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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: June 10, 2010

LOCATION: First Floor Public Hearing Room
400 R Street
Sacramento, CA 95816

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD
Deborah Veale, RPh
Tappan Zee, Public Member

BOARD MEMBERS NOT PRESENT: Shirley Wheat, Public Member

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

Call to Order

President Weisser called the meeting to order at 9:34 a.m.

President Weisser recognized former board president Ken Schell.

General Announcements

I. Possible Action on Proposed Regulation Section 1707.5.

a. Discussion Regarding Adoption of New Section at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Drug Container Labels, Including Comments Received During the April 28-May 13, 2010 Comment Period

Background

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

Since July 2009, the board had dedicated a portion of every meeting to develop this regulation including convening three special board meetings in August 2009, February 2010, and this June 2010 meeting principally to focus on the regulation.

Here is an overview of the timelines since the board initiated the rulemaking:

October 22, 2009	Board initiates rulemaking and directs staff to release the proposed language for 45 days
Nov. 20, 2009 – Jan. 4 2010	Initial (45-day) Comment Period
January 20, 2010	Regulation hearing. Board reviews comments received during 45-day comment period. Board moves to modify the regulation text and issue a 15-day public comment period.
February 17, 2010	Board again reviews all comments received during the 45-day comment period and reaffirms its vote to modify the text of the regulation and issue a 15-day public comment period.
Feb. 22 – Mar. 10, 2010	1st 15-Day Comment Period

April 22, 2010	Board Meeting (day 2) – Board considers comments received during 1st 15-day comment period, modifies proposed text of § 1707.5 (a)(1) and § 1707.5(a)(1)(D) and directs that a 2nd 15-day comment period be initiated
April 28 – May 13, 2010	2nd 15-Day Comment Period

Focus of SB 472's Requirements

Senate Bill 472 directed the board to focus on seven items in developing its patient-centered label regulation (§ 4076.5(c)):

1. Medical literacy research that points to increased understandability of labels.
2. Improved directions for use.
3. Improved font types and sizes.
4. Placement of information that is patient-centered.
5. The needs of patients with limited English proficiency.
6. The needs of senior citizens.
7. Technology requirements necessary to implement the standards.

Board Discussion

Executive Officer Virginia Herold stated that substantially fewer comments were submitted during the April 28-May 13, 2010 comment period than during the February comment period. She stated that the proposed regulation represents a compromise between the comments received on 12 versus 10-point font. Ms. Herold discussed the possible impact the new requirements may have on pharmacies who currently do not offer 12-point font on the label.

Dr. Ramón Castellblanch provided comment on the notification to consumers regarding the 12-point font option. He voiced concern that consumers will not make this request and stated that some pharmacies may not be able to comply with providing labels in both size fonts. Dr. Castellblanch expressed concern on the liability of this voluntary system.

Joshua Room, Deputy Attorney General, asked if pharmacies would default to a 12-point font if they could not provide both 10- and 12-point fonts.

Ms. Herold provided that the board is obligated to educate consumers on their rights in the marketplace. She stated that the department has expressed interest in producing a public outreach video on this issue and aid the board in other public education materials.

Ms. Herold provided that overall; board licensees do strive to comply with the law.

Deborah Veale stated that smaller pharmacies have indicated that this requirement will be problematic and difficult to comply with. She discussed some of the comments received and suggested that the board consider modifications to the regulation with respect to extended instructions and identifying the appropriate time for patient's to request 12-point font.

Greg Lippe suggested that pharmacies can ask their patients if they want the 12-point font when they ask if a childproof cap is desired. Ms. Veale suggested that the request for 12-point font could be made when the prescription is presented at the pharmacy.

Ms. Herold asked what pharmacies do now when including long instructions on the label.

Ms. Veale provided that some pharmacies often cut and paste the label to fit on the bottle, whereas others may include the instructions on a separate piece of paper.

Mr. Lippe expressed concern that it may be dangerous to only allow a consumer to request the 12-point font at the initial presentation of the prescription.

Dr. Randy Kajioka provided that available technology would allow a pharmacy to re-label a patient's medication at any point of care.

