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

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

DATE: January 27, 2009

LOCATION: Sheraton Hotel – Mission Valley
1433 Camino Del Rio South
San Diego, CA 92108

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, Chair
Robert Swart, PharmD
William Powers, Public Member

BOARD MEMBERS NOT PRESENT:
Susan L. Ravnan, PharmD
Shirley Wheat, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulations Manager
Karen Abbe, Public and Licensee Education Analyst
Tina Thomas, Enforcement Analyst
Tessa Fraga, Staff Analyst

Call to Order

The meeting was called to order at 1:05 p.m.

The meeting began as a subcommittee of the SB 472 Medication Label Subcommittee. Items on the agenda were open for discussion only.

1. Welcoming Remarks

Robert Swart introduced himself as acting chair for the committee. Dr. Swart introduced the members of the board who represent the subcommittee.

2. Review of Consumer Surveys Conducted by the Board of Pharmacy

Executive Officer Virginia Herold provided an update of the results of the consumer surveys the board is disseminating as part of its implementation efforts in SB 472.

Ms. Herold explained that in accordance with Senate Bill 472, the board intended to conduct six public meetings throughout California. The public forums were aimed at gathering information and input from consumers and the health professions for adopting regulations to standardize prescription labels. After poor attendance and a lack of public comment at the first meeting held in April 2008, the board shifted from a public forum format to questionnaires. This method of soliciting information proved less intimidating to consumers than individually speaking at public hearings.

Karen Abbe, Public and Licensee Education Analyst, shared that board staff administering the questionnaires have reported positive feedback when discussing the initiative with the public. Many of those surveyed suggested indicating the purpose for the prescription should be included on the label.

Ms. Herold indicated that the survey consists of five open-ended questions and provides a section for other comments. Data has been generated from the survey results and represents these responses and comments.

Ms. Abbe stated that a total of 606 consumers have completed surveys as of January 13, 2009. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions as indicated in the data.

Ms. Herold reviewed the following data results:

- When asked what information on the label was most important, the top responses were:
    - Directions for use - 18.6%
    - Name of drug; if generic, state brand name AND generic name - 18.1%
    - Dosage prescribed - 17.8%
    - Side effects/warnings/interactions/contraindications - 10.3%
    - Purpose of drug – state what condition medication is intended to treat - 6.9%
- When asked what to change on the prescription label, the top responses were:
    - Print should be larger or darker - 30.1%
    - Nothing needs to be changed on the label - 24.6%
    - Include purpose of the drug – state what condition the medication is intended to treat - 12%

- When asked what would make prescription labels easier to read, the top responses were:
    - Larger or bolder print – 60%
    - Highlighting directions for use and other information in colors other than black – 11.4%
- When asked for other suggestions for improving the label, the top responses were:
    - Easy-open lids should be used, no child-proof caps for seniors – 15.1%
    - Include purpose of the drug – state what condition the medication in intended to treat – 12.1%

Ms. Herold shared that the conclusions indicate most consumers participating in this survey would like 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 if the generic is being dispensed. 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.

Ms. Herold shared that the board will sponsor legislation this year to add the purpose of the drug to the label when requested by the patient. Having the purpose of the drug listed on the label was stated as a response to the following three questions:

1. What information is most important to you: 6.9% or 13.4% of all respondents
2. What would you change on the label: 12.0% or 11.1% of all respondents
3. Other suggestions for improving the label: 12.1% or 2.6% of all respondents

Ms. Herold indicated that such responses reflect public support to add the purpose of the drug to the label. These responses also coincide with expert suggestions including the purpose to the label will increase patient understanding and help to prevent medication errors.

Ms. Herold noted that 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.

Ms. Herold shared that efforts are being made to ensure that the questionnaire is being administered to diverse demographics including seniors and non-English speakers and stated that data will continue to be collected.

Public Comment:

John Cronin, California Pharmacist Association, questioned if the board indicated any distinction between the label on the bottle and the ancillary information that is provided within the label.

Ms. Herold indicated tht the respondents were provided with a sample prescription label as opposed to an ancillary label.

Dr. Cronin reflected back on three main changes that the consumers indicated on the surveys including visibility, readability, and ease of comprehension. He stressed the importance of emphasizing the purpose of the drug to the consumer. He questioned whether or not this emphasis can be made by changing the label.

Dr. Swart referenced sample labels presented during the board's meeting at the PACT Summit. The labels illustrated a suggested prescription label format with the label divided into 3 different sections, each focusing on specific information. He added that these labels were successful at emphasizing important information to the consumer.

Discussion continued regarding the improvement of prescription labels.

There was no additional board or public comment.

3. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy

Ms. Herold shared that the board has recently worked with the Pharmacy Foundation of California to develop a multiple choice survey of four close-ended questions that were available via a radio-sponsored survey. A total of 1,368 participated in the survey.

Ms. Herold provided the following survey results:

- When asked how often do you read the label on your prescription container, the responses were:
    - Everytime – 30%
    - Once in a while – 16%
    - Only the first time – 42%
    - Never – 12%
- When asked why you have the most trouble when you need to obtain information from the prescription container label, the responses were:
    - Finding it – 43%
    - Reading it/print too small – 37%
    - Print style is hard to read – 11%
    - Words used hard to understand – 24%
    - Information in wrong language – 5.5%
- When asked which of the following pieces of information on a prescription container's label are most important to you, the responses were:
    - Directions – 64%
    - Strength of medication – 37%
    - Brand name – 25%

Ms. Herold shared that a total of 778 females and 589 males participated in the survey.

Ms. Herold stated that Dr. Wolf has indicated interest in participating with this effort at a future meeting.

Board Discussion:

Ms. Herold discussed possible impacts that label standardization may have on the marketplace.

Mr. Powers referred to previous discussions between the board and the medical profession regarding this matter.

Ms. Herold confirmed that the board has met with the medical profession on two separate occasions. She added that they are not interested in active involvement at this time.

Mr. Powers suggested that the medical profession should be involved regarding the use of a medication schedule to convey and simplify dosage and use of instructions.

The committee discussed that a possible solution to the limited space on the prescription bottle would be to run the text horizontally.

Dr. Swart discussed that a larger container is required in order to use a label with horizontal text. He shared that many consumers complain about large containers. He suggested that the board ask consumers for their preference between having a larger container or having to turn the container to read some warnings.

Ms. Herold questioned whether research is available regarding the use of a horizontal label. She indicated that the consumer will have to turn the bottle on its side in order to read flat letters.

Discussion continued regarding horizontal labels.

Public Comments:

The committee discussed the use of highlighting on the label.

Dr. Cronin stated concern regarding technological requirements and adding highlighting to a label.

Dr. Swart responded that highlighting both the drug name and the patient name will help to alleviate confusion for consumers regarding their family member’s prescriptions.

Dr. Cronin indicated that standardizing highlighting on labels would require all pharmacies to have a color printer.

Dr. Swart provided that it would be beneficial to evaluate what information should be highlighted. He added that highlighted information on labels usually includes the pharmacy's phone number and the prescription number. He explained that label highlighting is usually implemented to expedite workflow processes rather than optimal patient delivery. He suggested that a balance between these two goals is possible after sufficient evaluation of what information should be highlighted.

Dr. Swart suggested focusing on identifying key items for label design in order to best help patients.

Dr. Cronin responded that there should also be a focus on providing a broad-base educational effort to both pharmacies and the consumer. He suggests that the board also study the difference between compliance and understanding.

Dr. Cronin clarified that consumers receive limited information and understanding when solely relying on the information provided on the label. He suggested that interaction with the healthcare professional will improve patient compliance and understanding.

Mr. Powers responded that counseling also helps with this effort.

Mr. Powers continued that a doctor also plays a role and explained that time is compressed for everyone involved in the system. He indicated that changing the label may not substitute the need for interaction between the consumer and healthcare professionals. He provided that several institutions have already researched testing comprehension and stated that the board does not have the capacity to test for this matter.

Dr. Cronin clarified that the board should review available research and incorporate findings into the report to the legislature in 2010.

Mr. Powers questioned whether or not complaints regarding the size of bottles warranted changes being made to the label.

Dr. Swart responded that the size of the bottle does impact a business and profits.

Mr. Powers provided that changes being made to the bottle will ultimately benefit the health of the consumer. He shared that this process will be unnecessary if consumers are unwilling to accept these changes.

Dr. Swart provided that 80% of consumers throw away the provided printout information regarding their medication without reading it. He suggested that future education should focus on encouraging consumers to read information that is currently being provided.

Mr. Powers responded that the information is often printed too small.

Dr. Swart agreed and responded that the size of the print needs to addressed.

Dr. Cronin sought clarification on including distinguishable front and back sides to the label.

Dr. Swart responded that Safeway is currently testing this issue with a three-sided container including patient information, medication information, and the auxiliary label.

There was no additional board or public comment.

4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076)

Ms. Herold provided that California's requirements for prescription container labels includes elements targeted towards several areas including the pharmacy, the consumer, and regulatory issues. Ms. Herold suggested that the committee review California's requirements to determine whether or not each requirement is principally provided as information for the patient, for the pharmacy, or for the regulator.

Public Comment:

Dr. Cronin questioned if the committee intended to review the requirements and identify components that were no longer necessary to be included on the label and noted that the FDA has also established requirements.

