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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS
MINUTES

DATE: November 20, 2008

LOCATION: Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
D. Tim Dazé Esq., Vice President, Public Member
Shirley Wheat, Public Member
Stanley Weisser, RPh, Treasurer
James Burgard, Public Member
Robert Swart, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Kristy Schieldge, Senior Staff Counsel
Robert Ratcliff, Lead Supervising Inspector
Karen Abbe, Analyst
Tina Thomas, Analyst

President Schell called the meeting to order at 1:43 p.m.

President Schell explained that today's forum is being hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being.

1. Welcoming Remarks

President Schell stated that the Board of Pharmacy takes the Medication Safety Act very seriously and considers it a primary focus. He noted the significant degree of literature and study that has been conducted on the topic of patient-centered labeling. He explained that the board has facilitated forums such as today's in order to gain more input from the public which they serve. This input is needed to ensure that medication labels are designed in a way that will facilitate positive patient outcomes. President Schell stated that the board has a subcommittee in place to focus on the topic. The subcommittee has taken action to conduct surveys and attend outreach events as well in order to receive input from a wide variety of resources.

2. Improving Prescription Container Labels – What is the Status of the Research - (Michael S. Wolf, PhD, MPH and Stacey Cooper Bailey, MPH)

President Schell introduced Dr. Wolf and Ms. Bailey.

The board heard a presentation from Dr. Wolf which detailed the results of a research study conducted by Northwestern University, Louisiana State University and Harvard University over the past several years related to problems patients face when trying to read drug labeling. He added that the focus over the past year has shifted to finding ways to improve prescription drug labeling specifically. He stated that they have conducted several studies to identify specific aspects of how drug instructions are written and how drug labels are organized in order to support patient understanding and use.

Dr. Wolf reviewed current intervention targets, with primary targets being drug warnings and precautions, and "sig" instructions. He reviewed the value of patient-centered drug labels - that they are tangible, brief, repeatedly used, and are the only source of information for many. He shared results of studies which provided the percentage of patients reading their drug labels incorrectly. He described the numerous ways a simple sig can be interpreted, as well as significant dispensing variability based on interpretation by a pharmacist.

Dr. Wolf explained new studies currently in place relating to prescription instructions, drug warnings and precautions, standardized prescribing and improved physician counseling. Dr. Wolf stated the objective of an enhanced prescription label design and explained that the method of studies included an actual-use assessment. Dr. Wolf reviewed the specifics of an enhanced label prototype. The prototype involves a change in cylinder dimensions in order to minimize the "wrap around" of text within the label. He explained, however, that there are major obstacles to implementing such a label in regards to pharmacy software. He stated, however, that when the enhanced labels were provided on

prescriptions to patients within their study, the comprehension rate increased significantly. Dr. Wolf discussed drug warnings and suggested simplified information, which improves a patient's likelihood of understanding their label and adhering to it.

Ms. Bailey explained that, although the majority of their studies have been based around the English-speaking community, they have more recently placed focus on communities with limited English proficiency or are non-English speaking. She reviewed study results of the Latino population with language challenges, and identified specific states with the largest of those populations. Ms. Bailey stated that their studies involved research on pharmacies located within some of the larger Latino populated areas in four states, to assess their ability to translate prescription instructions and labels for those who need it. Within those states, 700 pharmacies were included in the study. Results indicated that 56% of those pharmacies had limited or no language translation capability. Additionally, of the 44% with language translation capability, 61% use a computer based translation program. She noted that the issue of translation capability is not limited to rural areas or areas with a small Latino population.

Dr. Wolf added that they are in the beginning process of developing actual-use assessments similar to those conducted on the English-speaking population and having them translated to be able to conduct similar studies in Spanish. He did not state when those results would be available.

Board Comments:

Mr. Weisser commented on a statistic from Ms. Bailey's presentation, with regard to the percentage of pharmacies that could provide translation services for prescription labels by way of a computer program. He asked how the pharmacies that do not have that capability provide the translation service.