Rosalyn Hackworth suggested that board should also consider how a patient would make this request with automated and over-the-phone refills.

Dr. Kajioka discussed the patient centered label elements and the limited space of the label. He suggested that the manufacturer name may not be needed in a 12-point font in order to save room on the label.

President Weisser provided that, based on his experience as a pharmacist, patients had to access the pharmacist and the pharmacy staff in order to make individualized requests.

Ms. Veale expressed concern regarding too much information being provided in 12-point font including the manufacturer name. She stated that the instructions should be in 12-point font.

Ms. Hackworth discussed the importance of providing the patient name in 12-point on the label to ensure the correct prescription is being dispensed to the correct patient.

Ms. Herold offered for the board members' viewing sample labels with differing font sizes utilized for the manufacturer name.

Dr. Ken Schell provided comment on customization within the pharmacy practice and the important relationship between the patient and the pharmacist.

The board discussed the inclusion of the manufacturer name as patient-centered element on the label.

Ms. Herold advised that the board will have an additional opportunity to make additional modifications and refinements when the requirements are readdressed in two years. She stated that the board must decide whether or not the regulation needs any additional refinement before proceeding.

Dr. Castellblanch asked if there is any available evidence on the importance of the manufacturer name on the label.

Ms. Herold provided that the manufacturer name can potentially be misunderstood as the name of the drug.

Dr. Kajioka stated that although the manufacturer name is required by law to be on the label, it does not need to be in 12-point font considering the limited space available on the label. He suggested that the name of the manufacturer be stricken from section 1707.5 (a)(1)(B).

Kristy Schieldge, DCA Senior Staff Counsel, indicated that this change would result in an additional 15-day comment period.

Discussion continued regarding the inclusion of the manufacturer name on the label. It was stated that the manufacturer name was often included in a smaller font size or was handwritten on the label by the pharmacist.

Dr. Castellblanch expressed concern that including the manufacturer name will actually help to reduce medication errors.

b. Public Comment

Fred Mayer, representing PPSI and the Gray Panthers, discussed several points regarding the regulation. He requested that all testimony provided at previous meetings be submitted to the Office of Administrative Law (OAL) and the United States Pharmacopeia. Mr. Mayer provided comment in support of 12-point font and language services in at least five languages. He indicated that the additional costs for providing 12-point font on the labels should not be passed on to the consumers.

Diana Madoshi, representing the California Alliance for Retired Americans (CARA) and the Villa Senior Network, shared that her pharmacy has denied her request to have the name of the medication and the dosage information in at

least a 12-point font on her label. She expressed concern that pharmacies are not able to meet this request as she was able to easily modify the font size on a sample label that she had designed on her home computer. Ms. Madoshi provided that pharmacy chains need to be accommodating to their consumers. She stated that the board has the authority to ensure that chains will provide larger font sizes for their consumers.

Roger Wright discussed important patient-centered elements that should be provided in 12-point font including the drug name, the patient's name, and the instructions. He provided comment on language services and advised that many patients are unable to advocate for themselves in this area. Mr. Wright provided that pharmacies will find a way to implement and comply with the regulation.

Ching-Jen Tu provided comment in support of larger font sizes and language options on the label to help patients read and understand their label.

Marty Martinez, representing the California Pan-Ethnic Health Network (CPEHN), expressed concern that the regulation does not reflect the intent of the original legislation.

Doreena Wong, representing the National Health Law Program, encouraged the board to use both the manufacturer name and the generic name on the label. She stated that the provided testimony supports the need for 12-point font. Ms. Wong expressed concern that language assistance is not provided in the regulation. She encouraged the board to take the lead in this area to ensure that all consumers have equal access to health care and pharmacy services.

Dr. Steve Gray, representing Kaiser Permanente, discussed the use of the manufacturer name in current pharmacy practice. He stated that providing the manufacturer name on the label in a smaller font would not be problematic. Dr. Gray discussed that it is more important to identify the brand name when a generic is being used than to identify the manufacturer.

