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

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
March 18, 2004

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-600

Present: John Jones, Chair and Board President
Stan Goldenberg, 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
Dana Winterrowd, Staff Counsel
Paul Riches, Legislation/Regulation Chief

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 reported that the board has been discussing and has sought comments on the issue of prescription drug importation from outside of the United States. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

President Jones reported that FDA Commissioner Mark McClellan was named to lead a committee that will conduct a study on the reimportation of lower-cost, U.S. manufactured prescription drugs from Canada. The one-year study was required under the new Medicare law and will examine whether the United States could safely reimport prescription drugs.

Paul Riches described various legislative proposals that have been introduced relating to the reimportation of prescription drugs from Canada. Some of the bills impact the board in that the board would be required to establish a Web site to provide price comparisons between American and Canadian prescription drug prices and provide a link to certified Canadian pharmacies. The bill would also require that the board "certify" Canadian pharmacies. The other legislative bills are designed to increase the public and private sector buying power for lower prescription drug prices. The board's Legislation and Regulation Committee will review these bills at its public meeting on March 30th, in Sacramento.

The committee discussed its purpose of public protection, which includes patient access to "safe and affordable" prescription medications and that the board should not be building a barrier to this access. The committee acknowledged that ideally the federal government should be establishing national policy to ensure this access and that the board should be supportive of all efforts in this regard.

Update on Implementation of Legislation Regarding Wholesalers

At its January meeting, the Board of Pharmacy acted to sponsor legislation to strengthen the regulation of wholesale facilities. Senator Figueroa agreed to author the legislation and introduced SB 1307. In its current format, the bill only contains the licensing provisions that the board approved last October and will be amended to included the additional provisions, which are:

- Pedigrees for all drugs beginning January 1, 2007
- Prohibition against the wholesaling of prescription drugs by pharmacies
- A $100,000 bond to secure payment of administrative fines and penalties
- Fines on per occurrence basis for specified violations (e.g. sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
- Definition of "closed pharmacy" as one only serving a distinct patient population and prohibits the owners of a closed pharmacy from owning a wholesale facility

In addition, Assembly Member Negrete McCloud introduced AB 2682, which would require the board to adopt regulations requiring pedigrees and governing wholesale distribution in California consistent with the federal regulations. The bill would also require all out-of-state wholesalers selling or distributing prescription drugs into California to be licensed. Another bill, SB 1427 was introduced by Senator Ackerman and would establish felony penalties for counterfeiting drugs.

Legislation Chief Paul Riches noted that the Board of Pharmacy's vote to support this legislative proposal was a difficult one because the board didn't want to impede legitimate business. Mr. Riches reported that he has been working constructively with the wholesale community to resolve some of their issues and believes that an agreement will be reached. One solution has been to include language that would give the Board of Pharmacy flexibility to extend the implementation date of the pedigree requirement for at least one year. Another issue is the prohibition that a wholesaler cannot own a "closed pharmacy". A proposed resolution may be a

due diligence requirement on the wholesale facility instead. This proposal would be in addition to the current proposed provision that prevents a pharmacy from wholesaling prescription drugs.

SB 1307 is scheduled for hearing in the Business and Professions Committee on April 12th.

Conversion to Paper Invoices to Electronic Billing by Wholesalers for Drug Purchases

Executive Officer Patricia Harris explained that the Board of Pharmacy received a letter from Ralphs seeking clarification regarding the conversion from paper invoices for drug purchases to electronic billing. Ralphs is seeking clarification of its record-keeping duties because its wholesale supplier(s) has/have decided to convert from paper to electronic invoices. Specifically, Ralphs wants to know if it is permitted to no longer keep paper copies of invoices on file but have such invoices electronically available. If so, it wants to know how long Ralphs must keep electronic invoices available for inspection.

The request for clarification from Ralphs was forwarded to board's counsel for review and comment. Counsel advised that the pertinent statutes relating to this issue are Business and Professions Code sections 4081, 4105, and 4333. Section 4081 requires that records of "manufacture and of sale, acquisition, or disposition of dangerous drugs and of dangerous devices" be available for inspection at all times, and that such records be "preserved for at least three years from the date of making." (Bus. & Prof. Code § 4081, subd. (a)). Section 4105 similarly requires that records of acquisition or disposition be readily available on licensed premises, and that such records be preserved for three years from the date of making. (Bus. & Prof. Code § 4105, subds. (a), (c)). The same records-availability and three-year preservation period is applied to filled prescriptions by Section 4333. (Bus. & Prof. Code § 4333, subd. (a)).

The only one of these statutes, which mentions electronic record keeping, is Section 4105. Subdivision (d) thereof allows that records may be kept electronically so long as a hard copy and an electronic copy can always be produced. (Bus. & Prof. Code § 4105, subd. (d)).

