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

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

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

DATE: January 23, 2008

LOCATION: Town & Country Resort and Convention Center
500 Hotel Circle North
San Diego, CA 92108

COMMITTEE MEMBERS PRESENT:
Stanley Goldenberg, RPh, Chairperson
William Powers, Public Member
Ruth Conroy, PharmD
Rob Swart, PharmD
D. Timothy Dazé, Esq., Public Member

OTHER BOARD MEMBERS PRESENT:
Kenneth H. Schell, PharmD
Andrea Zinder, Public Member
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Graul, RPh
Stanley C. Weisser, RPh
Shirley Wheat, Public Member
James Burgard, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst
Tina Thomas, Staff Analyst

CALL TO ORDER

Chairperson Goldenberg called the meeting to order at 4:52 p.m.

A. DEVELOPMENT OF AN ETHICS COURSE FOR PHARMACISTS, MODELED AFTER THAT DEVELOPED BY THE MEDICAL BOARD OF CALIFORNIA

Mr. Goldenberg referred to information provided in the meeting materials regarding development of an Ethics Course for Pharmacists. The purpose of the course will be to use it as an enforcement option when establishing discipline parameters for licensees.

Dr. Ravnan and Dr. Swart served on a board subcommittee to review ethics course options. The board evaluated the need to develop a course for pharmacists similar in structure to that used by the Medical Board for physicians. The board will need to promulgate regulations for this program or secure statutory requirements. Staff will develop draft language to establish this program statutorily and bring it to the Enforcement Committee for comment.

Mr. Goldenberg asked if there were any comments from the board to add to the written materials provided in the packet. There were none.

B. DISCUSSION REGARDING PHARMACIST/TECHNICIAN REGISTRY FIRMS USED TO STAFF PHARMACIES

Mr. Goldenberg referred to a problem of unlicensed or suspended pharmacists working in pharmacies that have been placed by pharmacist registry companies. He also referred to unlicensed pharmacy technicians working in pharmacies placed by "temp" agencies.

Ms. Herold noted that this is an item that was brought to the Enforcement Committee as a proposed legislative solution. Board staff is interested in developing the requirements for a registration program for those firms that place pharmacists and pharmacy technicians in pharmacies on a temporary basis.

Ms. Herold stated that registries periodically place unlicensed/suspended pharmacists and pharmacy technicians when making temporary placements in pharmacies. The board has no jurisdiction over a registry; it can only discipline a pharmacist or pharmacy technician placed and the pharmacist in charge (PIC) hiring the individual. Registering the companies that employ these individuals would provide recourse for the board to discipline a registry for placing a suspended/unlicensed pharmacist or pharmacy technician. The current situation leaves the public and the profession at risk without a consequence.

Supervising Inspector Bob Ratcliff added that community pharmacies and hospital pharmacies use personnel placed by registries under the assumption that the personnel is currently licensed to practice. In their contracts with registries, pharmacies state that they

understand that the registry is providing appropriately licensed personnel. The PIC does not necessarily confirm the status of someone's license, after they have been placed in the pharmacy by the registry.

Dr. Ratcliff stated that this problem has been identified during board inspections, and has become a matter of consumer safety.

A discussion ensued regarding the severity of this problem. A board member noted that often a registry will notify a pharmacy of the name of a pharmacist that will be placed, yet a different pharmacist will report for duty. This prevents a PIC from doing any type of background check or license check prior to personnel arriving on-site.

The board supported the idea of registering or otherwise tracking these contract placement agencies to prevent unlicensed or suspended personnel from serving the public.

In answer to a question from a board member, Ms. Herold noted that the penalty for a pharmacist found working in a pharmacy with a suspended license would likely be revocation of his/her license. A pharmacist found working in a pharmacy with a license that had not been renewed could result in a cite and fine, depending on the circumstances. Ms. Herold emphasized that due diligence is the responsibility of the employment registry placing these individuals, although the employing pharmacy is also responsible. The registries should regularly update their records.

Mr. Room recommended criminal action if there is widespread evidence of an agency or registry employing suspended or unlicensed pharmacists. Unlicensed practice is an underlying criminal violation; aiding or abetting unlicensed practice of pharmacy would also be a potential criminal violation.

