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

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: August 19, 2009

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

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
Randy Kajioka, PharmD, Vice President
Stanley C. Weisser, RPh, Treasurer
Ramón Castellblanch, PhD, Public Member
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member
Shirley Wheat, Public Member

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Susan L. Ravnan, PharmD
Robert Swart, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Carolyn Klein, Legislation and Regulation Manager
Tessa Fraga, Staff Analyst

Call to Order

President Schell called the meeting to order at 9:37 a.m.

President Schell recognized Department of Consumer Affairs Director Brian Stiger.

Mr. Stiger introduced himself to the members of the board. He discussed the department's enforcement proposals and future plans to enhance the enforcement program.

A. Summary and Background of Board Efforts to Implement SB 472 (Corbett, Chapter 470, Statutes of 2007) Patient-Centered Medication Labels

President Schell provided an overview of Senate Bill 472 (Chapter 470, Statutes of 2007). He stated that that the goal is patient safety and accessibility.

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

Executive Officer Virginia Herold reviewed the following survey results:

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

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

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

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

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

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

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

- Easy-open lids should be used; no child-proof caps for seniors
  (30 of 158 responses = 19.0%)

- Include purpose of the drug – state what condition the medication is intended to treat
  (22 of 158 responses = 13.9%)

Ms. Herold provided that the survey results have been used to complete the proposed language for the regulation. She indicated that the survey and the survey results are available on the board's Web site.

No board or public comment was provided.

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

Ms. Herold reviewed 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 provided that SB 472 was enacted pursuant to SCR 49 (Speier) as a means to reduce medication errors. She stated that SCR 49 was sponsored by the California Pharmacists Association (CPhA).

Presentation to the Board

Ms. Herold provided an overview of the requirements of SB 472. She stated that SB 472 added section 4076.5 to the Business and Professions Code, relating to the development of patient-centered prescription drug labels. Ms. Herold

indicated that California is the first state that has been charged to design a patent-centered label.

Ms. Herold reviewed the logistical issues involved with the development of SB 472 with regards to container size and the limited space available on a prescription label. She provided that the developed regulation must allow flexibility in the size of the label to accommodate a diversity of containers and packages and to focus on the standardization of the patient-centered information. She stated that patient-centered information is best displayed with the following guidelines: use of a sans serif font, a minimum of a size 12 typeface, avoidance of all capital letters, use of numerals instead of text for numbers, highlighting or bolding for emphasis, and “chunking” or clustering of patient-centered elements into one area of the label.

Ms. Herold provided that according to researcher Dr. Michael Wolf, standardization of directions for administration instructions can accommodate 90 percent of all labels’ directions. She stated that standardizing directions for use will ease the development of translations and assure that patients who can read a language other than English will still be able to read the important directions for use on the label as well as increasing consistency and maximizing comprehension.

Ms. Herold prompted the board with a variety of questions to consider with the development of the regulation. These questions included:

- Should the board specify the minimum size of the area for the clustered patient-centered elements on a label?
- Should the board develop translations in the top five languages for directions for use?
- How shall the board deal with labels for the remaining 10 percent of directions for use that are not in the standardized list? Should the pharmacy be required to translate these directions if necessary?
- What about the requirements of the physical description of the contents of a medication by B&P 4076(a)(11)(A) – should the board require these be translated into diverse languages, or should a picture of the pill be considered as complying with the directions?
- If the board translates the directions for use – how should the board deal with translating other patient-centered items on the label?
- The National Boards of Pharmacy (NABP) also identified expiration date as patient-centered. Does the board wish to reclassify this component?
- What about auxiliary labels – how should the board deal with these?

Ms. Herold provided that the board will need to reevaluate and review the requirements of this regulation after at least the first 4 years and then periodically thereafter.

Dr. Anandi Law, representing Western University of Health Sciences College of Pharmacy, highlighted her research on prescription labeling. She discussed the elements of a modified label that has been designed to increase patient comprehension and ease of use. Such elements included a dosing table that indicates what time the patient needs to take the medication.

Board Discussion

Stanley Weisser asked if the table added to the modified label has resulted in any confusion for patients.

Dr. Law responded that patients will be allowed to take the modified labels home to use for a month. She stated that they will seek patient input regarding the functionality of this table.

Ramón Castellblanch suggested that the refill information be provided in a larger font size. He also asked whether there was consideration for the use of a picture of the tablet instead of a written description.