Ed Sherman, representing the California Pharmacists Association (CPhA), provided comment in support of mandating that all out-of-state prescriptions comply with the regulation. He discussed the additional costs associated with the requirements and advised that adequate implementation time is needed. Mr. Sherman added that the manufacturer name is generally irrelevant in most cases.

Michael Negrete discussed the importance of listing the brand name when a generic is dispensed. He stated that the brand name is more valuable information on the label than the manufacturer name.

Dr. Castellblanch expressed concern that a generic may not be the equivalent of the brand name.

Mr. Negrete provided that pharmacies must dispense generics that have been identified by the U.S. Food and Drug Administration (FDA) as equivalents.

Mr. Room provided that the board does not have the authority by this regulation to require the language “generic for” on the label.

Missy Johnson, representing the California Retailers Association, requested that the regulation be amended to specify that the patient must make their request for 12-point font at the time the prescription is filled to alleviate impacted workflow issues. She also requested that the board minimize the amount of elements deemed patient-centered including the manufacturer name. Ms. Johnson expressed concern regarding implementation time and asked the board to consider an implementation time of 12 months.

Dr. Castellblanch asked for statistics on patients who can effectively advocate for themselves.

Ms. Johnson indicated that she is unaware of statistics in this area. She indicated that pharmacies at the store level make every reasonable to effort to accommodate their patients’ requests.

Lynn Rolston, representing the California Pharmacists Association (CPhA), provided that CPhA was the original sponsor of SCR 49. She stated the board to implement the regulation in the least disruptive way. Ms. Rolston discussed several issues including mail order and central fill prescriptions, the high volume of prescriptions being filled today, long wait times for prescriptions, decanting of medications, and the need for sufficient implementation time. She stated that there is a potential danger in requiring a pharmacist to supply a label in a language that they cannot read.

Dr. Castellblanch provided comment on the anecdotal evidence presented throughout this process. He asked about the availability of evidence regarding the decanting of medication.

Ms. Rolston stated that she does not have evidence in this area. She stated that many caregivers have indicated that decanting is a prevalent problem.

Ms. Herold clarified that mail order prescriptions are subject to the requirements of the regulation.

Nancy Tilcock, representing CARA, expressed concern that patients won’t be adequately informed about the 12-point font option in order to make this request. She requested that the board not place the burden on the patients to make this request.

Dr. Gray provided that an implementation period will be needed. He expressed concern that patients may be required to request 12-point font upon first presentation of the prescription to the pharmacy. Dr. Gray discussed the growing use of electronic prescriptions that go directly from the prescriber to the pharmacy. He stated that in this case, the request for 12-point font must be made to the prescriber.

Ryan Brooks asked Dr. Gray how Kaiser Permanente accommodates requests for a larger font at the prescriber level.

Dr. Gray provided that Kaiser pharmacists are taught that the essence of filling a prescription is custom packaging in order to accommodate individual needs.

Dr. Castellblanch provided that his electronic prescriptions are already filled and labeled by the time he arrives to the pharmacy from his doctor's office at Kaiser.

Dr. Gray stated that the federal government has mandated the move towards electronic prescriptions. He stated that physicians are often offered financial compensation for providing electronic prescriptions. Dr. Gray indicated that in 2016, there will be penalties imposed for those not providing electronic prescriptions.

Ms. Veale asked if there is a solution in this area.

Dr. Gray stated that he believes that the solution is to not establish a regulatory standard of practice that would allow it to be permissible not to adjust a label because the request was not made when the prescription was initially presented.

Mr. Brooks asked why it would be difficult to educate prescribers to ask what font size the patient prefers when writing a prescription.

Dr. Gray indicated that this would require that 150,000-200,000 prescribers in California be adequately educated regarding this new practice.

Dr. Kajioka provided that this issue should be addressed by prescriber groups as well. He stated that the pharmacist will take the time at any point of service to repackage or relabel to meet the needs of the consumer.

Dr. Castellblanch provided that the regulation specifies that the request for 12-point is made by the consumer, not the prescriber.

Ms. Veale provided that she believes the pharmacy would honor the prescriber's request to provide a 12-point font for the patient.

William Young recommended that the board revise the font minimum to be 12-point font and allow the patient to request a 10-point font if desired. He added that proper implementation time is necessary.

