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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
July 2, 2003

Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Don Gubbins, Board Member
Bill Powers, Board Member
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
Ron Diedrich, Liaison Deputy Attorney General
Enforcement Staff

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

Committee Chair John Jones began the discussion by stating that Senator Alarcon requested an opinion from the Attorney General on several questions regarding the importation of prescription drugs from Canada. He stated it was unknown when the opinion would be published and none of the questions were about the use of storefront facilities by consumers to access prescription drugs from Canada.

It was also stated that importation of drugs from foreign countries is a federal issue and within the purview of the FDA. There is a provision that has been proposed as part of the pending Medicare legislation that would allow for the reimportation of drugs from Canada. Although current federal law allows for reimportation, the secretary of Health and Human Services must approve such action and has chosen not to do so.

California Pharmacy law specifies that the board's primary purpose is consumer protection. It is the board's discretion as to what action it will take. The board will investigate any consumer complaint that involves a prescription drug from Canada irrespective of how it was obtained. The board is concerned that consumers have access to safe prescription drugs. It is not the board's position to pursue complaints for economic or competitive reasons. Moreover, a business has the ability to pursue a private right of action for unfair businesses practices under Business and Professions Code section 17200.

It was expressed that the Board of Pharmacy should advocate to the FDA that it move forward to allow other entities to import prescription drugs from Canada. There is currently a mechanism in place for manufacturers. It was argued that a similar licensing process could be implemented for wholesalers and pharmacies that would ensure the safety of the prescription drugs being imported from Canada.

Proposed Modification to Quality Assurance Regulation

At the April Board meeting, the Enforcement Committee discussed the proposed language that was submitted to amend CCR 1771(c) regarding the notification of the patient and prescriber when a prescription error has occurred. It was requested that this issue be returned to the Enforcement Committee with direction to the stakeholders to develop language to address those situations when a patient has not ingested the medication. The stakeholders recommended the following modifications:

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless ~~the~~ **a** pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall ~~immediately~~ **as soon as possible, and working in collaboration with the prescriber or the prescriber's agent, ~~or if unavailable, another prescriber then treating the patient,~~** communicate to the patient **or the patient's representative or care provider** ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error. **The provisions of this subsection (c) shall only apply to medication errors in which the patient took, or was administered a drug in error.**

Concern was expressed that the language did not include those situations where the prescriber should be notified if there is significant harm because the patient's therapy was delayed as a result of the error. Clarification was sought as to the distinction between notifying the prescriber "immediately" or "as soon as possible." An example was provided in the hospital setting where a patient may have been administered a drug in error at night and the harm was not significant. In this situation, the pharmacist could notify the prescriber the next day. However, in some cases, the pharmacist should notify the prescriber immediately because there has been significant harm, even if happened at night. The proposed language allows the pharmacist to use his/her professional judgment to determine the appropriate process of notification.

It was also noted that the language should be clarified regarding patient notification because proposed modifications appear to require that the patient be notified in collaboration with the prescriber. While it is usually the patient that notifies the pharmacist in the community setting, the language was not intended to require the pharmacist to notify the patient in collaboration with the prescriber.

The committee recommended that the Board of Pharmacy amend CCR, title 16, section 1711(c) as discussed with the changes to the language that would clarify the concerns discussed about the delay in therapy and the patient notification.

Proposed Regulation of Wholesale Drug Transactions - CCR 1784 and 1785

Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract" drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transaction. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of the drug. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

Comments were made that the proposed regulation sections impede legitimate business transactions and modifications were suggested. It was also stated that the PDMA allows for intra-company sales, which may be contrary to the proposed section 1784. While the board has been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. This new legislation identifies a list of drugs that require a statement of prior sales.

Chair John Jones requested interested parties to submit proposed language for continued discussion by the Enforcement Committee.

Request for Pharmacy Records by Authorized Officers of the Law

Executive Officer Patricia Harris stated that it has been brought to the board's attention that pharmacies are choosing not to provide prescription records when requested by an authorized officer of the law engaged in an official investigation. Whether to provide the record or not, is a decision that the licensee must make. The board does not advise licensees in this regard.

However, there is some misinformation that is being given to the officers as to why the pharmacy will not release the records without an investigative subpoena. One reason is that the Board of Pharmacy requires an investigative subpoena to document the release of the records and without it, the pharmacy will be cited for violation of pharmacy law.