Dr. Law provided that the financial implications for making the changes will need to be evaluated. She indicated that the use of picture was considered.

Dr. Castellblanch questioned if there is any research regarding the use of written warnings versus warning pictograms.

Dr. Law responded that pictograms often lead to confusion.

Greg Lippe suggested that the refill information be presented in the same color as the information presented above it.

Dr. Castellblanch discussed the addition of the purpose of the medication to the label. He suggested that white space be added between the directions and the purpose.

Dr. Law discussed the use of a list that provides both a medical indication and a suggested patient friendly indication.

Public Comment

Jay Mandavorn, representing the Veterans Administration, expressed concern regarding the use of warning pictograms. He suggested that a stop sign could be used in conjunction with a written warning to help consumers identify important information.

Vic Guzynd, representing the California Alliance for Retired Americans (CARA), suggested that the doctor's name be listed for refills and that the date of expiration be provided in a larger font size.

Diana Madoshi, also representing CARA, expressed support for the dosing table included on the model label. She suggested that the check mark in the table be made a larger size.

Steve Gray, representing Kaiser Permanente, provided that research conducted by Kaiser has shown that using the phrase "no refills" can cause some patients to discontinue using their medication. He suggested that this phrase not be used.

Randy Kajioka asked how many characters fit in the directions field of the modified label.

Dr. Law responded that there is room for 6 lines of directions.

President Schell discussed the fixed timeframes in the table and questioned if it would be possible to allow some flexibility in these indications to meet the specific needs of patients.

Dr. Law provided that more work will be done in this area to define more flexible boundaries.

Mr. Weisser sought clarification regarding the font size used on the model label.

Dr. Law provided that a variety of font sizes were used ranging from 4 to 12-point. She stated that the patient's name is in 12-point and the name of the drug and the directions are both provided in 9-point.

There was no additional board or public comments.

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

Ms. Herold reviewed the draft language for the patient-centered labels regulation. She advised that the draft language provided on the board's Web site is not an up-to-date version.

Presentation to the Board

Ms. Herold highlighted the goals of SB 472 and explained that the board should finalize the regulation as soon as possible so that industry has approximately one year to implement the new requirements. She provided that if the language is not

finalized so that it can be noticed, the board may need to schedule a September Board Meeting to finalize the regulation.

Ms. Herold provided that the board has identified four main elements of a label that are the most important to patients and should be emphasized including the name of the patient, the name of the drug and its strength, the directions for use, and the purpose of the drug. She reviewed the following elements that have been identified to maximize the presentation of the patient-centered elements on a label:

- Type of font: sans serif is regarded as the easiest to read
- Size of font: at least a 12-point
- Cluster patient-centered information into one area
- Use of bold typeface of highlighting
- Use of numerals instead of text for numbers
- Standardized directions as much as possible

Ms. Herold clarified that sans serif is a category of fonts.

Tessa Fraga, Administrative Analyst, highlighted recommended font types and size for increased readability of prescription labels. She explained that general recommendations are varied and are often dependent on the product being produced. Ms. Fraga provided that the U.S. Food and Drug Administration (FDA) enacted a regulation that requires nonprescription drugs to carry clear, simple and readable labeling. She stated that specific requirements include a minimum type size of 6-point, a clear, easy-to-read type style such as Helvetica or Universe, with no more than 39 characters per inch, and the use of graphical highlights such as contrast or white space. Ms. Fraga reviewed recommendations offered by the field of health literacy including the use of a sans serif font in 12-point, avoidance of all capital letters for words and phrases, and the use of numbers instead of the text equivalent.

Ms. Herold provided that the use of a 12-point is emphasized across all types of readability indexes.

Ms. Herold presented several example labels that have been designed to emphasize the identified patient-centered elements in a specified area of the label. She reviewed decision points for the board including:

- Should there be specification of the minimum size of patient-centered area of the label (40%, 50%, etc of the total label size)?
- Should elements be set up in a “template format” like a check?
- Will standardized components (specific sized area, font size) work for all labels and containers?
- Will standardized components work for all pharmacy environments and container shapes – round, square containers, and triangular containers?

Mr. Weisser provided that a larger font would make it easier to find important refill information including the phone number of the pharmacy and the prescription number.

