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

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES

DATE: September 14, 2010

LOCATION: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

COMMITTEE MEMBERS PRESENT:
Randy Kajioka, PharmD, Chair
Greg Lippe, Public Member
Ramón Castellblanch, Public Member
Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Tessa Fraga, Staff Analyst

Call to Order

Chair Kajioka called the meeting to order at 9:51 a.m.

1. Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations:
   - 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions
   - 16 California Code of Regulations Section 1793.7 Regarding Requirements of a Pharmacy Employing Pharmacy Technicians

   Chair Kajioka provided that earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare. He advised that this meeting will be the first time the board or one of its committees has the opportunity to discuss these requests.

Presentation to the Committee

Scott Huhn, PharmD, Regional Compliance Manager for Omnicare, provided a presentation to the board on each of the following requests.

1. Request to Modify 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions

Current Regulation

1745. Partial Filling of Schedule II Prescriptions.
(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:
(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or
(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.
(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.
(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:
(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;
(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;
(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and
(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Request

Modify regulation section 1745(c)(2) to allow pharmacies, when partially filling a Schedule II controlled substances prescription (C-II prescription), to modify a computer record instead of the prescription document itself. Currently, the board's requirements for partially filling a CII prescription are to annotate the prescription document itself.

This modification would require rulemaking process by the board.

Discussion

Dr. Huhn reviewed CFR section 1306.13(b) which states, "For each partial filling, the dispensing pharmacist shall record on the back of the prescription **(or on another appropriate record, uniformly maintained, and readily retrievable)** the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist."

Dr. Huhn stated that Omnicare is requesting that § 1745(c)(2) be amended to incorporate this alternative allowance from CFR § 1306.13(b). If amended, § 1745(c)(2) would read:

> (2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription (or on another appropriate record uniformly maintained and readily retrievable), also recording the initials of the pharmacist dispensing the prescription;

Dr. Huhn stated that this change would allow for the option of electronic records and would eliminate the need to retain and document a hard copy for each partial fill. He explained that it can be cumbersome to retrieve and document the hard copy for each partial fill over the course of 60 days.

Greg Lippe expressed concern that the electronic record will not be consistent with the original prescription.

Dr. Huhn provided that the original prescription would only contain the initial information and the electronic record would include all updated information.

Ramón Castellblanch requested clarification on the current standard.

Executive Officer Virginia Herold provided that the current regulation has remained unchanged since it was promulgated. She advised that at the time it was promulgated, computers were not used in pharmacies at the same level they are used today.

Supervising Inspector Robert Ratcliff added that the current regulation allows for better patient care for those people who may not live for an extended length of time. He recommended that a simple word change be made to change "and" to "or":

> (2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

Ms. Herold asked if this would create any confusion from an enforcement perspective.

Dr. Ratcliff indicated that this option would not be a problem for enforcement activities. He suggested that pharmacies develop policies and procedures to ensure that all staff pharmacists maintain records in the same manner.

Mr. Lippe expressed concern regarding this process in the event a pharmacy's computer system crashes. He explained that if this were to happen, the information available on the hard copy would not be updated or accurate. Policies and procedures should be required to explain how records would be created and maintained.

Dr. Hunh provided that information is stored daily to either a disc or an external hard drive.

Mr. Lippe suggested that pharmacies be required to only use information on the electronic record if the original hard copy has been modified. He also suggested that pharmacies be required to only maintain electronic records if they have available technology.

Dr. Kajioka discussed that not all pharmacies have the same available technology. He cautioned the committee from being overly prescriptive in this area.

Ms. Herold suggested that the following be added to § 1745(c)(2):

> A pharmacy that partially fills a prescription pursuant to this section shall do so according to policies and procedures developed by the pharmacy.

Mr. Zee expressed concern that allowing pharmacies to develop their own policies and procedures would lead to inconsistency.

