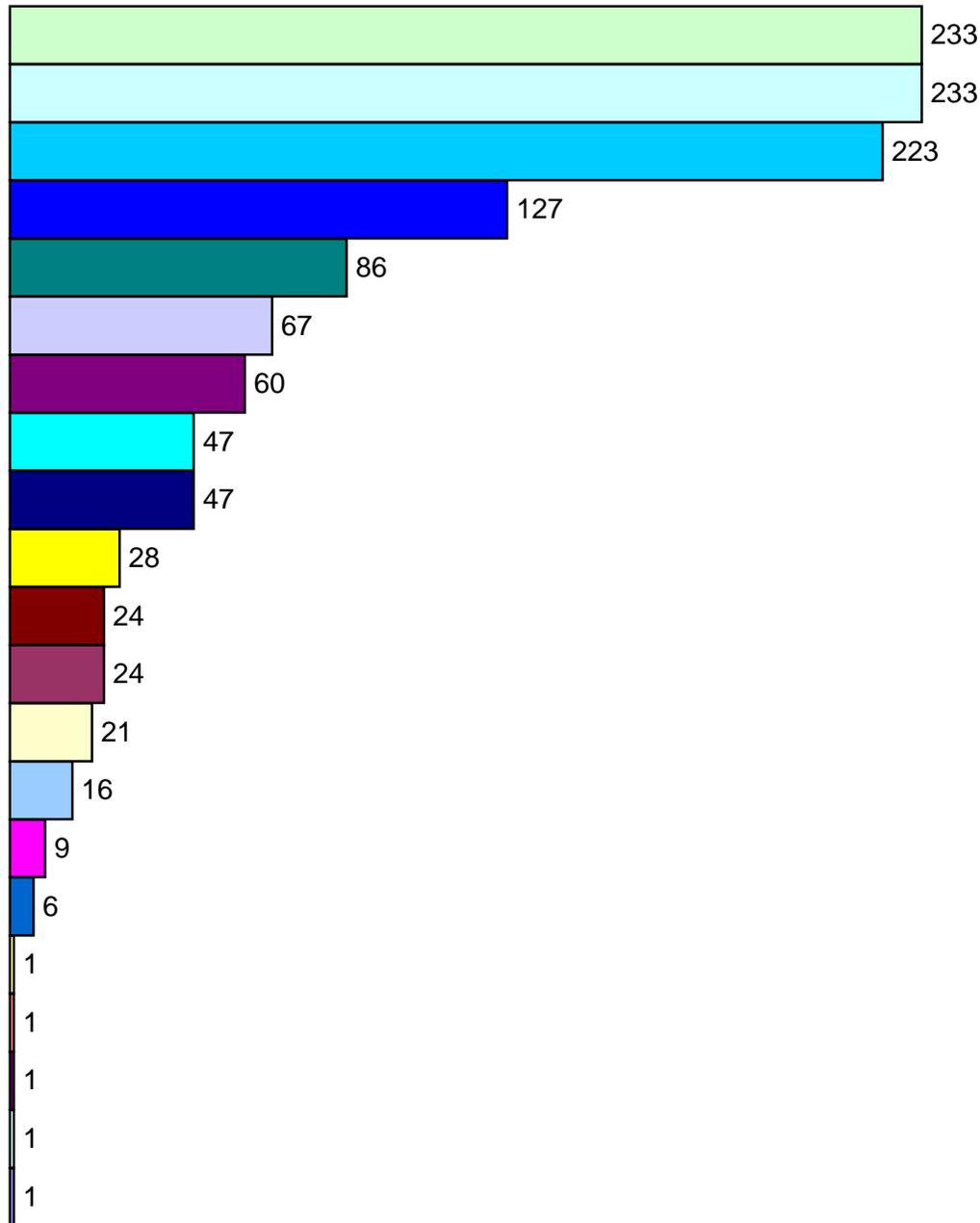
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (25 of 146 responses = 17.1%)

Include purpose of drug - state what condition medication is intended to treat (19 of 146 responses = 13%)

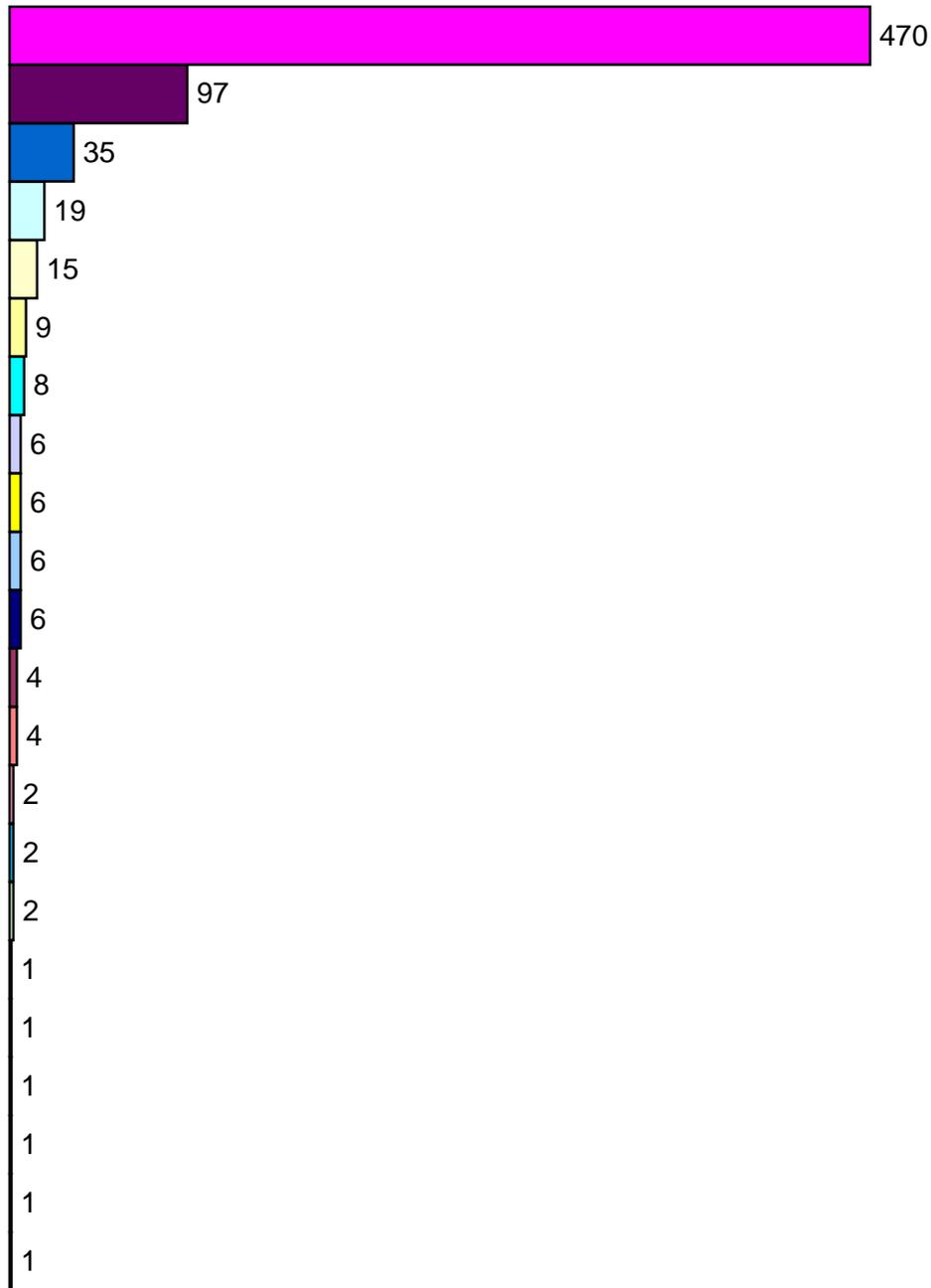
CONCLUSIONS: Most consumers participating in this survey strongly supported larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. Color printing and highlighting on labels was suggested to bring attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

QUESTION #1: What information on the label is most important to you?
646 surveys returned (1,256 responses to Question #1) as of April 21, 2009



- Directions for use
- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Phone numbers (NOT printed in close proximity to each other)
- Prescribing doctor's name and contact phone number
- Description of pill (shape/color) or illustration
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- With a large family, keep all prescriptions in the same place
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

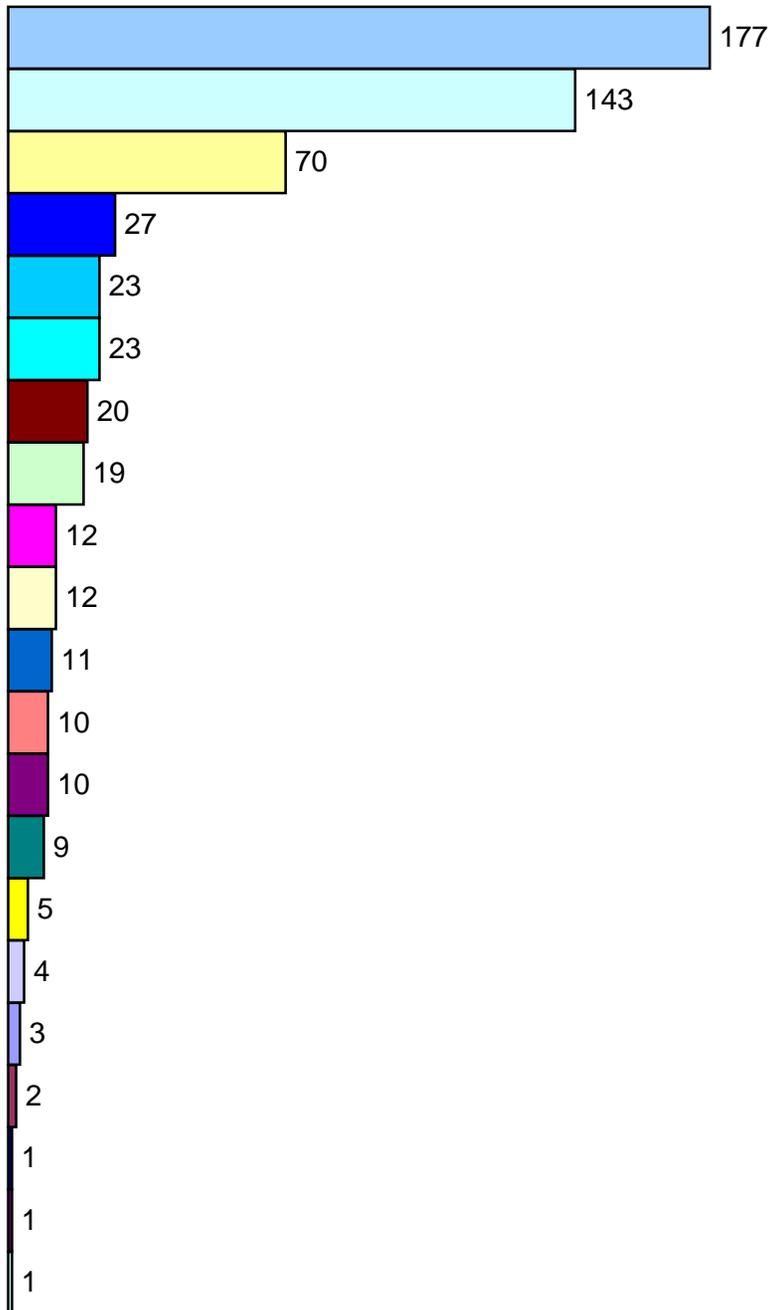
QUESTION #2: Do you understand the directions on the prescription label?
646 surveys returned (697 responses to Question #2) as of April 21, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- Abbreviations should be eliminated
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- I do not understand directions that only say "Take as directed"
- Bullets/spacing on label would be helpful; directions should be typed
- No long paragraphs; use fonts w/o serifs (such as Arial or Tahoma)
- Label from Kaiser understandable, label from Rite Aid not as clear
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

646 surveys returned (583 responses to Question #3) as of April 21, 2009



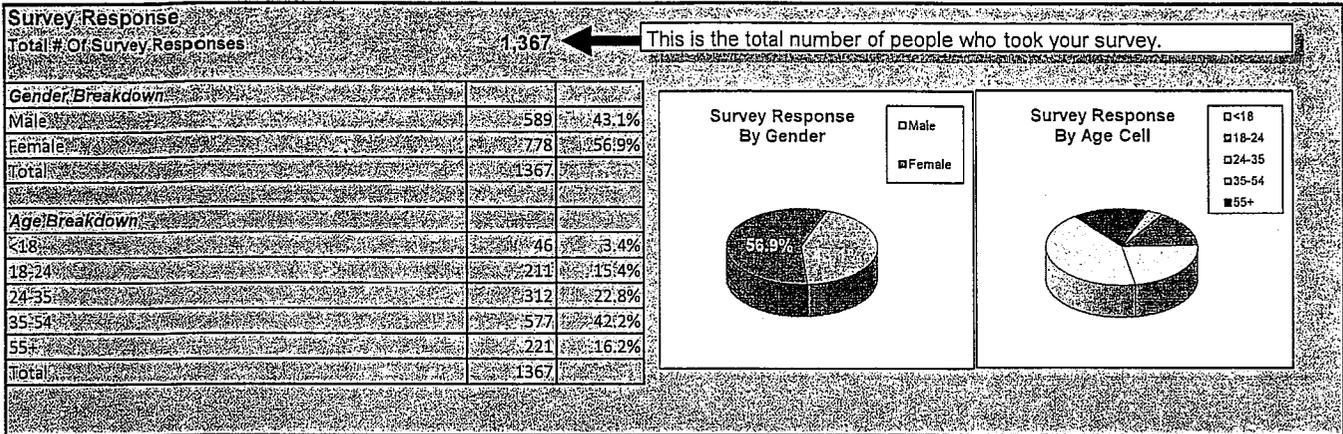
- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Standardize location of info; uniform label; show information in same order
- Include direct phone numbers for easier communication with doctor/pharmacy
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Print in patient's primary language; bilingual wording
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- Label should (1 response) should not (1 response) refer patient to websites
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times

Attachment 3

*Radio Survey Results
Conducted January 2009*

Advertiser CA Pharmacy
Date 1/23/2009

Please Note: Demographic response shown below represents members of the station's database and does not always correlate directly to the stations larger listening audience. In most cases you will see a 10 to 15% positive female bias in the database when compared to the station's larger listening audience



*Tell us about your HEALTH!