Mr. Lippe provided that the example utilizing the Tahoma typeface is the easiest to read.
President Schell also provided support for use of the Tahoma typeface.

Shirely Wheat sought clarification regarding whether a minimum standard is being established when indicating that patient-centered information should be in an area that is 50% of the total label size. She also asked whether the prescription number and the pharmacy contact information are considered patient-centered information.

Ms. Herold confirmed and stated that pharmacies can choose to enlarge these areas. She provided that the board has indicated that the prescription number and the pharmacy contact information is not considered patient-centered information. Ms. Herold clarified that the information provided on the example labels, with exception to the purpose, is currently required by law.

President Schell asked if the consumer survey results indicated a demand for the physician's name or the phone number of the pharmacy.

Ms. Herold responded that this information was not significantly requested. She provided that the consumers indicated a strong demand for a larger and easier to read font.

Ms. Wheat provided that according to the survey results, 43% of respondents indicated that they have trouble finding information on the label. She stated that the "checkbook" model would ensure that specified information is always found in a specified location on the label regardless of where the prescription is filled.

Mr. Lippe recommended the use of highlights instead of increasing the font size to emphasize other important information.

Dr. Castellblanch provided support for the use of the "checkbook" model. He emphasized the charge of the board to develop a standardized label.

Joshua Room, Deputy Attorney General, sought clarification regarding whether the regulation would include the avoidance of use of all capital letters.

Ms. Herold provided that the regulation reflects the available research, the National Boards of Pharmacy (NABP) model, and the work of the board. She stated that the board must define a regulation that is clear and specific. She advised that the more specific the regulation is, the more difficult it will be for industry to comply with the requirements.

Rosalyn Hackworth provided support for the “checkbook” model. She sought clarification regarding any research on the highlighting colors used on labels and the use of a different color for each family member.

Ms. Herold provided that the prescription bottle used by Target includes a different color band for each family member. She stated that using different colors for each family member will be complicated if patients have their prescriptions filled at a variety of pharmacies.

Dr. Castellblanch provided that research has indicated that the use of yellow or blue highlighting is preferred on labels. He stated that the use of all caps is not conclusive.

Mr. Room provided that based on his own background and experience in publishing, the use of all caps in a smaller font creates a better visual impression without impacting or sacrificing space.

Ms. Herold provided that the amount of space provided in-between lines also has an impact.

Ms. Herold highlighted the elements of the proposed regulation with respect to the needs of seniors, standardizing the directions for use, and the needs of patients with limited English proficiency. She discussed the requirements of SB 853 (Escutia, Chapter 713, Statutes of 2003).

Ms. Herold proved an overview of the California Endowment project which is aimed to translate and pilot test the top five non-English languages in California. She indicated that the program researcher, Michael Wolf, PhD, has conducted research to translate the common directions for use in the top five non-English languages.

Ms. Herold recommended that the board utilize these translated directions for use.

Ms. Herold highlighted the tradeoffs involved with the development and implementation of the requirement of the proposed regulation.

The board evaluated the presented tradeoffs and discussed the board’s liability with regards to providing and mandating translations. It was advised that the board would assume greater liability if it mandates the use of translations.

There was no additional board discussion. No public comment was provided.

4. Directions for Use on Prescription Labels

Ms. Herold reviewed the 17 directions for use established by Dr. Wolf that have been compiled in the proposed language.

Michael Wolf, PhD, representing Northwestern University, highlighted findings from a study that focused on a patient-centered approach to designing prescription labels and providing prescription instructions. He provided that about 90 percent of all directions for use will fit into one of the established standardized directions for use. Dr. Wolf indicated that the United States Pharmacopeia (USP) will be utilizing these directions in their own standards.

Board Discussion

Dr. Castellblanch sought clarification regarding whether the use of the 17 directions would have comparable benefits to the Universal Medication Schedule (UMS).

Dr. Wolf clarified the purpose of the UMS.

Mr. Room asked if the use of tables or charts on labels would benefit health literacy issues.

Dr. Wolf responded that the use of graphic aides tends to be problematic. He advised that research regarding the benefit of graphical representation is inconclusive.

Dr. Castellblanch sought clarification regarding the usefulness of graphic representations for warnings.

Dr. Wolf provided that it is difficult to convey a clear message with the use of a picture.

Dr. Castellblanch discussed the possibility of providing a short statement on the label to refer the patient to another document that would list the warnings.

