



California State Board of Pharmacy
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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES**

DATE: December 6, 2010

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

COMMITTEE MEMBERS

PRESENT: Randy Kajjoka, PharmD, Chair
Greg Lippe, Public Member, Treasurer
Ramón Castellblanch, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General (Via Conference Phone)
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Susan Cappello, Enforcement Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Kajjoka called the meeting to order at 1:35 p.m.

Chair Kajjoka conducted a roll call. Committee members Kajjoka, Lippe, and Castellblanch were present.

1. Presentations to Request Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)

Chair Report

Chair Kajioka provided background on this issue. He stated that effective January 1, 2011, the board's requirements for patient-centered labels go into effect as 16 California Code of Regulations Section 1707.5.

Chair Kajioka indicated that also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments.

Chair Kajioka advised that to allow such an exemption, the board will need to promulgate regulations.

Request from Medco for Infusion Pharmacies

Dennis McAllister and Don Filibeck, representing Medco, requested an exemption from the patient-centered labeling requirements of section 1707.5 for 6 California infusion pharmacies that are part of the Accredo Health Group, Inc. and affiliates. Mr. McAllister and Dr. Filibeck provided an overview of how infusion pharmacies operate and explained how they can provide appropriate consumer protection and education without the patient-centered labels.

Mr. McAllister discussed that home infusion and specialty pharmacy practices are "high touch" in nature and exceed patient education and safety that is intended by the requirements.

Dr. Filibeck provided that the pharmacies satisfy the following requirements of SB 1489. The specific exemption for infusion pharmacies occurs in Business and Professions Code section 4076.5(e) (effective 1/1/11):

- (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
 - (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
 - (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
 - (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
 - (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

Dr. Filibeck indicated that the pharmacies are fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Dr. Filibeck discussed that patients are provided health-professional-directed education and open communication between patients and staff to ensure appropriate and comprehensive care is provided. He stated that a plan of care is developed in conjunction with the patient's physician.

Mr. McAllister and Dr. Filibeck reviewed sample labels provided to the committee and expressed concern that a larger or longer label, resulting from increased labeling requirements, may not be able to be appropriately attached to the medication.

Mr. McAllister provided that this exemption is needed to provide safe and effective care to patients.

Discussion

Mr. Lippe asked whether the exemption is being requested because of cost.

Dr. Filibeck provided that the request is being made in the interest of patient safety. He discussed that the objective is to assist patients with being self sufficient and independent in their care.

Mr. McAllister provided that the size of the label is a significant issue. He discussed the use of mini-bags and advised that large labels cover the majority of the bag and restrict the patient's ability to see any particulate matter.

Dr. Castellblanch sought clarification regarding the frequency of a patient's regular contact with a nurse or pharmacist.

Dr. Filibeck provided that the frequency of contact is dependent on the therapy. He indicated that most home infusion requires weekly contact.

Dr. Castellblanch reviewed the instructions provided on the sample labels. He expressed concern regarding technical terms used on the examples. Dr. Castellblanch discussed the importance of patient and caregiver comprehension and competence.

Dr. Filibeck provided that appropriate support is provided and in some cases daily visits by a nurse are provided until all family members or caregivers feel comfortable with administration of the medication.

Mr. McAllister discussed the special nature of this type of care and stated that it is different than chronic care.

Chair Kajioka commended Medco for its multidisciplinary efforts to educate patients. He expressed concern regarding readability of the label. Chair Kajioka asked whether Medco could comply with the font size requirement.

Dr. Filibeck discussed the possibility of offering additional materials to help support the label. He stated that patients are initially assessed to determine that they are viable candidates for treatment at home.

Chair Kajioka asked how the quality of care is mandated.

Dr. Filibeck stated that JACHO requires a care planning process requirement.

Mr. McAllister discussed that this type of care is specific and does not involve the general population.

Mr. Lippe discussed that the request appears to meet the requirements for the exemption.

Executive Officer Virginia Herold announced that Deputy Attorney General Joshua Room is available for comment via conference phone.