This is not true. When an officer takes prescription record(s), the pharmacy should be given a receipt identifying the records. If a board inspector should ever ask for the same records, the pharmacy should be able to produce the receipt to document release of the records to an authorized officer of the law. Concern was expressed that receipts are not detailed enough to document to an inspector what records may have been released. Response was provided that this is a concern that the pharmacy should seek legal counsel. It was suggested that the board write a newsletter article on this issue.

Deliver of Prescription Drugs Pursuant to Business and Professions Code section 4059.5

It was requested that the board consider its interpretation of Business and Professions Code section 4059.5 to allow for the delivery of prescription drugs to a secured area when a pharmacy is closed. The law requires that the dangerous drugs must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge.

It was presented that due to various local ordinances and environmental factors, delivery of prescription drugs must take place after the pharmacy is closed. It was requested that the board consider the delivery of the prescription drugs to a secured area as the prescription drugs still being in transit. It is when the pharmacy takes possession of the drugs that the drugs would be considered delivered to the pharmacy in compliance with 4059.5. The wholesaler would be responsible until such time that the pharmacy took possession.

The committee discussed this request and agreed that it would recommend that the board consider such an interpretation and the statute be changed consistent with the interpretation. However, once the prescription drugs were delivered to the "secured area", the drugs would no longer be in "transit." The pharmacy would then be responsible for the prescription drugs.

Off-Site Order Entry of Hospital Medication Orders

Dr. Cacciatore of CardinalHeath presented a proposal to license a pharmacy service center in California. This would be an office-based, licensed pharmacy staff with experienced hospital pharmacists. The hospital would transmit new orders to the service center after the hospital pharmacy closes or when needed via fax or digital imaging. Pharmacists at the pharmacy service center would remotely access the hospital computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes. Pharmacists would also be available via a toll free number to answer medication questions from nursing and medical staff.

The pharmacy service center would have access to the hospital pharmacy computer system through a secure, virtual private network. The pharmacy service center would

also enter into a Business Associate agreement with the hospital and would be in full compliance with HIPAA and state privacy laws.

It was noted that Business and Professions Code section 4071.1 allows for a pharmacist to electronically enter a prescription or order into a hospital's computer from any location outside the pharmacy or hospital with the permission of the pharmacy or hospital. Health and Safety Code section 11164.5 allows for electronic data transmission or computer entry of prescriptions for controlled substances if authorized by federal law and with the approval of the Board of Pharmacy and the Department of Justice.

Dr. Cacciatore stated that CardinalHealth will be submitting a community pharmacy application for licensure of this facility. He also stated that he will submit a written request for approval Health and Safety Code section 11164.5 to enter in the hospital computer system controlled substances. He will be submitting a request for approval to the Department of Justice and the Board of Pharmacy.

The committee agreed that the licensure of this facility as a community pharmacy was appropriate and directed staff to work with the Department of Justice regarding the approval process as provided in the Health and Safety Code for controlled substances. The committee also agreed to recommend that the executive officer be delegated the authority as part of the licensing process to approve these requests.

Report on the MBC/Board of Pharmacy Joint Task Force Meeting on Prescriber Dispensing

Chair John Jones reported that the Medical Board of California and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

He stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Implementation of federal HIPAA Requirements

The Enforcement Committee was provided with the NABP document prepared on the frequently asked questions regarding HIPAA. Specifically the questions are: What protected health

information can be disclosed to pharmacy inspectors? What information can inspectors access? and Are inspection activities included in the accounting of disclosures? In addition, a detailed description of the board's "Statement of Authority" was provided. This document will be used for a newsletter article and the sections of law specifying the board's authority will be added to the board's inspection report.

Pharmacists Recovery Program

It was reported that Maximus, Inc. is the new contractor for the board's Pharmacists Recovery Program, effective July 1, 2003. Leslie Hanover is the board's case manager. She is a licensed Marriage Family Therapist with experience in mental health and substance abuse since 1986. The 800 number has been transferred to the new contractor. The participants and the professional associations have been notified of the new contractor. An article will also be published in the next newsletter.

Strategic Objectives for 2003/04

Chair John Jones identified the board's strategic objectives for 2003/04 that were developed during the board's strategic planning session at its April meeting.

Discussion of Issue not Noticed on the Agenda

CPhA expressed concern that the Board of Pharmacy is requiring pharmacies to dispense and label medical supplies and OTC drugs in accordance with the requirements for prescription drugs because Medi-Cal requires that they be dispensed upon a prescription for reimbursement. It was noted that DME providers dispense these same medical supplies without meeting the same prescription requirements as pharmacies or with a pharmacist oversight. The Enforcement Committee agreed to research this issue for further discussion at the next Enforcement Committee meeting in September.