Mr. Room sought clarification regarding whether the repetitive nature of the 17 directions is attributed to the fact that they are intended to be translated. He discussed the translation of bracketed information to allow for a more flexible language structure.

Dr. Wolf responded that certain elements are repetitive and that it may be possible to reduce this redundancy.

Dr. Kajioka asked if consideration had been given to the route of administration and sample directions for other forms of medications.

Dr. Wolf provided that research in this area is limited.

Dr. Castellblanch asked if a specific color for highlighting has been deemed to be more helpful for consumers.

Dr. Wolf provided that the use of yellow highlighting was found to be harsh for the elderly and causes difficulty with reading. He stated that there is a consensus that light powder blue works well for highlighting as it provides enough contrast and is not as bright as yellow.

Dr. Castellblanch questioned if there is any evidence regarding increased decanting of medication when a larger container is used to accommodate a larger font.

Dr. Wolf provided that he is currently studying the use of a 30 dram bottle. He advised that the use of a 12-point font is a good standard.

Public Comment

Diana Madoshi, representing the California Alliance for Retired Americans, provided that it is common for consumers to transfer their medications into a more convenient container such as a pill box organizer.

Ms. Herold asked Dr. Wolf for a review of the California Endowment project

Dr. Wolf provided that the California Endowment project is intended as a proactive approach for evaluating and translating the standardized directions for use in the top 5 languages in California.

There was no additional board or public comment.

5. Public Comment

William Powers, representing the California Alliance for Retired Americans (CARA) and a member of the SB 472 Committee, provided that labeling is an important, yet small part of the medication error issue. He commended the board and its staff for their efforts. Mr. Powers encouraged the board to focus on keeping labels as standardized as possible to protect the consumers.

Mr. Weisser asked Mr. Powers if CARA has addressed the issue of pediatric dosage. He expressed concern regarding populations that are at great risk with regards to medication errors.

Mr. Powers provided that CARA focuses it efforts on the concerns of the senior population.

Dr. Castellblanch sought input regarding the tradeoff of requiring a larger container to accommodate a larger font size on the label.

Mr. Powers provided that the readability and understandability of a label are the key elements.

Margie Metzler, representing the Gray Panthers, thanked the board for its efforts in this area.

Steve Gray, representing Kaiser Permanente, provided that the technology in this area has substantially changed. He stated that Kaiser has secured a new contract for a pharmacy system that allows for label flexibility in terms of design to meet requirements nationwide. Dr. Gray discussed several safety factors including the use of barcodes. He discussed SB 853 and the difference between interpretation and translation.

Mr. Room asked Dr. Gray for an opinion regarding whether the board should mandate a font size for a prescription number and the phone number of the pharmacy.

Dr. Gray provided that he believes this is not necessary. He stated that the focus should be on the information that is clinically important.

There was no additional public comment.

B. Discussion and Possible Action to Initiate Rulemaking to Adopt 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

1. Discussion of Provisions for the Board's Regulation to Establish Patient-Centered Medication Labels

   The board stated they would address each subdivision of the proposed regulation separately.

Section 1707.5 (a)

Board Discussion

The board discussed subdivision (a) of the proposed regulation. It was suggested that the language be modified to accommodate the "checkbook" model format.

There was no additional board discussion. No public comment was provided.

MOTION: to revise proposed section 1707.5 (a) to read “Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label, and shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:”

M/S: Castellblanch/Weisser

Support: 6 Oppose: 0

Board Discussion

The board discussed paragraphs 1 through 5 provided in subdivision (a). The use of white space and highlighting was evaluated.

Public Comment

Ruth Conroy, representing Walgreens, expressed concern regarding the 12-point font requirement. She stated that Texas has recently passed a law that requires a 10-point font. Ms. Conroy provided that Walgreens would like the board to adopt the use of a 10-point font as it is sufficient for the finite amount of information provided on the label

Ms. Herold provided that the Texas law requires a 10-point Times Roman font to be used only for the expiration date and the prescription number.

Mr. Room clarified that according to the Texas law, the 10-point font is required for a variety of information. He stated that Texas also has an exception that any information not provided in a 10-point font must be provided to the patient in another form in at least a 10-point font.