Ms. Herold asked whether a patient's comprehensive drug therapy is being monitored by the pharmacy.

Mr. McAllister provided that other medications will be noted in the patient's log. He confirmed that the Medco Pharmacies are only providing the patient with the specialty medications as required by their infusion therapy.

Ms. Herold expressed concern regarding the technical information included on the sample labels.

Mr. McAllister and Dr. Filibeck provided assurance that appropriate support and supplemental information will be provided to the patient.

Ms. Herold advised that the statute requires weekly or more frequent follow up by a nurse or pharmacist. She stated that patients on 30 day monitoring would not qualify for this exemption.

Dr. Filibeck indicated that Medco will comply with this requirement.

Dr. Castellblanch sought clarification regarding dose changes and how this would be indicated on the label.

Dr. Filibeck provided that dose changes occur with the next delivery of the medication. He stated that patients will be notified regarding dose changes.

Chair Kajioka discussed that medication information is discussed during consultation between the pharmacist and the patient as well as between the physician and the patient. He provided that label information is supplemental to the information provided during consultation.

Dr. Filibeck provided that patients are consulted before a change is made to their medication.

Mr. Lippe asked whether patients are asked whether or not they understand the changes being made.

Dr. Filibeck discussed that patients are counseled to ensure they understand and are comfortable with their medication.

Dr. Castellblanch asked what font size is used on the example labels.

Dr. Filibeck provided that he is unsure of the exact font size used on the label.

Ms. Herold stated that a significant segment of the population in California can not read English. She asked if the labels can be printed in other languages.

Dr. Filibeck indicated that the labels can be translated into Spanish. He stated that there are available resources to print labels and supplemental materials in other languages.

Supervising Inspector Robert Ratcliff discussed the example labels provided by Medco. He stated that the labels appear to have more than 50 percent of white space and asked why this space can not be used to satisfy the patient-centered labeling requirements.

Dr. Filibeck provided that the white space is used to increase readability for patients to easily locate label information. He stated that patients are educated to look in specific areas to locate certain pieces of information.

Dr. Ratcliff asked whether Medco will comply with the requirement to list specific elements in a specified order as required by the regulation.

Dr. Filibeck provided that the order of label information can be changed.

Dr. Ratcliff discussed the ability for other organizations to rework their current labels in order to comply with the new requirements of the regulation.

Public Comment

Fred Mayer, representing the California Alliance for Retired Americans (CARA), urged the board to not grant this exemption. He provided comment on the importance of maintaining readability and reducing medication errors. Mr. Mayer suggested that the

board not act on this request until Medco can specify a specific font size that will be used on their labels.

Al Carter, representing Walgreens, provided support for the request. He discussed that it is difficult to create a standardized label to meet the needs of this specialized and specific group.

Mr. Lippe asked what size font is currently being used by Walgreens infusion pharmacies.

Mr. Carter provided the committee with a copy of a standard label in a 10-point font currently being used.

The committee reviewed the label. Ms. Herold requested that Medco provide additional sample labels before the February 2011 Board Meeting.

Mr. Carter provided that Walgreen's chain pharmacies and infusion pharmacies will comply with the labeling requirements. He stated that the labels meeting these requirements should be implemented by late January 2011.

There was no additional discussion or public comment.

Request from CPhA's Long-Term Care Academy

Paige Tally, representing the California Pharmacists Association (CPhA), asked the committee to recommend to the full board an exemption from SB 1489 in 4076.5(d) for skilled nursing facilities as allowed by the following:

- (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

Ms. Tally provided an overview of skilled nursing facilities and stated that these facilities contract with a long-term care facility to provide medications. She stated that medication is securely maintained and is administered to the patients by either a

licensed nurse or a trained medication administrator. Ms. Tally indicated that patients do not need to understand the label directions on their medication containers as they do not receive these containers.

Ms. Tally stated that the new labeling requirements are intended for the regular outpatient population and would not significantly improve care in skilled nursing facilities.