1368 Respondents

589 Males

778 Females

How often do you read the label on your prescription containers?

Total	Percent	M	F	Answer
424	30.9%	28.2%	33%	Every time I take the drug
228	16.7%	18.8%	15%	Once in a while
586	42.8%	40.2%	44.9%	Only before I take it for the first time
171	12.5%	15.1%	10.5%	Almost never

When you need to obtain information from the prescription container label, do you have the most trouble: (Select up to two answers)

Total	Percent	M	F	Answer
606	44.3%	46.2%	42.9%	Finding it on the label
513	37.5%	37%	37.9%	Reading it because the print is too small
155	11.3%	12.4%	10.5%	Reading it because the print style is hard to read
363	26.5%	23.1%	29%	Understanding it because the words is too technical
80	5.8%	6.8%	5.1%	Understanding it because it is not in your native language

Which of the following pieces of information on a prescription container's label are most important to you? (Select up to three)

Total	Percent	M	F	Answer
340	24.9%	27%	23.3%	The brand name of the drug
270	19.7%	20.7%	19%	The generic (chemical) name of the drug
883	64.5%	59.6%	68.4%	The directions for taking the drug
427	31.2%	29%	32.9%	The strength of the drug
175	12.8%	11.7%	13.6%	The number of pills in the container
474	34.6%	33.6%	35.3%	The expiration date for the drug
235	17.2%	14.3%	19.4%	The condition for which the drug was prescribed
114	8.3%	9.2%	7.7%	The description of the drug (color, shape, identifying marks, etc)
211	15.4%	13.8%	16.7%	The name of the patient
106	7.7%	8.8%	6.9%	The name of the prescriber (doctor, nurse practitioner, dentist, etc)
97	7%	6.1%	7.7%	The date the pharmacy provided the drug
83	6%	6.6%	5.5%	The name of the pharmacy
154	11.2%	11.7%	10.8%	The phone number of the pharmacy
292	21.3%	19.9%	22.4%	The prescription refill number

What would you change on a prescription container's label to improve it?

better printed labels! because sometimes, half of the label is missing!
bigger font, maybe a web address that you can go to about the drug
Bigger Font.
Bigger fonts or highlighted directions for the use of the drug
bigger print
bigger print
bigger print
bigger print
Brand name of the generic so we know what it is!
clarity
Color coding information
Compile information in sections rather than dispersing all over the label.
easier to read
font
font
have it on a printed handout instead of the bottle
Have precautions printed on label instead of stuck on with stickers.
Have the option to use different colored labels, which would help those who have many meds for different family members in one household.
Highlight the important info
I take prescription pills all the time and I think they are just fine.
I usually don't any problems with the labels. I think they are fine.
I would change the way things are worded so that it is more understandable.
I would make the print a little bigger.
i would put what condition it was for on the bottle. it would make things easier for people that have to take many pills that are not good at memorizing pill "types" or names
I'm pretty much ok with labels the way they are
LABEL SIZE
Labled the bottle better
large letters
larger font's
larger print
larger print

larger print
larger print
larger print and easy directions to follow
Less drug facts, bigger directions
lots
Make info more apparent.
make it peaple friendly so that u know what is being takin and not what ur doc jus told u
make the label bigger so more information can be written on it.
Make the label more legible. not everyone has perfect vision
make the print bigger
Make the print larger and in lamens terms.
make the words bigger☐
Making the directions for taking more clear. 2 times a day, not 2X daily
mmmm
more explanations
More information on the drug itself rather than on a handout given when the prescription is picked up at the pharmacy.
more legible☐
most common side effects
my name lol
n/a
na
no
no
no
no
not sure
Not Sure
NOT SURE YET....
nothin
nothing

nothing
Nothing at this time
plenty
print size
Printed in words i can understand
simplify
The description of the drug
the font size
The multiple names.
The size of print on label
The size of the font.
The writing it's very small.
what conditions the meds are used for
what other drugs should not be taken
What the drug is actually for.
where do I start?

The logo for the Pharmacy Foundation of California features a thick, black, curved line that starts on the left, arches over the text, and ends on the right. The text "Pharmacy Foundation" is in a large, bold, sans-serif font, and "of California" is in a smaller, bold, sans-serif font below it.

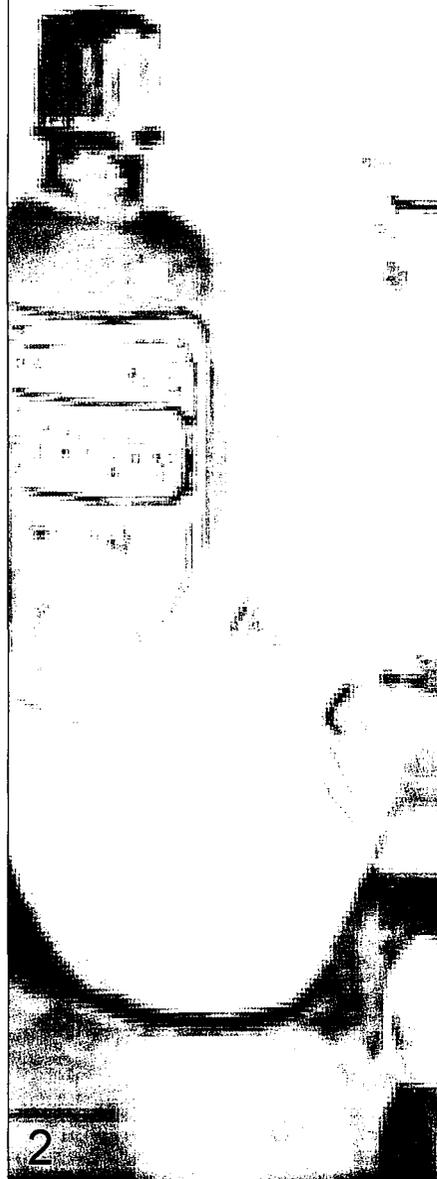
Pharmacy Foundation
of California

Consumer Rx Label Survey

Michael J. Negrete, PharmD

CEO, Pharmacy Foundation of California

www.PharmacyFoundation.org



Survey Objective

- To identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels

Methodology

- Online survey distributed by Entercom broadcasting
 - One of the five largest radio broadcasting companies in the United States
 - Nationwide portfolio of 110 stations in 23 markets, including San Francisco, Boston, Seattle, Denver, Portland, Sacramento and Kansas City
- Survey made available during January '09 on radio station websites that stream their audio

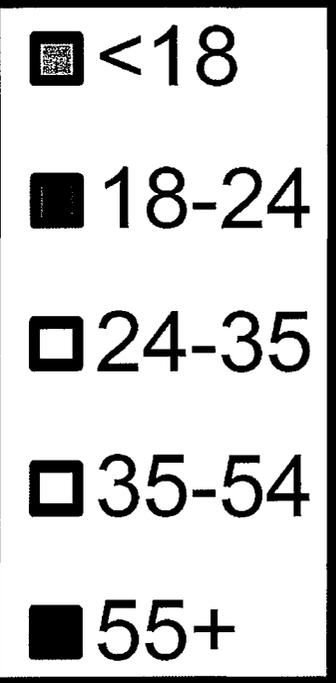
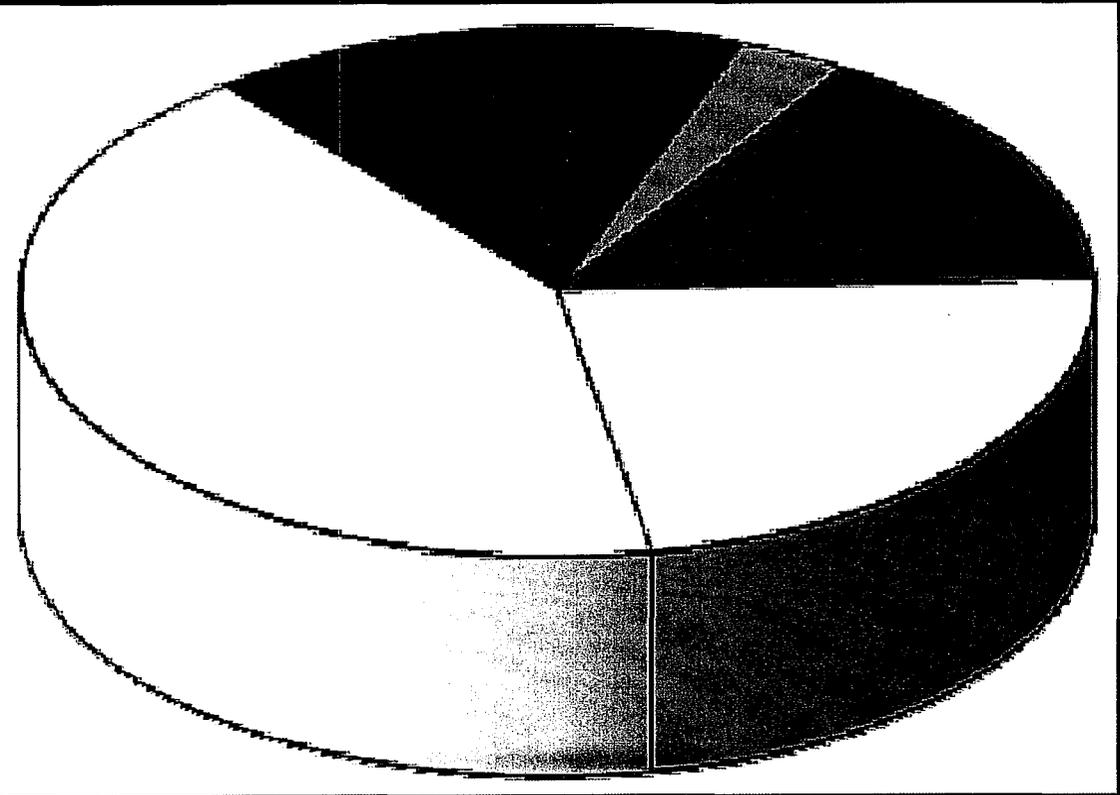
Methodology

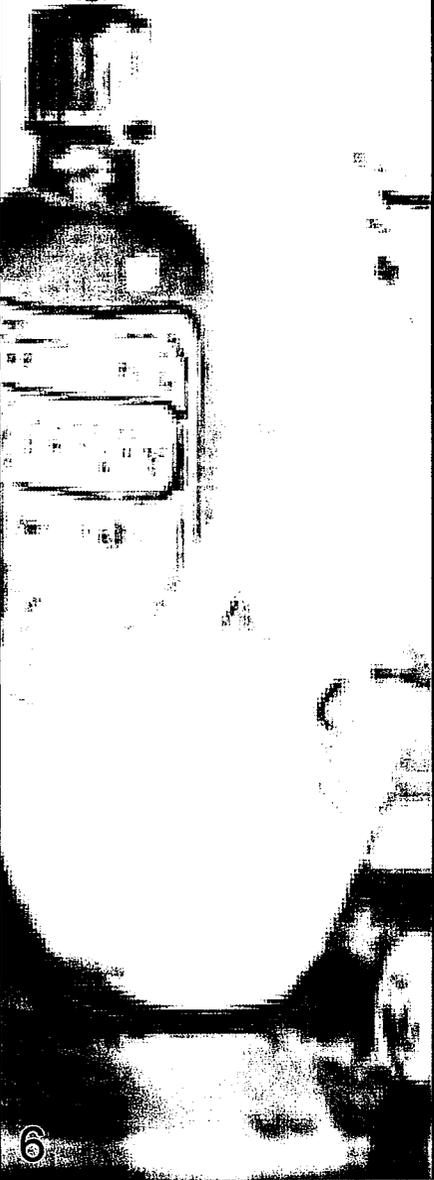
- Survey consisted of four questions:
 - How often do you read the label on your prescription containers?
 - When you need to obtain information from the label, what do you have the most trouble with?
 - Which parts of the label are most important to you?
 - What would you change on the prescription label to improve it?