Ms. Bailey responded that there were various sources that those pharmacies used to assist them, including bi-lingual pharmacy staff members and website search engines.

Robert Swart asked if their study included what is required in other states with regard to the prescription label.

Dr. Wolf responded that their research involved discussion with numerous state pharmacy boards, which ultimately resulted in discovering 31 different variations of label requirements. He added that, even with the varying requirements that would need to be taken into consideration, it still appears feasible to accommodate those requirements with the enhanced labeling prototype discussed. He did note the issue of smaller bottles, however, and the challenges with space in relation to the potential of larger font size requirements.

Mr. Weisser commented on the issue of verbiage with relation to medication schedules (i.e. mealtimes, specific times, morning, etc.).

Dr. Wolf responded that it is a very large topic of discussion. He noted that many physicians, for example, are against using mealtimes. He added that there is consensus that the higher priority is to clarify whether or not a medication is to be taken with a meal or not.

Discussion continued regarding the issue of which verbiage should be used to indicate when to take medication.

Jim Burgard asked if the study considered the potential of a standardized size bottle.

Dr. Wolf responded that they did not include that consideration, but would find that to be valuable. He added that it would be best to have a minimum size bottle.

Virginia Herold asked if there is anything that Dr. Wolf can state unequivocally as "this is what we know".

Dr. Wolf referred to a paper in the Annals of Pharmacotherapy, published in 2007. He explained that the paper went through a systematic review of the evidence to date to support the content and format of drug labels. He added that they also have a table which lists issues of recommended font size, bold type, etc. which he can forward to the Board. Dr. Wolf stated that what they have repeatedly found to be most useful to patients, and their understanding of the use of their medication, are the items displayed on the left side of the enhanced label prototype reviewed during the discussion. He noted the importance of indication as a key item that should be included, based on their research.

Robert Ratcliff asked if there has been any consideration to converting to a "zip-loc" type bag instead of bottles.

Dr. Wolf responded that the topic of preventing medication overdoses in pediatrics was recently discussed at a meeting with the Institute of Safe Medication Practices. He stated that the potential of plastics bags might be considered, but more likely with relation to over-the-counter drugs. He added that he has heard discussions involving various packaging solutions, but does not know how that will move forward. He noted his support of the medication bottles manufactured specifically for Target pharmacies.

Ms. Herold referred to a discussion at the prior board meeting, and noted the issue raised by manufacturing companies in the need for medication bottles to be round in order for their equipment to accommodate them. She discussed the

potential to turn the label in the other direction on the bottle, for printing purposes.

Dr. Wolf responded that it would allow for more characters per line in that format.

Public Comments

Larry Lovett referred to labels translated into other languages. He asked if there was any review on the accuracy of the translation, and noted the issue of various "dialects" and uses of terminology amongst different countries and regions.

Ms. Bailey responded that they are hoping to conduct studies on the issue in the future, and noted the hesitation of some pharmacies in translating prescriptions as they are unsure if it will be understood correctly by the patient.

Larry Drechsler stated his support of the enhanced label prototype. He referred to the issue of verbiage in specifying when to take their medication, and noted the importance of ensuring patients take all doses as required by centering the times on something they can relate to. He shared concern over the topic of non-identifiable drugs that lack a stamp, etc. He stated that the markings and design are essential in order to avoid confusion and medication errors. Mr. Drechsler touched on prior discussion of limiting the amount of warning labels. He questioned how that would be accomplished with consideration of legal requirements of many specific warning labels on particularly dangerous drugs.

Dr. Wolf responded on the issue of connecting dosages with mealtimes, as well as the issue of ensuring medications are taken with food when identified as such. He stated the importance of including that information as part of the "sig", rather than as a separate warning label. He agreed with Drechsler's comment on drug design and markings, and noted the importance of ensuring consistency in those markings with relation to generic drugs. Dr. Wolf discussed the items included in the third panel of the prototype, which includes the warning labels. He stated that it would be ideal to gain input from pharmacists and utilize their expertise on what is most important in terms of auxiliary warnings. He discussed the option of noting a label on the bottle, directing the patients to review the inserts provided with their medication which will address warnings, etc.