There was no additional board discussion or public comment.

c. Possible Action to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Drug Container Labels

Mr. Weisser reviewed the following options before the board:

1. Adopt the regulation as noticed for comment on April 28, 2010
2. Modify the regulation to accommodate recommendations or comments and release modified text for a 15-day comment period
3. Modify the regulation and re-notice if for 45 days

The board discussed a motion to adopt the regulation to require a 12-point font for the name of the patient, the name of the drug with the recognized trade name if provided, and the directions for use. The purpose could be in at least 10-point font and the manufacturer information would be deleted from the 12-point area of the label.

Tappan Zee stated that this change would result in another 15-day comment period. He expressed concern about the time being taken to move this regulation. Mr. Zee provided comment in support of the current proposed language.

Mr. Lippe provided an implementation period will be required regardless of whether the requirement is a 10-point font or a 12-point font. He stated that he believes providing the most important elements on the label in 12-point font promotes the ultimate goal of patient safety.

Mr. Brooks cautioned the board from being overly prescriptive. He discussed the potential for unintended consequences and encouraged the board to adopt the regulation as written.

Ms. Hackworth provided comment on patient safety with respect to the patient's ability to read their label and the prevalence of decanting.

Dr. Castellblanch discussed the importance of the information provided on the prescription label with regards to patient safety. He provided comment in support of the motion.

Public Comment

Bob Hanson, representing Safeway, discussed the implementation of child-proof caps. He stated that a request for 12-point font could be made similar to how a child-proof cap is requested.

Don Gilbert, representing Rite Aid, spoke in opposition to the motion. He reminded the board that DCA Director Brian Stiger supported the current language as a reasonable compromise. Mr. Gilbert stated that patients will change to a different pharmacy that will meet their needs.

Nan Brasmer, representing the California Alliance for Retired Americans, provided comment in support of 12-point font.

Doreena Wong, representing the National Health Law Program, recommended that the board require all elements on label to be printed in 12-point font.

Marty Martinez, representing the California Pan-Ethnic Health Network, provided comment in support of 12-point font.

MOTION: Modify Section 1707.5 (a)(1) to read as follows:
(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label~~. ***Each item shall be printed in at least a 12 –point, 10-point, sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and***~~ listed in the following order. Subparts A, B, and C shall be printed in at least a 12-point, sans serif typeface. Subpart D shall be printed in at least a 10-point, sans serif typeface.

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name ~~***and the name of the manufacturer***~~.

(C) Directions for use

(D) Purpose or condition, if entered onto the prescription by the prescriber.

M/S: Lippe/Castellblanch

Support: 3 Oppose: 5 Abstain: 1

Mr. Brooks offered a motion to adopt the regulation as currently written.

No public comment was provided.

MOTION: Direct staff to take all steps necessary to complete the rulemaking process including the filing of the final rulemaking package with the Office of Administrative Law. Authorize the executive officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt section 1707.5 in article 2 of division 17 of title 16 of the California Code of Regulations as noticed for public comment on April 28, 2010.

M/S: Brooks/Zee

Support: 6 Oppose: 2 Abstain: 1
The board discussed the implementation date and effective date of the regulation with regards to the statutory mandate and possible action at today's meeting. President Weisser suggested that the effective date be January 1, 2011 or upon filing, whichever date is later.

Assistant Executive Officer Anne Sodergren stated that the suggested effective date is consistent with the statutory mandate.

Ms. Schieldge provided an overview on the rulemaking process and encouraged the board to act in line with their legislative directive.

Public Comment

Missy Johnson, representing the California Retailers Association, stated that the board can discuss whether other organizations could pursue other legislative vehicles for the regulation at the July 2010 Board Meeting. She stated that industry has not delayed this legislative process.

Doreena Wong, representing the National Health Law Program, discouraged the board from approving a lengthy implementation period.

Mr. Room clarified that there is a legal requirement for the regulation to be filed with the Secretary of State.

Ms. Wong requested that the language assistance manual presented to the executive officer be included in the rulemaking file.

Ms. Schieldge indicated that the period for submitting additional comments has ended.