Results

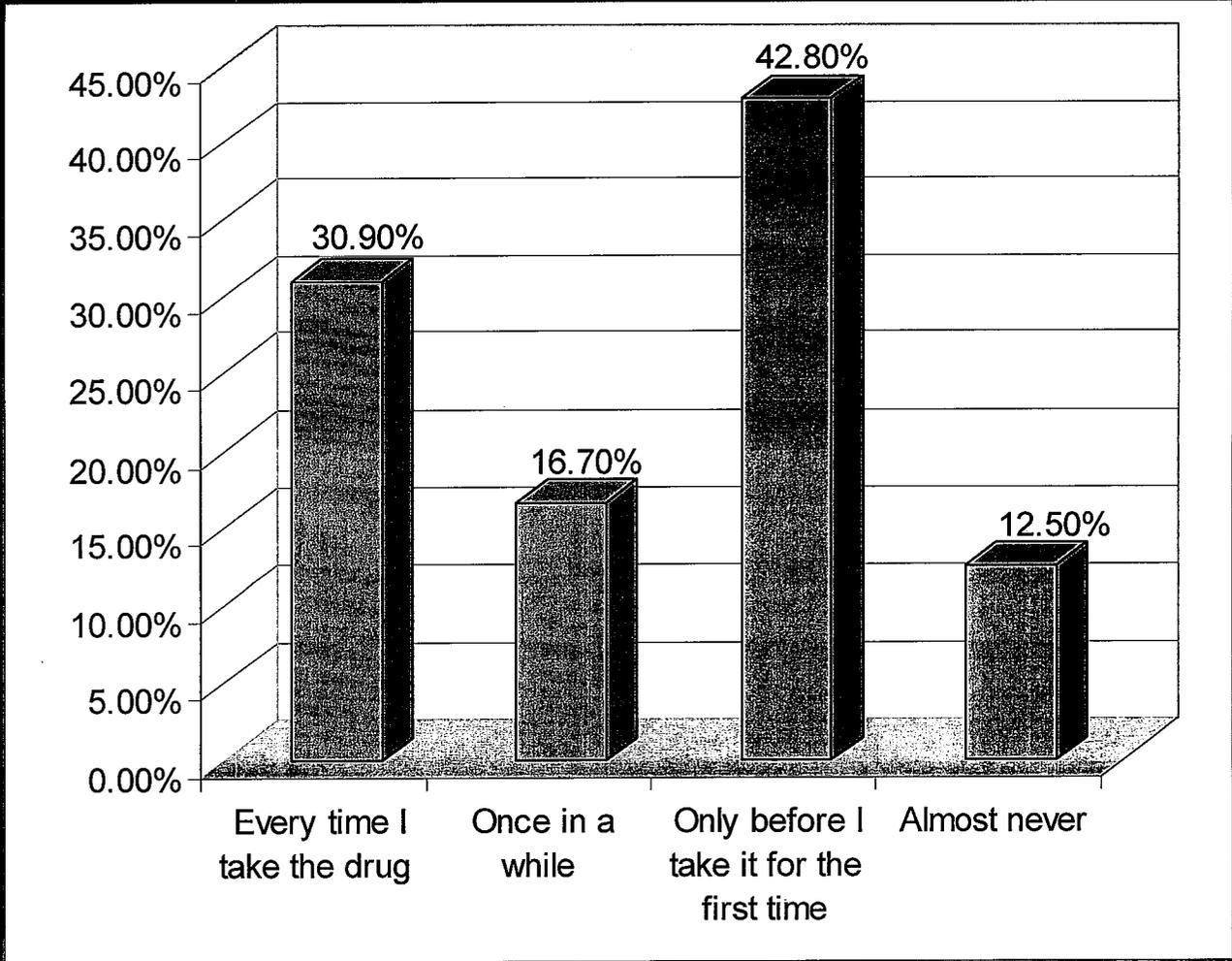
- 1,367 total responses
 - 59.6% female, 43.1% male
 - Age:





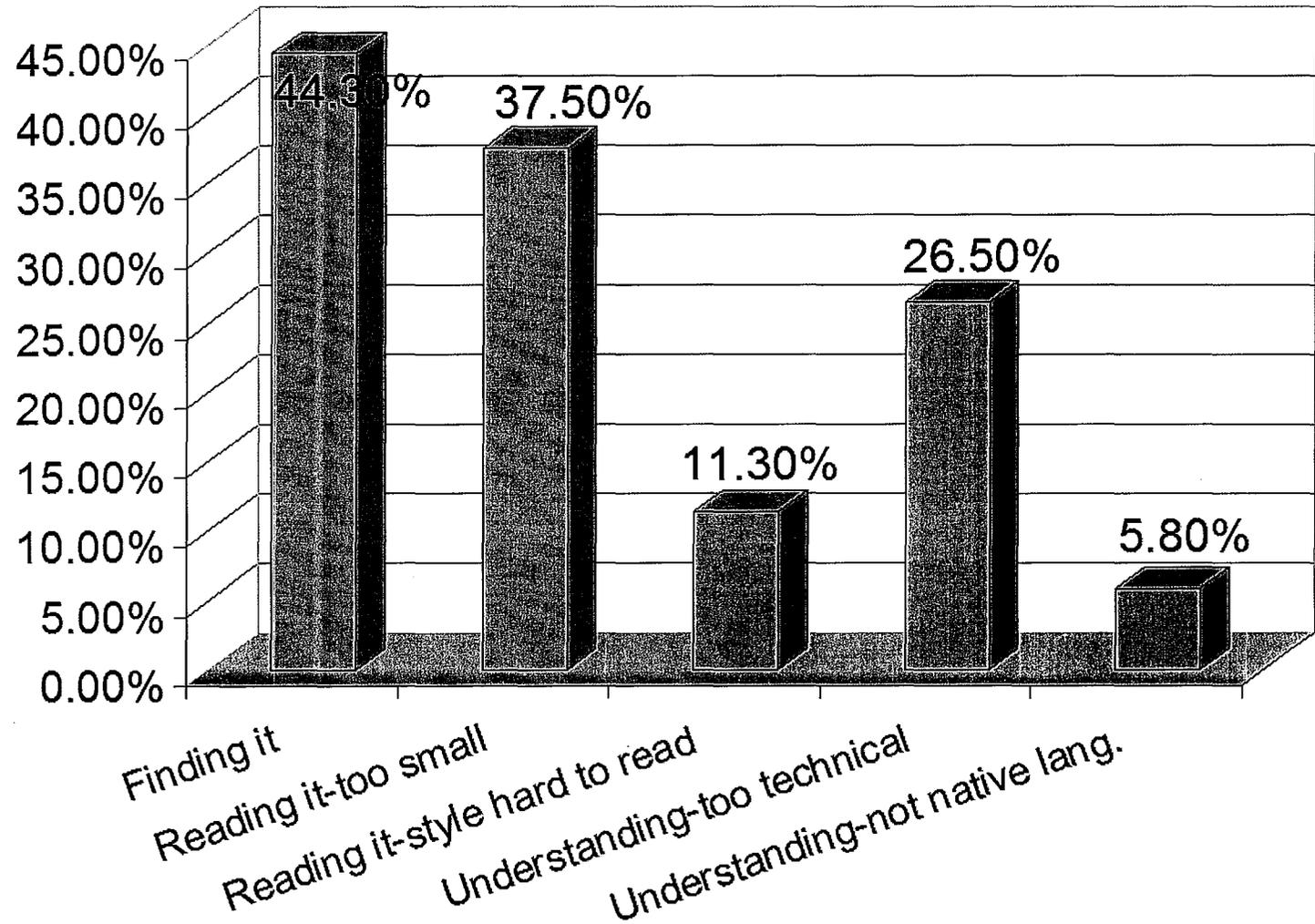
Results

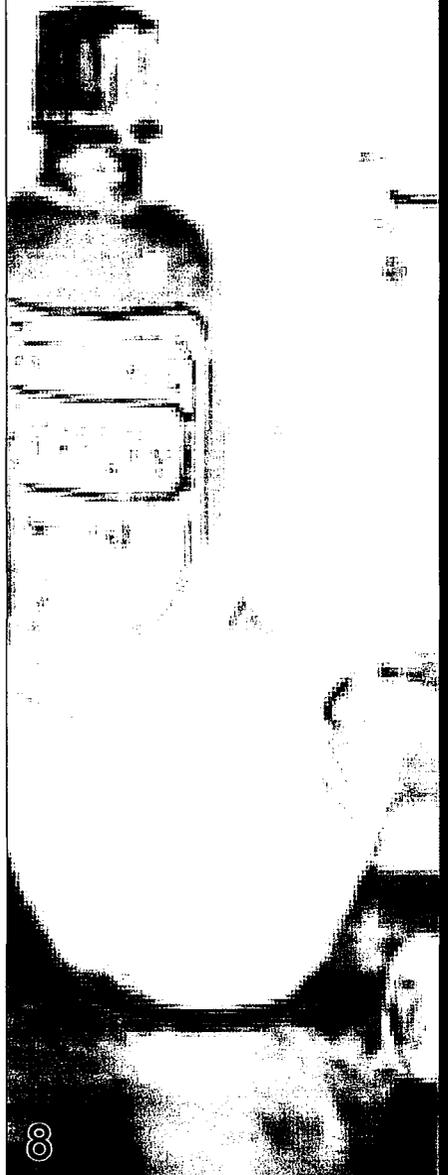
- How often do you read the label on your prescription containers?



Results

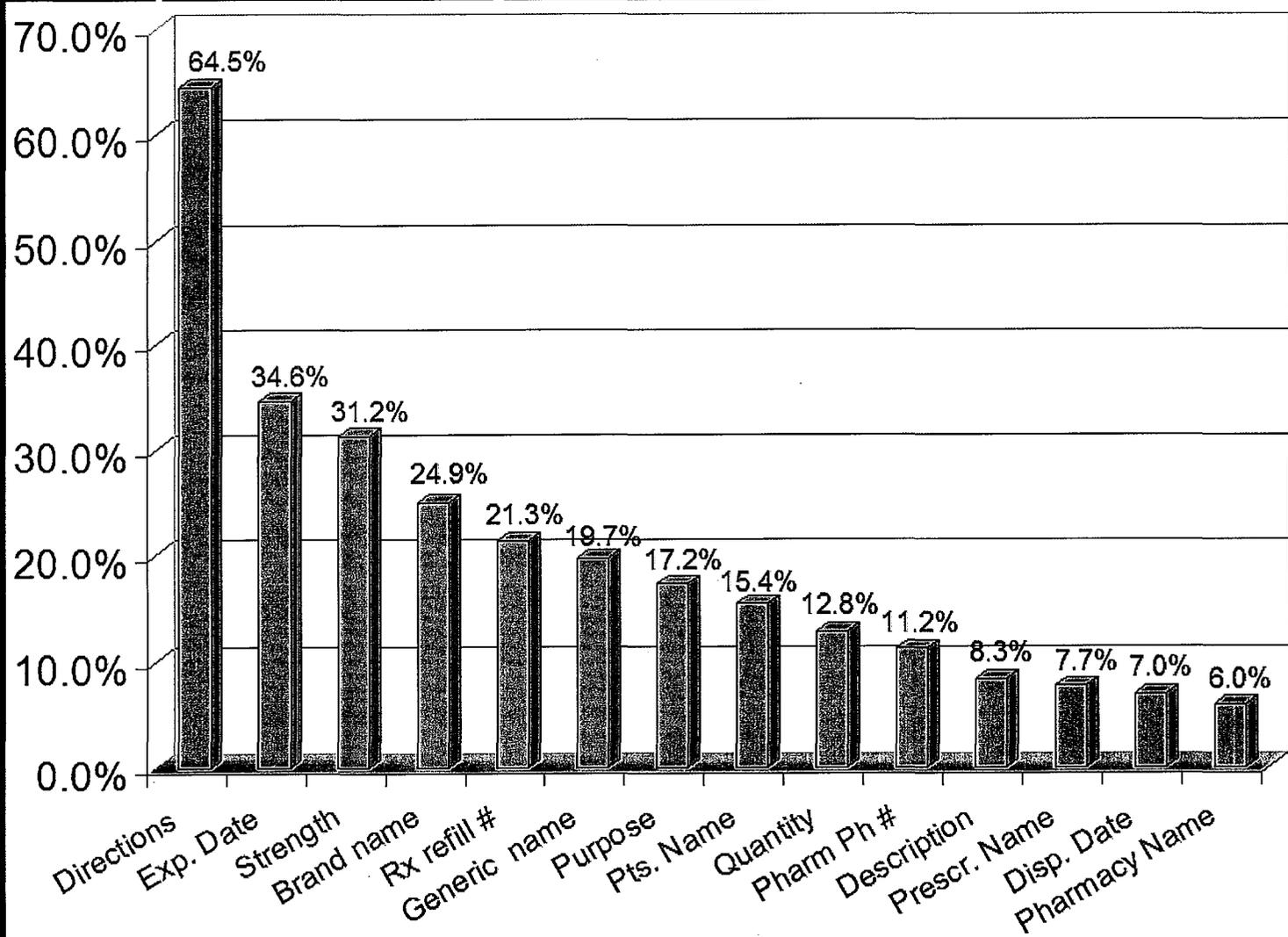
- When you need to obtain information from the label, do you have the most trouble:

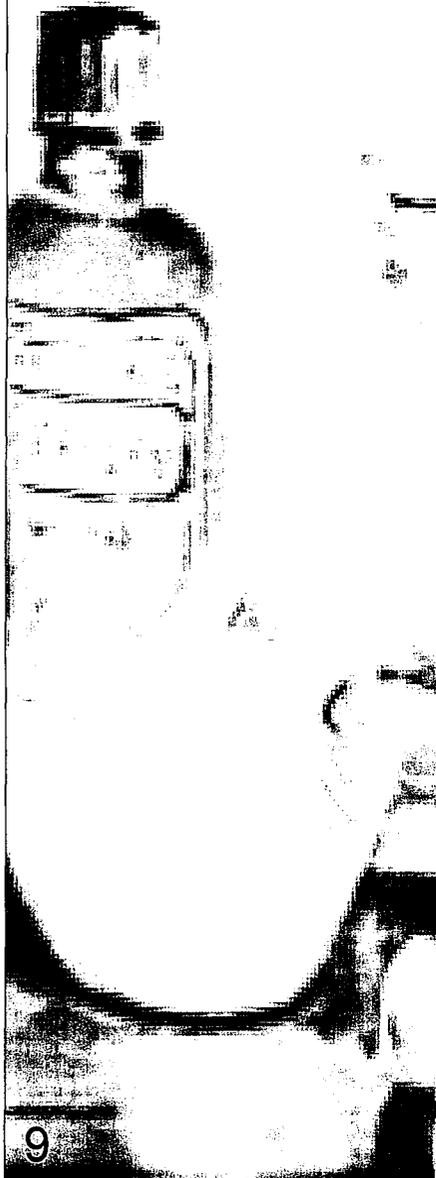




Results

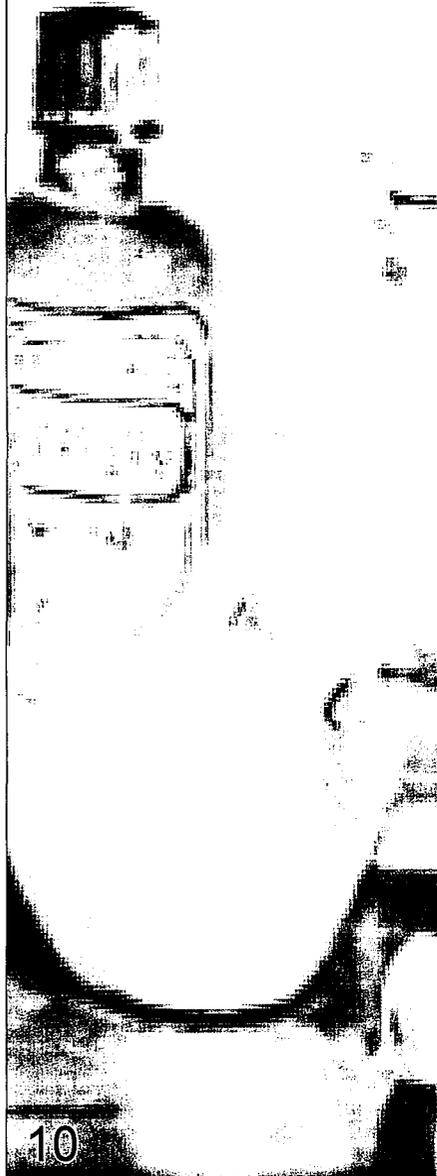
- Which parts of the label are most important to you?





Discussion

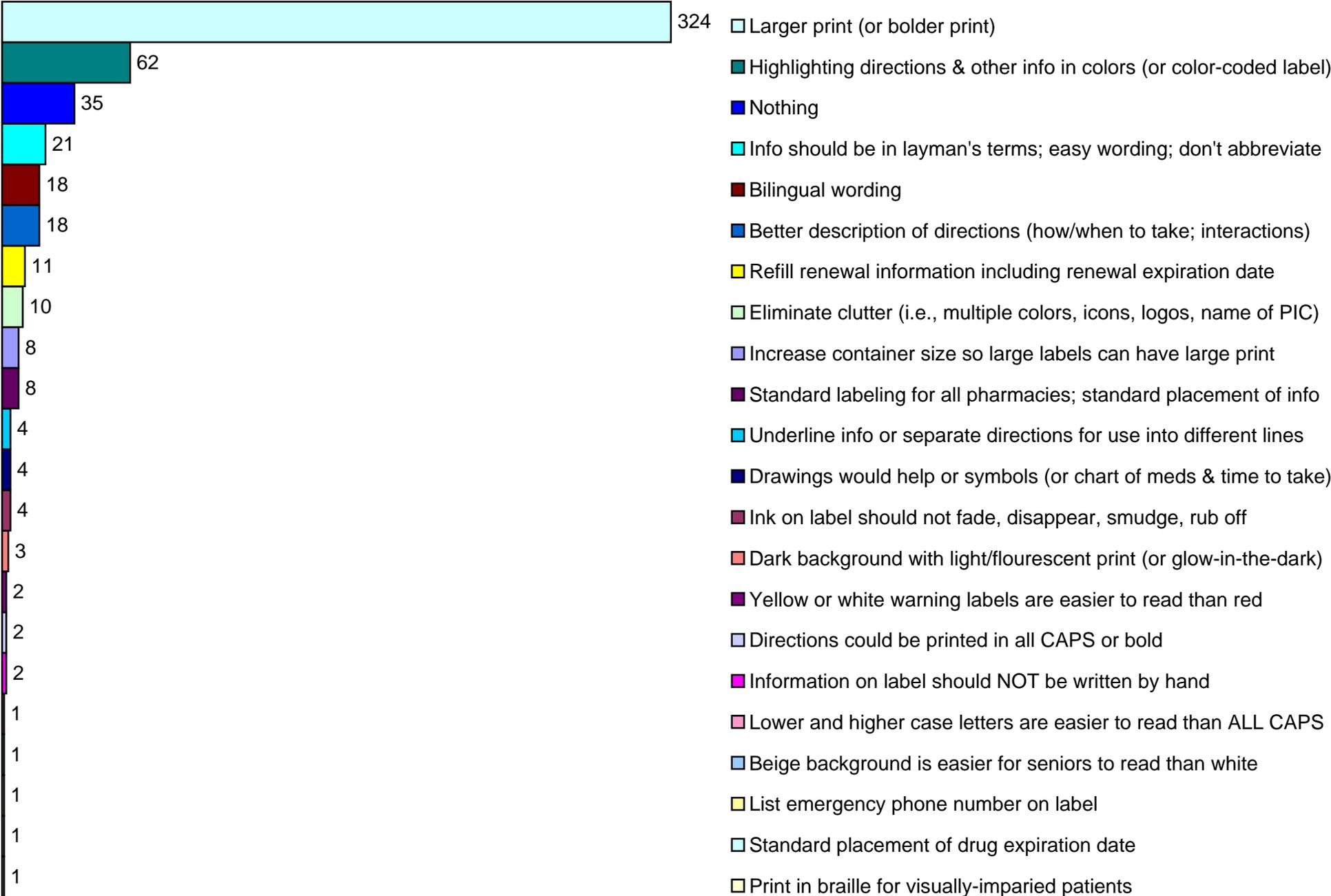
- What would you change on the prescription label to improve it?
 - Bigger print/size
 - Drug name(s)
 - Directions
 - Clarity
 - Purpose
 - Side effects/interactions
 - On label vs. stickers
 - “Chunking” – Info should be laid out in identifiable sections



Discussion

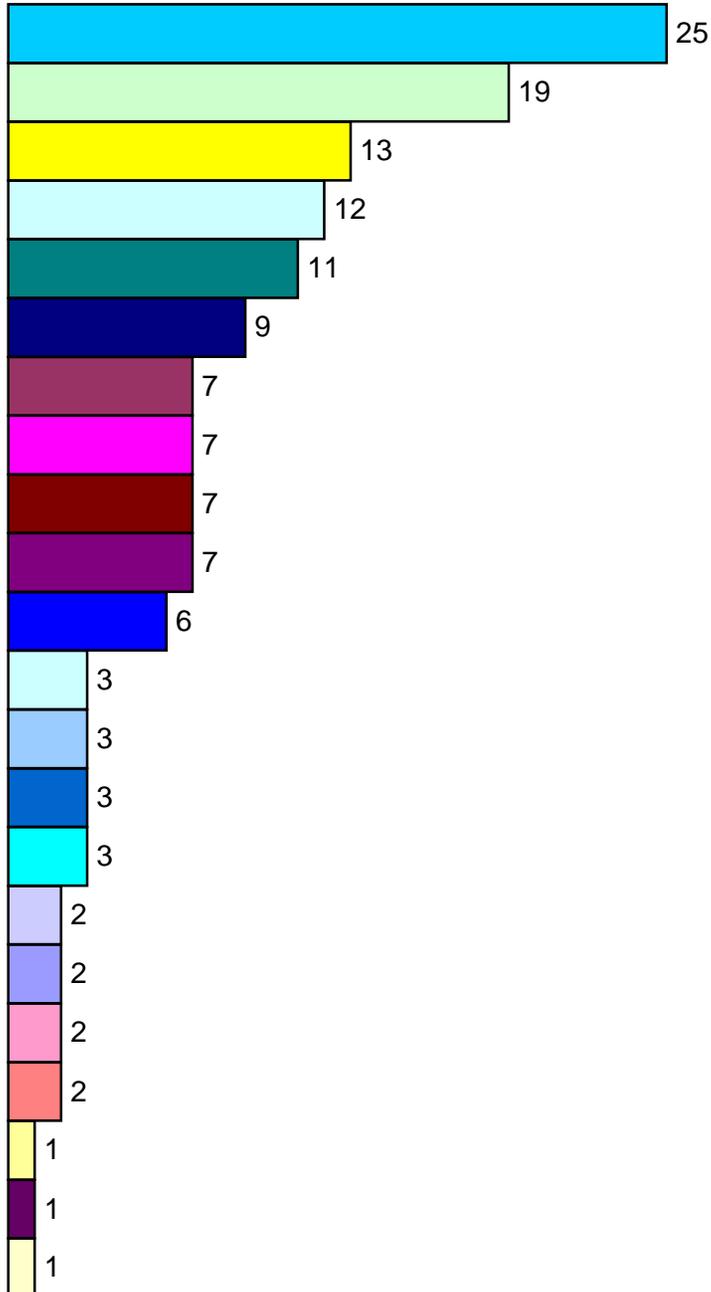
- Limitations
 - Representation of the sample
 - Reliability of self-reported information
- Need to encourage more frequent reading of the Rx label
- Label is crowded which requires things to be small & makes info difficult to find
- “Directions for use” is seen as particularly important

QUESTION #4: What would make the prescription label easier to read?
646 surveys returned (541 responses to Question #4) as of April 21, 2009



QUESTION #5: Other suggestions?