Tina Tarsitano shared concern over the root of administration, as well as whether the pharmacist has the liberty to alter the directions in relation to indicating the time a patient should take their medication.

Dr. Wolf responded, on the question of root of administration, that further testing is needed. He responded to the question of altering directions from the prescriber by explaining that the goal is to standardize those directions so that there is no need to alter them.

Melvin Snidman asked if labels with translated directions are also provided in English.

Ms. Herold stated that, in California, the requirements for prescription labeling do not specify any requirements in terms of which language(s) instructions must be provided in.

Ms. Bailey stated that similar discussions in New York have indicated that such federal regulations are in place. She deferred to legal counsel for accurate information.

Mr. Snidman noted the issue of causing too much alarm to patients if numerous auxiliary warning labels are included.

Dr. Wolf responded that it is a concern by many physicians, but added that it is also a concern of patients if the information is withheld.

3. Patient Health Literacy in the U.S. and its Impact on Health – Michael Villaire (Institute for Healthcare Advancement)

President Schell introduced Mr. Villaire and provided his background.

Mr. Villaire discussed patient health literacy in the United States, including the impact of low health literacy on health care processes and services.

Mr. Villaire provided definitions on literacy and health literacy and explained that it essentially refers to a person's ability to understand standard health information pamphlets, etc. He reviewed two national surveys on adult literacy. Mr. Villaire explained the three types of literacy – prose, document and quantitative literacy, and explained the four literacy levels (below basic, basic, intermediate and proficient) identified by the National Assessment of Adult Literacy (NAAL). He provided the results of findings from the NAAL Health Literacy studies, with statistics relating to the population's literacy levels as explained. The NAAL statistics indicated, for example, that a person at the "below basic" literacy level would only have a 67% probability of being able to read a medical appointment date on a hospital appointment form. Additionally, a person at the "intermediate" literacy level would only have a 67% probability of understanding what time to take their medications from reading a prescription label. Mr. Villaire provided some of the effects of low health literacy on the population, including how it affects the public's ability to understand many aspects of their healthcare. Specifically, people with low health literacy are twice as likely as others to be hospitalized, more likely to have chronic health issues and less likely to seek treatment.

Public Comments:

Tina Tarsitano referred to the NAAL survey, and asked which languages were most commonly identified in relation to health literacy.

Mr. Villaire stated that the NAAL survey was conducted in English only.

4. Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling – Vanessa Cajina (Latino Coalition for a Healthy California)

Mr. Dazé introduced Ms. Cajina and provided her background.

Ms. Cajina explained that the Latino Coalition for a Healthy California was one of three organizations that initiated the standardization of prescription drug labeling in California.

Ms. Cajina provided the definition of health literacy by the Institute of Medicine. She noted that prescription drugs are regularly used to measure health literacy. She discussed "To Err is Truly Human" – a large-scale research study that tested patient health literacy with relation to prescription instructions. The study also clarified that simplification and explicit dosing instructions are in great need in order to reduce medication errors and increase patient safety. She noted that the study was only conducted in English.

Ms. Cajina provided statistics on languages spoken within California and other states. She discussed measures other states have taken to provide language services in medical settings, and indicated that there are four models in place nationally. Those models include:

- Telephonic interpreting
- Direct interpreter reimbursements
- Direct reimbursement to providers
- Language service agencies and brokers

Ms. Cajina noted that, outside of the medical setting, there have been very few efforts to provide language services. Ms. Cajina also provided statistics on the total Latino population within California.

Ms. Cajina provided history on prescription labeling legislation. She reviewed California's push for medication safety, which included the SCR 49 initiative. She explained that SB 472 was a result of the SCR 49 findings and provided the background on both.