Discussion

Mr. Lippe provided that he reviews all of his medication prior to administration during stays in the hospital.

Ms. Tally provided that this exemption is being requested for skilled nursing facilities and not for hospital settings. She discussed that it is not typical for a skilled nursing facility patient to request to review their medication.

Mr. Lippe asked Ms. Tally if she is aware of the percentage of medication errors that occur in skilled nursing facilities.

Ms. Tally provided that she is unaware of this number. She offered to provide this information for the February 2011 Board Meeting.

Dr. Castellblanch asked how a patient in a skilled nursing pharmacy would be able to evaluate their medication if desired. He sought clarification regarding whether this medication contains a label on the container.

Ms. Tally provided that the medication is labeled.

Dr. Castellblanch requested a copy of the label being used in this setting.

Ms. Tally agreed to provide a label for the February 2011 Board Meeting.

Chair Kajioka reviewed the current labeling requirements under §4076. He indicated that these elements are required to be on the labels for medications administered in this setting.

Ms. Herold asked what will happen to the medication in the event a patient is discharged early if the exemption is granted.

Ms. Tally provided that currently this is dependent on the facility as medication can either go home with the patient or a new prescription will be issued.

Ms. Herold provided that if the exemption is granted, the medication will need to be relabeled to meet the requirements if it is sent home with the patient.

Chair Kajioka clarified that the exemption would only apply to medication labels used within the facility.

Dr. Ratcliff discussed that medication dispensed to a patient in a skilled nursing facility is the property of the patient and will need to be relabeled if it is to go home with the patient. He asked how long it would take to get medication relabeled in this setting.

Ms. Tally provided that relabeling the medication will not be a lengthy or challenging process.

Chair Kajioka provided that the committee will further evaluate this request.

Public Comment

Fred Mayer discussed that there should be standardization in this area. He expressed concern regarding the likelihood that a patient's medication will be relabeled prior to discharge.

Mr. Room clarified that this exemption would require a rulemaking to be initiated. He provided that the rulemaking process will include a hearing and the opportunity for public comment.

Ms. Herold provided comment on the complexity of this request. She stated that Ms. Tally has indicated that medication will be relabeled upon discharge of the patient to go home in order to comply with the regulation as the exemption only applies to medication within the skilled nursing facility.

Mr. Mayer cautioned the committee from granting this exemption and encouraged the board to maintain standardization.

Ms. Tally expressed concern that without the exemption, medication labels will be required to be printed in a foreign language.

DCA Staff Counsel Kristy Shellans clarified that the regulation does not require labels to be printed in a foreign language. She stated that translation services are required. Ms. Shellans indicated that the regulation does not become effective until January 2011, and as such, an exemption can not yet be granted. She advised that this discussion is only a policy discussion.

Dr. Castellblanch expressed concern regarding possible logistical problems in ensuring that medication is relabeled appropriately upon a patient's discharge.

Ms. Shellans recommended that companies interested in seeking an exemption provide data or samples to support their request. She suggested that requests contain at least the following: (1) an explanation as to why the company cannot comply with the new

requirements and (2) information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

Chair Kajioka asked Medco and CPhA to provide the requested samples for review. He requested that board staff provide direction to the companies to ensure that the requests address the committee's concerns.

2. Discussion Regarding Reporting Financial Settlements to the Board Under Sections 801-804 of the California Business and Professions Code

Chair Report

Chair Kajioka provided that the board recently undertook efforts to ensure that licensees and insurance companies are aware of their responsibilities to report to the board pursuant to sections 801 to 804 of the California Business and Professions Code. He stated that these provisions generally require the reporting to the board, by professional liability insurers and by licensees without professional liability insurance, of any settlement or arbitration award over \$3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

Chair Kajioka provided that in the September 2010 *The Script*, the board provided a notice of these reporting requirements.

Chair Kajioka provided that reporting to the board of these settlements is rare. He stated that in 2009/10, the board received 2,331 complaints. Chair Kajioka advised that only 11 complaints were reports under these sections.