Subdivision (d) of Section 4105 does not specify a different time period of preservation from the three-year period generally required by subdivision (c). Electronic records must therefore also be preserved and retrievable for a period of three years. Indeed, subdivision (d) begins "[a]ny records that are maintained electronically . . .," clearly indicating it is limited by the definition of "records" given by subdivisions (a) through (c). I t was explained that a licensed premises has the option of keeping its "records or other documentation of the acquisition or disposition of dangerous drugs and dangerous devices" (Bus. & Prof. Code § 4105, subd. (a)) in electronic rather than paper form. If it chooses to do so, however, those records must also be "retained on the licensed premises for a period of three years from the date of making." (Bus. & Prof. Code § 4105, subd. (c)). This means that the electronic records must be retained on the licensed premises for a period of three years from the date of making, "so that the pharmacist-in-charge, [or] the pharmacist on duty if the pharmacist-in-charge is not on duty," shall "at all times during which the licenses premises are open for business be able to produce a hard copy and electronic copy of all records of acquisition or disposition . . ." (Bus. & Prof. Code § 4105 (d)).

Ms. Harris summarized by stating that board counsel has advised that pharmacies can keep drug purchase records from wholesalers electronically rather than on paper so long as those records are retained on site and immediately available for inspection for a period of three years, and can at all times be produced in both hard copy and electronic form by an on-duty pharmacist.

The Enforcement Committee accepted counsel's advice and application of pharmacy law relating to electronic records of drug purchases from wholesalers.

Use of Robotic Technology in Hospital and Institutional Pharmacies and the Interpretation of Pharmacy Law that Pharmacist Must Check Each Medication

Executive Officer Patricia Harris stated that the board received a request from McKesson to review and approve its proposal for a ROBOT-Rx protocol in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by the ROBOT-Rx. McKesson proposes a protocol whereby a pharmacist would check 100% of the medications packaged by the ROBOT-Rx on a daily basis, and would for a period of no less than 30 days after the ROBOT-Rx is first deployed check 100% of doses dispensed by the ROBOT-Rx, but would then taper off to sampling only 5-10% of these doses.

It is McKesson's opinion that the Board of Pharmacy statutes and regulations are silent on the duty of a licensed pharmacist (or pharmacy) to verify dispensed medications from an automated dispenser and McKesson concludes that "it is within the discretion of the Board of Pharmacy staff to approve a protocol that would apply specifically to ROBOT-Rx technology" in inpatient settings. It is McKesson's desire that the Board approve this proposal, for reduced error checking of dispensed medications, over a requirement that all dispensed doses be checked.

Board counsel reviewed the request and advised that McKesson is correct that the Pharmacy Law is silent on the question of automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics contained in Business and Professions Code section 4186. There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. From this, it is McKesson's conclusion that there is a "gap" in the law that can be filled by its proposed "protocol."

It was counsel's opinion that in the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100% accuracy of dispensing. A licensee can only furnish dangerous drugs pursuant to valid prescription (Bus. & Prof. Code § 4059), except under specified circumstances (e.g., emergency, Bus. & Prof. Code § 4062), and can only furnish those dangerous drugs as prescribed (except where substitutions and generics are permitted, Bus. & Prof. Code §§ 4052.5, 4073).

The Pharmacy Law is violated, *inter alia*, where a prescription is dispensed in an insufficiently or inaccurately labeled container (Bus. & Prof. Code §§ 4076, 4077, 4078), where the drug dispensed deviates from requirements of a prescription (Cal. Code Regs., tit. 16, § 1716), or where the prescription dispensed contains significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (Cal. Code Regs., tit. 16, § 1761). These provisions apply to all dispensing, regardless of setting.

Thus, the licensees' duties to ensure accuracy of prescription dispensing do not depend on a particular method of delivery. Whether dangerous drugs are dispensed by hand or by use of the ROBOT-Rx or some other automated delivery system, the licensees' duties do not change.

It was explained that the same duty to seek 100% accuracy of dispensing that applies to hand-dispensing by way of California Code of Regulations, title 16, section 1716 (and section 1761) applies just as strongly to dispensing performed by an automated delivery system. If McKesson is correct that ROBOT-Rx is a more accurate method of filling prescriptions, taking out human error that might otherwise occur, it should increase the likelihood of compliance. The use of an automated system like ROBOT-Rx does not, however, give licensees a "free pass" for a certain number of dispensing errors that may nonetheless occur.