Ms. Cajina reviewed efforts that some pharmacies have done to improve language services, including “talking pill bottles”, translated labels provided by Walgreen’s and Rite Aid, and printing labels and audio information in other languages. She also acknowledged the efforts being made by the Board of Pharmacy in order to obtain input from the public to improve prescription labeling and, ultimately, patient safety.

5. Perspective of California’s Seniors to Improve Prescription Container Labeling – Ramon Castellblanch (California Alliance for Retired Americans)

Mr. Dazé introduced Dr. Castellblanch and provided his background.

Dr. Castellblanch explained that the California Alliance for Retired Americans (CARA) has been working on SB 472 for some time, and look forward to continuing to work with the board in the future. He stated that California is being watched by the rest of the country to see what action will be taken on this topic of prescription label standardization. In other countries, it is also matter of “trial and error” He explained that countries in Europe have standardized labels, but continue to revise the standards as they attempt to make improvements and find a solution that will work for everyone.

Dr. Castellblanch indicated that CARA had a convention in October 2008, where two sessions were held to gain input from the senior community on what is most important to them relating to their prescription labels. He noted that there were 30-40 senior citizens in each session. Dr. Castellblanch provided a summary of the feedback given in the sessions, which included visual-friendly formatting (white space, headers, etc.), font size, highlighting, a minimum size bottle and language accessibility. He stated that concern was shared during the sessions over the description of the pill as well as changes in the color and size of pills when changing dosage. He added that there was positive feedback relating to the medication schedule (i.e. breakfast, bedtime). He also noted that additional questions were raised on various topics by the group, such as

- Temperature storage information
- What to do if a patient misses a dose of medicine
- What to do if having dental work completed
- When to get a refill (before they run out)
- Expiration dates

Dr. Castellblanch stated that they hope to have subsequent meetings as were conducted in October. He explained that CARA meets monthly, with a substantial size group in attendance. He added that CARA and their members would be interested in joining with the Board of Pharmacy to conduct future forums and looked forward to continuing to work with them on SB 472.

6. Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy

Ms. Herold acknowledged Karen Abbe, Public and Licensee Education Analyst, for her efforts in formatting, distributing and compiling the survey results for prescription labeling.

Ms. Herold pointed out the fact that California now has only two years to have standards established and the pharmaceutical industry prepared. She noted that California is the first to establish these standards, and other states will be watching and looking to the California boards for leadership.

Ms. Herold reviewed the factors to be considered in standardizing prescription labels, as mandated by SB 472. Those factors included:

- Medical literacy research
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- Needs of patients with limited English proficiency
- Needs of seniors
- Technology requirements for implementation

Ms. Herold reviewed the SB 472 date requirements, including a report due to the legislature of the board's progress in 2011. Additionally, the board must report the status of implementation to legislature in 2013. She noted the value of this report, as it may be necessary to complete the progress in stages. She explained that the "road map" to the improvement of patient labels is not clearly laid out, and more collaborative work may be necessary. Ms. Herold explained that the regulations will go into effect on January 1, 2011. The goal of the Board of Pharmacy, however, is to have regulations in place in 2009, allowing the software vendors a full year to tailor their software technology to the requirements. She explained that the requirement applies to all California patients acquiring prescription medications, and thus the requirement will apply to pharmacies as well.

Ms. Herold provided the specific requirements according to Business & Professions Code 4076 as it pertains to the prescription label. She explained the subcommittee's responsibilities in terms of the information to be gathered for prescription label standardization. She stated that surveys have been brought to the forum and welcomed assistance from the industry in distribution. Ms. Herold did note, however, that the most successful surveys have been those that are distributed to the public on an individual "one-on-one" basis.

Ms. Herold stated that the first public forum was held in April, 2008 and was held within the author's district. She noted, however, that the turnout to the forum was significantly low. Thus, survey forms were created and distributed through other various venues. Ms. Herold reviewed the survey results to date and noted those items within the label which were listed as the highest importance to the public. Those items included 1) directions for use 2) dosage prescribed and 3) name of the drug as well as others. Additional survey data was reviewed and can be viewed on the board's website. Ms. Herold noted that there were a significant number of surveys completed in other languages as well. She encouraged use of the translated surveys by those who have Spanish speaking constituents.