Chair Kajioka provided that in 2009, there were approximately 360 million prescriptions filled and dispensed in California by pharmacies. He indicated that the board received notice from patients and from other sources of 307 medication errors during 2009/10. Chair Kajioka stated that this further indicates the high degree of under-reporting under these statutory sections.

Discussion

Ms. Herold provided that the board expects the profession to comply with this reporting requirement.

Chair Kajioka discussed that the reporting is to be done by either the professionals' liability insurer or by the licensee if they do not carry professional liability insurance.

Ms. Shellans provided that the plaintiff's counsel should also file a report with the board. She indicated that the plaintiff should file a report if they did not have representation.

Discussion continued regarding reporting in this area. Concern was expressed regarding the enforcement of this requirement. Chair Kajioka suggested that the board

work with the Department of Insurance on this issue. Dr. Castellblanch recommended that the board also consult the Department of Managed Health Care.

Ms. Herold provided that staff is asking the board for direction on how it would like to proceed with addressing this issue.

No public comment was provided.

3. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

- a. Proposed Amendment to 16 California Code of Regulations Section 1762, Regarding Submission of Records to the Board

Chair Report

Chair Kajioka provided an overview on the background of this issue. He stated that beginning in July 2009, the Department of Consumer Affairs has been working with health care boards to improve capabilities to investigate and discipline errant licensees to protect the public from harm. Chair Kajioka indicated that these results yielded the Consumer Protections Enforcement Initiative (CPEI). He explained that the CPEI was comprised of a three pronged solution designed to ensure that investigations were completed and final action taken against a licensee within 12 – 18 months. Chair Kajioka provided that the solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the board's needs to collect information and monitor performance, and additional staff resources.

Chair Kajioka provided that many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). He stated that unfortunately this bill failed passage early in the year during its first policy committee. Chair Kajioka advised that subsequent to that, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

Chair Kajioka provided that in addition to working with the department on a department wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. He advised that language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Chair Kajioka explained that because of the timing with the legislative cycle, these provisions were not pursued this year.

Chair Kajioka provided that more recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. He stated that the board expressed concern on many of the provisions and with one exception, did not take action on the items.

Chair Kajioka provided that during the October 2010 Board Meeting, board members were advised that the department continues to encourage boards to pursue regulations changes that were previously incorporated into SB 1111. He stated that consistent with this department's request, the board considered several proposed regulation changes.

Discussion

Dr. Castellblanch discussed the upcoming change in administration and questioned whether these provisions are needed considering this change.

Ms. Herold discussed that the board can evaluate whether or not these provisions are good consumer protection policy to advance on its own. She stated that the board can determine at any time that it does not wish to pursue these provisions.

Ms. Shellans requested that the committee consider whether the proposals should be pursued.

The committee evaluated the proposed language (provided below) by each subdivision.

§1762. Unprofessional Conduct Defined

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 without lawful excuse 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.

Discussion – Subdivision (a)

Ms. Shellans reviewed subdivision (a). She stated that this provision would specify that gag clauses in civil suit settlements would constitute unprofessional conduct.

Chair Kajioka offered support to this provision.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(a).

M/S: Lippe/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

Discussion - Subdivision (b)

Ms. Shellans reviewed subdivision (b). She stated that this provision would specify that failure without lawful excuse to provide information as requested by the board within 15 days of the receipt of the request or as specified would constitute unprofessional conduct.

Dr. Castellblanch asked why the “good cause” provision was struck from the language.

Ms. Shellans provided that the board indicated at the October 2010 Board Meeting that it was not comfortable with this language.

Mr. Lippe provided that 15 days seems like a short period of time to comply.

Ms. Shellans provided that 15 days is considered adequate time to respond to a subpoena for business records under current California law.

Discussion continued. The committee evaluated an appropriate timeframe for this provision and conditions sufficient to deem "good cause."

