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

ENFORCEMENT COMMITTEE MEETING

September 13, 2005
Hilton Burbank Airport & Convention Center
2500 Hollywood Way, Director A & B
Burbank, CA 91505

Present: William Powers, Chair, Board Member
Marian Balay, Board Member
Stan Goldenberg, R.Ph., Board President and Member

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, Liaison Counsel, Deputy Attorney General

Call to Order

Chair William Powers called the meeting to order at 9:45 a.m. He apologized for the late start due to a flight delay. It was announced that committee member David Fong would not be attending the meeting due to other commitments related to Hurricane Katrina.

Importation of Prescription Drugs

Chair Powers reported that the importation of prescription drugs is an ongoing issue that continues to be on the agendas of the Enforcement Committee and Board of Pharmacy meetings.

Articles were provided. It was noted in one article that an organization called Partnership for Prescription Assistance (**www.pparx.com** at 888-477-2669) lets consumers find out in one-step, eligibility information for any of the 275 programs that offer cost savings to consumers.

Proposed Revisions to the Disciplinary Guidelines

Executive Officer Patricia Harris explained that the Board of Pharmacy has adopted via regulation its disciplinary guidelines. The board follows these guidelines in its disciplinary actions. They are used by Administrative Law Judges (ALJs) when issuing proposed decisions and the executive officer in negotiating stipulations. The last major revisions to these guidelines were in 2001. She explained that

draft revisions were provided for the committee's review. The sections of the guidelines that were provided included the Introduction, Factors to be Considered in Determining Penalties, Mitigating Evidence and Standard and Optional Terms and Conditions of Probation. Staff will also revise the remaining sections of the Disciplinary Guidelines – Categories of Violations and Recommended Penalties and Model Disciplinary Orders – that are primarily an update of code sections and consistency with the model orders.

Ms. Harris stated that the revisions are to clarify language, ensure that the terms and conditions are consistent (where appropriate) for all license types, to modify language to ensure consistency with statutory changes and to add new terms of probation. She discussed the significant changes to the standard terms and conditions:

- Reporting to Board: Adds language clarifying that failure to comply with this term constitutes a violation of probation and results in an extension of probation.
- Notice to Employers: Requires that the direct supervisor, owner **and** pharmacist-in-charge (PIC) are required to be provided with notice of respondent's probation; requires that each new PIC be notified of respondent's probation; and clarifies that failure to comply constitutes a violation of probation.
- No Preceptorships, Supervision of Interns: Deletes the term "preceptorship" to reflect the new law change, adds cannot serve as a consultant and that assumption of any unauthorized supervision responsibilities constitutes a violation of probation.
- Reimbursement of Board Costs: Adds option of revocation of license without further notice or opportunity to be heard for failure to pays costs as directed, and clarifies that failure to pay costs will be considered a violation of probation.
- Tolling of Probation: Adds language that further defines the circumstances and when probation is considered tolled, clarified definition of "cessation of practice" and that failure to comply with notification requirements in this provision constitute a violation of probation.
- Violation of Probation: Adds language that clarifies clarify that automatic termination of any stay ordered by the board will take place as directed in specified conditions.
- Reexamination Prior to Resuming Work: Deletes this provision for an exemptee since examination of an exemptee is no longer required.

The significant changes to the optional conditions of probation for pharmacists and interns were discussed. They were:

- Actual Suspension: Moves the language to Model Orders.
- Restricted Practice: Adds the option of not working in a compounding pharmacy during probation. The committee recommended that this restriction be limited to a pharmacy licensed to compound injectable sterile drug products only and the compounding of these drug products.
- Pharmacist Examination: Updates this condition to reflect new statutory examination requirements (Multi-State Jurisprudence Examination), and adds the requirement for additional semester units for failing to pass the exam after four attempts.
- Mental Health Examination: Adds clarifying requirements for submission of name and qualifications of a licensed mental health practitioner for board prior approval, submission of commencement of psychotherapy, changes in treatment and practitioner, frequency of therapy and requirement of evaluation.

- Psychotherapy and Medical Evaluation: Adds provision of ongoing treatment until therapist recommends and board approves that no further treatment is needed, and that respondent must cease practicing at any time the treating therapist finds that the respondent cannot practice safely.
- Pharmacists Recovery Program (PRP): Clarifies automatic suspension for participants not in compliance with program, added requirement of respondent to pay administrative fees as invoiced by the PRP and added the option of requiring the respondent to work in a pharmacy setting with access to controlled substances for a period of six months prior to successful completion of probation.
- Random Drug Screening: Clarifies automatic suspension for confirmed positive tests.
- Abstain from Drugs and Alcohol Use: Adds provision that respondent shall not be in the same physical location as individuals who are using illicit drugs even if respondent is not personally ingesting the drugs.
- Supervised Practice: Adds requirement that respondent cannot practice pharmacy and that respondent's license is automatically suspended until the board approves the supervisor.