Public Comments:

Melvin Snidman referred to the requirements from legislature. He suggested an additional requirement that the prescriber's professional degree title and telephone number should be indicated.

Response was provided that the telephone number is a requirement.

Larry Lovett stated that the federal caution requirement was excluded.

Dr. Ratcliff responded that it is only required for controlled substances

Dr. Wolf stated that he hopes the board does not get "bogged down" with details. He reiterated the fact that the rest of the country is watching California and looking to our state for direction. He pointed out that decisions will need to be made that best represent the majority of the public, and that it is not feasible to accommodate all requests given. He noted that too much detail can also create distraction, which causes more harm than good.

Doreena Wong (National Health Law Program) asked if outreach has been done by way of translated surveys and attending events focused on languages besides Spanish.

Ms. Herold listed some of the other events that were focused on specific cultures as well as seniors. She noted that the questionnaire has only been translated into Spanish.

Ms. Wong asked what the deadline is for completion of surveys. She added that she believes there are additional community-based organizations that may be able to assist in collection of input.

Ms. Herold responded that if Ms. Wong would like to assist, please do so as quickly as possible. She added that the data is needed sooner rather than later

and would appreciate being provided with contacts that can assist with distributing surveys to additional constituents.

7. Public Comments for Items Not on the Agenda

Dawn Bronsema (CARA) stated that she attended the CARA convention. She said that she was inspired by the discussion and assisted in collecting surveys. She shared general results of the survey, which included 1) larger font 2) medication schedule 3) purpose of the drug 4) generic name, and 5) description of the pill. She stated that CARA has meetings all over the state several times a year, and have access to a substantial representation of the senior community. She concluded by stating that they are available to help where needed on this important project.

Bryan Hui (Tongon Community Service Center) provided background on the Tongon community, specifically the elder portion of that community which have health issues and are non-English speaking. He shared the experience of an individual from the Tongon community who passed away, as she did not understand and, thus did not follow-through, on her treatment and drug prescription as provided.

Anita Le (PALS For Health) explained that their organization is a language service provider and that they train individuals on language proficiency for the purpose of becoming interpreters. She stated that she was speaking on behalf of PALS for Health, as well as a consumer. She gave examples of her experiences in relation to misunderstandings of medication and how it relates to health literacy. Ms. Le stated that PALS for Health would like to assist the Board of Pharmacy in reaching out to the Asian-American community.

Doreena Wong (National Health Law Program) provided background on their organization. She explained that they have been working with the limited-English and immigrant population for many years, and agreed with the importance of assisting those populations in understanding their medicine. She stated that a webinar was conducted to discuss the efforts being made in addressing the issue of health literacy with relation to language barriers. She noted Title 6 of the 1964 Civil Rights Act. They hope to have the results of a research study available soon, which will indicate the prescription label requirements within each state. She reiterated the connection between decreased health literacy and health outcomes, and that it is exacerbated when language barriers exist. Ms. Wong provided examples of patient illness as a result of poor health literacy and language barriers to the treatment or prescription information provided. She noted that on November 13, 2008 the Attorney General settled with the CVS and Rite Aid to provide translated labels as well as counseling in six different languages. She explained that this decision will result in 2000 CVS and Rite Aid pharmacies providing those services across the country in the near future.

8. Next Steps

The committee will continue with the prescription label surveys and provide a report of the results to the board at the January Board Meeting.

9. Public Comments for Items Not on the Agenda

No public comments were provided.

The board acknowledged Melvin Snidman who has been a pharmacist for 50 years. Dr. Swart provided Mr. Snidman with a Board of Pharmacy 50-year pin.

Mr. Snidman stated that the board is doing a good job. In regards to labeling, there is no simple solution to resolving the issue. He provided an example of child who was not recovering from illness due to a misunderstanding by the parent of how to provide the medicine.

The meeting was adjourned at 4:26 p.m.