Ms. Shellans provided that the intent of the language is to give a broader exemption that can be applied in a case-by-case basis.

Mr. Room discussed that concern has also been expressed regarding board access to records it is not entitled to request. He indicated that the lawful excuse is intended to address this concern.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed that a subpoena is typically negotiated. He stated that lawful excuse would include negotiations.

Ms. Shellans provided that she does not believe lawful excuse is intended to go to negotiation. She stated that this provision is a request for records, not a subpoena.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(b).

M/S: Castellblanch/Lippe

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (c)

Ms. Shellans reviewed subdivision (c). She stated that this provision would specify that failure to comply with a court order or subpoena for records would constitute unprofessional conduct.

Chair Kajioka stated that this is a prudent provision.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(c).

M/S: Castellblanch/Lippe

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (d)

Ms. Shellans reviewed subdivision (d). She stated that this provision would specify that failure to notify the board about an arrest, indictment, conviction or discipline as specified would constitute unprofessional conduct.

Dr. Castellblanch sought clarification regarding the intent for this provision.

Chair Kajioka provided that this provision will ensure a more timely response.

Assistant Executive Officer Anne Sodergren discussed the challenges involved with receiving court documents and arrest records from the respective agencies. She stated that this provision removes this challenge and puts the burden on the licensee.

Mr. Lippe offered a proposal to recommend that the board pursue this provision.

Public Comment

Dr. Gray discussed that he finds subdivision (d)(4) to be ambiguous and broad. He discussed the extensive monitoring system that large organizations would need in order to comply with this provision. Dr. Gray suggested that this language be revised to provide more clarity.

The committee discussed relevant information to be reported to the board including discipline in another state.

Ms. Shellans explained that significant information to be provided to the board includes notification of suspension, restriction, or probation of a license

Ms. Herold discussed the need for the board to be notified of sanctions by the Centers for Medicare and Medicaid Services (CMS) and issues of dishonorable discharge.

Mr. Lippe withdrew his proposal. He offered a second proposal for board staff to rework this language to be brought back for consideration by the committee.

Chair Kajioka suggested the use of “substantially related to the practice of pharmacy” in the revised language.

Ms. Sodergren expressed concern that use of this phrase may leave it to the discretion of the licensee to determine whether or not an action is “substantially related” and is required to be reported to the board.

MOTION: Direct staff to rework the proposed text for §1762(d)(4) for consideration by the committee.

M/S: Lippe/Castellblanch

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (e)

Ms. Shellans reviewed subdivision (e). She stated that this provision would specify that the board is authorized to revoke a license or deny an application for an act requiring an

individual to register as a sex offender. Ms. Shellans advised that the board has current authority to take disciplinary action for criminal conviction, and as such, this new provision may not be necessary.

The committee discussed the application of this provision and the current California laws that require registration as a sex offender.

Dr. Ratcliff discussed that this provision would provide the board with better ability to take action against a licensee for this conduct.

Mr. Lippe made a proposal to recommend that the board pursue this provision.

Public Comment

Dr. Gray stated that this subdivision seems like an exception to the general rules outlined in the previous provisions.

Ms. Sodergren clarified the intent of this provision. She stated that an act requiring registration as a sex offender would constitute unprofessional conduct.

Dr. Gray suggested that the provision be reworded to clarify this intent.

Ms. Schellans clarified that the fact that a licensee is required to register as a sex offender constitutes unprofessional conduct.

Dr. Gray expressed concern that this area is not substantially related to the practice of pharmacy.

Ms. Shellans provided that this concept derived from the Dental Practice Act which deems a licensee unfit to practice if they are required to register as a sex offender.

Dr. Ratcliff discussed the evolving practice of pharmacy involving more patient contact. He asked the committee to consider whether it is appropriate for a licensee who is required to register as a sex offender to provide an immunization to a child.

Ms. Shellans advised that the penalty for this provision is within the discretion of the board.

Chair Kajioka discussed that this provision would not mandate revocation or specific discipline action and provides the board with flexibility with regards the appropriate penalty imposed.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(e).

