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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary September 29, 2004

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

Present: William Powers, Chair
Stan Goldenberg, R.Ph., Board President and Member
David Fong, Pharm.D.

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room Deputy Attorney General

Call to Order

Enforcement Committee William Powers called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

The Enforcement Committee was provided background information on activities in this area since the last board meeting. It was noted that the Governor had not yet acted on the various legislative proposals that would assist Californians in obtaining prescription drugs from Canada. The committee was also given a copy a letter from Governor Schwarzenegger to Secretary Tommy Thompson dated August 20, 2004, expressing concern about the growing cost of prescription drugs and his strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers. In the letter, he also encouraged the Bush Administration to aggressively pursue its discussions to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development.

In an effort to do this, the Governor put forward “California Rx” that seeks to provide assistance to these Californians. The proposal would establish a drug discount program for low-income uninsured residents through a state contract with a Pharmacy Benefit Manager (PBM). The intent is for Californians that lack insurance would be able to present this discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The program would be available to low-income seniors and uninsured Californians up to 300% of the federal poverty level (\$47,000 for a family of three) to secure meaningful discounts in prescription drug costs.

There was general discussion regarding “California Rx”. The board was strongly encouraged to take an active role in the development of this proposal and asked that it be discussed at the October board meeting. It was noted that while a bill hasn’t been introduced, the information will be provided as part of the Legislative/Regulation Committee’s report and would be included if a bill is introduced next year. The board is very sensitive to this issue and is tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The intent of the Governor’s proposal, “California Rx” is to improve access as an alternative to importation.

It was reported that Senate Health and Human Services Committee held an informational hearing on September 21st. The hearing included an in-depth overview of “California Rx”, the timeline for implementation, and the estimated cost savings. Representatives were invited to present a critical analysis of the proposal, its feasibility and overall benefit when compared to some of the drug importation proposals that were introduced over the past legislative session.

It was suggested that for future meetings, this agenda topic be titled “Importation of Prescription Drugs” since the issue is more than the reimportation of prescription drugs from Canada.

Proposed Legislative Change to Update the Law Regarding the Pharmacist Recovery Program (Bus. & Prof. Code sec. 4360 – 4373)

Executive Officer Patricia Harris reviewed the draft proposal for updating the statutory provisions related to the Pharmacists Recovery Program (program). She explained that while most of the proposed changes are minor, technical revisions to more closely conform the statute to the current operation of the program, some of the changes are substantive.

Ms. Harris noted that the most substantive change effects section 4362. This section specifies who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects current operation of the program.

The substantial change made is that licensees that enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such “self-referrals” are confidential and the board is generally not informed of their identities. This “confidentiality” can be voided if the program administrator believes the licensee may present a threat to the

public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

The draft proposes to prohibit the board from taking enforcement action against the self referred licensee based on their entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take an enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

Another substantial change is to section 4368, which removes the mandate that the board enter into a contract with a professional association to promote the program and coordinate outreach to encourage voluntary participation. The board has not entered into such a contract with a professional association for over five years. Given the current fiscal constraints on the board, it is unlikely that such a contract would be reestablished in the foreseeable future and removing the statutory mandate would seem appropriate. The board can use other means to educate licensees about the availability of the program. The board could always enter into such a contract, if it desired, without the statutory mandate.

It was asked if the board had considered including pharmacy technicians in the program. It was noted that the intent is to rehabilitate pharmacists so that they may return safely to the practice of pharmacy. As a health professional, the pharmacist has much more invested in their education and training and thus more incentive to seek treatment. The program also encourages the pharmacist's participation and rehabilitation while providing the oversight necessary to ensure patient safety without undue punishment to the impaired pharmacist.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed legislative changes relating to the Pharmacists Recovery Program.