Ms. Harris also presented the proposed new terms and conditions of probation to be added to the disciplinary guidelines:

- Coordination and Monitoring of Prescription Use (for chemically dependent pharmacists and interns): This optional term requires the coordination and monitoring of respondent's prescription use for controlled substances and/or dangerous drugs by a physician, nurse practitioner or psychiatrist.
- Pharmacy Self-Assessment Mechanism (PSAM) (for pharmacists and interns): Requires respondent to complete the Pharmacy Self-Assessment Mechanism administered by the National Association of Boards of Pharmacy.
- No Being Designated Representative in Charge (DRIC): As a standard condition of probation, designated representatives (formerly called exemptees) cannot be designated representatives in charge.
- Posted Notice of Probation (premises): Requires all licensed premises on probation to post a notice of probation during the probation.

The committee discussed the proposed revisions. Supervising Inspector Joan Coyne whose team monitors the probationers and PRP participants explained that an increasing challenge to her team is the monitoring of probationers outside a licensed pharmacy. She explained that language was added to the tolling provision to clarify when a pharmacist ceases to practice pharmacy and probation is then tolled; however, it is difficult to determine when a pharmacist ceases to practice if the pharmacist is not practicing in a pharmacy. Probationers may be working in a position that requires licensure as a pharmacist but the position is not in a pharmacy or entity licensed by the board. Examples of these practice sites include insurance companies, Pharmaceutical Benefits Managers (PBMs) and Department Health Services (DHS) MediCal. The board often times has no ability to monitor the respondent in these types of "practice" settings. She stated that a provision is being added to the probation condition for pharmacists who must participate in the PRP to require the pharmacist to practice in a pharmacy and have access to controlled substances for six consecutive months in order to successfully complete the PRP. This provision is important to assure public safety prior to the pharmacist completing probation.

She suggested a similar approach for all licensees on probation. The committee discussed possible options and directed staff to provide these options to the board.

The committee recommended that the board consider the revisions to the disciplinary guidelines and to provide options regarding the monitoring of pharmacists as to whether the pharmacist must practice in a licensed pharmacy during part or all of probation.

Self-Assessment Form for Wholesalers

Executive Officer Patricia Harris reported that Supervising Inspector Judi Nurse prepared a self-assessment form for wholesalers. This form is modeled after the self-assessment form for pharmacies and its primary purpose is to promote compliance through self-examination and education. Supervisor Nurse explained that the Fraud/Drug Diversion Team also has the responsibility for routine compliance inspections of wholesalers and the self-assessment form would be a valuable tool for wholesalers to assure their compliance with pharmacy law. In addition, the form would assist with the routine compliance inspections. It has been her team's experience that when inspections are performed, usually the exemptee-in-charge is not available and the exemptee that is present is not familiar with the operations. This is frustrating in that the inspector has traveled a considerable distance for the inspection. She explained that if the self-assessment form was completed and available, the inspector would still be able to perform a comprehensive review of the operations.

It was suggested that the draft form be shared with the board's stakeholders for review and comment. The committee recommended that the board adopt a regulation to require the self-assessment form for wholesalers. The proposal would require wholesalers complete the form by July 1 of every odd-numbered year, whenever a new wholesaler permit has been issued, or there is a change in the exemptee-in-charge. It was noted that until such time that a regulation was adopted, the form would be available to wholesalers for self-guidance and completion on a voluntary basis.

Review of Citation and Fine Program

Chair William Powers stated that at the June Enforcement Committee meeting, the California Retailers Association (CRA) requested that the review of the board's Citation and Fine Program be placed on the agenda for discussion the next Enforcement Committee meeting.

As requested, the matter was placed on this agenda. Subsequently, CRA requested that the agenda item be deferred until the December 7th meeting. Mr. Powers stated that it would be on the agenda again for the December meeting; however, since the topic was already noticed, opportunity to discuss the program was also be provided. He stated that the committee was provided with an overview of the investigation process, historical data that gave a three-year overview of the citation and fine program since its inception, which included, the number of citations issued, the type of citations issued and the violations, the number of appeals and the result of those appeals.

Legibility of Prescriptions

Ms. Harris reported that at the July Board meeting, Pharmacist Jim Colucci requested that the board consider a future agenda item to require all prescriptions be printed, typed, or computer generated to improve legibility and prevent prescription errors. During the discussion, the board was reminded of previous legislation related that required the Medical Board of California to perform a study on e-prescribing.

The legislation was AB1589 (Chapter 464, Statutes of 2001), which required the Medical Board to consult with the Board of Pharmacy and commission a study to evaluate the electronic transmission of prescriptions by physicians and surgeons and report its results to the Legislature on or before January 1, 2003. The bill specified that the Medical Board's report include recommendations on whether the electronic transmission of prescriptions should be encouraged, methods to encourage physicians and surgeons and other specified persons to use this method to transmit prescriptions, and to identify systems to protect the privacy of patients, including the issuance of a digital certification. AB 1589 did not appropriate funds for the Medical Board to conduct the study.