This interpretation is reinforced by Business and Professions Code section 4186, which states drugs may "be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile" and "provided to the patient [only] by a health professional licensed pursuant to this division." (Bus. & Prof. Code § 4186, subd. (b)). Section 4186 also requires policies and procedures to "ensure safety, *accuracy*, accountability, [and] security . . ." of dispensing (Bus. & Prof. Code § 4186, subd. (a) [emphasis added]), says that the *stocking* of automated systems may only be performed by a licensed pharmacist (Bus. & Prof. Code § 4186, subd. (c)), and requires that drugs dispensed comply with all statutory labeling requirements (Bus. & Prof. Code § 4186, subd. (g)).

Section 4186 indicates that the placement of an automated drug delivery system in a nonprofit or free clinic does not eliminate or vitiate the responsibility of the licensee overseeing that system for the accuracy of the drugs dispensed. That licensee must still comply with all of the statutes and regulations requiring accurate dispensing, and Section 4186 reinforces this responsibility by requiring policies and procedures to ensure accuracy as well as the direct involvement of the licensee in the stocking of the machine and the dispensing of drugs. The licensee still remains responsible for any errors that result from this delivery system. There is no exemption stated by Section 4186 to the general duties of licensees in this regard. Moreover, there is no reason to think that such an exemption would apply to an automated delivery system placed in any other setting, including the inpatient setting.

Therefore, counsel has advised that any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance that such error will occur, however minor, by eliminating human 100%

double-checking that may, in at least some cases, catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught but for this protocol.

Counsel advises that there is at present no statutory or regulatory requirement that licensees check 100% of all prescriptions dispensed by an automated delivery system. While licensees may elect to save costs by reducing their level of error checking, they do so at their own risk and that of the patient's safety. If it is the desire of the board to require 100% error checking by a pharmacist, and not permit this election, then additional statutes or regulations are needed.

Further, Ms. Harris explained that counsel does not recommend that the board approve the protocol McKesson proposes. First, there is no authority for the board to approve a protocol and to do so, may constitute an impermissible underground regulation. Second, under current law, it is the decision of the individual licensees to determine the level of risk of error they are willing to assume, and the steps they take to reduce or eliminate that risk.

The Enforcement Committee agreed with the conclusion of board counsel and clarified that this application of pharmacy law pertains to all pharmacies that use an automated delivery system not just to hospital or institutional pharmacies.

Proposed Revisions to the Public Disclosure Policy

Executive Officer Patricia Harris provided the Enforcement Committee with a revised public disclosure policy that included "Letter of Admonishment" that was added this year through new legislation and some other technical changes were made.

She stated that the board's "Record Retention Schedule" governs how long the board maintains its records. As long as the board maintains public records, they must be provided to the public upon request. Currently, the board's retains substantiated complaints such as citations for 5 years and disciplinary actions for 10.

When Business and Professions Code section 4315 was added to authorize the issuance of a letter of admonishment, it specifies that the pharmacy must keep the letter of admonishment for three years from the date of issuance. This three-year period is consistent with all other record keeping requirements required of board licensees.

When there is a public records request for a citation or letter of admonishment, only those documents are provided. A copy of the investigation report is not given.

Staff recommended that the "Record Retention Schedule" for substantiated complaints be changed to 3 years. Three years provides the board with sufficient complaint history to determine if disciplinary action is warranted. Moreover, 3 years is consistent with the

record keeping requirements for licensees. Also, with the board's diminishing resources, it is difficult to maintain the records for five year.

Collette Galvez from the Center for Public Interest Law suggested that the committee not recommend that the board change its public disclosure of substantiated complaints to 3 years. She advised that such a change is not consistent with the other health boards that maintain these records for at least 5 to 10 years. She also cautioned that three years of information may not be enough for a consumer to make an informed decision about a pharmacy or pharmacist.

Other comments were made that a licensee is more likely to challenge a citation and fine, if the licensee is aware that the citation is on the licensee's record for a minimum of five years. It was also noted that some type of a disclaimer should be included when a citation and fine is disclosed in that a citation is considered an administrative action (not discipline) and payment of the fine is considered resolution to the violation of law.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it amend its public disclosure statement and change its record retention schedule for substantiated complaints to three years.

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

Committee Chair John Jones commented that he anticipates over the next year that the implementation of SB 151 will be a standing agenda topic for this committee and the Board of Pharmacy. The triplicate requirement has been in place for over 60 years and the transitional changes to implement the new law over the next year are confusing. The board anticipates many questions and has been working hard especially with its limited resources to educate prescribers and pharmacists. The educational process will not be an easy feat.

Ms. Harris reported that the newsletter is scheduled for distribution at the end of March. Meanwhile, the articles on SB 151 are on the board's Web site. The articles have also been provided to the prescriber boards and professional associations so that they can educate their licensees and answer questions. Staff and board members have been working with various associations and pharmaceutical companies on educational programs and outreach efforts.