There was no additional board discussion or public comment.

MOTION: Establish an effective date for Title 16 California Code of Regulations Section 1707.5 of January 1, 2011 or upon filing, whichever date is later.

M/S: Schell/Hackworth

Support: 6 Oppose: 0 Abstain: 3

II. Department of Consumer Affairs Director's Report

Kimberly Kirchmeyer, DCA Deputy Director of Board and Bureau Relations, provided an update on the department's initiatives. She discussed the Consumer Protection Enforcement Initiative (CPEI), a systematic approach designed to improve formal discipline taken by health care boards to address three specific areas including administrative improvements, staffing and IT resources, and legislative changes. Ms. Kirchmeyer shared that the Legislative Budget Conference Committee has approved the CPEI at the full funding and staffing levels proposed in the Governor's FY 2010-11 Budget. She stated that the Legislative approval includes 138.5 authorized positions and more than $12.7 million for DCA's 18 healing arts boards, for purposes of reducing the current enforcement processing period from an average of three-years, in some cases, to an average of 12-18 months.

Ms. Kirchmeyer provided that the DCA had also received legislative approval during the regular budget hearing process to implement the BreEZe automation system that will provide all of DCA's customers with an integrated licensing and enforcement information technology solution that will be replacing DCA's current outdated legacy systems.

Ms. Kirchmeyer provided that the department has been conducting enforcement academies to develop and promote best practices.

Ms. Kirchmeyer indicated that SB 1111 did not pass out of the Senate Business and Professions Committee. She requested that the board review its statutory authority in this area. Ms. Kirchmeyer discussed new performance measurements established by the department and requested that the board be prepared to report on these areas in October 2010.

Ms. Kirchmeyer requested that the board add the implementation of SB 1441 as an agenda item at the next board meeting and to implement any standards that do not require any additional legal authority.

Ms. Kirchmeyer thanked the board and board staff for implementing email votes.

Ms. Kirchmeyer provided comment on continuing competency. She discussed that the department is encouraging a proactive approach in this area.

Ms. Kirchmeyer invited the board to attend a board member training sponsored by the department on July 27, 2010.

Ms. Herold thanked Ms. Kirchmeyer and the department's administration for their efforts towards the budget change proposal and the implementation of BreEZe.

No public comment was provided.

III. Development of Proposed Text for Possible Future Rulemakings

a. Discussion Regarding Possible Regulation Specifying Consumer Notice for Language Assistance Interpretative Services Provided in Pharmacies

The board resumed discussion of agenda item II with respect to the enforcement of the regulation.

Ms. Schieldge provided that the enforcement of the regulation would be at the discretion of the executive officer. She stated that the board can provide direction in this area.

Ms. Veale provided that the will of the board should direct enforcement.

Ms. Herold provided comment on enforcement issues the board may encounter with respect to licencees that are not in full compliance after January 1, 2011. She stated that if inspected licensees will be reviewed on a case-by-case basis and may need to provide implementation plans or readiness assessments to document their progress. Ms. Herold added that the inspectors may also educate licensees on the requirements during inspections.

Discussion continued regarding the efforts of licensees to comply and implement the requirements with good will. It was discussed that full compliance immediately following the effective date is not necessarily expected by all licensees.

Ms. Herold provided that pharmacies are already dealing with requests for larger font sizes on the label and have adopted means to accommodate this demand. She discussed available assistive devices such as magnifying glasses designed to attach to the medication bottle that may be used in the interim prior to full implementation of the requirements.

The board resumed its discussion of agenda item III. a.

President Weisser reviewed the possible language for future rulemakings provided in the board packet.

Ms. Veale suggested that the language be added to the existing consumer notice.

Dr. Castellblanch recommended that the board move forward with the recommended language.

Ms. Schieldge advised that the proposed language would require a change in current law.

Mr. Room provided that the proposed language was intended to be broad and includes all options in order to provide the board with flexibility.

President Weisser sought clarification regarding the timing of this process.

Mr. Room provided that the language can be included as an instruction to staff at time of adoption.

Dr. Kajioka expressed concern that the language may be overly prescriptive.