Mr. Zee expressed concern that the committee is moving beyond reviewing and or modifying the section and is instead addressing the issue of how pharmacies maintain their data.

The committee further discussed the option of allowing pharmacies to maintain electronic records or document on the original prescription. This option would be consistent with existing federal regulations.

Dr. Ratcliff provided that Business and Professions Code section 4070(c) requires that changes to electronic records must be made by a pharmacist as well as all changes must be noted to indicate the type of change made. He advised that computer crashes will impact the entire pharmacy and all prescriptions to be dispensed. Mr. Ratcliff recommended that pharmacists be allowed to exercise their professional judgment in this type of situation in order to take care of the patient.

Ms. Herold asked what percentage of a prescription that is partially filled may not reach the patient in a long-term care facility.

Dr. Hunh provided that typically all of the prescription is used.

Dr. Ratcliff provided that this amendment will eliminate the need for pharmacists to refer back to the paper copy of the prescription. He stated that nothing else within the current process will change.

No public comment was provided.

MOTION: Recommend to the full board that section 1745(c)(2) be amended to read:

> (2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

M/S: Zee/Lippe

Support: 4 Oppose: 0 Abstain: 0

2. Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to permit a pharmacy technician to do the final check of a medication if the container is bar coded.

Current Regulation

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and

storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

There is no waiver process for such a procedure of board regulations, unless an experimental program is conducted with a school of pharmacy pursuant to 16 CCR section 1706.5. Unless this route is pursued, the board would need to consider a rulemaking process to modify section 1793.7.

1706.5 Experimental Programs In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board. (c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Request

Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to authorize a pharmacy technician utilizing bar-code scan under supervision of a pharmacist to perform the medication label check prior to delivery to the patient.

Discussion

Dr. Hunh stated that the goal of this request is to improve pharmaceutical care for patients, reduce medication errors, and allow pharmacists to focus on patient-centered activities such as medication therapy management.

Dr. Hunh provided that 12 states have approved this process. He stated that verification confirms that the prescription was filled according to the practitioner's order. Dr. Hunh explained that a pharmacist is actively supervising the medication verification process and is identified on the end of day reports in the operating system.

Dr. Hunh discussed the benefits of bar-code technology and added that it is recommended by the Institute for Safe Medication Practices and the National Association of Boards of Pharmacy (NABP).

Dr. Kajioka asked who would be indicated as the dispenser.

Dr. Hunh provided that both the technician and the pharmacist will be indicated as the dispenser.

Dr. Kajioka provided that the current regulation does not show that technicians have any ownership of the prescriptions that are dispensed.

Dr. Hunh sought clarification on how section 1793.8 would apply to this area.

Dr. Kajioka provided that he does not believe that the board has authority to waive a regulation unless the procedure is part of an experimental program conducted with a school of pharmacy. He requested that the board seek clarification on this issue from the board's legal counsel.

It was the consensus of the committee to seek legal clarification from board counsel and suggested that Omnicare develop an experimental program with a school of pharmacy.

Dr. Hunh asked if the board will provide any written notice to Omnicare to use to approach the schools of pharmacy.

Ms. Herold recommended that Omnicare develop a proposal to bring before the full board before approaching schools of pharmacy.

No public comment was provided.

2. Question and Answer Session 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 Kajioka provided that at the last Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010. He indicated that the answers to these and other submitted questions have been compiled into a document and will be posted on the board's Web site. Chair Kajioka stated that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka requested any additional questions from the public.

Public Comment

Howard Switzey, representing Kaiser Permanente, sought clarification regarding § 1735.6(a) – Compounding Facilities and Equipment with regards to the board's intent and enforcement of this requirement.

Dr. Ratcliff provided that the board will be ensuring that all equipment within the facility is calibrated and certified as required. He stated that ensuring that the facility itself meets building standards is not within the board's jurisdiction.

Dr. Ratcliff requested that all questions from the public also be submitted in writing to be added to the compounding question and answer document that will be made available on the board's Web site.