Dr. Castellblanch provided that the board should compose the regulation based on the available evidence regarding the 12-point font in order to secure the safety of the patient.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), expressed concern with the proposed language. She stated that NACDS believes that the free market should decide font sizes and does not support the mandate of a 12-point sans serif font. Ms. Staples expressed concern that the proposed language and amendments are too prescriptive.

Discussion continued regarding font size. It was clarified that the board has been directed to improve font types and size.

Michael Negrete, representing the Pharmacy Foundation of California, sought clarification regarding whether both the brand name and generic name is required in subdivision (a)(2).

Dr. Kajioka provided that the intent of the requirement is for the generic name to be provided with the brand name. He stated that this is standard practice.

Bob Hanson, representing Safeway, stated that mandating a 12-point font may create space complications for labels for patients with a long name or drug name. He encouraged the use of a smaller font to eliminate these complications.
Steve Gray, representing Kaiser Permanente, discussed a current California law that requires instructions given to a patient or a visually impaired individual be provided in a 14-point font. He stated that the industry standard is to indicate the manufacture identification instead of the manufacture name. Dr. Gray suggested that the board follow this standard.

Mr. Room clarified that the language of the regulation is reflective of the statute.

Discussion continued regarding the use of brand and generic names. Evidence regarding duplicate therapy was discussed.

Dr. Gray encouraged the board to implement the consistent use of the generic name.

Mr. Room responded that this would conflict with the board's statute.

Missy Johnson, representing the California Retailers Association (CRA), provided support for the previous comments. She sought clarification regarding the proposed regulation and the possible impact of future legislation.

Mr. Room provided that if the language conflicted with the code the section would need to be revised in the regulation.

Neel Prasad, representing Target, provided that the current Target label extends from the front of the bottle to the back. He asked whether the requirement to cluster specific information into 50% of the label would apply to the front of the label or the entire label.

Mr. Room provided that the 50% requirement applies to the entire label.

The board continued to discuss this section with regards to font size and the available "real estate" on the label. Discussion focused on the size differentiation between a 10-point font and a 12-point font.

There was no additional board or public comment.

MOTION: to approve paragraphs 1 through 5 of proposed subsection (a) as follows:

1. Name of the patient
2. Name of the drug, brand and/or generic

(Manufacturer's trade name, or the generic name and name of the manufacturer)
3. Strength of the drug
4. Directions for use
5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.

M/S: Lippe/Wheat

MOTION: to table this issue.

M/S: Wheat/Lippe

Section 1707.5 (b)

No board or public comment was provided.

MOTION: to revise subdivision (b) to read "For added emphasis, the label may also highlight in bold typeface or color or use 'white space' the items listed in subdivision (a)."

M/S: Weisser/Lippe

Support: 6 Oppose: 0

Section 1707.5 (c)

Board Discussion

Ms. Herold provided that there are two options for the proposed language for subdivision (c). She explained that the two options differ simply with regards to style.

Public Comment

Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), expressed concern that this section may eliminate the inclusion of other pertinent information on the label. He suggested that the language be changed to avoid interference with section 1707.5 (a).

The board discussed a revision to this language. It was the consensus of the board to revise the language.

There was no additional board or public comment.

MOTION: to revise section 1707.5 (c) to read “The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typeface.”

M/S: Lippe Weisser

Support: 6 Oppose: 0

Section 1707.5 (d)

Board Discussion

Mr. Room suggested that the language of subdivision (d) be modified to replace “shall use” with “include one or more.”

Mr. Lippe sought clarification regarding whether this section eliminates the inclusion of the phrase “take as directed” on the label.

Ms. Herold provided that it does not.

Mr. Room clarified that this subdivision is considered a minimum and reflects only a segment of available prescriptions. He stated that there is the possibility for more directions to be developed for other forms of medications.

Discussion continued regarding the applicability of the 17 directions.

Ms. Herold provided that the intent of this section is to provide a basic and understandable template to provide consistency across all pharmacies.

Public Comment

Michael Negrete, representing the Pharmacy Foundation of California, sought clarification regarding whether this section will allow a pharmacist to interpret a prescription and rewrite it to apply to one of the 17 directions.

Mr. Room confirmed.

Dr. Negrete provided that the use of the phrase “take as directed” is open ended.

Neel Prasad, representing Target, discussed a prescription that indicates dosage in the morning and afternoon as opposed to the morning and evening. He asked how this situation will be addressed.

Dr. Kajioka provided that pharmacists must use professional judgment as there will not be a template for all situations.