Ms. Herold provided that adding more content to the current posters may be problematic. She stated that providing the notices on a video screen may be a possible alternative that addresses issues involving limited space on the posters and within a pharmacy.

Mr. Brooks cautioned that being too prescriptive may lead to a missed possibility to inform the public.

Dr. Castellblanch stated that the board should consider what the consumer will actually see and look at while waiting for their prescription at the pharmacy.

Discussion continued regarding the possible language. Clarification was requested on the potential conflict between a pharmacy requirement and federal regulation.

No public comment was provided.

b. Discussion Regarding Possible Regulation Specifying Consumer Notice About the Availability to Request Prescription Drug Container Labels in Larger Font Sizes

Background

At its January, February and April 2010 Board Meetings, and within the context of discussions to develop requirements for patient-centered prescription drug container labels, the board heard suggestions that consumers should be notified of various components of the patient-centered prescription drug container label regulations – such as a consumer's right to request a larger font on their prescription label, and that language interpretation services are available. These suggestions were also included in some comments received during the public

comment periods for the proposed rulemaking.

One proposal would reorganize existing Section 1707.2 (which contains requirements for two existing “Notice to Consumers”), combine these with the two new proposed notices, and place the “Notice to Consumers” at new Section 1707.6 of Title 16 of the California Code of Regulations.
Also, in establishing new requirements, the board may wish to consider adding other parameters; such as

- How many languages (e.g., five most dominant languages in CA or in the Community--those for which MediCal provides written materials)
- Require the board to develop the written notice(s) and make them available to pharmacies (like the board does for the Notice to Consumers posters required by §1707.2)

Ms. Veale provided that the language regarding the four categories of information available in 12-point font may be confusing to the consumer. She suggested that the notice simply state that consumers have the right to request 12-point font.

Mr. Room cautioned that consumers may misunderstand that they are entitled to all information in 12-point font.

Dr. Kajioka provided that many patients request that the label accommodate visual impairment and not a specific font size. He suggested that visual impairment can be noted in a patient’s profile.

Ms. Veale provided that not all patients may consider themselves to be visually impaired.

Public Comment

The board heard public comment on agenda items III. a and b.

Rebecca Cup, representing Ralphs, provided that if the language is not specific consumers may assume they are entitled to a font size larger than 12-point.

Missy Johnson, representing the California Retailers Association, requested that the Notice to Consumers include information regarding the availability of the 12-point font with the identified elements. She discussed that requiring pharmacies to post notices in each of the languages for which interpretive services are available will be burdensome due to limited wall space and as some pharmacies provide services in over 120 different languages.

Ms. Veale asked what signage is currently being used to advertise these language services.

Ms. Johnson provided that many pharmacies keep a placard at the pharmacy counter and present it to patients who indicate that they do not speak English. She explained that patients can point to their language on the placard in order to receive appropriate interpretive services.

Ms. Herold requested a copy of this placard.

Ms. Veale asked if various methods for notifying consumers such as the placard would be permitted.

Mr. Room provided that this would be at the board's discretion. He explained that the proposed language allows for both a posting and placard method.

The board discussed the establishment of parameters that would identify what languages should be available with respect to geographical location. Concern was expressed that limiting the available languages may contradict the efforts of the pharmacy industry which is currently providing services in over 100 languages. It was suggested that the board convene a panel at the next board meeting to provide guidance in this area.

There was no additional board discussion or public comment.

c. Discussion Regarding Possible Regulations to Strengthen Board Enforcement Programs Pursuant to the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Dr. Castellblanch requested that the board resume its discussion of agenda item III. a. He suggested that the board require that the pharmacist orally communicate the 12-point font option to the patient.

Public Comment

Missy Johnson, representing the California Retailers Association (CRA), provided that CRA would be opposed to such a requirement. She stated that this requirement would set a new precedent to require pharmacy staff to inform patients of the information provided on the Notice to Consumers.

There was no additional public comment.

The board commenced its discussion of agenda item III. c.