MOTION: Direct board staff to develop a legislative solution regarding pharmacy personnel registries including those firms that place pharmacists and pharmacy technicians in pharmacies on a temporary basis.

M/S: POWERS/DAZÉ

SUPPORT: 4 OPPOSE: 0

C. DISCUSSION REGARDING THEFT OF PRESCRIPTION MEDICINE FROM SUPPLY CHAIN PARTNERS

Mr. Goldenberg referred to the issue of thefts of prescription drugs from common carriers, and the fact that drugs stolen from transportation companies end up in the supply chain. Diversion of medication from common carriers is an issue of consumer safety.

Ms. Herold noted that drug wholesalers either have contract carriers like FedEx, or they use their own carriers. She gave an example of a pharmacy that received a shipment of medication, but the pharmacist did not open the box to verify the contents received. Controlled substances were missing from the shipment, and the pharmacy later notified the board of the discrepancy. The board subsequently cited and fined the pharmacist and the wholesaler.

Mr. Goldenberg commented on the lack of authority of the board to require a background check of a transportation carrier.

Dr. Conroy spoke about the difference between PICs receiving controlled substance orders via FedEx verses directly from a wholesaler. She gave an example of a shipment directly from Cardinal, which would result in the Cardinal carrier waiting for the PIC to check the contents of the shipment. When an order arrives via FedEx, it is unlikely that the FedEx driver will wait for the PIC to check the contents of the shipment of controlled substances. Dr. Conroy emphasized that items missing from a shipment, whether the discrepancy was found while the driver was there or had left, would still result in items missing from a shipment. Citing and fining a pharmacist for not checking the contents of a box while the driver is present does not prevent drugs from being diverted; instead, it punishes the person who is the victim of a crime, not the person who diverted the drugs.

Mr. Powers suggested that the authority to resolve this problem extends beyond the board, such as the DEA or local police.

Dan Lucent, representing Walgreens, stated that a problem has persisted in that a box is opened and items are missing from the order. Determining when, where, and how the product was diverted has been an issue for Walgreen's. They recruited the assistance of the FBI who subsequently planted a "mole" in a large delivery company. The investigation revealed five employees illegally diverting products. Mr. Lucent suggested that the board ask for assistance from an outside agency such as the FBI to assist in enforcement efforts.

Mr. Room suggested that pedigree requirements would help deter these problems. He said that pedigree would assist in determining where in the supply chain that drugs are diverted.

A suggestion was made to bring attention to the issue of diversion in an issue of *The Script*.

Steve Gray, representing Kaiser Permanente, spoke about deliveries made to loading docks of hospitals. A delivery to a loading dock must subsequently be delivered to the hospital pharmacy within 24 hours. He noted a persistent problem that Kaiser is having with a national common carrier in getting that carrier to make their deliveries directly to hospital pharmacies so that pharmacists can sign for the deliveries. They have been in contact with FedEx, DHL, and UPS, regarding California's requirements. Dr. Gray noted that drug diversion is more likely to occur when shipments are made to large loading docks and the boxes must pass through several hands before finally reaching a pharmacy.

Dr. Gray suggested that the board send a letter to major transportation carriers referring to California's requirements. He also referred to advance shipping notices, and that pharmacists compare the products received against the advance shipping notices to determine if products are missing. Dr. Gray gave an example of a diversion problem that resulted in identification of people in a manufacturer's shipping department; the products were not properly packaged before being sent to wholesalers.

Mr. Dazé spoke about the possibility of regulating common carriers that deliver pharmaceutical products.

Mr. Room advised that some common carriers are licensed as wholesalers, with regard to those who store or manipulate products. He warned there could be federal preemption issues on direct regulation of common carriers, but he will research the matter further.

Mr. Room also suggested that Dr. Gray submit a written request to the board regarding his ideas to address the issue. The request would include proposed language for the board to consider regarding a letter to major carriers, and background information to help shape the content of the letter.