Steve Gray, representing Kaiser Permanente, expressed concern regarding the interpretation and impact of this section. He discussed a current regulation that restricts pharmacists from deviating from the original prescription.
Ms. Herold provided that nothing in the regulation is intended to prohibit a pharmacist from exercising commonly accepted pharmaceutical practice when dispensing a prescription.

Dr. Gray provided that based on his experience with common pharmacy practice variation from the prescriber's prescription is not allowed. He discussed that interpretations of these directions can be arbitrary.

Discussion continued regarding the consequences of modifying original dosage instructions.

Bob Hanson, representing Safeway, discussed the arbitrary interpretations of the directions. He stated that this section will establish a new set of standards that contradict the common practice of pharmacy.

Discussion continued regarding the interpretation of the directions for use.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that NACDS recommends that this section be stricken in its entirety.

Ruth Conroy, representing Walgreens, discussed the applicability of the directions. She explained that pharmacists feel that they must type the label exactly how the prescription was written by the prescriber. Dr. Conroy stated that in her opinion pharmacists should be given permission to alter the directions on a prescription so that it can be understood by the patient.

Missy Johnson, representing the California Retailers Association (CRA), provided that the language within this section sets up the pharmacist to make a judgment that may be against the information provided to the patient by the prescriber. She stated that CRA would prefer this section to be taken out of the regulation.

William Young, representing California Pharmacists Association (CPhA) and Kaiser Permanente, discussed that the directions will interfere with the current practice of pharmacy. He encouraged the board to reconsider this section.

The board discussed the option of tabling this issue pending further consideration.

MOTION: to approve section 1707.5 (d) as written.

M/S: Castellblanch/Hackworth

The board chose to table this motion.

Section 1707.5 (e)

President Schell provided that subdivision (e) will be addressed pending the finalization of section 1707.5 (d).

There was no additional board discussion. No public comment was provided.

Section 1707.5 (f)

The board did not discuss subdivision (f).

Section 1707.5 (g) and (h)

President Schell reviewed subdivision (g) and (h).

The board discussed that these subdivisions, which refer to translations, may not be necessary if the directions for use from section 1707.5 (d) are not adopted. The board's liability for providing translations was also discussed.

Mr. Room provided that the first sentence of section 1707.5 (g) is redundant with section 1717.5 (e) and should be stricken from the regulation. He clarified that both sections (g) and (h) are translation requirements being placed on pharmacies.

The board decided to further discuss this section at a future meeting.

Public Comment

Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), expressed concern with subdivisions (g) and (h). He discussed the logistical issues that can complicate translations. Dr. Gray explained that pharmacies will not be able to fulfill these requirements due to technology limitations.

Mary Staples, representing the National Association of Change Drug Stores (NACDS), stated that the NACDS would recommend that the board strike subdivisions (g) and (h). She stated that the NACDS currently provides 800 numbers at their pharmacies to provide patients with oral translations. Ms.

Staples explained that pharmacists are not comfortable dispensing a prescription that they do not understand when their license may be in jeopardy.
Dr. Castellblanch sought clarification regarding the new Texas legislation with regards to Spanish translations.

Mr. Room provided that the Texas law does not include requirements for translations.

Ms. Wheat provided that she would not support subdivisions (g) and (h) as written. She expressed concern that the translations would put pharmacists in an uncomfortable position and may provide patients with a false sense of security with the information provided on the label. Ms. Wheat suggested that, if the board does choose to pursue translations, English directions should be provided along with the secondary translation.

Dr. Castellblanch provided that Spanish is the primary language of a large population of Californians. He stated that the board is required to address this.

Assistant Executive Officer Anne Sodergren asked how New York pharmacies represented by the NACDS are complying with the translation requirements in that state.

Ms. Staples provided that the New York regulation has not yet been signed.

Missy Johnson, representing the California Retailer Association (CARA), expressed concern regarding a possible emergency situation where an emergency responder locates a patient's prescription bottle with a label that is not printed in English.

There was no additional board or public comment.

MOTION: to strike section 1707.5 (g).

M/S: Wheat/Lippe

The board chose to table this motion.

2. Public Comment

No public comment was provided.

C. Schedule for Adoption and Implementation of Section 1707.5.

President Schell provided that enhancements to the proposed regulation need to be made. He stated that an additional meeting will be planned.

