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

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
December 15, 2004

Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room, Suite 1030
Sacramento, CA 95814

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

Importation of Prescription Drugs

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

The committee was provided a copy of SB 19 that was introduced by Senator Ortiz on December 6, 2004. The purpose of the bill is to establish the California Rx Program, to be administered by the Department of Health Services. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under this program. The bill also establishes eligibility criteria and application procedures for California residents to participate in the program.

The bill would also require the Department of Consumer Affairs to implement, as part of the California Rx Program, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs. The Web site shall include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for cutting costs on medications, including guidance concerning generic drugs.

In addition, the Web site shall include information about ordering prescription drugs from Canada and other countries. The Web site is to include a list of pharmacies that the Board of Pharmacy has determined meet pharmacy management practices required of pharmacies licensed to operate in California and the United States and a list of medications that can be ordered through the Web site from licensed pharmacies in Canada and other countries.

The department may either provide a direct link for consumers to pharmacies in Canada and other countries or provide a link for consumers to other Web sites if the Board of Pharmacy determines that the pharmacies listed in those other Web sites meet pharmacy management requirements that apply to California licensed pharmacies.

Also the committee was provided with a press release issued by the federal FDA regarding action it took against a company for the importation of prescription drugs into the U.S.

Request from Safeway Inc. for Waiver of California Code of Regulations section 1717(e) to Install and Use an Automated Dispensing Device

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asteres ScriptCenter, at various Long Drug Stores in California.

The board granted to Longs Drug Stores a waiver of the prohibition(s) stated by that section to permit the use of an automated dispensing device that allows a patient to access his/her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

The Board of Pharmacy received a second request for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit. This waiver request is from

Safeway Inc. to use the dispensing units at its various Safeway and /or Vons Pharmacies in California. Ron Bingaman, R.Ph., Corporate Pharmacy Director for Safeway Inc. presented the request for the waiver. He reported that since the October board meeting, Longs has placed a unit in one of its pharmacies. From November 30 to December 14th, Mr. Bingaman stated that 281 patients had signed up to use the system, 33 patients had used the system. Over all 52 prescriptions were dispensed and 10% of the 52 (or 5 prescriptions) were picked-up after hours.

The Enforcement Committee advanced to the Board of Pharmacy the request from Safeway Inc. 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 Safeway, board member David Fong recused himself.

Proposed Regulation Change to Delete California Code of Regulations section 1717(e) and to Add Section 1713 – To authorize the Use of Drop Boxes for Prescriptions and to Authorize the Use of an Automated Dispensing Device for Refill Prescriptions Medications

At its October meeting, the Board of Pharmacy approved two waivers of section 1717(e). The first waiver allowed Longs Drug Stores to use a secure drop box for receiving prescription orders from patients. The second waiver authorized the use of a self-serve, automated dispensing device for patients to pick-up their refilled prescriptions.

Based on this action, the board then approved a proposed regulation change to allow these practices without a waiver. The proposal relocates existing provision 1717(e) into a new section 1713 and provides the authorization for both the drop boxes and self-service automated dispensing device. The proposed language authorizes a patient to deposit a prescription in a secure container that is at the same address or adjoining the licensed premises and the pharmacy is responsible for the security and confidentiality of the prescriptions deposited in the container. The proposed regulation also allows a patient to access his/her filled prescriptions from an automated dispensing device under the following conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

While the board approved the regulation change, it has not been noticed for a regulation hearing. President Goldenberg directed that the proposal be placed on the December Enforcement Committee agenda for additional review and discussion.

President and Committee member Goldenberg encouraged Asteres to work with a neutral third party to formally study the use of the automated dispensing unit and its impact on patients. It was believed that such a study would better support the proposed regulation and to address the concerns that have been expressed that such a dispensing device removes the pharmacist from the refill process and patient access.

Request from Advanced Pharmacy Solutions for Waiver of California Code of Regulations, title 16, section 1717(e) to Allow for the Delivery of Prescription Medications to a Licensed Home Health Agency

Advanced Pharmacy Solutions requested a waiver of section 1717(e) so that they may deliver Synagis to a licensed home health agency for administration at a patient's residence. It was suggested that the board's counsel review the basic interpretation of 1717(e) in that the regulation does allow for the delivery to a licensed home health agency.

Concern was expressed that about the storage of this prescription medication at the home health agency prior to delivery to a patient specifically in some situations where the delivery may be throughout California. It was also asked as to what happens to the medication if it is not administered to the patient.

The Enforcement Committee recommended that the Board of Pharmacy support this waiver request and suggested that Dr. Roache attend the January board meeting to answer any questions that the board may have.

Proposed Amendment to Business and Professions Codes section 4104 – Mandatory Reporting to the Board of Pharmacy of Impaired Licensed Individuals

Supervising Inspector Joan Coyne presented a request to amend B & P Code section 4104 that would mandate all pharmacies to report a licensed individual to the board if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Current statute only requires that a pharmacy have in place procedures to protect the public when a licensed individual is known to be chemically, mentally or physically impaired to the extent it affects his or ability to practice pharmacy. The law does authorize the board to adopt regulation that would establish requirements for reporting to the board the conduct or incidents described in the law. Currently there is no regulation in place that requires a pharmacy to report impaired licensees to the board.