646 surveys returned (146 responses to Question #5) as of April 21, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Different colored bottles or caps would help identify medications
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via pharmacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do when dose missed; pharmacist (foreign grads) must speak clearly
- Labels should be waterproof; labels should include barcodes to confirm correct drug
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

Attachment 4

SB 853, Escutia, Chapter 713,
Statutes of 2003
Health Care Language Assistance

Senate Bill No. 853

CHAPTER 713

An act to amend Section 1367 of, and to add Sections 1367.04 and 1367.07 to, the Health and Safety Code, and to add Sections 10133.8 and 10133.9 to the Insurance Code, relating to health care coverage.

[Approved by Governor October 8, 2003. Filed with
Secretary of State October 9, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 853, Escutia. Health care language assistance.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. A willful violation of the act is a crime. Existing law provides for the regulation of health insurers by the Department of Insurance.

This bill would require the Department of Managed Health Care to adopt, not later than January 1, 2006, regulations establishing standards and requirements to provide health care service plan enrollees with access to language assistance in obtaining health care services. Pursuant to the bill, the regulations would require health care service plans and specialized health care service plans to implement programs to assess enrollee needs, and to provide translation and interpretation for medical services and translation of vital documents to enrollees, and to report to the department regarding internal policies and procedures related to cultural appropriateness. The bill would require the regulations to provide that a health care service plan is in compliance with the requirements if it is required to meet and meets the same or similar standards, as imposed by the Medi-Cal program. The bill would require the department to consider specified factors and to seek public input. The department would be required to regularly review information regarding compliance and make recommendations for changes and to report certain information biennially to the Legislature and specified advisory committees.

This bill would impose similar requirements on the Insurance Commissioner and health insurers that contract with health care providers for alternative rates of payment to ensure that insureds have access to translated materials and language assistance in obtaining health care services.

This bill would require a contract between a health care service plan and a health care service provider to ensure compliance with the standards adopted by the board.

By placing additional requirements on health care service plans, the violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1367 of the Health and Safety Code is amended to read:

1367. A health care service plan and, if applicable, a specialized health care service plan shall meet the following requirements:

(a) Facilities located in this state including, but not limited to, clinics, hospitals, and skilled nursing facilities to be utilized by the plan shall be licensed by the State Department of Health Services, where licensure is required by law. Facilities not located in this state shall conform to all licensing and other requirements of the jurisdiction in which they are located.

(b) Personnel employed by or under contract to the plan shall be licensed or certified by their respective board or agency, where licensure or certification is required by law.

(c) Equipment required to be licensed or registered by law shall be so licensed or registered, and the operating personnel for that equipment shall be licensed or certified as required by law.

(d) The plan shall furnish services in a manner providing continuity of care and ready referral of patients to other providers at times as may be appropriate consistent with good professional practice.

(e) (1) All services shall be readily available at reasonable times to each enrollee consistent with good professional practice. To the extent feasible, the plan shall make all services readily accessible to all enrollees consistent with Section 1367.03.

(2) To the extent that telemedicine services are appropriately provided through telemedicine, as defined in subdivision (a) of Section 2290.5 of the Business and Professions Code, these services shall be considered in determining compliance with Section 1300.67.2 of Title 28 of the California Code of Regulations.

(3) The plan shall make all services accessible and appropriate consistent with Section 1367.04.

(f) The plan shall employ and utilize allied health manpower for the furnishing of services to the extent permitted by law and consistent with good medical practice.

(g) The plan shall have the organizational and administrative capacity to provide services to subscribers and enrollees. The plan shall be able to demonstrate to the department that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management.

(h) (1) Contracts with subscribers and enrollees, including group contracts, and contracts with providers, and other persons furnishing services, equipment, or facilities to or in connection with the plan, shall be fair, reasonable, and consistent with the objectives of this chapter. All contracts with providers shall contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism under which providers may submit disputes to the plan, and requiring the plan to inform its providers upon contracting with the plan, or upon change to these provisions, of the procedures for processing and resolving disputes, including the location and telephone number where information regarding disputes may be submitted.

(2) A health care service plan shall ensure that a dispute resolution mechanism is accessible to noncontracting providers for the purpose of resolving billing and claims disputes.

(3) On and after January 1, 2002, a health care service plan shall annually submit a report to the department regarding its dispute resolution mechanism. The report shall include information on the number of providers who utilized the dispute resolution mechanism and a summary of the disposition of those disputes.

(i) A health care service plan contract shall provide to subscribers and enrollees all of the basic health care services included in subdivision (b) of Section 1345, except that the director may, for good cause, by rule or order exempt a plan contract or any class of plan contracts from that requirement. The director shall by rule define the scope of each basic health care service that health care service plans are required to provide as a minimum for licensure under this chapter. Nothing in this chapter shall prohibit a health care service plan from charging subscribers or enrollees a copayment or a deductible for a basic health care service or from setting forth, by contract, limitations on maximum coverage of basic health care services, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(j) A health care service plan shall not require registration under the Controlled Substances Act of 1970 (21 U.S.C. Sec. 801 et seq.) as a condition for participation by an optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 of the Business and Professions Code.

Nothing in this section shall be construed to permit the director to establish the rates charged subscribers and enrollees for contractual health care services.

The director's enforcement of Article 3.1 (commencing with Section 1357) shall not be deemed to establish the rates charged subscribers and enrollees for contractual health care services.

The obligation of the plan to comply with this section shall not be waived when the plan delegates any services that it is required to perform to its medical groups, independent practice associations, or other contracting entities.

SEC. 2. Section 1367.04 is added to the Health and Safety Code, to read:

1367.04. (a) Not later than January 1, 2006, the department shall develop and adopt regulations establishing standards and requirements to provide health care service plan enrollees with appropriate access to language assistance in obtaining health care services.

(b) In developing the regulations, the department shall require every health care service plan and specialized health care service plan to assess the linguistic needs of the enrollee population, excluding Medi-Cal enrollees, and to provide for translation and interpretation for medical services, as indicated. A health care service plan that participates in the Healthy Families Program may assess the Healthy Families Program enrollee population separately from the remainder of its enrollee population for purposes of subparagraph (A) of paragraph (1). A health care service plan that chooses to separate its Healthy Families Program enrollment from the remainder of its enrollee population shall treat the Healthy Families Program population separately for purposes of determining whether subparagraph (A) of paragraph (1) is applicable, and shall also treat the Healthy Families Program population separately for purposes of applying the percentage and numerical thresholds in subparagraph (A) of paragraph (1). The regulations shall include the following:

(1) Requirements for the translation of vital documents that include the following:

(A) A requirement that all vital documents, as defined pursuant to subparagraph (B), be translated into an indicated language, as follows:

(i) A health care service plan with an enrollment of 1,000,000 or more shall translate vital documents into the top two languages other than

English as determined by the needs assessment as required by this subdivision and any additional languages when 0.75 percent or 15,000 of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(ii) A health care service plan with an enrollment of 300,000 or more but less than 1,000,000 shall translate vital documents into the top one language other than English as determined by the needs assessment as required by this subdivision and any additional languages when 1 percent or 6,000 of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(iii) A health care service plan with an enrollment of less than 300,000 shall translate vital documents into a language other than English when 3,000 or more or five percent of the enrollee population, whichever number is less, excluding Medi-Cal enrollment and treating Healthy Families Program enrollment separately indicates in the needs assessment as required by this subdivision a preference for written materials in that language.

(B) Specification of vital documents produced by the plan that are required to be translated. The specification of vital documents shall not exceed that of the Department of Health and Human Services (FHHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)), but shall include all of the following:

(i) Applications.

(ii) Consent forms.

(iii) Letters containing important information regarding eligibility and participation criteria.

(iv) Notices pertaining to the denial, reduction, modification, or termination of services and benefits, and the right to file a grievance or appeal.

(v) Notices advising limited-English-proficient persons of the availability of free language assistance and other outreach materials that are provided to enrollees.

(vi) Translated documents shall not include a health care service plan's explanation of benefits or similar claim processing information that is sent to enrollees, unless the document requires a response by the enrollee.

(C) (i) For those documents described in subparagraph (B) that are not standardized but contain enrollee specific information, health care service plans shall not be required to translate the documents into the

threshold languages identified by the needs assessment as required by this subdivision, but rather shall include with the documents a written notice of the availability of interpretation services in the threshold languages identified by the needs assessment as required by this subdivision.

(ii) Upon request, the enrollee shall receive a written translation of the documents described in clause (i). The health care service plan shall have up to, but not to exceed, 21 days to comply with the enrollee's request for a written translation. If an enrollee requests a translated document, all timeframes and deadline requirements related to the document that apply to the health care service plan and enrollees under the provisions of this chapter and under any regulations adopted pursuant to this chapter shall begin to run upon the health care service plan's issuance of the translated document.

(iii) For grievances that require expedited plan review and response in accordance with subdivision (b) of Section 1368.01, the health care service plan may satisfy this requirement by providing notice of the availability and access to oral interpretation services.

(D) A requirement that health care service plans advise limited-English-proficient enrollees of the availability of interpreter services.

(2) Standards to ensure the quality and accuracy of the written translations and that a translated document meets the same standards required for the English language version of the document. The English language documents shall determine the rights and obligations of the parties, and the translated documents shall be admissible in evidence only if there is a dispute regarding a substantial difference in the material terms and conditions of the English language document and the translated document.

(3) Requirements for surveying the language preferences and needs assessments of health care service plan enrollees within one year of the effective date of the regulations that permit health care service plans to utilize various survey methods, including, but not limited to, the use of existing enrollment and renewal processes, subscriber newsletters, or other mailings. Health care service plans shall update the needs assessment, demographic profile, and language translation requirements every three years.

(3) Requirements for individual enrollee access to interpretation services.

(4) Standards to ensure the quality and timeliness of oral interpretation services provided by health care service plans.

(c) In developing the regulations, standards, and requirements, the department shall consider the following:

(1) Publications and standards issued by federal agencies, such as the Culturally and Linguistically Appropriate Services (CLAS) in Health Care issued by the United States Department of Health and Human Services Office of Minority Health in December 2000, and the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)).

(2) Other cultural and linguistic requirements under state programs, such as Medi-Cal Managed Care Policy Letters, cultural and linguistic requirements imposed by the State Department of Health Services on health care service plans that contract to provide Medi-Cal managed care services, and cultural and linguistic requirements imposed by the Managed Risk Medical Insurance Board on health care service plans that contract to provide services in the Healthy Families Program.

(3) Standards adopted by other states pertaining to language assistance requirements for health care service plans.

(4) Standards established by California or nationally recognized accrediting, certifying, or licensing organizations and medical and health care interpreter professional associations regarding interpretation services.

(5) Publications, guidelines, reports, and recommendations issued by state agencies or advisory committees, such as the report card to the public on the comparative performance of plans and reports on cultural and linguistic services issued by the Office of Patient Advocate and the report to the Legislature from the Task Force on Culturally and Linguistically Competent Physicians and Dentists established by Section 852 of the Business and Professions Code.

(6) Examples of best practices relating to language assistance services by health care providers and health care service plans, including existing practices.

(7) Information gathered from complaints to the HMO Helpline and consumer assistance centers regarding language assistance services.

(8) The cost of compliance and the availability of translation and interpretation services and professionals.

(9) Flexibility to accommodate variations in plan networks and method of service delivery. The department shall allow for health care service plan flexibility in determining compliance with the standards for oral and written interpretation services.

(d) The department shall work to ensure that the biennial reports required by this section, and the data collected for those reports, are consistent with reports required by government-sponsored programs and do not require duplicative or conflicting data collection or reporting.

(e) The department shall seek public input from a wide range of interested parties through the Advisory Committee on Managed Health Care or other advisory bodies established by the director.

(f) A contract between a health care service plan and a health care provider shall require compliance with the standards developed under this section. In furtherance of this section, the contract shall require providers to cooperate with the plan by providing any information necessary to assess compliance.

(g) The department shall report biennially to the Legislature and the Advisory Committee on Managed Health Care, or other advisory bodies established by the director, regarding plan compliance with the standards, including results of compliance audits made in conjunction with other audits and reviews. The reported information shall also be included in the publication required under subparagraph (B) of paragraph (3) of subdivision (c) of Section 1368.02. The department shall also utilize the reported information to make recommendations for changes that further enhance standards pursuant to this section. The department may also delay or otherwise phase in implementation of standards and requirements in recognition of costs and availability of translation and interpretation services and professionals.

(h) (1) Except for contracts with the State Department of Health Services Medi-Cal program, the standards developed under this section shall be considered the minimum required for compliance.

(2) The regulations shall provide that a health plan is in compliance if the plan is required to meet the same or similar standards by the Medi-Cal program, either by contract or state law, if the standards provide as much access to cultural and linguistic services as the standards established by this section for an equal or higher number of enrollees and therefore meet or exceed the standards of the regulations established pursuant to this section, and the department determines that the health care service plan is in compliance with the standards required by the Medi-Cal program. To meet this requirement, the department shall not be required to perform individual audits. The department shall, to the extent feasible, rely on audits, reports or other oversight and enforcement methods used by the State Department of Health Services.