A representative from Albertson's/Savon, concurred with remarks made by Mr. Lucent regarding drug diversion from common carriers. He stated that the DEA is facing the same jurisdictional quandary that the board is currently discussing. Common carriers are under the jurisdiction of the FBI because they carry controlled substances across state lines. He noted an effort underway to regulate common carriers either by registering with the DEA in a new category, or by changing the DEA 106 form to allowing common carriers to be identified as a potential contributing factor to loss of controlled substances. He suggested that the board draft a letter of support to the DEA on this issue.

Mr. Room asked the representative from Albertson's/Savon to provide the referenced background information regarding DEA's efforts to the board for review.

D. DISCUSSION OF THE IMPACT OF PHARMACY REBATES OR "GIFTS" TO PATIENTS TO TRANSFER PRESCRIPTIONS

Mr. Goldenberg referred to pharmacies that offer rebates or cash gift cards for new or transferred prescriptions. He emphasized that the practice results in fragmented care for consumers that transfer prescriptions from pharmacy to pharmacy. A complete medication profile is important so that pharmacists can protect patients against adverse drug events.

Mr. Goldenberg expressed concern that a pharmacist can be disciplined by the board for a clerk or technician providing a rebate to a Medicaid or Medicare patient, even if the pharmacist had no knowledge of the transaction.

Mr. Room advised that it is a violation of federal law to provide a prescription transfer rebate to a patient when all or part of the prescription will be paid by Medicaid or Medicare.

Mr. Goldenberg noted that as a result of these problems, coupons and rebates for prescription transfers are not accepted in some other states.

Ms. Herold suggested consumer education be used first to warn people of the dangers of repeatedly transferring prescriptions, which can result in inadequate medication profiles. A legislative solution to the problem could be met with opposition from consumer groups.

Mr. Powers noted that the board should help consumers understand that it is a health issue, not a financial issue. He recommended that board staff contact New York, New Jersey, and Massachusetts regarding their history with the coupon/rebate issue. Board staff should report back to the Enforcement Committee with their findings.

Supervising Inspector Judi Nurse suggested that pharmacist education be used to help pharmacies identify when the coupons/rebates can be accepted. She also referred to confusion of pharmacists regarding federally subsidized prescriptions.

Mr. Room referred to the July 2007 issue of *The Script* and that an article in that issue related to coupons/rebates for prescription transfers.

Ms. Herold clarified that the article stated, “Title 42 of the United States Code, sections 1320a-7b prohibits the offer of any remuneration directly or indirectly, overtly or covertly, in cash or in kind to induce a person to order a service or item for which payment may be made wholly or partially under a Federal health care program (e.g., Medicare, Medicaid, Medi-Cal). Anyone violating this code may be guilty of a felony and subject to a fine or imprisonment or both.”

Mr. Graul noted that in his experience, consumers do not repeatedly transfer prescriptions to take advantage of coupons and rebates. He has found that new stores or stores that are underperforming and trying to get new business offer the coupons. Mr. Graul stated that there are relatively few customers that bounce back and forth from pharmacy to pharmacy, in response to coupons or rebates.

Kathy Lynch, representing CPhA, noted that the issue of coupons/rebates is becoming a more prevalent issue for independent pharmacists. She spoke about the applicable exclusions that should be printed on the back of the coupons/rebates. Ms. Lynch offered to bring relevant information on the issue to the next Enforcement Committee Meeting.

Dr. Gray noted that when patients reach the donut hole, they are more likely to use the coupons/rebates. He also noted that the coupons could be used in a positive way because patients are encouraged to have all their prescriptions filled in one place. He recalled that board policy prohibited the use of coupons regarding prescription transfers, but later dropped the issue because it lacked the authority to do so.

Dr. Gray emphasized that this issue is complex and it has drug benefit structure and design implications, federal verses state law implications, and other issues regarding what

constitutes an inducement to transfer a prescription. He also noted that there could be an inducement to having a doctor call a new prescription in to a particular pharmacy. So the issue of inducement does not just affect transferred prescriptions.

Mr. Goldenberg stated that the matter would be put on the agenda for the next Enforcement Committee Meeting.