M/S: Lippe/Kajioka

Support: 2 Oppose: 0 Abstain: 1

4. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Chair Report

Chair Kajioka provided that Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Chair Kajioka provided that to facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings. He advised that the most recent version of the standards was approved in April 2010, however discussion on standard 4 continues via a subcommittee.

Chair Kajioka referenced to the following 16 standards in their current form.

1. Clinical diagnostic evaluation
 - Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
 - i. Qualifications for the licensed practitioner performing the evaluation.
 - ii. Acceptable standards for such evaluations.
 - iii. Identified elements of the report.
 - iv. Timeframes to complete the process and prohibition of the evaluator having a financial relation, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
 - Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
 - Specifies that the licensee will be subject to random drug testing at least two times per week.
 - Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
3. Communication with a licensee's employer, if applicable
 - Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
 - Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing
 - Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on).
 - Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
 - Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
 - Establishes criteria for the collection sites and laboratories processing the results.
5. Group meeting attendance
 - Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
 - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
 - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
7. Worksite monitoring
 - Allows for the use of worksite monitors.
 - Specifies the criteria for a worksite monitor.
 - Establishes the methods of monitoring that must be performed by the worksite monitor.
 - Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
 - Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
8. Positive drug test
 - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
 - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
 - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
9. Ingestion of a banned substance
 - Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.

10. Consequences for major and minor violations

- Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
- Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.

11. Return to full time practice

- Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.

12. Unrestricted practice

- Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.

13. Private-sector vendor

- Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
- Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
- Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.

14. Confidentiality

- For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
- Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.

15. Audits of private-sector vendor

- Requires an external independent audit every three years of a private-sector vendor providing monitoring services.

- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards

- Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
- Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Discussion

Ms. Herold provided that some of the proposed changes to the disciplinary guidelines would facilitate implementation of portions of these uniform standards.

Dr. Kajoka sought clarification regarding the establishment of the SACC and the subcommittee.

Ms. Sodergren provided that the SACC, comprised of the executive officers of the DCA's healing arts licensing boards, was established by SB 1441 to formulate the standards. She stated that the SACC established a subcommittee of board representatives to develop general parameters for consideration to assist in this process.

No public comment was provided.

5. Discussion Regarding Proposed Modifications to the Board's *Disciplinary Guidelines*

Chair Report

Chair Kajioka provided that California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action. This regulation section was last amended in May 2009.

Chair Kajioka provided that during the October 2010 Board Meeting, the board voted to direct staff to work on updating the Disciplinary Guidelines for the board. He stated that the board has initiated work on identification of proposed changes, many of which have been developed by counsel, but there is still additional work that needs to be done. Chair Kajioka advised that in addition to identifying changes to the language, it is recommended that the guidelines be reorganized.

Chair Kajioka provided that work on the guidelines will continue over the next several months and will be discussed during the next committee meeting for possible action.

Discussion

Mr. Room indicated that the guidelines are a work in progress. He discussed that typically the guidelines are subdivided by license type. Mr. Room suggested that this organization be streamlined to provide one general area for terms and conditions of probation for all license types. He recommended that the board evaluate the guidelines upon further revision.

Ms. Herold discussed the workload involved in this process. She welcomed direction from the committee and stated that the committee can consider the guidelines at a later date as Mr. Room suggested.

Mr. Lippe suggested that a subcommittee be established to assist in this process.

Dr. Castellblanch sought clarification on diversion programs. He asked if there has been any consideration for prevention in this area.

Mr. Lippe provided that the board established the Pharmacists Recovery Program (PRP) for licensees with substance abuse. He stated that the PRP yields positive results.

Ms. Herold provided that the PRP is used as a monitoring program to ensure public safety. She stated that there are currently 75 participants in the program, 30 of which are self referrals. Ms. Herold advised that participants can be terminated from the program for failure to derive benefit or if they have been deemed a public risk.

Dr. Castellblanch expressed concern regarding the current number of PRP participants considering the current population statistics regarding substance abuse.