Background

Since July 2009, the Department of Consumer Affairs has been working with health care boards to upgrade their capabilities to investigate and discipline

errant licensees to protect the public. The result of these efforts yielded the Consumer Protection Enforcement Initiative (CPEI) which is a comprehensive three-pronged solution: a new computer system; additional staff resources; and legislative changes. The CPEI solution will achieve the goal that average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months.

Many of the legislative changes were incorporated into SB 1111 (Negrete-McLeod). During the April 2010 Board Meeting, the board was advised that SB 1111 failed passage in a policy committee, so the board did not discuss SB 1111 in any detail during that meeting. Since that time, the department has identified provisions contained in the bill that could be implemented through regulations, and further requested that all healing arts boards develop language and initiate the rulemaking process.

Ms. Sodergren suggested that the board discuss the policy behind SB 1111 as it reviews each regulation.

Ms. Herold provided that the possible regulation language was developed to correspond with the board's regulatory authority to implement some of the provisions in SB 1111. She advised that some of the provisions in SB 1111 would require legislation to implement.

§1760. Disciplinary Guidelines

Proposed Amendments

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~10/2007~~ 6/2010), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

(a) Notwithstanding the disciplinary guidelines, any proposed decision issued by an Administrative Law Judge in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that contains any findings of fact that: (1) the licensee engaged in any act of sexual contact with a patient, client or customer; or,

contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license or placing the licensee on probation.

(b) Subdivision (a) shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides services as a licensed pharmacist to his or her spouse or person in an equivalent domestic relationship.

(c) For the purposes of this section, "sexual contact" has the same meaning as defined in subdivision (c) of Section 729 of the Business and Professions Code and "sex offense" has the same meaning as defined in Section 44010 of the Education Code.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Ms. Schieldge reviewed the proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations. She explained that sexual misconduct is currently identified as unprofessional conduct under Business and Professions Code section 726. Ms. Schieldge stated that the amendments will implement the SB 1111 goal to make sexual misconduct a more serious offense and provide the board with discretion with discipline in this area.

Mr. Brooks sought clarification regarding consensual sexual relationships between a pharmacist and a patient.

Mr. Room provided that this relationship would be considered misconduct.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comment on the role of a pharmacist in a variety of settings. He suggested that the board focus on the inappropriate use of a sexual relationship for sexual purposes.

Ms. Herold provided that the board has disciplined pharmacists for trading drugs for sex under existing law.

Ms. Schieldge provided that the current disciplinary guidelines do not contain standards for sexual misconduct. She suggested that the board may wish to address this issue.

There was no additional board discussion or public comment.

§1762. Unprofessional Conduct Defined

Proposed Amendments

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority cited: 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301 Business and Professions Code.

Ms. Schieldge highlighted the proposed additions to section 1762 to add additional grounds for disciplining licensees.

The board evaluated the intent of the proposed additions and discussed whether or not these changes would strengthen the board's program.

Ms. Herold provided that these additions provide the board with additional charging sections and allows for board discretion and flexibility when prosecuting and disciplining licensees.

Ms. Sodergren provided that some court jurisdictions do not notify the Department of Justice (DOJ) of felony charges, arrests, convictions, or

disciplinary action. She explained that requiring the licensee to notify the board will ensure that the board is informed of this unprofessional misconduct.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente and the California Pharmacists Association, expressed concern that the board would be authorized to take action against licensees for acts not related to the pharmacy practice.

Mr. Brooks provided that the board opens many cases involving moral turpitude.

Mr. Room provided that this is not an expansion of the subject matter that the board currently considers. He explained that there is currently only a prohibition on affirmative misrepresentations. Mr. Room provided that this requirement would affirmatively require that licensees notify the board regarding arrests or convictions when they are not being asked about these actions specifically.

Ms. Schieldge clarified that an action reported by a licensee will still be analyzed to determine if it substantially relates to the practice of pharmacy. She stated that any such action would only be public information if the board took action on it.

Bob Ratcliff, Supervising Inspector, sought clarification regarding how subdivision 1762 (b) relates to current section 4332.

Ms. Schieldge indicated that B&P Code Section 4332 makes it a criminal offense to refuse to provide records. Proposed section 1762(b) would make it unprofessional conduct and grounds for revocation of a license to fail to provide records as requested by the board.