Mr. Switzey asked whether § 1735.3(b) requires that records be documented every time a product is used for compounding.

Dr. Ratcliff indicated that records for a product are to be updated with regards to use, acquisition, storage, and destruction.

Mr. Switzey provided that industry is seeking guidance regarding end product testing.

Dr. Ratcliff provided that the board expects each institution to implement process validation in this area.

Discussion continued regarding end product testing and the compounding requirements. Chair Kajioka provided that the board wants to allow flexibility in this area to allow pharmacists to exercise their professional judgment.

Chair Kajioka suggested that a small subcommittee be created to address questions regarding the compounding regulations.

There was no additional committee discussion or public comment.

3. Update on California's Drug "Take Back" Programs from Patients

Chair Kajioka provided that at the 2010 July Board Meeting, the board reviewed a proposed draft of a CalRecycle report to the Legislature on the implementation of drug take back programs from patients seeking to destroy their unwanted medications.

Chair Kajioka provided that this report to the Legislature is required by SB 966 (Simitian, Chapter 562, Statutes of 2007), and is due December 1, 2010**.** He stated that the legislative report must:

> . . . include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

Chair Kajioka provided that during the board meeting, staff was directed to provide comments on this draft. He indicated that these comments were submitted to CalRecycle in mid-August. Chair Kajioka added that these comments were provided in the committee's packet.

Chair Kajioka provided that on September 25, 2010, the federal Drug Enforcement Administration (DEA) will host a nationwide drug take back event so the public can dispose of its unwanted/unneeded medications.

Public Comment

Steve Gray, representing Kaiser Permanente, asked for more detail regarding the DEA event.

Ms. Herold provided that more information will be provided by a DEA representative during the next agenda item.

There was no additional committee discussion or public comment.

4. Presentation by the Michael Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles

Chair Kajioka provided that as has been discussed at prior Enforcement Committee and Board Meetings, drug diversion issues and prescription drug abuse are serious enforcement matters for the board and other regulators.

Presentation to the Committee

Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, provided information on DEA activities or objectives aimed at preventing drug diversion and prescription drug abuse.

Mr. Lewis provided an overview of the DEA Regulations to permit e-prescribing of controlled substances. He discussed parties involved in this process including application providers, prescribing practitioners, and pharmacies.

Mr. Lewis expressed concern that prescription drugs have impacted the attitudes of teenagers who believe that prescription drugs are “much safer” than illegal drugs. He stated that teenagers are reporting that prescription drugs are more readily available than illegal drugs and can often be found in the medicine cabinets within their homes.

Mr. Lewis discussed the increasing frequency and volume of drug diversion of controlled substances in California. He stated that diversion involves many groups including practitioners, pharmacists, employees, and patients and involves various motivations such as addiction, physical dependence, resale for money and/or illegal drugs, power, control or importance, and sex. Mr. Lewis reviewed commonly diverted drugs including oxycontin, hydrocodone, xanax (alprazolam), codeine cough syrup, amphetamines, and valium.

Mr. Lewis provided that the DEA will be hosting a National Drug Take Back Day on September 25, 2010. He explained that, together with the help of local and state law enforcement agencies, this event provides the public an opportunity to return unused controlled substances. Mr. Lewis indicated that the DEA will be providing collection boxes and will transport and incinerate the collected drugs. He advised that needles and sharps containers will not be collected.

Public Comment

Steve Gray, representing Kaiser Permanente, asked if non-controlled substances will also be collected. He asked whether posters are available to help advertise the event.

Mr. Lewis indicated that non-controlled substances will be accepted. He provided that posters are available and that the DEA has asked law enforcement and community groups to help advertise for the event.

A member of the public asked if this will be a one time event.

Mr. Lewis provided that there are plans for a second drug take back day in about 6 months.

Dr. Castellblanch asked if there will be any publicity surrounding the events planned.