(3) The determination pursuant to paragraph (2) shall only apply to the enrollees covered by the Medi-Cal program standards. A health care service plan subject to paragraph (2) shall comply with the standards established by this section with regard to enrollees not covered by the Medi-Cal program.

(j) Nothing in this section shall prohibit a government purchaser from including in their contracts additional translation or interpretation

requirements, to meet linguistic or cultural needs, beyond those set forth pursuant to this section.

SEC. 3. Section 1367.07 is added to the Health and Safety Code, to read:

1367.07. Within one year after a health care service plan's assessment pursuant to subdivision (b) of Section 1367.06, the health care service plan shall report to the department, in a format specified by the department, regarding internal policies and procedures related to cultural appropriateness in each of the following contexts:

(a) Collection of data regarding the enrollee population pursuant to the health care service plan's assessment conducted in accordance with subdivision (b) of Section 1367.06.

(b) Education of health care service plan staff who have routine contact with enrollees regarding the diverse needs of the enrollee population.

(c) Recruitment and retention efforts that encourage workforce diversity.

(d) Evaluation of the health care service plan's programs and services with respect to the plan's enrollee population, using processes such as an analysis of complaints and satisfaction survey results.

(e) The periodic provision of information regarding the ethnic diversity of the plan's enrollee population and any related strategies to plan providers. Plans may use existing means of communication.

(f) The periodic provision of educational information to plan enrollees on the plan's services and programs. Plans may use existing means of communications.

SEC. 4. Section 10133.8 is added to the Insurance Code, to read:

10133.8. (a) The commissioner shall, on or before January 1, 2006, promulgate regulations applicable to all individual and group policies of health insurance establishing standards and requirements to provide insureds with appropriate access to translated materials and language assistance in obtaining covered benefits. A health insurer that participates in the Healthy Families Program may assess the Healthy Families Program enrollee population separately from the remainder of its population for purposes of subparagraph (A) of paragraph (3) of subdivision (b). An insurer that chooses to separate its Healthy Families Program enrollment from the remainder of its population shall treat the Healthy Families Program population separately for purposes of determining whether subparagraph (A) of paragraph (3) of subdivision (b) is applicable and shall also treat the Healthy Families Program population separately for purposes of applying the percentage and numerical thresholds in subparagraph (A) of paragraph (3) of subdivision (b).

(b) The regulations described in subdivision (a) shall include the following:

(1) A requirement to conduct an assessment of the needs of the insured group, pursuant to this subdivision.

(2) Requirements for surveying the language preferences and assessment of linguistic needs of insureds within one year of the effective date of the regulations that permit health insurers to utilize various survey methods, including, but not limited to, the use of existing enrollment and renewal processes, newsletters, or other mailings. Health insurers shall update the linguistic needs assessment, demographic profile, and language translation requirements every three years. However, the regulations may provide that the surveys and assessments by insurers of supplemental insurance products may be conducted less frequently than three years if the commissioner determines that the results are unlikely to effect the translation requirements.

(3) Requirements for the translation of vital documents that include the following:

(A) A requirement that all vital documents, as defined pursuant to subparagraph B be translated into an indicated language, as follows:

(i) A health insurer with an insured population of 1,000,000 or more shall translate vital documents into the top two languages other than English as determined by the needs assessment pursuant to paragraph (2) of subdivision (b) and any additional languages when 0.75 percent or 15,000 of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(ii) A health insurer with an insured population of 300,000 or more but less than 1,000,000 shall translate vital documents into the top one language other than English as determined by the needs assessment pursuant to paragraph (2) of subdivision (b) and any additional languages when 1 percent or 6,000 of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(iii) A health insurer with an insured population of less than 300,000 shall translate vital documents into a language other than English when 3,000 or more or five percent of the insured population, whichever number is less, indicates in the needs assessment pursuant to paragraph (2) of subdivision (b) a preference for written materials in that language.

(B) Specification of vital documents produced by the insurer that are required to be translated. The specification of vital documents shall not exceed that of the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance (65 Federal Register 52762 (August 30, 2000)), but shall include all of the following:

- (i) Applications.
- (ii) Consent forms.
- (iii) Letters containing important information regarding eligibility or participation criteria.

(iv) Notices pertaining to the denial, reduction, modification or termination of services and benefits, the right to file a complaint or appeal.

(v) Notices advising Limited English proficient persons of the availability of free language assistance and other outreach materials that are provided to insureds.

(vi) Translated documents shall not include an insurer's explanation of benefits or similar claim processing information that are sent to insureds unless, the document requires a response by the insured.

(C) For those documents described in subparagraph (B) that are not standardized but contain insured specific information, health insurers shall not be required to translate the documents into the threshold languages identified by the needs assessment pursuant to paragraph (2) of subdivision (b) but rather shall include with the document a written notice of the availability of interpretation services in the threshold languages identified by the needs assessment pursuant to paragraph (2) of subdivision (b).

(i) Upon request, the insured shall receive a written translation of those documents. The health insurer shall have up to, but not to exceed 21 days to comply with the insured's request for a written translation. If an enrollee requests a translated document, all timeframes and deadlines requirements related to the documents that apply to the health insurer and insureds under the provisions of this chapter and under any regulations adopted pursuant to this chapter shall begin to run upon the health insurer's issuance of the translated document.

(ii) For appeals that require expedited review and response in accordance with the statutes and regulations of this chapter. The health insurer may satisfy this requirement by providing notice of the availability and access to oral interpretation services.

(D) A requirement that health insurers advise Limited English proficient insureds of the availability of interpreter services.

(4) Standards to ensure the quality and accuracy of the written translation and that a translated document meets the same standards required for the English version of the document. The English language documents shall determine the rights and obligations of the parties, and the translated documents shall be admissible in evidence only if there is a dispute regarding a substantial difference in the material terms and conditions of the English language document and the translated document.

(5) Requirements for individual access to interpretation services.

(6) Standards to ensure the quality and timeliness of oral interpretation services provided by health insurers.

(c) In developing the regulations, standards, and requirements described in this section, the commissioner shall consider the following:

(1) Publications and standards issued by federal agencies, including the Culturally and Linguistically Appropriate Services (CLAS) in Health Care issued by the United States Department of Health and Human Services Office of Minority Health in December 2000, and the Department of Health and Human Services (FIHS) Office of Civil Rights (OCR) Policy Guidance 65 (65 Federal Register 52762 (August 30, 2000)).

(2) Other cultural and linguistic requirements under state programs, including the Medi-Cal Managed Care Policy Letters, cultural and linguistic requirements imposed by the State Department of Health Services on health care service plans that contract to provide Medi-Cal managed care services, and cultural and linguistic requirements imposed by the Managed Risk Medical Insurance Board on health insurers that contract to provide services in the Healthy Families Program.

(3) Standards adopted by other states pertaining to language assistance requirements for health insurers.

(4) Standards established by California or nationally recognized accrediting, certifying, or licensing organizations and medical and health care interpreter professional associations regarding interpretation services.

(5) Publications, guidelines, reports, and recommendations issued by state agencies or advisory committees, such as the report card to the public on the comparative performance of plans and reports on cultural and linguistic services issued by the Office of Patient Advocate and the report to the Legislature from the Task Force on Culturally and Linguistically Competent Physicians and Dentists required pursuant to Section 852 of the Business and Professions Code.

(6) Examples of best practices relating to language assistance services by health care providers and health insurers that contract for alternative rates of payment with providers, including existing practices.

(7) Information gathered from complaints to the commissioner and consumer assistance help lines regarding language assistance services.

(8) The cost of compliance and the availability of translation and interpretation services and professionals.

(9) Flexibility to accommodate variations in networks and method of service delivery. The commissioner shall allow for health insurer flexibility in determining compliance with the standards for oral and written interpretation services.

(d) In designing the regulations, the commissioner shall consider all other relevant guidelines in an effort to accomplish maximum accessibility within a cost-efficient system of indemnification. The commissioner shall seek public input from a wide range of interested parties.

(e) Services, verbal communications, and written materials provided by or developed by the health insurers that contract for alternative rates of payment with providers shall comply with the standards developed under this section.

(f) Beginning on January 1, 2008, the department shall report biennially to the Legislature regarding health insurer compliance with the standards established by this section, including results of compliance audits made in conjunction with other audits and reviews. The department shall also utilize the reported information to make recommendations for changes that further enhance standards pursuant to this section. The commissioner shall work to ensure that biennial reports required by this section, and the data collected for the reports do not require duplicative or conflicting data collection with other reports as may be required by government-sponsored programs. The commissioner may also delay or otherwise phase in implementation of the standards and requirements in recognition of costs and availability of translation and interpretation services and professionals.

(g) Nothing in this section shall prohibit a government purchaser from including in their contracts additional translation or interpretation requirements, to meet the linguistic and cultural needs, beyond those set forth pursuant to this section.

SEC. 5. Section 10133.9 is added to the Insurance Code, to read:

10133.9. Within a year after the health insurer's assessment pursuant to paragraph (2) of subdivision (b) of Section 10133.8, health insurers shall report to the Department of Insurance on internal policies and procedures related to cultural appropriateness, in a format specified by the department, in the following ways:

(a) Collection of data regarding the insured population based on the needs assessment as required by paragraph (2) of subdivision (b) of Section 10133.8.

(b) Education of health insurer staff who have routine contact with insureds regarding the diverse needs of the insured population.

(c) Recruitment and retention efforts that encourage workforce diversity.

(d) Evaluation of the health insurer's programs and services with respect to the insurer's enrollee populations, using processes such as an analysis of complaints and satisfaction survey results.

Attachment 5

Elements of a Patient-Centered Label



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Phone (916) 574-7900
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**Assessment of Components in California Business and Professions Code Section 4076
Regarding Prescription Container Labels of Greatest Importance to Consumers**

List generated by the SB 472 Medication Label Subcommittee, January 27, 2009

OF MOST IMPORTANCE:

Trade Name/Generic Name
Directions For Use
Strength

OTHER ELEMENTS REQUIRED:

Patient's Name
Prescriber's Name
Pharmacy Name
Pharmacy Address
Prescription Number
Quantity
Expiration Date
Condition
Physical Description

Patient-Centered Information Focus of Task Force on Uniform Prescription Labels

Recognizing that prescription drug labels may currently require and highlight information pertinent for pharmacists rather than clearly displaying information critical to what the patient needs to know, the Task Force on Uniform Prescription Labeling Requirements agreed that major changes must be made to labels to ensure that information is provided in a uniform, patient-centered format. Keeping this in mind as they considered changes to prescription drug labeling, the task force, which met December 6, 2008, in Tucson, AZ, undertook the following charges.

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing these issues so as to increase readability and comprehension of labels by patients.

Early on in their discussions, the task force members agreed that it was important to create a clear, concise statement regarding the focus and purpose of their recommendations for prescription labeling. The members recommended that this statement be endorsed by the NABP Executive Committee and distributed to interested stakeholders. Through this statement, the task force members communicated their belief that labels should be used solely to provide patients with important information about medication use. The statement also in-

cluded the assertion that prescription labels should not replace critical pharmacist care responsibilities.

The task force members identified some critical pharmacist care responsibilities as (1) patient identification and (2) patient counseling. Patient identification encompasses patient data elements, such as the address. These elements are important identifiers for matching the prescription to the patient but do not warrant inclusion on the label, as this type of information should be contained in other patient identification systems. The task force members agreed that patient counseling is the single most effective component to increase and improve patient compliance and avoid medication errors. Because of this, they believe that prescription labels should be designed to supplement patient counseling, but not replace it in any way.

Numerous studies cite 12-point, sans-serif fonts as providing the best readability; therefore, the task force members included this feature in its recommended amendments to the *Model Act* language addressing prescription drug labeling. Recognizing the relatively small

real estate afforded by 2" by 4" labels for prescription bottles, the task force identified critical information that should be presented in this larger, 12-point font versus important information for patients that could be provided in a smaller font size. Additionally, the task force identified several pieces of data, such as the pharmacy fax number, that could be removed from prescription drug labels because that information can be found through other sources and is not vital to patient safety.

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- Patient name
- Directions for use and, if included on prescription drug order, the purpose/indication
- Drug name and strength
- Date by which the medication should be used

The task force also recommended that the following information be included in the *Model Act* as mandatory data elements for labels, but that this data should not supersede the aforementioned

critical information in size or emphasis.