D. Public Comment

No public comment was provided.

The meeting was adjourned at 3:33 p.m.

SB 472 Regulation Requirements for Patient-Centered Labels

Virginia Herold
Executive Officer
California State Board of Pharmacy

B & P Code Section 4076.5(a)

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

Patient-Centered Label

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

B & P Code Section 4076.5(b)

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

B & P Code Section 4076.5(c)

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

B & P 4076.5(c) (continued)

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

B & P Code Section 4076.5(d)

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

The Label Serves a Number of Purposes

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

NABP Policy

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

NABP Policy (continued)

- *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.*

Logistic Issues in Developing this Regulation:

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

If the Container is Too Large

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

A Container Could Be Too Small for the Standardized Label

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

Result on Regulation:

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

Directions for use

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

Directions for use

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

Standardizing Directions for Use

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

General rules:

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

General Rules:

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

Question:

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

Question:

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

Question:

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

Question:

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

Question:

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

Question:

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

Question:

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

Reevaluation:

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

Questions:

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

Finalizing the Regulation

Patient Centered Labels

Adopt Section 1707.5

Today's Outcome

Goal: to finalize the regulation as soon as possible so that industry has approximately one year to implement.

- **Finalize regulation language so it can be noticed to take action at the next board meeting.**
- **If the language is not finalized so it can be noticed, the board will need to set a September Board Meeting date to finalize the regulation.**

Patient Centered Labels

From SB 472: patient-centered labels:

- **Increase patient understandability of the label**
- **Contain improved directions for use**
- **Contain improved font types and sizes**
- **Place information in a patient-centered fashion**
- **Address the needs of patients with limited English proficiency**

Patient-Centered Labels

- Address the needs of senior citizens
- Consider technology requirements needed to implement the standards

SB 472

- **Directs the board to rely upon medical literacy reach that points to increased understandability of labels**
  - **-- The board has used the available research in this area to develop the proposed regulation requirements.**
  - **-- It has also conducted consumer surveys of its own.**
  - **--Staff propose ongoing review with research findings.**

Patient-Centered Elements

***Goals: Make it easy to read, easy to find, consistent from label to label*.**

1. Identify elements of a label most important to patients and emphasize these:

- **Name of Patient**
- **Name of Drug and Strength**
- **Directions for Use**
- **Purpose**
- **Expiration date?**

Patient-Centered Elements

2. Maximize the presentation of the patient-centered elements on a label

- **Type of Font: Sans Serif is regarded as easiest to read**
- **Size of Font: at least 12 point**
- **Cluster patient-centered information into one area**
- **Use bold typeface or highlighting**
- **Use numerals instead of text for numbers**
- **Standardize directions as much as possible**

Decision Points

- Should there be specification of the minimum size of patient-centered area of label (40%, 50%, etc of the total label size)?
- Should elements be set up in a “template format” like a check?
- Will standardized components (specific sized area, font size) work for all labels and containers?
- Will standardized components work for all pharmacy environments and container shapes – round, square containers, triangular containers?

Needs of Seniors

Elements of the proposed regs:

- **Highlight key information on label**
- **Specify typefaces, font sizes and emphasis (bold, highlight) to improve readability**
- **Clustering info into one area of the label**
- **Standardize directions for use**
- **Add purpose of the medication**

Standardizing Directions for Use

- Promotes increased patient comprehension how to take meds when directions are consistent
- Promotes better comprehension when written at a basic reading level
- Allows translation of directions

Needs of Patients with Limited English Proficiency

- **Need translated labels**

  How to address issues?

  --Pharmacist/pharmacy staff must be able to read label

  --Many languages in use in CA

  --Requirements of SB 853

Requirements of SB 853

from the DMHC

Q:What is the responsibility of a pharmacy providing medicine to an HMO-insured patient who cannot read English to provide labels and

supplemental written material in the language of the patient?

A: The relevant code sections under the Knox-Keene Act are Health and Safety Code Section 1367.4 and Title 28, California Code of Regulations, Section 1300.67.04.

Under the regulations of the Knox-Keene Act, pharmacies that contract with a managed care plan to provide prescription drugs ordered by the plan's physicians would be considered a "point of contact" for purposes of language assistance requirements.

However, we look to the health plan (not the pharmacy directly) to provide the Department a description of the arrangements the plan will make to provide or arrange for the provision of timely interpretation services at no charge to limited English proficient (LEP) enrollees at all points of contact where language assistance is needed. [See Section 1300.67.04 (G)(i-vi).