Supervising Inspector Coyne reported that as supervisor of the Pharmacist Recovery Program (PRP)/Probation team, she oversees the investigations on licensees that self-use of drugs and alcohol. Her team monitors probationers and recovery program participants. She reviewed recent cases involving impaired pharmacists.

She stated that her review indicated that a substantial number of incidents of theft and self-use of drugs, improper use of alcohol and obvious mental impairment by practicing pharmacists were never reported to the board. In many instances the discovery was made while the pharmacist was at work filling and dispensing prescriptions for patients. It was only after additional

incidents with subsequent employers or an arrest was the impaired pharmacist or technician brought to the attention of the board.

Dr. Coyne explained that her research revealed that too many times, the pharmacy merely requested the resignation of the individual or terminated him/her from employment. And in some cases, the pharmacy would seek restitution for the stolen drugs in cash or a signed promissory note, followed by termination that allowed the pharmacist or technician to practice elsewhere. Usually the board didn't become aware of an impaired licensee until a serious prescription error was made or, a patient, co-worker or conscientious employer at a new work location reported the impaired licensee. It was also discovered through subsequent board investigations that individuals had lost prior jobs because of chemical, mental or physical impairment affected their practice. She added that her review showed 22 cases where subsequent investigations would probably not have materialized had a prior employing pharmacy been required to report an employee whose practice was affected.

She concluded her presentation by stating that an impaired pharmacist or technician is a threat to the health and safety of the public. Early discovery of an impaired individual will not only protect the public but will also allow intervention and hopefully rehabilitation of that individual.

She recommended Section 4101 be amended to read:

4104. (a) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license. (b) Pharmacies shall report to the board the identity of ~~have in place procedures for taking action to protect the public when~~ a licensed individual employed by or with the pharmacy if the licensed individual is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy within 30 days of admission or termination of employment. ~~(c) The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b).~~

There was discussion as to clarify the requirement that a pharmacy must report the identity of an individual if the licensed individual "is known to have engaged" in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Dr Coyne replied that often times it is the pharmacy that has terminated the licensed individual because there is evidence to support that the licensed individual had engaged in the illegal conduct or the licensed individual has admitted to the acts. As a means to increase the likelihood of reporting by pharmacies of pharmacists suffering from drug or alcohol impairment (or mental or physical illness), or pharmacists engaging in theft/diversion of controlled substances, DAG Room suggested that the board may wish to consider amending Business and Professions Code section 4104 to confer immunity from civil liability arising from such reporting to the board.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed amendments to Business and Professions Code section 4104 incorporating the clarifying changes that were discussed.

Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005

Over the last year, the Board of Pharmacy has been implementing the changes to the prescribing and dispensing requirements for Schedule II controlled substances. The board has been working very hard educating pharmacists and prescribers on the new requirements and has been coordinating efforts with the Bureau of Narcotics Enforcement (BNE), the Medical Board of California, other prescribing boards and the professional associations. Since January 2004 (and before), the board has provided over 30 presentations on SB 151 that have included telephone conference calls that have involved large number of individuals.

Starting January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a board-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

In summary the changes that take effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an "approved" printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2). (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, the board has prepared a series of articles that will appear in the January newsletter and on the board's Web site.

Meanwhile, the Department of Justice (DOJ) is proposing some amendments and additional provisions to make technical changes to effectuate the administration of the CURES program.

The proposed amendments are as follows:

- DOJ would be the originating agency for fingerprint processing (instead of the Board of Pharmacy).

- DOJ would collect a fee for processing criminal background checks.
- The applicant class that that must submit criminal background checks would be clarified.
- The Board of Pharmacy and DOJ would be authorized to make any examination of the books and records of any applicant or visit and inspect the business.
- The Superior Court would be authorized to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action based on the request of the law enforcement agency bringing the criminal action.
- The approved security printers would be required to print security prescriptions forms with a vendor identification code issued by DOJ.
- The security prescription form would be required to have a check box by the name of each prescriber to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

DOJ is requesting that the Board of Pharmacy support these proposed changes. Staff is recommending that the board support them and in addition is proposing additional amendments. It is staff's recommendation that the Board of Pharmacy no longer approve security printers. The board absorbed this workload initially to assist with the transition from the triplicate prescription form to the new tamper-resistant forms printed by "approved" printers. It is no longer necessary that both the Board of Pharmacy and DOJ approve the printer. It should be the sole responsibility of DOJ.

It was noted that the legislation introduced this year would probably address many more clean-up issues with SB 151.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed amendments as proposed by the Department of Justice and the proposed amendment by staff that the Board of Pharmacy no longer approve security printers. The approval process would be the sole responsibility of the Department of Justice.

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 becomes effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs.

The Enforcement Committee will be monitoring the implementation of this legislation. One area of close oversight will be 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 pedigree must contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.

The pedigree must contain all of the following information: (1) the source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source (2) the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers (3) the business name, address, and if appropriate, the state license number, including a California license number if available, each owner of the dangerous drug and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug (4) a certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

It is anticipated that Radio Frequency Identification technology (RFID) will 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.