In 2001, Medical Board staff consulted with Paul Riches, Legislation Coordinator for the Board of Pharmacy, who suggested that the Medical Board review a November 2001, California Health Care Foundation Report titled, E-Prescribing. The Medical Board reviewed the report, adopted it as meeting the requirements of AB 1589, and submitted the report to the Legislature. A copy of the report was provided.

It was also reported to the committee that current legislation, Senate Concurrent Resolution (SCR) 49 (Speier 2005) relating to medication errors, would create a panel to study the causes of medication errors and recommend changes in the health care system that reduces errors associated with the delivery of prescription and over the counter medication to consumers. The resolution would require the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006. It is anticipated that SCR 49 will be passed by the Legislature this session. A copy of the resolution was also provided.

The committee agreed that Pharmacist Colucci's request transcends many health professional boards and the issue of prescription legibility and its impact on patient safety and prevention of prescription errors and the e-prescribing as a solution should be considered by the SCR 49 panel.

Clarification of DEA Requirements

It was reported that on January 18, 2005, the Drug Enforcement Administration (DEA) published in the Federal Register a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of schedule II controlled substances by physicians. Given the comments on August 26, 2005, the DEA reiterated its principles under the Controlled Substances Act and DEA regulations. A summary of the notice was provided:

- DEA stands firm that the act of a physician writing multiple prescriptions for a schedule II drug on the same day with instructions to fill on a future date is the same thing as writing a refill which conflicts with the provision of CSA that provides "No prescription for a controlled substance in schedule II may be refilled."

- DEA clarified that the Interim Policy did not mean that patients who have been receiving prescriptions for schedule II medications for several years for the treatment of severe pain or attention deficit hyperactivity disorder were required to see the physician each month in order to get another prescription. Physicians that properly determine there is a legitimate medical purpose and acting in their usual course of professional practice can determine whether a patient for whom they are prescribing a schedule II must be seen in person each time a prescription is issued or whether seeing the patient less frequently is consistent with sound medical practice and appropriately safeguards against diversion and misuse.

- If a physician decides to issue the schedule II prescription without seeing the patient, the physician can mail the prescription to the patient or to the pharmacy to be filled. Alternatively, the physician can fax a schedule II prescription to the pharmacy but the pharmacy must have the original signed prescription prior to dispensing the drug to the patient.

- The DEA and CSA regulations contain no specific limit on the number of days worth of schedule II controlled substance that a physician may authorize per prescription. However, any state limitations in place would apply.

DEA plans to complete its review of comments submitted last January and plans to issue a new Federal Register document. Ms. Harris explained that the board has taken the lead from Medical Board of California on this issue. In its April 2005*Action Report* publication, Medical Board of California (MBC) caution physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

In its April 2005 newsletter, MBC stated that unless DEA changes its position, physicians must see their patients each time a prescription for a Schedule II drug is written. However, MBC provided clarification in its July newsletter that stated the term "see" has implied to some that patients must be seen "face to face" each time and this was not the board's intent. It is MBC's position that the amount prescribed and period for follow-up is not dictated by the DEA, and is subject to the standard of care. MBC provided the following statement as guidance and clarity to physicians who prescribe Schedule II controlled substances to their patients:

> *When prescribing Schedule II controlled substances to patients, the length of time and quantity of each Schedule II prescription should be based on the needs of each patient and must be within the standards of responsible prescribing.*

New Labeling Requirements – Physical Description of the Dispensed Medications

On January 1, 2006, new information must be added to labels on prescription containers dispensed from outpatient pharmacies. This requirement is the physical description of the dispensed medication, including its color, shape and any identification code that appears on the tablets or capsules. The exceptions to this labeling requirement are:

- Prescriptions dispensed by a veterinarian;
- Dispensed medications for which no physical description exists in any commercially available database;
- New drugs for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file; and
- When a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to section 1250 of the Health and Safety Code (e.g., acute care hospital, skilled nursing facility, and correctional treatment center) and the prescription drug is administered to a patient by a licensed certified nurse-midwife, nurse practitioner, physician assistant or pharmacist who is acting within his or her scope of practice.

This requirement appears in the Business and Professions Code section 4076(a)(11)(A).

Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Wholesalers

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight is the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

The industry anticipates that Radio Frequency Identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

During the last year, the board and enforcement committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape

presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

Ms. Harris reported that board has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. She also stated that through the board's participation with this group and others, a list of questions and answers are being developed that will be shared at the next enforcement committee meeting in December.

Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He stated that Amgen, a billion dollar company that is headquartered in California, is the leading human therapeutics company in the biotechnology industry. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Upon conclusion of his presentation, Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

Adjournment

Chair Powers adjourned the meeting at 12:15 p.m.