**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:** June 16, 2010

**LOCATION:** Bonderson Building
901 P Street, Hearing Room 102
Sacramento, CA 95814

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

**COMMITTEE MEMBERS NOT PRESENT:** Shirley Wheat, Public Member

**STAFF PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

## ***Call to Order***

Chair Kajioka called the meeting to order at 9:37 a.m.

## ***General Announcements***

### 1. Discussion Regarding the Drug Enforcement Administration's Proposed Regulations for the E-Prescribing of Controlled Substances

Dr. Randy Kajioka stated that the federal Drug Enforcement Administration (DEA) released on March 22, 2010 proposed requirements to enable e-prescribing of controlled drugs. He stated that until June 1, 2010, federal law did not allow the electronic prescribing of written prescriptions for controlled drugs. Dr. Kajioka indicated that the comment period on the proposed interim final rule ended on May 31, 2010.

Dr. Kajioka provided that at the April 2010 Board Meeting, the board was led in a discussion of the proposed, highly technical requirements by Deputy Attorney General Joshua Room. He stated that after a short discussion, the board agreed to send a request to the DEA to extend the comment period another 120 days so that the board and others could carefully read and consider the more than 330 pages of requirements and policy statements released by the DEA.

Executive Officer Virginia Herold advised the committee that the DEA has not responded to the board's request and has not yet trained field agents in this area. She recommended that the board consider convening a summit to discuss the guidelines in detail and provide guidance to industry on implementation. Ms. Herold indicated that this issue will be discussed during the July 2010 Board Meeting by e-prescribing advocates.

Dr. Kajioka made a recommendation that an ad hoc subcommittee be established.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, provided that Kaiser is encouraged that the guidelines have been released. He indicated that state law requires that the board and the Department of Justice (DOJ) must ratify the system for e-prescribing developed by the DEA. Dr. Gray suggested that the ad hoc committee should consider this as part of the process. He recommended that because the standards are so high, the board should consider adopting the regulations/guidelines as established by the DEA. Dr. Gray advised that Kaiser anticipates that it will take at least one year to modify the systems to conform to the DEA rules.

Dr. Kajioka indicated that the DOJ and other stakeholders will be invited to participate in this process.

Dr. Ramón Castellblanch asked if other entities have indicated where they are with respect to implementation.

Ms. Herold stated that she is unsure where others are in terms of implementation.

There was no additional board discussion or public comment.

**MOTION:** Establish an ad hoc committee to review and provide guidelines on the Drug Enforcement Administration's proposed regulations for the e-prescribing of controlled substances.

M/S: Kajioka/Lippe

Support: 3 Oppose: 0 Abstain: 0

## 2. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

### Background

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect.

Dr. Kajioka provided that at the January 2010 Board Meeting, Phil Burgess representing Asteres made a presentation to the board seeking a waiver from 1713(d) to allow automated dispensing machines to be located in areas other than the requirements of this section. He stated that at the meeting, the board asked Mr. Burgess to refine his request and return to the board so the board would more fully understand the proposal.

Dr. Kajioka provided that during the December 2009 Enforcement Committee Meeting and the subsequently January 2010 Board Meeting, Phil Burgess requested a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. He indicated that in making the request, Mr. Burgess stated that his client Asteres would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist. Dr. Kajioka explained that whereas the initial proposal was to place the device in a hospital waiting room for refills for employees, at the board meeting, the request was far broader and would allow

the machines to be placed anywhere and could be used for patient delivery of refill medications as well.

Mr. Burgess discussed the importance of patient access as a means to improve patient compliance.

Mr. Burgess requested that the board waive regulation section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals to allow for the installation of the ScriptCenter “pickup” system in a hospital environment whereby the unit is not directly attached to the pharmacy. He made a second request for a special waiver to allow for a pilot of this system to demonstrate that improved access will increase medication adherence. Mr. Burgess indicated that he would like the waiver for a five-year period.

Ms. Herold asked how many employees would be involved in this system.

Mr. Burgess indicated that he believes several thousand employees could participate.

Dr. Kajioka asked how the system impacts the patients relationship with the pharmacist.

Mr. Burgess provided that the refills are personally filled by a pharmacist. He stated that patients elect to be involved in the system and can easily call a pharmacist when picking up their prescriptions.

Dr. Castellblanch asked how the system is being used in other states.

Mr. Burgess indicated that a variety of other states are utilizing the machines for both new prescriptions and refills.

Ms. Herold reviewed the experimental programs provision in section 1706.5.

Mr. Burgess requested that the board allow schools of pharmacy to work with the hospitals that are utilizing the system to asses the positive benefit.

The committee discussed the need for specific measurements to assess this process.

Robert Ratcliff, Supervising Inspector, requested clarification on the definition of “secured area.”

Mr. Burgess reviewed the elements of a secured area including video cameras monitoring the machine and the individuals accessing the machine, signature logs, thumb print records, external monitoring of the machine, and audit trails. He stated that the machines can be located at each hospital campus and can be

bolted to the floor of the facility. Mr. Burgess added that patients will have telephone access to an inpatient pharmacist within the hospital that can access the patient's drug information history via an integrated computer system.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanent, provided support for the proposal and the system's ability to improve compliance. He stated that a collaboration with schools of pharmacy may be a viable way to determine how this system impacts the pharmacist-patient relationship and quality of care. Dr. Gray encouraged the committee to recommend that the board consider the waiver and support the collaboration with schools of pharmacy.

Dr. Kajioka asked if the machines would only be located in licensed hospitals.

Mr. Burgess stated that the machines would only be in licensed hospital pharmacies.

Dr. Kajioka recommended that Asteres partner with a school of pharmacy to establish a pilot program and identify some measures to assess the program.

Dr. Kajioka indicated that this proposal will be reviewed by the board's legal counsel.

There was no additional board discussion or public comment.

**3. Presentation of a Drug Distribution Model Proposed by Medco Health Solutions, Using Two Pharmacies, Each with Specialized Functions**

Dr. Dennis McAllister, representing Medco Health Solutions, presented a proposed drug distribution model whereby services are provided to community pharmacies in a Central Fill/Central Processing arrangement. He indicated that Medco patients will elect to participate in this process. Dr. McAllister stated that the model meets the requirements of section 1707.4 as all prescriptions will be dispensed in California by a licensed California pharmacy. He advised that the model does not include controlled substances.

Dr. McAllister provided that the model is currently in operation in several states. He indicated that Rite Aid is currently partnering with the project and it is intended that other chain stores will participate as well. Dr. McAllister added that Medco has established 14 therapeutic resource centers to provide patients with improved and specialized care.

The committee discussed the model process. It was clarified that in instances where the medication is not picked up by the patient, the pharmacy will destroy

the medication through a reverse distributor. All documentation and records will be available for the board for inspection. Medco is the owner of the prescriptions filled at the central fill center. It was indicated that the model provides labor savings for the participating chain pharmacies.

Ms. Herold suggested that the prescription label include information indicating that the prescription was filled by Medco. She recommended that Medco locate a therapeutic resource center in California.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, offered support for this concept and discussed the error reduction achieved in this refill process. He stated that the DEA has approved this concept and has adapted rules that may allow for "depoting" of controlled substances. He expressed concern regarding dual labeling as it leads to confusion by the patient.

Dr. McAllister asked whether the board considers a renewed prescription to be a refill.

Dr. Kajioka indicated that a renewed prescription is considered a refill.

There was no additional board discussion or public comment.

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

Dr. Kajioka provided that since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. He stated that the proposed changes have taken various forms. Dr. Kajioka advised that the goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. He advised that formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

Dr. Kajioka provided that in addition to the additional staff resources being sought, board staff completed a comprehensive review of our internal processes to identify ways to streamline our processes, reduce timelines and improve our effectiveness. He stated that board staff identified 18 improvements and is working towards full implementation. Dr. Kajioka referenced to the following summary of changes initiated to date as well as the status.

1. Complete case assignments on line.
   Status: Completing testing of the new process. Staff is working to finalize written procedures.

2. Complete review of draft accusations on line
   Status: Accusations are now reviewed on line by field staff. Staff will finalize written procedures.
3. Prescreen complaints at assignment with an AGPA - AGPA would follow up to ensure that complaints are assigned. Screen out non-jurisdictional and close or refer as appropriate.
   Status: Training is complete and this provision is implemented. As indicated in previous months, this is a temporary solution, and full implementation cannot be achieved without staff resources.
4. AGPA to complete license history instead of board inspector including past CI's, assignments, violations and outcomes of those. Past inspections, date and who completed them.
   Status: A draft template is developed, however pre-populated reports are not yet in place. Initiated pilot with limited investigator staff.
5. Develop a method to automatically populate information on the investigation report instead of using expensive inspector time.
   Status: A draft template is developed, however pre-populated reports are not yet in place. Initiated pilot with limited investigator staff.
6. Train non-attorney staff to prepare default decisions to speed investigation closures.
   Status: Training completed. Board staff preparing some default decisions in-house.
7. Secure automated fingerprint background checks and criminal record information from the Department of Justice.
   Status: Implemented and staff trained.
8. Begin drafting some Petitions to Revoke Probation in house.
   Status: Internal staff completed first PTR. Draft is currently undergoing review.

Ms. Herold provided that board staff is moving towards the electronic transfer of documents to field staff. She indicated that the staff is also working towards providing the board the ability to vote online.

No public comment was provided.

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

Dr. Kajioka provided that in the February 2010 *The Script,* the board promoted the take-back guidelines developed by the California Integrated Waste Management Board pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007) with the assistance of the Board of Pharmacy.

Dr. Kajioka provided that since April 2010, board inspectors have been directed to take pictures of drug take back programs in place in pharmacies, and to encourage compliance with the state's guidelines.

Dr. Kajioka provided that the Drug Enforcement Administration (DEA) continues to be concerned about these programs nationally, and is working with counties that are establishing principally short-term take back programs for controlled drugs. He indicated that in some communities, law enforcement is working with the DEA to take back controlled drugs at law enforcement facilities.

Dr. Kajioka provided that on July 20, 2010 the CalRecycle Program, which took the place of components of the California Integrated Waste Management Board, will hold a workshop on home-generated pharmaceutical waste collection and disposal. He stated that the purpose is to generate data that will be included in a report to the Legislature by the end of 2010.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, provided comment on several initiatives for the adoption of take back programs. He discussed a city ordinance to require pharmacies to take back needles. He stated that this ordinance could be expanded to also require the take back of drugs.

Phil Burgess, representing Asteres, provided that there is a demand for pharmacies to be involved in take back programs.

There was no additional board discussion or public comment.

**6. 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**

Supervising Inspector Robert Ratcliff reviewed the following questions and answers that have been submitted to the board regarding the board's compounding regulations.

- 1735.3(a)(6) & 1751.2(a) – For the purposes of these sections, would patients of an infusion center (those receiving chemotherapy administered in a clinic setting) be considered "inpatients" and therefore be exempt from such labeling requirements?

  1735.3(a)(6) provides for the exemption for records of the manufacturer and lot number for products compounded on a one time bases for administration within 24 hours to an inpatient in a health care facility licensed under § 1250.

- 1735.8(c):

1. What is the board's expectation for the frequency of quantitative and qualitative analysis of a given product?
2. Does every product and/or formulation compounded by a pharmacy have to undergo qualitative and quantitative analysis? If not, can the board provide guidance for selecting products to be analyzed?
3. Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?

The board's expectation is that the compounded product meets the prescriber's prescription requirements. The pharmacy needs to have policies and procedures in place to insure said compliance. It will be up to the pharmacy to determine this compliance.

Batch produced sterile compounding from one or more non-sterile ingredients requires documented end product testing for sterility and pyrogens and shall be quarantined pending results (1751.7(c)).

1751.7(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

- Are gowns required when preparing cytotoxic agents if using barrier isolator?

1751.5(c) The requirements of ~~this~~ subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients

- Is an NRP providing compounded product into CA required to meet the same staffing requirements as CA pharmacies?

  No, the NRP must comply with the requirements of their resident state.

- What constitutes sterile compounding?

  Refer to section 1735.

  **§1735. Compounding in Licensed Pharmacies.**

  (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

  (1) Altering the dosage form or delivery system of a drug

  (2) Altering the strength of a drug

  (3) Combining components or active ingredients

  (4) Preparing a drug product from chemicals or bulk drug substances

  **§1751. Sterile Injectable Compounding; Compounding Area.**

  (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

- Is it any IV admixture, such as adding 20 mEq KCl to 1000ml NS?

  Yes.

- What happens in a situation where an IV is made to be used on a one time basis for administration within 24 hours for a registered inpatient of a health care facility and product is not used and returned to the pharmacy? Can it be reused?

  No.

- Is a master formula record equivalent to a "recipe card?"

  Yes.

- When compounding a product, is it required to have master formula record available and used when the product is compounded?

  Yes, the master formula record is required to be available pursuant to section 1735.3(a).

  **§1735.3. Records of Compounded Drug Products.**

  (a) For each compounded drug product, the pharmacy records shall include:

  (1) The master formula record.

  …

  (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

- Is it required to inspect the master formula record as part of pre-check process?

  Refer to section1735.2 (f)(i). It is recommended that the master formula record is reviewed prior to compounding.

  (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

  (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

- What are the requirements for compounding documentation?

  **§1735.3. Records of Compounded Drug Products.**

  (a) For each compounded drug product, the pharmacy records shall include:

  (1) The master formula record.

  (2) The date the drug product was compounded.

  (3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) The equipment used in compounding the drug product.

(8) A pharmacy assigned reference or lot number for the compounded drug product.

(9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded.

- When using exemption to compound a one time Vancomycin IV with a seven day expiration date and to be used within 24 hours, is the manufacturer and lot number required?

  No.

- When must the manufacturer and lot number be recorded?

  This information must be documented if the product is not for a one time use for a specific patient to be used within 24 hours.

- How will the board insure compliance by NRP's?

Refer to section 4127.2. NRP's will also submit appropriate Compounding Self Assessment forms to the board.

**4127.2. Nonresident Pharmacy – License to Compound and Ship Injectable Drug Products into California Required**

(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:
(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.
(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.
(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.
(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

- Please clarify a question regarding reconstitution and compounding (i.e. – The package insert of an IV antibiotic states to reconstitute and then dilute in 100ml of D5W before administration).

  Refer to section 1735.

  **§1735. Compounding in Licensed Pharmacies.**

  (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

- Is the dilution per the manufacturer's instructions and adding to the IV solution considered compounding?

  Yes.

- What specifically will be required or what process is acceptable to achieve such quality assurance?

  Refer to sections 1735.8 and 1735.7.

**§1735.8. Compounding Quality Assurance.**

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

**(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.**

**(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.**

**(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.**

**§1735.7. Training of Compounding Staff.**

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug

- Are proprietary drug delivery systems such as ADD-Vantage, Mini-Bag Plus, and At Eas considered compounded products after the vials have been attached to the IV bags?

Refer to sections 4127.1 and 1735.

**4127.1. License to Compound Injectable Sterile Drug Products Required**

…

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:
(1) The sterile powder was obtained from a manufacturer.
(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

**§1735. Compounding in Licensed Pharmacies.**

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

- When recycling an IV that was previously compounded by the pharmacy, can the previous lot number of the recycled IV be used as long as the lot number can be traced to all the requirements listed in section 1735.3?

  Yes.

- What is a "reliable supplier?"

  Refer to section 4163 and 1783.

  **4163. Unauthorized Furnishing by Manufacturer or Wholesaler**
  (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.
  (b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices….

  **1783. Manufacturer or Wholesaler Furnishing Drugs and Devices.**
  (a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
  (b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also

means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

- Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts? Can a pharmacy mix two creams in equal parts?

  Yes, a pharmacy may do both. Both activities are considered compounding.

- Can a pharmacy do the above compounding without having a special certification for compounding, or being held to all the requirements?

  There is no special certification/licensure for non-sterile compounding. However, all the other requirements of section 1735 et seq. must be complied with.

- Our medical center's policies and procedures have the initial dose of an IV admixture compounded in the pharmacy satellite to assure timely initiation of therapy, with all subsequent doses mixed in the centrol pharmacy. Is the initial IV admixture compounded in the satellite subject to the recording requirements?

  All record documentation is required with the possible exception of 1735.3(a)(6).

- Does section 1735.5 require a pharmacy to test each and every compounded product for integrity, potency, quality, and labeled strength of the compounded product?

  No. However, if the compounded product involves a complex process it would seem prudent to have documentation of the final product. This is even more important when the product is compounded on a more routine basis.

  Compounding involves not just the QA process, but staff training, equipment maintenance, proper documentation and appropriate analysis of products compounded.

  **§1735.5. Compounding Policies and Procedures.**

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

**§1735.7. Training of Compounding Staff.**

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

**§1735.8. Compounding Quality Assurance.**

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

## 7. Pharmacies Dispensing Prescriptions for Internet Web Site Operators

Dr. Kajioka provided that at the December Enforcement Committee, the committee was advised that the board's inspectors have investigated a number of cases where California pharmacies are filling prescriptions from Internet Web sites in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Dr. Kajioka provided that many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. He stated that California law allows the board to issue citations at $25,000 per invalid prescription delivered to patients in California.

Dr. Kajioka provided that over the last 18 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. He stated that the Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

Dr. Kajioka provided that The *July 2008 The Script reminded* pharmacies not to participate in such scams. He stated that at public speaking events, this is one area touched on by board speakers.

Dr. Kajioka provided that one project recently initiated by board staff is the development of a short video on the dangers of purchasing drugs online. He stated that the board is working with the Department of Consumer Affairs on this video, which we plan to have completed by the end of the summer.

Mr. Ratcliff provided that pharmacies are facilitating the illegal distribution of prescription drugs from the Internet. He stated that from discussion with the owners of several of these pharmacies investigated by the board, the pharmacies receive an offer via a faxed notice offering amounts as low as between $3 and $6 per prescription plus drug costs to fill these orders. Mr. Ratcliff advised that the economics greatly benefit the Web site operator. He indicated that the patient may pay $100 to $200 purchase a prescription from the Internet – the pharmacy may get $6 or $10 from such a sale.

Ms. Herold advised that this issue is a serious concern for the board. She stated that the board will issue substantial fines for pharmacies participating in this activity.

**Public Comment**

Dr. Gray, representing Kaiser Permanente, suggested that the board provide more information regarding what is not considered an internet pharmacy.

Ms. Herold provided that these cases typically involve controlled drugs where numerous patients in California and other states get prescription drugs they order from a Web site. She stated that these prescriptions are written by a physician that is contracted with the Web site and is located in a state different than where the patient lives.

Dr. Castellblanch asked whether this issue should be referred to the Legislation and Regulation Committee.

Ms. Herold provided that many of these cases are referred for administrative action. She stated that additional legislation in this area may be needed. Ms. Herold suggested that the Enforcement Committee continue to identify solutions in this area prior to referring it to the Legislation and Regulation Committee.

There was no additional board discussion or public comment.

## 8. Post Implementation Review of the Board's Criminal Conviction Unit

Dr. Kajioka provided that included as part of last year's budget, was a staff augmentation for the board to establish the Criminal Conviction Unit within the board.

Dr. Kajioka provided that as of July 1, 2009, there were 1708 investigations pending. He indicated that as of June 1, 2010, that number was reduced 629 investigations pending. Dr. Kajioka stated that additionally over 1900 cases have been completed. He referenced to the following snapshot of the final disposition of those cases.

| | |
|---|---|
| Referred for Formal Discipline | 190 |
| Citation and Fine Issued | 112 |
| Letter of Admonishment Issued | 152 |
| B&PC 4301 Letter Issued | 633 |
| Closed No Further Action | 785 |
| Closed Referred to PRP | 2 |
| Closed Other | 30 |
| Closed No Violation | 1 |
| | 1905 |

Dr. Kajioka provided that this unit was envisioned to be a "beginning to end" unit, meaning that the staff would not only complete the investigation, but also complete the final processing as well, e.g. issue the citation and fine, refer the matter to the Office of the Attorney General, etc.

Assistant Executive Officer Anne Sodergren provided that these results demonstrate that appropriate resources allow the board to effectively meet its consumer protection mandate.

No public comment was provided.

## 9. Update of the Committee's Strategic Plan 2010-11

Dr. Kajioka provided that at the July 2010 Board Meeting, the board will update its 2010-11 Strategic Plan. He stated that the Enforcement Committee's strategic goals, objectives and tasks are being updated and will be provided at the meeting.

Ms. Sodergren provided that the Enforcement unit managers reviewed the plan in advance of this meeting and are recommending inclusion of the following task:

- Identify investigative and enforcement internal processes improvement.

Ms. Herold suggested that the committee also consider including a review of pharmacies dispensing drugs for internet providers.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, suggested that the board evaluate language requiring clinical experience referenced in section 4052.2. He also recommended that the board discuss the requirement that the board report its actions to the National Practitioner Database.

Ms. Herold provided that the board is reporting to the database.

Dr. Castellblanch sought clarification regarding any preventative programs offered by the board or by any other states.

Ms. Herold provided that education is facilitated through the Pharmacists Recovery Program. She stated that the Enforcement Committee and the Communication and Public Education Committee can collaborate in this area.

Ms. Sodergren provided that the department is looking at improving proactive actions. She stated that inspectors educate licensees regarding the legal requirements during routine inspections and with self assessment forms.

There was no additional board discussion or public comment.

**MOTION:** Approve the 15 tasks identified in Objective 1.5 in the Enforcement Committee's Strategic Plan and add the following additional tasks:

16. Complete review of pharmacies dispensing prescriptions for Internet web site operators
17. Evaluate language requiring clinical experience referenced in section 4052.2
18. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB)

M/S: Lippe/Kajioka

Support: 3 Oppose: 0 Abstain: 0

## 10. Enforcement Statistics

Dr. Kajioka provided that the Enforcement statistics will be compiled at the end of the fiscal year and will be provided for the July 2010 Board Meeting along with a three year fiscal comparison.

No public comment was provided.

## 11. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:05 p.m.

## GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

| | |
|---|---|
| Objective 1.1<br><br>Measure: | Achieve 100 percent closure on all board investigations within 6 months.<br><br>Percentage of cases closed. |
| Tasks: | 1. Complete all desk investigations within 90 days (for cases closed during quarter).<br>2. Complete all field investigations within 120 days (for cases closed during quarter).<br>3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days. |
| | |
| Objective 1.2<br><br>Measure: | Manage enforcement activities for achievement of performance expectations<br><br>Percentage compliance with program requirements |
| Tasks: | 1. Administer the Pharmacists Recovery Program.<br>2. Administer the probation monitoring program.<br>3. Issue citations and fines within 30 days<br>4. Issue letters of admonition within 30 days<br>5. Obtain immediate public protection sanctions for egregious violations.<br>6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation. |
| | |
| Objective 1.3<br><br>Measure: | Achieve 100 percent closure on all administrative cases (excluding board investigation time) within one year by June 30, 2011.<br><br>Percentage closure of administrative cases within one year. |
| Objective 1.4<br><br>Measure: | Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011.<br><br>Percentage of licensed facilities inspected once every 3 year cycle. |
| Tasks: | 1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.<br>2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.<br>3. Initiate investigations based upon violations discovered during routine inspections. |
| | |

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|---|---|
| Objective 1.5<br><br>Measure: | Initiate policy review of 25 emerging enforcement issues by June 30, 2011.<br><br>The number of issues. |
| Tasks: | 1. Monitor the implementation of e-pedigree on all prescription medications sold in California.<br>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.<br>3. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.<br>4. Evaluate establishment of an ethics course as an enforcement option.<br>5. Participate in emerging issues of the national level affecting the health of Californians regarding their prescription medicine.<br>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.<br>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.<br>8. Liaison with other state and federal agencies to achieve consumer protection.<br>9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.<br>10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.<br>11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.<br>12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.<br>13. Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.<br>14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.<br>15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements. |