It is the health plan's responsibility to comply with the obligations for availing enrollees with interpreter services at all points of contact. Then the plan makes those arrangements, agreements with the point of contact, e.g., pharmacy, provider office, facility etc.

California Department of Managed Health Care, August 18, 2009

Translations

- California Endowment project to translate and pilot test top five non-English languages in California (Spanish, Chinese, Russian, Vietnamese, Korean). Lead researcher: Michael Wolf, PhD Funded for two years, beginning August 2009

"We have proposed and tested labeling standards based on health literacy and human factors research. English enhanced Rx instructions instilled with these characteristics will be linguistically and culturally adapted to 5 common languages in California. This set of multilingual instructions will be pilot-tested in San Francisco, CA and Chicago, IL to ensure generalizability. Instructions can be directly disseminated to pharmacies; impacting practice and policy within California and nationally."

Trade Offs

- **The larger the font specified, the easier to read, but the greater the likelihood that a larger container will be needed.**
- **The larger the container, the greater the likelihood that a patient will remove the medication from the container and put it in a more “portable” container simply due to the bulky size.**

Trade Offs

- **Specifying the minimum size of the label to house only patient-centered information will develop a template–like, consistent area for patient information. This will aid patients in locating this information on any label. The larger the area specified for this information (especially if the minimum font size is specified), the greater the potential for a larger container to be used.**

Trade offs

- **If label requirements are too strict about layout: this will limit the type of container in use**

  (Target's label, triangular containers, central fill pharmacies' automated lines, unusual containers)

Trade offs

- **Specifying the directions for use as proposed in the draft regulation – Dr. Wolf estimates will account for about 90 percent of label directions in use. Not all directions for use can be standardized at this time (a project for future amendments to the regulation).**

Trade offs

- **Less standardization of directions also will result in some directions not being translated by the board.**
- **However, many languages in use in California will not have translations provided by the board/via the California Endowment project.**

Trade offs

- **Draft of regulation aims at translating directions for top five languages – what about translation of patient-centered information on the rest of the label?**

  (e.g., purpose of drug, description of the medicine)

Trade offs

- **The more information that is specified as patient-centered and emphasized, the more the potential exists for too much clutter on the label (which decreases readability).**

  Does the board want to add as patient-centered the expiration date? The description of the medicine?

Trade Off

Should the board require both English and the translation to appear on the label?

1707.5 Patient Centered-Labels on Medication Containers

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

(a) Each of the following items shall be clustered into one area of the label, and shall be printed in at least 12-point, san serif typeface:

1. Name of the patient
2. Name of the drug, brand and/or generic (Manufacturer's trade name, or the generic name and name of the manufacturer)
3. Strength of the drug
4. Directions for use
5. Purpose or condition, if entered onto the prescription [or otherwise known to the pharmacy and its inclusion on the label is desired by the patient]

(b) For added emphasis, the label may also highlight in bold typeface or color items listed in subdivision (a).

(c) The remaining required elements for the label specified in Business and Professions Code section 4076 shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a), and may appear in any style and size typefont.

Or: Display of all other elements on the prescription drug label required by Business and Professions Code section 4076 may appear in any style or size type font, provided that the label can still meet the requirements of subdivision (a). The placement of these items on the drug label shall not obscure the emphasis on or placement of the items listed in (a).

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

1. Take 1 tablet at bedtime
2. Take 2 tablets at bedtime
3. Take 3 tablets at bedtime
4. Take 1 tablet in the morning
5. Take 2 tablets in the morning
6. Take 3 tablets in the morning
7. Take 1 tablet in the morning, and Take 1 tablet at bedtime
8. Take 2 tablets in the morning, and Take 2 tablets at bedtime
9. Take 3 tablets in the morning, and Take 3 tablets at bedtime
10. Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
11. Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
12. Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
13. Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
14. Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime

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

(e) By October 2010, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in (d) into at least five languages other than English, to facilitate use thereof by California pharmacies.

(f) Beginning in October 2010 and thereafter, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(g) The board shall provide translations of the above-listed translations in at least the five most dominant non-English languages used in California. When instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (d) the pharmacy shall secure its own translation.

(h) For patients who cannot read English but can read in another language, upon request, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient.