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

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
June 23, 3004

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

Present: John Jones, Chair
Stan Goldenberg, Board President and Member
Bill Powers, Public 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
Joshua Room Deputy Attorney General

Call to Order

Enforcement Committee Chair John Jones 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 National Association of Boards of Pharmacy (NABP) held an Importation Enforcement Workshop and Task Force meeting on June 22-23, 2004, to address the issue of importation and the prosecution of entities involved in this activity. Also provided was the NABP's updated report on the most recent action by state boards of pharmacy against storefronts, pharmacies, and other groups and individuals who facilitate or assist in the illegal importation of unapproved prescription medication from Canada. Other documents were: the Interim Findings from the Guiliani Partners LLC report on the examination and assessment of prescription drug importation from foreign sources to the United States and a letter from McKesson Corporation to the Task Force on Importation.

There was general discussion of the legality of this practice and the various legislative proposals that have been introduced at the federal and state level that would allow for the safe importation of prescription drugs from Canada. It was requested that the committee recommend to the Board

of Pharmacy that it write a letter to Governor Schwarzenegger advising him on the legality of such a practice. The committee noted that both the Governor and the Legislature have their own counsel to advise them on legal issues. Also, opponents to the legislation could advise the Governor about federal requirements regarding importation.

Board President Stan Goldenberg committed that the issue of importation of prescription drugs will continue to be an agenda item for this committee and the board. It is 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 and will continue to provide this forum. Finally, both Congress and the California legislature are considering legislation concerning importation and it is proper for the board to wait until the legislative process has concluded.

Disclosure of Citation and Fines to the Public

At its last meeting, the Board of Pharmacy revised its disclosure policy. During the discussion, licensees expressed concern regarding the disclosure of administrative citations. Administrative citations are not considered discipline of a license. However, they do represent the resolution of an investigation or complaint that has been substantiated and is disclosed to the public.

To address the concerns of licensees, the following language has been added to the citations to advise the licensee: "If a hearing is not requested to contest the citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For cases where no fine has been issued the following will be provided:

"No fine has been assessed with this citation and no proof of abatement has been ordered. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If the citation is not contested, the citation shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For disclosure to the public, the following language will be provided:

The issuance of a letter of admonishment and/or a citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The final administrative action including payment of a fine does not constitute an admission of the violation(s) charged and is considered satisfactory resolution of the matter. (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

Request from Rite Aide Corporation to Accept Biometric Fingerprint Recognition Technology as a Substitution to a Pharmacist Signature on the Prescription Label

Rite Aid Corporation requested a waiver of CCR, title 16, sections 1793.3 and 1793.7 to accept Rite Aid's biometric fingerprint recognition technology as a means of complying with the requirement that a pharmacist must sign the prescription label as a means of verifying a prescription that a pharmacy technician has prepared.

Rite Aid plans to fully use a biometric fingerprint authentication system in its approximately 3,400 pharmacies nationwide with implementation in California by November 2004. The purpose of the biometric system is to provide pharmacy associates with secure access and authorization necessary to create, edit and delete prescriptions during the dispensing process. The biometric function includes the ability to register one or more of the user's fingers, and to use the biometric scan of the fingerprint(s) for secure authorization. It was explained that signing in with the biometric scan then permits Rite Aid to identify the pharmacy associate responsible for various phases of the dispensing process. This technology allows for a more secure authorization of a pending prescription order, including an order prepared by a pharmacy technician.

The committee discussed that the use of biometric fingerprint technology is a viable alternative to the pharmacist's signature on the prescription label; however, a legislative change would be required. The requirement to sign the prescription label is found in Business and Professions Code section 4115(f). The board's inspectors were supportive of such a legislative change to use this technology since it appears to be more reliable and legible than an initial on the label often written in haste.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it support a statutory change to Business and Professions Code section 4115(f) that would allow another verification process other than a signature as approved by board regulation.