Questions were asked as to how pharmacies that do not fill schedule II prescriptions need to report the data to the Department of Justice (DOJ). It was explained that the law specifies that this is a decision of the DOJ. However staff will seek clarification from DOJ for licensees. It was noted that the board has received 6 security printer applications. The board has been advising prescribers that if they are concerned that they will run out of their triplicate prescription forms before they will have their new controlled substances forms, then they should reorder triplicate prescription forms before

July 1, after which time, the triplicates will no longer be available. Many pharmacists have been contacting the board seeking validation that triplicate prescriptions are good for six months.

Report from the NABP Task Force on Limited Distribution and Shortage of Medications

The Enforcement Committee was provided a copy of the NABP task force report on the limited distribution and shortage of medications. The task force met in November 2003 after the Enforcement Committee discussed this issue last September. The committee discussed this issue at the request of Stan Goldenberg. His request was based on a Citation and Fine Committee's review of a consumer complaint regarding the inability of a pharmacy to fill the patient's prescription because the pharmacy didn't have the medication due to a manufacturer's shortage.

A patient had filed a complaint with the board against a pharmacy for not providing her with all the Enbrel that she was prescribed. The pharmacist only dispensed 4 kits instead of the 8. The pharmacist informed the patient that he was unable to fill her entire prescription due to a shortage of the medication. The patient was upset because she specifically had registered with the drug manufacturer to avoid such situations. The manufacturer assured her that they were sending the pharmacy her entire order. The patient felt that the pharmacy was giving her medication to other patients. In this specific case, the complaint was closed with no further action.

Last September, when the Enforcement Committee discussed this issue, it determined that these types of complaints would be handled on a case-by-case basis. If the pharmacist does not fill a prescription according the prescriber's order, then he/she may be in violation of CCR, title 16, section 1716 (variation from a prescription). The reason would be that the prescriber wrote for a specific quantity and if the pharmacist didn't dispense this quantity (for whatever reason), but labels the prescription as if he/she had, then it may be considered prescription error (mislabeled prescription container). However, the final disposition would depend on the specific facts of each case.

There was discussion that the committee's decision last September was contrary to the recommendation to the NABP task force. The task force recommended that the pharmacist-in-charge develop, implement, and maintain policies and procedures that address drug shortages or drug product discontinuance. Also, that implementation by pharmaceutical manufacturers of restricted medication distribution programs should not be permitted unless the programs are based on sound scientific and clinical evidence that is in the best interest of the patient.

Continuing Education Outreach Program to Licensees

President John Jones reported that Board of Pharmacy is going on its second year of providing continuing education to pharmacists. The program has been updated and a copy was provided in

the meeting materials. He explained that the program was also modified for presentation to the graduating classes of the four pharmacy schools.

Review of Strategic Plan

Ms. Harris stated that as a part of the board's annual strategic plan update, the Enforcement Committee reviews its goals and objectives for any recommended changes.

Staff provided a recommendation to add an objective similar to that of the licensing goal. The objective is: Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005. One of the tasks tracked in this section is "the importation of drugs from foreign countries", which is done by the Enforcement Committee.

Since July, the Enforcement Committee has addressed various public policy initiatives related to compliance and compliance but there is no objective to track the tasks:

- Reimportation
- Modification to the Quality Assurance Regulation Regarding Patient Notification
- Proposals Regarding Wholesale Transactions
- Clarification Regarding Prescription Records by Authorized Officers of the Law
- Review of Pharmacy Law Regarding the Delivery of Medications After the Pharmacy is Closed and a Pharmacist is not Present
- Off-Site Order Entry of Hospital Medication Orders (Bus. & Prof. Code Section 4071.1)
- Prescriber Dispensing
- Implementation of federal HIPAA Requirements
- Prohibition of Pharmacy-Related Sinage
- Implementation of Enforcement Provisions from SB 361
- Implementation of SB 151 (Elimination of the Triplicate)
- Dispensing Non-Dangerous Drugs/Devices Pursuant to a Prescriber's Order for Medi-Cal Reimbursement
- Authorized Activities in a Pharmacy
- Review of Quality Assurance Program
- Limited Distribution and Shortage of Medications
- Conversion of Paper Invoices to Electronic Billing
- Automated Dispensing

The Enforcement Committee agreed to recommend to the Board of Pharmacy that the following objective be added to the enforcement goal: Initiate policy review of 25 emerging enforcement issues by June 30, 2005. And the measure would be: The number of issues

Adjournment

Committee Chair John Jones adjourned the meeting at 12:30 p.m.