McKesson reported that EPCglobal, a non-profit organization, has developed broad industry standards for the use of electronic product codes (EPC) in global commerce. An EPC is a simple "license plate" that uniquely identifies objects (items, cases, pallets) in the supply chain. Multiple committees within EPCglobal are currently working to develop standards and fully examine both the feasibility and the ramifications of implementing EPCs to support the use of RFID with pharmaceutical products. EPCs can securely store information about a specific product in a tag that is affixed by the manufacturer. With the development of global standards and the utilization of RFID technology, EPCs will provide for immediate, automatic, and accurate identification of any pharmaceutical item in the supply chain and will enable the industry to track a product's distribution history, which constitutes an e-pedigree. The industry goal is to develop EPC standards by the summer of 2005, with the expectation of meeting the FDA's requirements for recommended time frame for implementation of electronic track and track technology by late 2007.

Meanwhile, the National Association of Boards of Pharmacy (NABP) announced in November that it is exploring the creation of a clearinghouse of pedigree data. To facilitate the collection and maintenance of electronic pedigree information, NABP stated that it would establish a task force of state regulators, manufacturers, wholesalers, pharmacies, government regulators, and information technology experts to explore the feasibility of creating a clearinghouse for relevant information to establish an electronic pedigree. The task force will work with EPCglobal to create the necessary standards for the development of e-pedigree software. It is the intent of NABP to act as an honest broker to facilitate the creation of policies and business rules for the exchange of information among trading partners.

T3Ci, is 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. This presentation was for informational purposes only.

Currently, they are pilot testing their system with various manufacturers. It is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

Cardinal Health requested that the Board of Pharmacy consider an exemption from the registration and licensure process for out-of-state distributors that solely provide intra-company transactions of dangerous drugs and dangerous devices into California. It is their position that such an exemption is warranted because it is practical while retaining the safeguards that the board is trying to achieve. It is their position that this approach is practical because it reduces the unneeded paperwork, which would be required in licensing all out-of-state entities. It is also their position that it is not necessary to license such related out-of-state wholesalers.

They argue that the Board of Pharmacy has jurisdiction over the transaction and affected parties at issue. The in-state wholesaler, which receives the shipment from the related out-of-state wholesaler, is licensed with the board. The board has the ability to bring an enforcement action against the in-state wholesaler for any transgressions, which may result from an inappropriate shipment into California by the related out-of-state wholesaler. This would include any action that the board may take against the in-state entity's corporate parent. Third, all transactions would be traceable and readily accounted for given the relationships of the entities involved.

It was presented that these intra-company transactions for which Cardinal was requesting an exemption would only take place when there was a temporary shortage of a drug and the in-state licensed wholesaler was unable to fill the order. Staff counsel commented that the Board of Pharmacy doesn't have the authority to provide an exemption to the licensure requirement. Such an exemption would require a statutory change. Cardinal stated that it was their position that under the proposed change that takes effective January 1, 2005, an inter-company transfer would not constitute a transaction at wholesale. Counsel advised Cardinal submit their request and legal analysis in writing for board review and consideration.

Pharmacist-in-Charge Certification Program at the College of Pharmacy, Western University of Health Sciences

Jesse Martinez, Executive Director of External Affairs and Development and Sam Shimomura, Associate Dean Professional and Student Affairs at the College of Pharmacy, Western University of Health Sciences presented an overview of a course of study in the skills required to become a pharmacist-in-charge (PIC) in California. It will be a 12-week advanced elective course in their curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a PIC.

In addition, Western plans to develop a 15-hour "certificate" course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a PIC position. They plan to offer the "certificate" program to all interested licensed pharmacists in convenient sites in southern and northern California starting in the second quarter of 2005.

The vision for the PIC "certificate" CE program is a format that includes an experiential component with workshop discussions and lectures presented by experts with "real world" experience. The faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. They also asked for participation from the Board of Pharmacy. They requested that board member or inspector with expertise in community and hospital outpatient pharmacy self-assessment process be a part of the training program. The final format that would include a board representative is open at this time. It was explained that the core content of the PIC certificate program would be in the areas of compliance with the board's self-assessment form.

Executive Officer Patricia Harris commended WesternU College of Pharmacy for the development of a PIC certificate program and expressed interest in the board's willingness to participate in the development of such a program. One concern expressed is the commitment of board resources to actively participate in the training program. Supervising Inspector Robert Ratcliff agreed to work with WesternU College of Pharmacy to determine how best the board could support their efforts.

New Statutory Changes Effective January 1, 2005

The Enforcement Committee was provided with an overview of the new statutory changes that will become effective January 1, 2005. These changes will be in the board's January newsletter. Comments were made clarifying some of the changes.

Meeting Dates for 2005

The Enforcement Committee set its meeting dates for 2005: March 9th – Burbank, June 22nd – Sacramento, September 13th – Burbank and December 7th – Sacramento.

Adjournment

Committee Chair William Powers adjourned the meeting at 12:45 p.m.