- Pharmacy name
- Pharmacy telephone number
- Prescriber name
- Fill date (the date the prescription was dispensed)
- Prescription number
- Drug quantity
- Number of refills
- Product description
- Auxiliary information

In addition, the task force recommended the *Model Act* be amended to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Through its discussions on which information should be included on prescription labels, the task force recognized that its recommendations represent a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. Because the *Model Act* is not intended to contravene state and federal laws or regulations, the task force supports NABP working with relevant agencies and organizations to allow implementation of the patient-centered label the task force developed.

Finally, the task force also recommended

that NABP work with the American Medical Association, the Federation of State Medical Boards, the Centers for Medicare and Medicaid Services, and other relevant organizations to require that medication indications be included on written and electronic prescription drug orders. The task force members discussed how providing on a prescription the purpose for which a drug was prescribed is an important tool for protecting patients. With this tool, pharmacists can better counsel patients on how and why they are taking the medication. This concept has a history of support among NABP members as evidenced by NABP Resolution No. 100-7-04, Medication Indication on the Prescription, which was passed by the membership at its Annual Meeting in 2004; the task force members felt that with the profession's focus on patient-centered labels that the time was well suited to pursuing this change.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2009 meeting. The full report of the task force is available on the NABP Web site at www.nabp.net under News/Press. ®



Report of the Task Force on Uniform Prescription Labeling Requirements

Members Present:

Michael J. Romano (PA), *chair*; Barry J. Boudreaux (NV); Karen DiStefano (RI); Patricia Donato (NY); Virginia Herold (CA); Ronald Huether (SD); William Prather (GA); Leo H. Ross (VA)

Others Present:

Karen M. Ryle, *executive committee liaison*; Carmen Catizone, Melissa Madigan, Larissa Doucette, *NABP staff*

Guests:

Colleen Brennan, *United States Pharmacopeia*; Darren K. Townzen, *National Council for Prescription Drug Programs*

The Task Force on Uniform Prescription Labeling Requirements met December 6, 2008 at the JW Marriott Starr Pass Hotel, Tucson, AZ.

This task force was established in response to Resolution 104-3-08, Task Force on Uniform Prescription Labeling Requirements, which was approved by the NABP membership at the Association's 104th Annual Meeting in May 2008.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act*) addressing these issues so as to increase readability and comprehension of labels by patients.

Recommendation 1: Endorse and disseminate statement on prescription labeling.

The task force recommends that the NABP Executive Committee endorse the following statement on the issue of prescription labeling and disseminate it to all interested stakeholders:

The purpose of the prescription label is to provide critical information to the patient so that he or she may use the medication appropriately and comply with the medication regimen. The label should be patient-centered. 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. Further, the label should not be used as a sole means to determine compliance with pharmacy laws and regulations by pharmacy regulators.

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.

Background:

Upon review and discussion of the issue of prescription labeling and concerns related to patients' understanding of such labeling, the task force determined it is important to clearly identify for what purposes prescription labels should and should not be used. As stated above, members felt that labels should be used solely to provide patients with important information about medication use. They agreed that prescription labels should not replace critical pharmacist care responsibilities. Identified were two such primary responsibilities: patient identification and patient counseling. On these issues, the task force stated the following:

1. Patient Identification – Patient data elements, such as address, are important identifiers but do not warrant inclusion on the label; instead, such information should be contained in other patient identification systems upon which a pharmacist relies to ensure that the patient receives his or her medication and to avoid confusion among patients with similar names or whose names may bear suffixes such as “Jr” or “Sr” within a family group.
2. Patient Counseling – The single most effective component to increase and improve patient compliance and avoid medication errors, as documented in numerous studies, is appropriate patient counseling. The prescription label is designed to supplement this critical pharmacist responsibility and not replace it in any way. Pharmacists cannot avoid their legal and professional responsibilities by deferring counseling activities to the prescription label. Further, boards of pharmacy cannot regulate counseling activities through the prescription label.

Recommendation 2: Amend the NABP Model Act language addressing prescription drug labeling.

The task force recommends that NABP Executive Committee approve amendments to the *Model Act* that will ensure prescription labels are organized in a patient-centered manner and that mandate the following data elements appear on the prescription label. The task force has consciously removed some data elements historically included on prescription labels to make room for the most critical patient information.¹

¹ Insert examples of recommended labels

- A. 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.
 - i. Legal name of the patient. If patient is an animal, include the last name of the owner, name of the animal, and animal species.
 - b. Directions for use.
 - i. The directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order.
 - 1. Boards of pharmacy and licensees should recognize that “take as directed” may not provide sufficient information for the appropriate use of the medication. “Take as directed” is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. “Take as directed” should not be used in lieu of patient counseling.
 - 2. It is understood that prescription drug orders often do not include the indication for use.
 - ii. Language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
 - c. Drug name.
 - i. Name of the drug.
 - ii. If written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name].”
 - iii. If a fixed combination generic product is dispensed, use the United States Pharmacopeia (USP) publication of Pharmacy Equivalent Names (PEN) abbreviation. If no PEN has been officially issued by the USP, label the medication *secundum artem*.
 - iv. Include drug name suffixes, such as CD, SR, XL, XR, etc.
 - d. Drug strength.
 - i. Strength of the drug.
 - e. “Use by” date.
 - i. Date by which medication should be used; not expiration date of medication or expiration date of prescription.
 - ii. Format as: “Use by: MM/DD/YY.”
- B. Important Information for Patients – Must appear on the label but should not supersede Critical Information for Patients.
- a. Pharmacy name.
 - i. Name of the dispensing pharmacy. Boards of pharmacy should recognize that some pharmacies “do business as” a name other than the corporate name.
 - b. Pharmacy telephone number.

Report of the Task Force on Uniform Prescription Labeling Requirements

- i. Phone number of the dispensing pharmacy. Recognizing that a central fill pharmacy may be involved in the filling process, boards of pharmacy should not require more than one telephone number on the label.
- c. Prescriber name.
 - i. Name of the prescriber.
 - ii. Format – “Prescriber: [prescriber name].”
- d. “Fill date.”
 - i. Date the prescription is dispensed, which will change with each subsequent refill. Format – “Date filled: MM/DD/YY.”
 - ii. The “fill date” and “use by” date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.
 - iii. The term “fill date” should be defined in the *Model Act*.
- e. Prescription number.
 - i. Identifies the number of the pharmacy record under which the prescription information is recorded.
- f. Drug quantity.
 - i. Quantity of drug dispensed.
 - ii. Format – “Qty: [number].”
- g. Number of refills.
 - i. Number of remaining refills.
 - ii. Format – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy recordkeeping system.
- h. Product description.
 - i. Written or graphic description of medication dosage form.
- i. Auxiliary information.
 - i. Auxiliary labels – information should be evidence based, standardized, and demonstrated to compliment the prescription label.

Examples of compliant labels include the following:

Pharmacy Name:	Date Filled: MM/DD/YY	Cautions:
Phone:	Rx No.:	
Purpose:		
Patient Q. Name		
Prescriber:		
Take 1 tablet in the morning and 2 tablets at bedtime.		
Description:		
Drug Name and Strength		
Generic for:	Qty:	
Use by: MM/DD/YY	Refills:	

Pharmacy Name: Phone: Patient Q. Name	Purpose: Take 1 tablet in the morning and 2 tablets at bedtime.
Rx No.: Date Filled: MM/DD/YY Prescriber:	Cautions:
Drug Name and Strength Generic for:	Description:
Qty: Refills: Use by: MM/DD/YY	

Recommendation 3:

The task force recommends that NABP work with federal and state agencies and pharmacy stakeholders to advocate for and ultimately achieve changes in state or federal laws and regulations and industry standards to support a patient-centered label.

Background:

The task force recognized that Recommendation 2 represents a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. In some situations, this recommendation will be contrary to existing federal and state laws and regulations and industry standards. The *Model Act* cannot and is not intended to contravene state and/or federal laws or regulations. The task force understands this and supports NABP working with relevant agencies and organizations to allow the use of a patient-centered label.

Recommendation 4:

The task force recommends that the NABP Executive Committee approve amendments to the *Model Act* to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Background:

The task force wanted to give states the option to allow pharmacies to include these elements on the label if they felt they were necessary.

Recommendation 5:

The task force recommends that NABP work with relevant organizations, including the American Medical Association, the Federation of State Medical Boards, and the Centers for Medicare and Medicaid Services (CMS), to require that medication indications be included on all prescriptions including but not limited to written and electronic prescription drug orders.

Background:

Task force members agreed that this item of information is vital for appropriate medication counseling. It was felt that this was a good time to approach CMS about the possibility of requiring prescribers to include such information in order to be reimbursed for their services.

<p>Patient S. Name</p> <p>Ursodiol 300MG Capsule Generic for Actigall</p> <p>Take capsule twice a day with food</p>	<div data-bbox="894 551 979 651" style="border: 1px solid black; padding: 2px; display: inline-block;">Logo</div> Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555 Rx #: 1234567 Refill: 0 Prescriber: Dr. Smith
White, Oblong Capsule Expires: MM/DD/YY Quantity: 25	

<p>Patient S. Name</p> <p>Ursodiol 300MG Capsule Generic for Actigall</p> <p>Take capsule twice a day with food</p>	<div data-bbox="935 1344 1019 1444" style="border: 1px solid black; padding: 2px; display: inline-block;">Logo</div> Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555 Rx #: 1234567 Refill: 0 Prescriber: Dr. Smith
White, Oblong Capsule Expires: MM/DD/YY Quantity: 25	



Pharmacy Name
1625 N. Market Blvd
Sacramento, CA 95834
(555) 555-5555

Rx #: 1234567
Qty: 100
Expires: MM/DD/YY

Refills: 3

Patient S. Name

Condition:

Ursodiol 300MG

Generic for: Actigall

Physical Description: White, Oblong
Capsule

Prescriber: Dr. Jonathan D. Smith

Take one capsule
twice a day with
food



Pharmacy Name
1625 N. Market Blvd
Sacramento, CA 95834

(555) 555-5555

Ursodiol 300MG Capsule
Generic for Actigall
Take capsule twice a day with food

Patient S. Name

Condition

Rx #: 1234567 Refills: 0

Qty: 50

Expiration Date: MM/DD/YY

Prescribed by:

Logo	Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555	Rx #: 5555555 Qty: 100 Expires: MM/DD/YY Refills: 3
	Patient S. Name Condition: Fluoxetine 20MG Generic for: Prozac Physical Description: Capsule	Take one capsule by mouth one time daily
Prescriber: Dr. Smith		

Pharmacy Name	(555) 555-5555
<small>1625 N. Market Blvd, Sacramento, CA 95834</small>	
Patient S. Name EPIPEN 0.15 MG 2-PAK AUTO-IDEY Rx #: 1234567 Qty: 2 Expires: MM/DD/YY Refills: 1 before MM/DD/YY Prescriber: Prescriber S. Name	Use intramuscularly lateral thigh as needed for severe allergic reaction

Rx #: 7777777 Qty: 480ML Expires: MM/DD/YY Refills: 2	Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555	Logo
Patient S. Name Condition: Promethazine/Codeine Syrup Physical Description: Clear, Purple-Red, Peach-Mint, Syrup	Take one table spoon three times a day as needed for cough	
Prescriber: Dr. Smith		

(e) The periodic provision of information regarding the ethnic diversity of the insurer's insured population and any related strategies to insurers providers. Insurers may use existing means of communication.

(f) The periodic provision of educational information to insureds on the insurer's services and programs. Insurers may use existing means of communication.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 6

*Standardized Directions for
Use for Medication Labels*

PROTOTYPE DOSAGE INSTRUCTIONS FOR PHARMACY TRASCRIPTION

ENGLISH	SPANISH
Take 1 tablet at bedtime	Tome 1 pastilla en la noche
Take 2 tablets at bedtime	Tome 2 pastillas en la noche
Take 3 tablets at bedtime	Tome 3 pastillas en la noche
Take 1 tablet in the morning	Tome 1 pastilla en la mañana
Take 2 tablets in the morning	Tome 2 pastillas en la mañana
Take 3 tablets in the morning	Tome 3 pastillas en la mañana
Take 1 tablet in the morning, and Take 1 tablet at bedtime	Tome 1 pastilla en la mañana, y 1 pastilla en la noche
Take 2 tablets in the morning, and Take 2 tablets at bedtime	Tome 2 pastillas en la mañana, y 2 pastillas en la noche
Take 3 tablets in the morning, and Take 3 tablets at bedtime	Tome 3 pastillas en la mañana, y 3 pastillas en la noche
Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening	Tome 1 pastilla en la mañana, 1 pastilla en el mediodía, y 1 pastilla en la noche
Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening	Tome 2 pastillas en la mañana, 2 pastillas en el mediodía, y 2 pastillas en la noche
Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening	Tome 3 pastillas en la mañana, 3 pastillas en el mediodía, y 3 pastillas en la noche
Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime	Tome 1 pastilla en la mañana, 1 pastilla en el mediodía, 1 pastilla en la tarde, y 1 pastilla en la noche
Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime	Tome 2 pastillas en la mañana, 2 pastillas en el mediodía, 2 pastillas en la tarde, y 2 pastillas en la noche
Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime	Tome 3 pastillas en la mañana, 3 pastillas en el mediodía, 3 pastillas en la tarde, y 3 pastillas en la noche
Take 1 tablet as needed for pain. You should not take more than X tablets in one	Tome 1 pastilla cuando la necesita Ud. para el dolor.

day.	Ud. no debería tomar más de X pastillas en un día.
Take 2 tablets as needed for pain. You should not take more than X tablets in one day.	Tome 2 pastillas cuando las necesita Ud. para el dolor. Ud. no debería tomar más de X pastillas en un día.