Mr. Lewis provided that the DEA planned an Open House for the media and will also be planning television spots, radio and morning show announcements, and electronic banner ads. He indicated that collection site information has been posted at www.dea.gov.

Dr. Kajioka asked how other law enforcement groups can participate.

Mr. Lewis stated that the DEA has reached out to as many law enforcement agencies as possible. He indicated that some departments are unable to staff the event as it is scheduled for a Saturday and overtime is not permitted.

Ms. Herold provided that the board has already sent a subscriber alert and plans to send a second alert closer to the event.

Ms. Herold discussed the diversion cases investigated by the board. She indicated that the number of diversion cases has significantly increased over the last two years. She advised the committee that this is an important issue to be addressed by the board.

Mr. Lewis provided that the DEA would like to work closer with the board on cases and ways to prevent diversion.

Dr. Castellblanch asked if there are any available reports regarding organized crime and pharmacies.

Mr. Lewis provided that the DEA is conducting investigations regarding gangs attempting to purchase pharmacies or meet with pharmacists. He indicated that

the DEA has not produced a study or report regarding organized crime involved with pharmacies.

Orriette Quandt sought clarification on e-prescribing requirements regarding whether companies who authenticate prescriber's signatures have been identified.

Mr. Lewis provided that these companies are often working with a state regulatory board or some type of certification service. He stated that the DEA headquarters may be able to provide more information on this area.

Dr. Quandt discussed that prescribers are trying to electronically prescribe controlled substances and are being told by application providers that this practice is legal.

Mr. Lewis provided that this information should be reported to the DEA for further review.

Dr. Gray indicated that Kaiser has been notified that the Washington D.C. DEA office has a list of acceptable certifying agencies.

There was no additional committee discussion or public comment.

5. Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies

Presentation to the Committee

Supervising Inspector Judi Nurse provided an overview of the presentation that she and Executive Officer Virginia Herold gave in May regarding pharmacy thefts and robberies from pharmacies, and from various entities in the pharmaceutical supply chain (e.g., common carriers) to a group of San Diego pharmacists brought together by the DEA at a forum to discuss and prevent drug diversion.

Dr. Nurse discussed three main areas: (1) increased awareness among pharmacists about diversion, (2) prevention of diversion and theft from pharmacies, and (3) the importance of dispensing responsibly using corresponding responsibility. She reviewed the increase in diversion in pharmacies and indicated that the board's diversion cases have increased by 40 percent over the past few years.

Dr. Nurse explained that pharmacists are responsible for the security of the drugs and are the last line of defense against diversion of drugs to the streets, either by theft from the pharmacy or inappropriate dispensing of controlled substances.

She stated that the board's responsibility includes education and the protection of the consumer by aggressively pursing those who do not comply.

Dr. Castellblanch asked whether oxycontin is the most commonly diverted drug.

Dr. Nurse provided that Vicodin products represent the largest volume of diverted drugs. She indicated that oxycontin and Ambien are also commonly diverted.

Dr. Castellblanch sought clarification regarding diversion from manufacturers and wholesalers.

Dr. Nurse provided that the board does not regulate manufacturers.

Ms. Herold provided that wholesalers in California are taking steps to combat diversion from the drug distribution process. She provided that the board still has cases involving deliveries from a wholesaler that are not delivered directly to the pharmacist as required by law.

Dr. Nurse discussed Business and Professions Code § 4059.5 which requires that all dangerous drugs or devices be delivered to a licensed pharmacy and signed for and received by a pharmacist. She indicated that this requirement is an important security measure to ensure that pharmacists are aware of what drugs are coming in and out of the pharmacy.