Discussion continued. It was the consensus of the board to bring this issue back before the board at a future meeting.

§1769. Application Review and Criteria for Rehabilitation

Proposed Amendments

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination

examiners shall be made available to the applicant. The board shall pay the full cost of such examination. If after receiving the report of evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 480, 482, 820, 4030, 4200 and 4400, Business and Professions Code.

Ms. Schieldge provided that under current law, the board has the authority to compel a mental or psychiatric evaluation of a licensee if it appears that the licensee may be incompetent. She stated that this provision would expand this authority to applicants. Ms. Schieldge indicated that currently the board pays for evaluations it so compels.

Ms. Herold provided that the board requires around five to ten evaluations per year for existing licensees.

Mr. Room provided that the board may also wish to consider competency for basis of evaluation.

Ms. Schieldge provided that SB 1111 and the proposed changes to section 1769 would address possible mental or physical illnesses affecting competency and not general competency issues.

Dr. Castellblanch expressed concern with the board deciding who may need to have the evaluation.

Discussion continued on the application of this provision.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided that this issue does exist among pharmacists and pharmacist interns; however, he stated that it is not prevalent.

There was no additional board discussion or public comment.

MOTION: To require that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report shall be received from the evaluator.

M/S: Veale/Hackworth

Support: 7 Oppose: 1 Abstain: 1

§1770. Substantial Relationship Criteria.

Proposed Language

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

(b) An applicant's, licensee's or registrant's crime or act shall be considered to be substantially related to the qualifications, functions or duties of the license or registration if such crime or act resulted in the licensee or registrant being required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law.

Authority cited: Sections 481, 4005, Business and Professions Code.
Reference: Sections 475, 480, 481, 4200, 4300, 4309 and 4301, Business and Professions Code.

Mr. Room reviewed the proposed amendments to section 1770. He explained that any sexual registration will be an automatic basis for revocation or denial.

Ms. Sodergren added that such an offense would also be automatically deemed substantially related to the qualifications, functions, or duties of the license.

Ms. Schieldge reviewed the elements considered when determining whether a license should be denied or revoked including the act or crime substantially related to the profession and the rehabilitation of the licensee.

Public Comment

Dr. Steve Gray, representing the California Pharmacists Association, expressed concern that this provision would apply to all crime or acts resulting in sexual registration and would automatically be deemed related to the pharmacy profession.

The board discussed the necessity of this proposal and the frequency of such circumstances amongst licensees.

William Young provided that this provision disregards any case-by-case consideration.

The board provided direction to counsel not to bring this issue back before the board.

There was no additional board discussion or public comment.

IV. Discussion Regarding Cost Recovery in Disciplinary Cases

Ms. Herold provided that over the last year, several board members have asked for a discussion of why full cost recovery is not obtained in every disciplinary action the board takes.

Ms. Schieldge reviewed the following California Business and Professions Code section authorizing cost recovery:

125.3. (a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licentiate to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licentiate who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licentiate who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

(k) Notwithstanding the provisions of this section, the Medical Board of California shall not request nor obtain from a physician and surgeon, investigation and prosecution costs for a disciplinary proceeding against the licentiate. The board shall ensure that this subdivision is revenue neutral with regard to it and that any loss of revenue or increase in costs resulting from this

subdivision is offset by an increase in the amount of the initial license fee and the biennial renewal fee, as provided in subdivision (e) of Section 2435.

The board discussed available means by which to obtain cost recovery including use of money judgment defaults. Board staff indicated that a report on current uncollectable cost recovery can be provided at the October 2010 Board Meeting.

Ms. Herold provided that collected cost recovery funds are deposited into the board's fund.

No public comment was provided.

V. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Mr. Brooks suggested that the petition for reinstatement form be revised to include information regarding the prohibition for a licensee to have access to controlled substances if they have ever been convicted of a crime. He requested that this item be added to the agenda for the next board meeting.

VI. Closed Session

Pursuant to Government Code section 11126(c)(3), the Board convened in closed session to deliberate on disciplinary decisions.

The meeting was adjourned at 4:20 p.m.