Proposed Legislative Change to Update the Law Regarding the Pharmacy Technician Program (Bus. & Prof. Code section 4115 and 4115.5)

The Enforcement Committee was provided with proposed changes to the pharmacy technician program. It was emphasized that most of the changes are technical and designed to make the statutes more clear. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist and applies this same supervision to interns. Concern was expressed that the supervision was limited to the dispensing of prescriptions especially as it pertains to interns. The committee agreed with this concern and directed that the language be modified accordingly.

The other changes are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change to 4115 is made to eliminate the exemption that

permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was added to allow personnel to work in those facilities until they could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Comments were made that provided general support with the proposed changes with an opportunity for the board to consider some possible enhancements. It was reiterated that the intent of this legislative proposal was not to change the ratio or the basic authority of pharmacy technicians. As legislation is introduced, the opportunity to address these issues is always available.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed legislative changes to the pharmacy technician program.

Proposed Legislative Change to Related to Letter of Admonishment (Bus. & Prof. Code section 4315)

The Enforcement Committee considered a revision to Section 4315, which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law. This section was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the Letter of Admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees that do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.). Accordingly, it is recommended that this requirement be eliminated.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed change to section 4315.

Proposed Regulation Change to Implement SB 1913 Related to the Use of Technologies to Record the Identification of a Pharmacist

Senate Bill 1913 amends Section 4115 to permit the board to allow the use of electronic technologies to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The proposed regulation text would allow the use of electronic methods of identifying the reviewing pharmacist. This section would also be an alternative means of documenting the pharmacist's review as required by CCR, title 16, sec. 1717(b)(1) and 1717(g).

The Enforcement Committee recommended that the Board of Pharmacy support this proposed regulation change that would authorize the use of technologies to record the identification of the pharmacist in lieu of the pharmacist initialing or signing a prescription record or label.

Request by Longs Drug Stores for Waiver of 1717(e) to Install a 24-Hour Kiosk

Longs presented its request to install convenient, secure and private, 24-hour prescription drop kiosks. It was explained that the kiosk would be installed adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off their prescriptions for the pharmacy to fill. The kiosk would be similar to a mailbox or drop off container used by video stores.

The Enforcement Committee advanced to the Board of Pharmacy the request from Longs Drug Stores for waiver of 1717(e) to use a 24-hour prescription drop kiosk; however, the committee did not make a recommendation regarding the request. Prior to the presentation by Longs Drug Stores, board member David Fong recused himself from the discussion.

Request by Longs Drug Stores for Wavier of 1717(e) to Install and Utilize Self-Service Dispensing Units

Longs Drug Stores requested a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California.

Representatives of the Asters ScriptCenter provided an overview of the dispensing unit. It is an automated, self-contained instrument that allows patients to access their filled prescriptions. The units will be installed in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of the patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing.

The Enforcement Committee advanced to the Board of Pharmacy the request from Longs Drug Stores for waiver of 1717(e) to use a self-service dispensing unit; however, the committee did not make a recommendation regarding the request. Prior to the discussing the request from Longs Drug Stores, board member David Fong recused himself.

Proposed Regulation Change to Add Section 1713 – Delivery of Prescriptions

Based on the request from Longs Drug Stores to permit the use of secure drop boxes for receiving prescription orders from patients and to use secure devices for dispensing filled prescriptions, staff drafted a regulation change that would permit both these activities should the board grant the waivers.

The prescription drop boxes would allow patients to drop off prescriptions in a secure container that is at the same address of the pharmacy or adjoining the licensed premises. The secure devices for dispensing refill prescriptions after hours is restricted to refill prescriptions that are not subject to the consultation requirement. The proposed draft relocates existing provision 1717(e) into a new section and provides the authorization for both the drop boxes and self-service dispensing devices.

Concern was expressed that the Board of Pharmacy should not act on this proposed regulation or the waiver request to use the self-service dispensing device until the board has a philosophical discussion regarding pharmacist consultation on refill prescriptions. Currently, the law doesn't require pharmacist consultation on refill prescriptions (only in the pharmacist's professional judgment or upon a patient's request); however, use of these self-service dispensing devices would remove the pharmacist completely away from the process. It was noted that pharmacy law doesn't require the pharmacist to physically provide the patient with the refill medication; a cashier does this.