Steve Gray, representing Kaiser Permanente, provided that the DEA law requires that all controlled substances are locked up in either a cage or vault within a wholesale facility. He stated that controlled substances within a hospital or pharmacy are often spread throughout inventory and are not required to be locked up. Dr. Gray provided comment on the role of common carriers with regards to the delivery of drugs. He indicated that pharmacies need help from the board, DEA, and Department of Justice to ensure that common carriers honor the law to ensure that all deliveries are delivered directly to the licensed pharmacy and are not left on a loading dock.

Dr. Castellblanch asked whether the board can enforce common carriers.

Ms. Herold provided that the board has no jurisdiction over common carriers.

Mr. Lippe asked whether it is typical to have camera surveillance over controlled substance storage areas.

Dr. Gray provided that this is not common. He indicated that Kaiser does lock up and have camera surveillance over Schedule II drugs storage areas.

There was no additional committee discussion or public comment.

The committee deferred discussion of agenda item 6 in order to discuss agenda item 7.

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

Dr. Kajioka provided that SB 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.

Dr. Kajioka provided that to facilitate implementation of these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings.

Dr. Kajioka provided that Business and Professions Code sections 4360 thru 4373 establish the Pharmacists Recovery Program (PRP) and establish some of the functions of the program as well as program participation criteria. He stated that the board contracts with a vendor, currently Maximus, Inc. to administer the PRP. Dr. Kajioka advised that under current law, this program is only available to pharmacists and interns.

Presentation to the Committee

Assistant Executive Officer Anne Sodergren provided an overview of SB 1441 and the uniform standards regarding substance-abusing healing arts licensees.

Ms. Sodergren advised that on August 4, 2010, a subcommittee convened to further discuss uniform standard four dealing with drug testing. She indicated that the subcommittee did not complete its revision of this standard and a future meeting will be set.

Ms. Sodergren highlighted the first standard and reviewed changes needed prior to implementation.

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.
    - Changes needed for implementation:

i. Pharmacists/Interns
    1. Contract change for PRP participants
    2. Regulation change (disciplinary guidelines)
ii. Other individuals
    1. Statutory change (establish program)
    2. Regulation change (disciplinary guidelines)

Ms. Herold asked the committee to discuss whether or not it deems this standard appropriate for all individuals. She indicated that currently, participants in the PRP undergo a clinical diagnostic evaluation; however, probationers may not.

Mr. Zee suggested that the board wait until the standards are final prior to implementation of the requirements.

Ms. Herold provided that the department has asked all healing arts boards to move forward with implementation of the standards. She indicated that the board's legal counsel has advised the board not to move too far forward until all standards are final.

Dr. Castellblanch asked whether the current evaluations act as a deterrent for current PRP participants.

Ms. Sodergren provided that the evaluations are used as a step in the rehabilitation process and not as a deterrent. She indicated that the evaluations provide baseline information regarding a participant's level of recovery, severity of substance abuse, and any underlying dual diagnosis information including mental illness.

Mr. Lippe asked whether a second evaluation is performed after a participant completes the program.

Ms. Sodergren provided that most PRP participants will be assessed regularly by a health support group facilitator (a licensed clinician). She indicated that treatment contracts also allow for annual reassessments. Ms. Sodergren stated that the board's disciplinary guidelines permit additional evaluations at the request of the board.

Dr. Castellblanch asked how the cost of the evaluation will impact pharmacy technicians.

Ms. Herold provided that the current model disciplinary guidelines do not include evaluations for technicians. She indicated that if ordered, this cost would be born by the technician. Ms. Herold suggested that the committee could recommend that evaluations be included in the model disciplinary guidelines if deemed an integral probation monitoring tool.

Mr. Lippe provided comment in support of requiring an evaluation as part of probation requirements. He stated that the evaluation would be beneficial in providing baseline information as will as identifying any risks if the individual reenters the program or has future discipline issues.

Chair Kajioka provided that an evaluation post program/probation completion would provide valuable information as to whether or not the individual is likely to relapse.

Chair Kajioka suggested that the committee revisit the standards after they have been finalized.

It was the consensus of the committee to discuss the standards at a future meeting when more information is available and the standards have been finalized. The committee requested that Ms. Herold communicate to the subcommittee the committee's interest in the standards and that it believes the clinical diagnostic evaluation is a strong and worthwhile tool.

Ms. Sodergren advised that there may be timing issues with implementing the standards as statutory changes may be needed. She indicated that regulation changes will be easier to implement.

Steve Gray, representing Kaiser Permanente, provided comment with respect to costs for pharmacy technicians. He advised that the cost of the evaluation may be covered by health insurance policies depending on what type of practitioner is required to administer the evaluation. Dr. Gray provided comment in support of the evaluations as a tool to provide baseline information when limiting a licensee's practice. He added that employers should be advised of a licensee's limited practice.

Mr. Lippe cautioned the board from focusing on the cost to a violator as a determining factor when considering whether an evaluation should be added as a requirement.

Ms. Sodergren advised that currently the board is required to post licensees' work restrictions; however, the reason for the restrictions cannot be disclosed.

Ms. Herold provided that standard discipline terms include that a licensee notifies all present and prospective employers of the terms, conditions and restrictions imposed by their decision.

Ms. Herold provided that the board may want to consider amending the disciplinary guidelines in the future to include a requirement for probationers to undergo a clinical diagnostic evaluation.

Ms. Sodergren reviewed each of the following standards and any changes needed in order to implement the requirements.

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Statutory change
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change
            - Regulation change (disciplinary guidelines)

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Regulation change (disciplinary guidelines)

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals

        - Statutory change (establish program)
        - Regulation change (disciplinary guidelines)

Ms. Herold provided that the board currently does not test PRP participants or probationers at this high of a frequency except in extreme cases.

Ms. Sodergren provided that the subcommittee is evaluating how this standard applies to cases where a person has already progressed into recovery at the time of his or her entrance into the program and whether this high frequency is needed. She stated that there is also a concern regarding whether it is more beneficial in terms of consumer protection to test at a higher frequency to catch noncompliance or less frequently to maintain randomness.

Ms. Herold provided that drug testing can be costly and could be burdensome especially for pharmacy technicians and pharmacist interns.

Dr. Kajioka provided that he believes the frequency to be an excessive amount. He stated that he believes that removing a practitioner from work who tests positive during random testing is achieving public protection.

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change (establish program)
            - Regulation change (disciplinary guidelines)

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change (establish program)
            - Regulation change (disciplinary guidelines)

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.
- Changes needed for implementation:
    - Pharmacists/Interns
        - Contract change for PRP participants
        - Regulation change (disciplinary guidelines)
    - Other individuals
        - Statutory change (establish program)
        - Regulation change (disciplinary guidelines)

8. <u>Positive drug test</u>
    - 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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Statutory change
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change
            - Regulation change (disciplinary guidelines)

9. <u>Ingestion of a banned substance</u>
    - 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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change (establish program)
            - Regulation change (disciplinary guidelines)

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Statutory change
            - Contract change for PRP participants
            - Regulation change (disciplinary guidelines)
        - Other individuals
            - Statutory change
            - Regulation change (disciplinary guidelines)

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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Statutory change
            - Contract change for PRP participants
        - Other individuals
            - Statutory change

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.
    - Changes needed for implementation:

- Pharmacists/Interns
  - Statutory change
  - Contract change for PRP participants
- Other individuals
  - Statutory change

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.
    - Changes needed for implementation:
      - Pharmacists/Interns
        - Statutory change
        - Contract change for PRP participants

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.
    - Changes needed for implementation:
      - Pharmacists/Interns
        - Statutory change
        - Contract change for PRP participants
      - Other individuals
        - Statutory change

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.
    - Changes needed for implementation:
      - Pharmacists/Interns
        - Statutory change
        - Contract change for PRP participants

16. Measurable criteria for standards
    - Establishes 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.
    - Changes needed for implementation:
        - Pharmacists/Interns
            - Contract change for PRP participants

Ms. Herold discussed challenges that the board may encounter when implementing the standards. She recommended that the board divide the standards into related categories for further evaluation. She discussed that once implemented, it will be more difficult to monitor probationers as their restrictions are decreased and lifted in a progressive fashion – probationary terms usually do not change during progression through probation.

Discussion continued regarding the standards. It was the consensus of the committee to wait for further clarification before making a recommendation to the board. It was requested that the standards be broken down into categories for a future discussion.

Ms. Herold discussed the department's contract and performance audit of Maximus for its diversion services. She indicated that a copy of the audit report will be posted on the board's Web site.

Mr. Lippe expressed concern regarding some of the deficiencies noted in the program regarding records and documentation.

Ms. Sodergren provided that the report focuses on the services provided by Maximus to six healing arts boards and one committee. She advised that the programs are not run the same and that the PRP reviews participants quarterly to ensure that the systematic checks are in place.

Mr. Lippe asked what follow-up will be done in response to the audit findings.

Ms. Herold provided that Maximus has had an opportunity to respond to the findings and has indicated that it will address the deficiencies.

Ms. Sodergren provided that the standards will require that the vendor be audited every three years.

Ms. Herold provided that board staff will be meeting with the department to discuss necessary follow-up action by the department.

The committee requested an update on the audit response at a future meeting.

No public comment was provided.

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

Background

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. These results yielded the Consumer Protections Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that investigation were completed and final action taken against a licensee within 12 – 18 months. The solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the boards needs to collect information and monitor performance, and additional staff resources.

Many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). Unfortunately, this bill failed passage early in the year during its first policy committee. Subsequently, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

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. Language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Because of the timing with the legislative cycle, these provisions were not pursued this year.

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. The board expressed concern on many of the provisions and with one exception, did not take action on the items.

Ms. Herold recommended that this issue be discussed by the full board. She provided that the department is working towards standardizing performance measures to be posted on board and department Web sites.

Ms. Herold discussed several challenges impacting the board as a result of the current budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibition, and furloughs. She stated that it will be a challenge for the board to meet the measuring standards and to

ensure that investigations are completed and final action is taken against a licensee within 12 – 18 months without the needed staffing.

Chair Kajioka referenced to the case timelines provided within the board packet.

Ms. Sodergren provided that the board's disciplinary guidelines have not been updated since 2008. She stated that the committee may wish to direct staff to initiate this review and bring recommendations back to the committee for evaluation.

No public comment was provided.

MOTION: Direct staff to initiate review of the disciplinary guidelines and report back recommended changes for future committee and board discussion and action.

M/S: Lippe/Kajioka

Support: 3 Oppose: 0 Abstain: 0

8. GS1 Schedules October 2010 Forum in San Francisco on Serialization and Track and Trace in the Pharmaceutical Supply Chain

Background

Since 2004, California has had statutory requirements to require all drug products sold in California to be electronically tracked back to the manufacturer, tracing every change in ownership – from the manufacturer, through wholesaler(s), to the pharmacy.

This secure, chain of custody system, is intended to safeguard California's pharmaceutical supply chain to prevent drug diversion, unauthorized resales into the supply chain, and the introduction of counterfeit drugs. These requirements model those of the FDA in their 2004 counterfeit task force report.

California's law has been amended twice since 2004 – in 2006 and 2008. The implementation of e-pedigree requirements in California is now on a phased-in schedule between 2015 and July 2017. Before these dates arrive, it was hoped that a federal law would be enacted to establish national standards for strengthening the supply chain.

Nevertheless, since the 2008 legislation, various companies in the supply chain have been working on the serialization piece to comply with California's requirements.

Chair Kajioka provided that in October 2010, GS1, which is a worldwide standards-setting organization, will hold a forum on serialization and tract and trace in California.

No public comment was provided.

9. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:34 p.m.