E. REQUEST FOR WAIVER OF 16 CCR SECTION 1713(A) TO PERMIT PHARMACY HOMECARE NETWORK TO DELIVER MEDICATION TO HOMES OF DELIVERY PERSONNEL FOR LATER DELIVERY TO PATIENTS

Ronald Marks spoke on behalf of Pharmacy Homecare Network. Mr. Marks serves as legal counsel representing Pharmacy Homecare Network regarding their request to ship prescription medicine to delivery drivers for later delivery to patients. California Code of Regulations 16 CCR Section 1713(a) provides that no licensee shall participate in any arrangement whereby prescription medicine is left at or picked up from or delivered to a place not licensed as a retail pharmacy. Section 1713(b) allows the board to waive Section 1713(a) for good cause shown.

The meeting materials included a letter from Mr. Marks to the board dated June 12, 2007 referring to 16 CCR Section 1717(e). For clarification, that section was moved to section 1713, and is the subject of Mr. Marks' remarks to the committee.

Mr. Marks stated that Pharmacy Homecare Network is located in Los Angeles. Some of the patients they serve live in San Diego and are fluent in Russian, though some also speak some English. Mr. Marks further stated that the owner of Pharmacy Homecare Network speaks Russian, as do his pharmacists and pharmacy technicians.

Current procedures of Pharmacy Homecare Network include sending medications via UPS to their delivery personnel. Mr. Marks identified Pharmacy Homecare Network delivery personnel present, Eco Sakianski and Leonid Fasman, both of whom speak Russian. Mr. Marks stated that both men were longtime employees of Pharmacy Homecare Network, one with nine years employment history with the company and the other with eleven. He explained that medications delivered to Pharmacy Homecare Network delivery personnel on any particular day are then delivered to patients later on that same calendar day.

Mr. Marks argued that delivery of medications to patients by Pharmacy Homecare Network personnel instead of via UPS was beneficial to those patients for several reasons. He referred to a language barrier because the patients speak Russian and UPS drivers generally do not. He also referred to elderly patients that cannot reach the door in time to respond to a UPS driver, and that they may not open their doors because they don't recognize the UPS driver.

Mr. Marks noted that UPS drivers who cannot make a delivery to a patient leave a note on the patient's door, and bring the item(s) back to the warehouse where they are stored. He

emphasized that the UPS note left on the door is written in English, and stressed that the language barrier is a problem.

Mr. Marks supported Pharmacy Homecare Network's current procedures whereby their drivers provide personal service and there is assurance that patients receive medications they need. He referred to a board investigation of Pharmacy Homecare Network on a matter relating to this procedure, which resulted in a citation and fine, and his position was that the board's finding was incorrect. Mr. Marks questioned whether board investigators had the information they needed to make the finding.

Mr. Room advised that the committee could hear the request, but any action subsequently taken by the full board would be prospective, not retroactive. He also noted that the previous citation and fine referred to by Mr. Marks had not yet reached a conclusion, due to a pending appeal.

Mr. Marks clarified that Pharmacy Homecare Network was appealing the citation and fine, but was also asking for a temporary waiver from the board pending the outcome of that appeal. He advised that Pharmacy Homecare Network wanted to continue its current procedures in the meantime.

Mr. Room recommended that the board not comment on the propriety of the activity in question relating to 16 CCR Section 1713(a). The board should not hear the facts of an appeal still pending because it could compromise the citation and appeal. Mr. Room further stated that the Enforcement Committee did not have authority to grant a waiver. The Enforcement Committee could only make a recommendation to the full board as to whether this type of activity should be permitted in the future.

Mr. Goldenberg recommended that Pharmacy Homecare Network or their representative(s) return to the Enforcement Committee after conclusion of their appeal, if they want to revisit the issue at that time.

MOTION: That the matter regarding the request from Pharmacy Homecare Network to waive 16 CCR 1713(a) be tabled until conclusion of their pending appeal of a cite and fine on the same matter.

M/S: DAZÉ/POWERS

SUPPORT: 4 OPPOSE: 0

F. REQUEST FROM INSTYMEDS REGARDING 72-HOUR DISPENSING RESTRICTION

Gregory Matzen spoke on behalf of InstyMeds. Mr. Matzen serves as legal counsel to InstyMeds regarding their request for an exemption from the 72-hour dispensing restriction. The meeting materials included correspondence to the board from Mr. Matzen relating to a request for exemption of Business and Professions Code Section 4068(a)(1) and (6) and

Health and Safety Code Section 1261.6(e)(1). The InstyMeds Prescription Medication Dispenser System (system) is an automated prescription medication dispensing system, mainly used in hospital emergency settings. The system dispenses a full treatment regimen of acute medications (i.e., antibiotics, analgesics, etc.) to patients.