Ms. Herold indicated that with one exception, all pharmacists who come before the board with a substance abuse program are required to enroll in the program.

No public comment was provided.

Mr. Room ended his conference call with the committee at 3:54p.m.

6. Questions and Answers on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Chair Report

Chair Kajioka provided that at the June 2010 Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July. He stated that the answers to these and other submitted questions have been compiled into a document. Chair

Kajioka advised that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka provided that the questions and concerns voiced earlier with the regulations have not occurred since mid-summer.

Chair Kajioka provided an opportunity for new questions to be submitted by the public.

Clarification was requested on several areas. It was suggested that the questions on the document be numbered. The revised Q&A document will be posted on the board's Web site.

Chair Kajioka requested that further questions be submitted in writing to be evaluated by the subcommittee.

7. Discussion Regarding Whether Patients Should Be Allowed to Take Their Multi-Dose Medications Home Upon Discharge From a Hospital

Presentation

Deanne Calvert, JD, representing Sanofi Aventis, discussed the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use. She stated that these multi-dose products include inhalers, eye drops, insulin, and topical creams that are ordered for the patient during a hospital stay but are not in the patient's control while the patient is in the hospital. Ms Calvert advised that because they are not labeled for patient self-use, they are destroyed when the patient is discharged, even though the patient has been charged for the whole product.

Ms. Calvert discussed a project by Spectrum Health, a hospital system in Michigan, which evaluated whether it was feasible to implement a system that would allow patients to take home these medications. She indicated that this project was successful in identifying a generic preprinted label to be added to the patient barcode label that would meet all federal and Michigan state regulations regarding properly labeling medication for dispensing at discharge.

Ms. Calvert discussed outreach efforts for this process in other states and sought input regarding any California laws that would prohibit this process.

Discussion

Chair Kajioka asked who is responsible for the labels.

Ms. Calvert provided that the labeling is completed by a team of hospital pharmacists.

Ms. Herold suggested seeking input from hospitals regarding this process.

Dr. Castellblanch discussed the article regarding this project. He asked whether the authors have any relationship to Sanofi Aventis.

Ms. Calvert provided that she has no knowledge of a relationship. She stated that the article was found in a trade publication and that there was no participation in advance of the publication.

Public Comment

Steve Gray, representing Kaiser Permanente, stated that the waste of medications is a serious issue. He suggested that Ms. Calvert also work with the California Department of Public Health.

8. Provision of the First Ethics Course Pursuant to 16 California Code of Regulations Section 1773.5

Chair Report

Chair Kajioka provided that in mid-November, the Institute for Medical Quality provided the first ethics course for pharmacists under the requirements specified in 16 California Code of Regulations sections 1773 and 1773.5. He stated that 12 pharmacists, ordered to complete this course as a condition of their probations, were enrolled. Chair Kajioka provided that the course will follow these individuals over the next 12 months. He advised that periodic reports of the progress of this course will be provided to the committee and board in the future.

Chair Kajioka provided that there is a second course provider interested in providing a course that meets the parameters of section 1773.5; however, the board is not aware that this course has actually been provided or scheduled at this time.

Chair Kajioka provided that whereas the board is not specifically involved in the course provided, as a new program, the board will be kept updated as probationers take and complete these courses.

No discussion or public comment was provided.

9. Review and Discussion of Enforcement Statistics and Performance Standards of the Board

Chair Kajioka referenced the statistics and performance measures provided in the committee packet.

Discussion

Ms. Herold provided that the measures will be posted online effective December 8, 2010. Ms. Herold reviewed the board's timelines. She discussed that the filling of

current staff vacancies will help to improve these timelines as well as to further the board's consumer protection mandate.

No public comment was provided.

10. Public Comment for Items Not on the Agenda

Steve Gray encouraged the committee to address the enforcement of patient consultations as well as the importance of adding the purpose of the medication on the label as a future agenda item.

The meeting was adjourned at 4:59 p.m.