Ms. Herold responded that it was the intent of the committee to identify requirements that are most important to the consumer and that the board will also need to review the FDA requirements.

Ms. Herold discussed the requirements from California Business and Professions Code Section 7076.

The committee's experiment generated the following results:

- Trade name – for the patient
- Generic name – for the patient
- Name of the manufacturer – for the regulator
- Directions for use – for the patient
- Patient name – for both the patient and the pharmacy
- Prescribers name – for the patient
- Issue date – not determined
- Pharmacy name – for both the patient and the pharmacy
- Address of pharmacy – for both the patient and the pharmacy
- Phone number of pharmacy – for both the patient and the pharmacy
- Prescription number – for both the patient and the pharmacy
- Strength of the drug – for both the patient and the pharmacy
- Quantity of the drug – for the patient
- Expiration date – for the patient

- Condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription – for the patient
- Physical description of the dispensed medication including the color, shape, and any identification codes that appear on the tablets/capsules – for the patient

Ms. Herold asked for the committee to establish a list of the most important requirements to a patient from the perspective of a regulator.

Kristy Schieldge, DCA Staff Counsel, provided that the legislation directed the committee to improve directions for use, improve font types and sizes, and placement of information. She added that these elements should be considered when making recommendations to the board.

Mr. Powers sought clarification on the recommendations indicated in the research.

Assistant Executive Officer Anne Sodergren provided that the survey results indicate the top three responses for label information as directions for use, the name of the drug, and the dosage prescribed.

Ms. Herold suggested that the committee prioritize the requirements to determine what should be printed in a larger font on the label.

Discussion continued regarding prioritizing label information.

The committee discussed the board's proposal to add the purpose of the drug on the prescription label.

Dr. Swart stated that the medical board would need to agree to include the purpose for the drug on the prescription. He discussed that drugs are used for a variety of different purposes and that these purposes may be unclear to the patient and the pharmacist.

Ms. Herold indicated that the board is seeking legislation to include the purpose for the medication on the label. She added that the patient will be asked for the purpose before it is added to the label. She explained that the pharmacist may need to handwrite the purpose onto the label.

Mr. Powers discussed that many patients are unaware of the purpose for their medication.

Ms. Herold responded that the legislation will require the purpose if requested by the patient.

Dr. Cronin questioned if the board is interpreting that the current law prohibits the pharmacist from indicating the purpose of the drug when requested by the patient. He sought clarification on whether or not including the purpose is in violation of the law.

Ms. Herold responded that there are many elements included on a label that are not specifically required by law.

Dr. Schell stated concern for patient privacy. He discussed that adding the purpose to the label will also impact the pharmacy, not just the patient.

Discussion continued regarding patient consultation and indicating the purpose on the label.

Dr. Cronin suggested discussing this issue within an article in the board's newsletter and suggested that the board provide an interpretation of current legislation.

Mr. Powers responded that an article may not adequately address issues of legislation.

Ms. Schieldge advised the board against interpreting existing law.

Dr. Schell indicated that further action on this matter should be considered during subsequent meetings.

Ms. Herold reviewed that the three elements identified as most important to the patient included the name of the drug, directions for use, and the strength of the drug.

There was no additional board or public comment.

5. Timelines for Project Deliverables

Dr. Schell provided that when SB 472 was enacted, the board had the following general timeline:

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

Dr. Schell shared that the board is on schedule with respect to the timeline, but there is much work to accomplish in the first half of 2009 to ensure the regulations are fully ready by the end of the year. The sooner the board finalizes the requirements, the more time that will be available to pharmacies to comply with the requirement by January 1, 2011.

Dr. Schell stated that, ideally, the rulemaking will be completed before the end of this year. To meet this ambitious deadline:

- By the April Board Meeting, the general requirements for the labels should be in draft form.
- A regulation should be ready by July for board action. If not, a special board meeting may need to be convened in advance of the October Board Meeting.
- Board action to adopt the regulation should occur no later than the October Board Meeting.

Dr. Schell noted that the board's executive officer and SB 472 Subcommittee will continue to work with the experts in the field of health literacy and patient-centered label design to develop the regulation's requirements for labels.

Much research material on designing patient-centered labels was already shared with the board in advance of the November 20, 2008 Board Meeting Forum on SB 472.

Dr. Schell provided that patient-centered labels are not the only issue when considering consumer safety. He advised the board to continue to work closely with the public and members of the industry for further progress.

6. Public Comment

No public comments were provided.

7. Future Meeting Dates

The next subcommittee meeting was scheduled for March 12, 2009, at 6 p.m. in Sacramento.

Dr. Schell stated that one item which will be discussed during this meeting will be the development of additional meetings needed to complete this process.

The meeting was adjourned at 3:24 pm.