The Enforcement Committee moved this proposed regulation to the Board of Pharmacy for its consideration. The committee did not provide a recommendation.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

The Enforcement Committee was provided more question and answers on changes to the law regarding the prescribing and dispensing of controlled substances especially as it to the new prescription forms and requirements. These questions have been added to the board's Web site.

It was reported that board is continuing its outreach efforts to educate all health professionals on these new changes.

Status Report on the Legislation Related to Wholesalers (AB 2682 and SB 1307)

It was reported that these bills strengthen the licensure and regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs and are awaiting the Governor's signature. The board carefully developed the provisions in these bills to directly address issues found during its investigations of wholesale violations in California and the recommendation for the changes came from this committee.

Discussion on How the Board of Pharmacy Can Improve Communication and Facilitate Communications with the Public and Licensees

At the board's July meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public. To this end, each of the board's committees will hold a public meeting before the October board meeting

with this topic listed as a discussed item. The goal is to establish a dialogue with the stakeholders on improving communication, and to bring any suggestions to the next board meeting. The committee was provided with a copy of the memorandum that was prepared by the Assistant Executive Officer for the Communication and Public Education Committee. This document provided an overview of the several broad based means of communication that the board has with the public and its licensees.

A comment was made that the board has done an outstanding job at its many outreach efforts especially the programs on pharmacy law and much of the feedback has been. It was noted however that the best communication that the board can offer is the dialog that board inspectors have with licensees and informing them of the tools that are available. However, concern was expressed that there is a disconnect between the inspector and the board. It was encouraged that the inspection focuses on education first. As previously suggested at other meetings, the board was encouraged to hold its meetings at the schools of pharmacy.

Review of Draft Self-Assessment Forms

Chair William Powers noted that the draft self-assessment forms were not completed for review at this meeting. However, section 1715 requires that the pharmacist-in-charge complete a self-assessment by July 1, of every odd year. It is the intent of the board to update the self-assessment forms with the many new law changes so that it can be used by July 1, 2005. To do this, the board must review the forms at its October meeting so that it can act on the regulation change at the January board meeting.

Discussion Regarding Routine Compliance Inspections and Citation and Fine Program

Inspections

Supervising Inspector Dennis reported that in July 2001, the board reinstated its routine inspection program with the goal of inspecting every pharmacy within 3 years. The compliance team will meet this goal by June 30, 2005. Although the team has done a tremendous effort within existing resources to meet the three-year goal, the projections did not take into consideration the licensure of approximately 600 new pharmacies a year or the implementation of the sterile compounding program for which the board did not receive new inspector positions. The compliance team plans to inspect over 1,500 pharmacies by the end of this fiscal year.

The Enforcement Committee acknowledged and commended the inspectors for their efforts.

Citation and Fine Program

It was reported to the Enforcement Committee for the period of May 1, 2001 – September 21, 2004, the board has issued 1,843 citation and fines. Of these, 135 citations with fines totaling over \$300,000 have not been collected. This is approximately 7% of the total number of citations issued and 20% of the fines. A large number of these citations are issued to cancelled/unlicensed pharmacy technicians, unlicensed premises and cancelled premises. Often times, the citations and fines are issued so that a public record is made, understanding that is

more than likely that the fine may not be collected. Staff advised the committee that it is exploring options on the collection of these unpaid fines.

New DEA Controlled Substances Registration Forms

The Enforcement Committee was given a letter from the DEA advising that as of October 1, it will change the style and appearance of the registration certificate. It will consist of two parts: one that can be displayed on the wall and a smaller wallet size version. The certificate will have an embedded watermark logo, to provide authentication and to deter counterfeiting. The DEA asked that this information be shared with licensees and will appear in the board's next newsletter.

Adjournment

Committee Chair William Powers adjourned the meeting at 12:30 p.m.