Mr. Matzen noted that the Enforcement Committee Meeting agenda item did not accurately reflect the reason for their appearance. He stated that InstyMeds was not seeking exemption of Business and Professions Code Section 4170(a)(5) as shown on the agenda. He said they were asking for clarification of a niche in the law, not a waiver of the law.

Mr. Matzen stated that they were seeking clarification of Business and Professions Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1). He spoke about a request made to InstyMeds from a rural hospital. The hospital was seeking a prescription dispensing machine for installation in their emergency room. Health and Safety Code Section 1261.6(e)(1) refers to a patient "of the facility" meaning a patient in that facility. Mr. Matzen argued that a patient in the emergency room was not a patient of the facility until or unless the patient is "admitted." He stressed that patients in the emergency room would not be patients in the facility.

Mr. Room advised that neither the board nor a committee of the board could offer an interpretation of the law. Individual parties can hire their own legal counsel who will provide an interpretation of the law. As a general matter, dispensing is limited to pharmacists, with certain limited conditions under which prescriber dispensing is permitted. Those conditions are enumerated by statute (i.e., dispensing from an office or during an emergency). There are currently no provisions permitting dispensing from an emergency room to a patient for more than a 72-hour supply of medicine. Mr. Room said that if that ability to dispense to an out-patient were desired, that would require a change in the law.

Ms. Herold noted that Mr. Matzen's letter dated June 22, 2007 specifically requested an exemption of Business and Professions Code Section 4068(a)(1) and (6) and Health and Safety Code Section 1261.6(e)(1).

Mr. Matzen clarified that he was no longer seeking a waiver, but instead, was seeking clarification because the regulations did not currently address this particular situation.

Mr. Powers stated that Mr. Room's comments provided clarification.

Matt Sneller, PharmD, spoke for InstyMeds, noting that the company had been in business for several years. They have approximately 80 prescription dispensing machines located in several states, the majority of which are in hospital emergency rooms. They also have machines installed in urgent care clinics and one small surgery center.

Dr. Sneller said that a rural hospital outside Bakersfield requested installation of an InstyMeds machine. That facility does not have 24-hour pharmacy services. The facility has a hospital pharmacy with a pharmacist present at all times. However, the hospital pharmacy does not do any "out-patient" dispensing. Dr. Snell gave an example of a

72-hour supply of a narcotic like Vicodin as opposed to a 72-hour supply of an antibiotic like Amoxicillin that should be taken for 10 days. Patients who have the full prescription in hand from the start are more likely to take the medication as directed for the full course of the prescription.

Mr. Goldenberg noted that since there had been no motion, there would be no action taken by the Enforcement Committee on this issue at this time.

G. COMMITTEE MEETING SCHEDULE FOR 2008

Ms. Herold advised that information would be posted on the board's Web site regarding the next scheduled meetings of the Enforcement Committee and next full board meeting.

H. ENFORCEMENT STATISTICS

Mr. Goldenberg noted that the meeting materials contained the board's Enforcement Statistics for Fiscal Year 2007/08.

I. MISC ITEM

Mr. Goldenberg advised that information regarding variations of quantity of a prescription was brought to the board's attention. He gave an example of a prescription written for 30 doses of a given drug, with 10 refills. He asked if a pharmacist could dispense a 90-day supply of the tablets, which would be three refills at one time. He noted that this is allowable by many Medicare Part D plans.

Ms. Herold noted that the board's inspectors considered this question several times in previous months. They indicate that if a prescriber desires a patient to receive 90-day supply, the prescriber needs to write a 90-day supply. In the case of writing a prescription with 10 refills, the prescriber did not write "fill a 90-day supply."

There was a discussion among board members regarding pharmacists filling prescriptions up to the quantity of that prescribed.

No further action was taken by the board.

ADJOURNMENT

Mr. Goldenberg adjourned the Enforcement Committee Meeting at 6:06 p.m.