Attachment 7

*Meeting Summary
Of the SB 472 Medication
Label Subcommittee Meeting
of March 12, 2009*



California State Board of Pharmacy
1625 N. Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SENATE BILL 472 MEDICATION LABEL SUBCOMMITTEE
MINUTES**

DATE: March 12, 2009

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

**BOARD MEMBERS
PRESENT:** Kenneth Schell, PharmD, Committee Chair
Robert Swart, PharmD
Susan L. Ravnar, PharmD
William Powers, Public Member

**BOARD MEMBERS
NOT PRESENT:** Shirley Wheat, Public Member

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Legislation and Regulations Manager
Karen Abbe, Public and Licensee Education Analyst
Tessa Fraga, Staff Analyst

Call to Order

Chair Schell called the meeting to order at 6:14 p.m.

1. Welcoming Remarks

Dr. Schell provided an overview of the agenda and explained the purpose of the meeting.

2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels

Executive Officer Virginia Herold provided an overview of SB 472 and its requirements.

Ms. Herold indicated that the board must implement the requirements of SB 472 by January 1, 2011. The Board will do this over a phased-in three-year period. During 2008, the board held a series of public meeting throughout California, gathering information and

input from consumers and the health professions for adopting regulations to standardize prescription labels. In 2009, the board will adopt regulations to standardize prescription labels. In 2010, all pharmacies dispensing drugs to California patients must convert their labels to this new format by the 2011 deadline. Ms. Herold provided that the board is currently on schedule.

Ms. Herold provided that regulations will be developed at the April board meeting. She indicated that the board would like to have regulations drafted by July in order for the board to take action by the end of 2009.

Public Comments

Al Hernandez Santana (Latino Coalition for a Healthy California) shared support to the board for its efforts for SB 472. He asked if an opportunity for comments would be available after the regulations have been drafted.

Dr. Schell indicated that there will be an opportunity for further comment.

Mr. Hernandez Santana questioned if the board planned on conducting more public hearings for consumers.

Ms. Herold indicated that the board will continue to conduct consumer surveys at health fairs statewide. She indicated that the public will be provided with a minimum of 45 days for public comment before regulations are adopted. Public comments are reviewed and may be considered for incorporation into the regulation.

Mr. Hernandez Santana urged the board to partner with the Latino Coalition for a Healthy California to ensure that the Latino population is provided an opportunity to provide public input.

Ms. Herold thanked Mr. Hernandez Santana and the Latino Coalition for a Healthy California for their support.

Mr. Schell indicated support and appreciation for the efforts of the Latino Coalition for a Healthy California.

William Powers provided that a Spanish version of the questionnaire is available.

Margy Metzler (Gray Panthers Chapter) offered continued support for the board's efforts towards implementing SB 472.

There was no additional board of public comment.

3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance

Martin Martinez (California Pan-Ethnic Health Network) provided an overview of SB 853. Passed in 2003, the bill mandates that all California health plans provide language assistance services to their enrollees. The legislation stipulates that all vital documents must be translated into threshold languages and interpretation services made available to enrollees.

Mr. Martinez suggested that the board participate with the implementation of this legislation and the translation of prescription labels.

Dr. Robert Swart expressed concern regarding the difficulty pharmacists may encounter while ensuring the accuracy of labels printed in a foreign language.

Mr. Martinez responded that quality control measures may need to be identified.

Dr. Schell provided that collaborative efforts are required to work towards a solution and to ensure access is not diminished.

There was no additional board of public comment.

4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472

Ms. Herold provided an overview of survey results. Most consumers participating in the survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

Karen Abbe, Public and Licensee Education Analyst, provided that the board conducted one-on-one interviews at 7 consumer outreach events in 2008. The actual survey results from these interviews are available.

Board Discussion:

Mr. Powers expressed concern regarding the sufficiency of the information gathered from the surveys.

Ms. Herold provided that the survey results support the available literature and research on this topic.

Discussion continued regarding sufficient sample size and the accuracy of the survey results.

5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472

Presentation to the Board:

Dr. Michael Negrete (Pharmacy Foundation of California):

Dr. Negrete provided an overview of the data results from the joint survey developed by the Pharmacy Foundation of California and the Board of Pharmacy. The survey focused on identifying key attitudes and knowledge of behaviors of California consumers related to prescription drug labels. The multiple choice survey of four questions was conducted via a radio-sponsored survey by Entercom broadcasting.

The four survey questions and their respective top responses are as follows

1. How often do you read the label on your prescription containers? - 42% responded 'Only before I take it the first time.'
2. When you need to obtain information from the label, what do you have the most trouble with? - 44% responded 'finding it.'
3. Which parts of the label are most important to you? - 64% responded 'directions.'
4. What would you change on the prescription label to improve it? – Top responses included bigger print/size, clarity, including the purpose, including side effects/interactions, and the use of "chunking" to present information in identifiable sections.

Dr. Negrete discussed possible limitations of the study including the representation of the sample and the credibility of self-reporting. He provided that directions for use are seen as particularly important and that patients should be encouraged to read their labels more frequently.

Board Discussion:

Dr. Swart discussed the challenges that arise when trying to include information on larger vials. He added that the results from the radio survey support the results from the board's survey.

Mr. Powers provided that he currently receives medications that have the purpose provided on the label.

Assistant Executive Officer Anne Sodergren provided that current law allows for the condition to be included on the prescription if requested by the patient, but not the purpose.

Discussion continued regarding the implications of providing the purpose on the prescription label. A consumer bottle, where the consumer personally wrote the purpose for their medication, was presented as an exhibit.

Public Comments:

Chad Morton suggested that the board consider alternative resources, outside of the label, to convey necessary information to the consumer.

Mr. Powers asked Mr. Morton for other suggestions.

Mr. Morton responded that patients need better education. He suggested that the board, along with the pharmaceutical industry and pharmacy profession, think outside of the box.

Ms. Metzler provided that she reads her prescription labels to ensure the information matches the information she received from the doctor.

There was no additional board or public comment.

6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)

Ms. Herold provided that the board held a Subcommittee Meeting on January 27, 2009 to evaluate patient-centered elements of prescription labels. Attendees were asked to discuss label requirements and to identify requirements that are the most patient-centered. Requirements identified as being the most patient-centered included patient name, generic name, drug name, drug strength, directions for use, physical description of drug, expiration date, quantity, pharmacy name, pharmacy address, pharmacy phone number, prescription number, refills, and prescriber.

Ms. Herold presented a variety of sample labels emphasizing these requirements. She provided that these labels can be used as a model. Ms. Herold discussed the implications of standardizing label formats, noting that companies are currently utilizing a variety of different shaped containers.

Discussion continued regarding the implications of standardizing label formats.

Public Comments

Dr. Negrete suggested that the board provide companies with approved formats or offer approval of formats that fulfill the patient-centered requirement criteria.

Mr. Morton suggested that the label be used to refer patients to an alternative source of information.

There was no additional board or public comment.

7. Legislative Proposal to Add "Purpose" to Prescription Container Labels

Dr. Schell provided that Senate Bill 470, introduced by Senator Corbett, would revise current law to require the label to include the purpose for which a drug is described if requested by the patient or if the purpose is indicated on the prescription. Dr. Schell added that this bill would result in a conforming change.

Ms. Herold provided that existing law authorizes a prescription to include the condition for which the drug is prescribed if requested by the patient. Ms. Herold discussed concerns regarding challenges to identifying the purpose and possible implications for pharmacy workload. She expressed the importance of adding the purpose to the label at this time and possible impacts for e-prescribing.

Public Comment:

Dr. Negrete offered support for the proposal. He provided that prescribing errors may be eliminated if the prescriber is required to indicate the purpose on the prescription.

There was no additional board or public comment.

8. Public Comment for Items Not on the Agenda

No public comment was received.

The meeting was adjourned at 7:42 p.m.

Attachment 8

*Third Quarterly Update on
the Communication and
Public Education
Committee's Goals for
2008-09*

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. 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. <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 data-bbox="365 745 1485 1123"> <p>2. Restructure the board’s website to make it more user friendly. <i>2006-2007: Website modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.</i> <i>Links added to obtain various information regarding medication safety, and drug interactions, and information from FDA regarding Medications and Medical Devices.</i> <i>Work Initiated on new website design to meet new state design standards.</i> <i>2007-2008: New website design completed in November 2007.</i> <i>Web page created consolidating all information on e-pedigree into one place.</i></p> <li data-bbox="365 1123 1485 1344"> <p>3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. <i>2006-2007: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.</i> <i>No additional meetings scheduled after January 2007.</i></p> <li data-bbox="365 1344 1485 1816"> <p>4. Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics. <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.</i> <i>Meanwhile discussion with UCSF lead to request for funding to continue project.</i> <i>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></p>

	<p>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.</p> <p><i>2006-2007: Governor signs AB 2583. Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster. Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.</i></p> <p><i>2007-2008: New "Notice to Consumers" approved by board and later by the Office of Administrative Law. New design and layout for two new Notice to Consumer posters are selected.</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. Evaluate the practice of pill splitting as a consumer protection issue.</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. Evaluate the SCR 49 Medication Errors Report for implementation.</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>
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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.*
- 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, CA.*
- Jan. 2009: Board publishes medication errors segment in its newsletter, The Script, describing several medication errors investigated by the board.*

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 1524 401"> <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> <li data-bbox="370 401 1524 1213"> <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 data-bbox="370 1213 1524 1726"> <p>3. Maintain important and timely licensee information on website.</p> <p><i>2006-2007:</i> 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.</p>

	<p>2007-2008: <i>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.</i></p> <p>1st Qtr 08/09: <i>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.</i></p> <p>2nd Qtr 08/09: <i>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.</i></p> <p>3rd Qtr 08/09: <i>Began process of making all PDFs on boards 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 <u>The Script</u>.</i></p> <p>4. Jan 2009: Board mails letter pursuant to SJR 19 regarding prohibition of healing arts licensees not to engage in torture.</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>July 2008: Board Member Goldenberg provides information about pharmacy law to medical staff at the Jewish Home Hospital.</i></p> <p><i>Board Inspector Orlandella represents the board to a group of seniors and provided general information and responded to questions in Roseville, CA</i></p> <p><i>Executive Officer Herold provides a presentation to a group of 150 individuals and agencies regarding California law and drug take back programs in communities.</i></p> <p><i>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.</i></p> <p>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.</i></p> <p><i>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.</i></p> <p>Sept. 2008: <i>Executive Officer Herold provides a presentation to AstraZeniga's government relations staff on SB 1307.</i></p> <p><i>Executive Officer Herold provides a presentation at the Generic Pharmaceutical Association's annual meeting on SB 1307.</i></p> <p><i>Executive Officer Herold participates in a web cast on California's pedigree requirements and SB 1307 (Ridley-Thomas) hosted by software provider SAP.</i></p> <p><i>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.</i></p> <p>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.</i></p> <p>Nov. 2008: <i>Executive Officer Herold and Assistant Executive Officer Sodergren attend Synergy 2009, an event sponsored by the California Pharmacists Association.</i></p> <p>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.</i></p> <p>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.</i></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 provided 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 presented information on "How to Survive a Board Inspection" to 80 pharmacists at a Vietnamese Pharmacist Association.

Board President Schell provided a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy.

Executive Officer Herold provided an update on board activities to the California Society of Health-Systems Pharmacists Board of Directors.

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

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

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

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

Executive Officer Herold served as one of three judged 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 staffed a booth at the CPhA's annual meeting answering pharmacy law and licensing questions.

Executive Officer Herold and President Schell discussed the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting.

Executive Officer Herold made a presentation to UCSF and UCSD students in a first year pharmacy school law class.

President Schell made a presentation to students at the USC School of Pharmacy.

President Schell spoke at an Eagle Scout ceremony in Sacramento.