Since there was significant support for this proposal, it was suggested that the amendment be placed in the board's omnibus bill this year if possible.

Evaluation of Implementation of the Quality Assurance Program

The National Association of Boards of Pharmacy (NABP) Foundation funded a study on medication errors in California. The purpose of the study was to chart the profession's implementation of the Board of Pharmacy's new regulation on quality assurance. The original intent of the study was to prospectively assess, through a board inspector questionnaire, which components of the quality assurance (QA) program were the most difficult for pharmacy to implement, over time. However after the evaluation was implemented, additional limitations were imposed that caused a re-evaluation of the original objectives. The objectives were changed to the following: identify and compile deficiency data and citation/fine data for the new QA regulation, identify the board inspectors' subjective interpretation of pharmacy's compliance with various aspects of

the regulation and identify and compile data on types of medication errors through a review of the board's citation and fine data.

The conclusion of the evaluation found that the Board of Pharmacy and its inspectors have fully embraced the concept of quality assurance in an effort to protect consumers through analysis of medication errors. This was supported subjectively through the interview process and objectively through the number and frequency of correction orders (deficiencies) and citations/fines issued by the board during the review period.

The evaluation also compiled a list of medication errors by type in an effort to further medication error prevention. These error types are similar to those reported by national patient safety programs. It was noted that further analysis will be necessary to determine if the implementation of quality assurance requirements actually impacts medication errors encountered by consumers.

It was suggested to share the information regarding the medication errors from the citation/fine data reports with licensees in the next newsletter.

Retired Status of a Physician License

Medical Board of California advised that starting July 1, 2004, a physician who is in retired status will not longer be eligible to practice medicine. While the physician will be exempt from paying a renewal fee and continuing education requirements, they will no longer be allowed to engage in the practice of medicine. The practice of medicine, of course, includes prescribing.

This information will be provided in the board's next newsletter.

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

Committee Chair John Jones explained that the implementation of this new law will continue to be a standing agenda topic for this committee and the Board of Pharmacy over the next year. The triplicate requirement has been in place for over 60 years and the transitional changes to implement the new law can be confusing. The board has had many questions and has been working diligently with its limited resources to educate prescribers and pharmacists. He added that the educational process will not be an easy feat and acknowledged and thanked those board members and staff who have contributed to this herculean effort.

The Enforcement Committee was provided a list of question and answers that will be placed on the board's Web site after legal review and approval. Clarification was sought on some of the questions and the answers will be revised accordingly.

Update on SB 1307 Regarding Wholesalers

The Board of Pharmacy is sponsoring SB 1307 to strengthen the regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs. The Enforcement Committee recommended to the board that it sponsor this legislation after discussing the issue for at least two years. The language was carefully developed to directly address issues found during its investigations of wholesale violations in California and the recommendation for the changes came from this committee. The bill contains the following major elements:

- Requires the development of a "pedigree" that tracks each drug through the distribution system beginning January 1, 2007, and the board may extend the implementation date for wholesalers to 2008 and pharmacies until 2009.
- Requires all out of state wholesalers shipping drugs into California to become licensed (This provision was placed in AB 2862).
- Increases the board's ability to fine for more serious violations related to wholesaling.
- Requires wholesalers to post a $100,000 bond to secure administrative fines and penalties.
- Restricts wholesale transactions by pharmacies.
- Requires that drugs be purchased only from licensed entities.
- Authorizes the board to embargo drugs when the board suspects or finds drugs that are adulterated or counterfeit.

As the bill has moved through the Legislature, the board through its President has continued to work with all interested parties to resolve issues related to some of the provisions and in those areas where the issues have been resolved, the bill has been amended accordingly.

Report on the Citation and Fine Program

Committee Chair John Jones reported that the citation and fine program has been in place for approximately two years. The first year, a board committee issued the citation and fines and now that function has been delegated to the executive officer. Data from the program was provided. It was noted that staff worked extraordinary hard over the last two months to eliminate a backlog of over 700 citations.

Adjournment

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