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

ENFORCEMENT COMMITTEE MEETING

Summary of Agenda Items Discussed – Not an Official Meeting
March 9, 2005

Present: Stan Goldenberg, R.Ph., Board President and Member

Staff: Patricia Harris, 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

Call to Order

Board President and committee member Stan Goldenberg announced that due to the cancellation of flights to the Burbank airport, Committee Chair Bill Powers was be unable to attend the meeting and due to a previous commitment, committee member Dave Fong would not be in attendance either. Because the Enforcement Committee did not have a quorum, staff counsel advised that an official meeting of the Enforcement Committee could not be held. Therefore, President Goldenberg discussed the agenda items and began the discussion 9:35 a.m.

Importation of Prescription Drugs

President Goldenberg 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 regarding legislation that was introduced in Washington that would allow various opportunities for prescription drug importation, anticipatory regulatory action by the Canadian Health Ministry that would impede Canadian importation to U.S. patients and Oregon's proposal to allow for importation. Also included was a letter from the Department of Health and Human Services to the Attorney General of Rhode Island regarding a recently enacted law in Rhode Island that authorizes the Rhode Island Board of Pharmacy to license Canadian pharmacies.

Concern was expressed that should the Canadian Health Ministry implement the proposed regulatory actions that would curtail the importation of prescriptions drugs from Canada, this

possibly could impact close to 2 million U.S. patients who may have difficulty in obtaining their prescription medications and choose other foreign sources.

Letter from Jeffrey A. Moss, Attorney for the Pharmacy Defense Fund Related to the Waiver of California Code of Regulations, title 16, sec. 1717(e) – Use of an Automated Dispensing Device

The Board of Pharmacy received a letter from Jeffrey Moss, an attorney for the Pharmacy Defense Fund. The letter expressed concerns regarding the board's issuance of a waiver pursuant to 1717(e) and the conditions for which the waiver was granted.

Supervising Inspector Dennis Ming reported that he inspected Longs Drug Store, #247 to determine the operational status of the Scriptcenter automated refill device installed at this location as a pilot program for dispensing certain select refill medications.

During the inspection, Supervisor Ming interviewed the pharmacist-in-charge (PIC) and representatives from Asteres Corporation. None of these individuals were contacted prior to the inspection.

Supervisor Ming confirmed that the Scriptcenter provided only selected refilled medications. During the course of the inspection, he asked the PIC to describe the operations of the Scriptcenter and what processes were in place to prevent dispensing drugs from the Scriptcenter that would require consultation. The PIC stated that to avoid inadvertent placement of "new" medications into the device, only those prescriptions with a prescription numerical suffix ending in .000 are processed into the device. It was explained that the Longs computer system (ADX) will not allow any medication without the correct suffix to be processed into the Scriptcenter. A bar code is produced and attached to the bag containing the medication. This bar code is scanned for identification and only then can the medication be dispensed from the device. The PIC further described that a pharmacist is responsible for conducting the final check of all medications for dispensing from the Scriptcenter to assure compliance that only refill medications are stocked in this system.

The PIC also provided copies of the Asteres Scriptcenter Training Instruction manual, the Scriptcenter Quick Reference Guide, and a copy of the Longs Drugs Scriptcenter In-Store Training manual.

It was Supervisor Ming's observation that the staff appeared to be well trained in the processing of prescriptions into the Scriptcenter, and that there were adequate safeguards in place to identify the correct drugs that could be dispensed from the device.

He explained that the PIC was asked to describe the process used to identify patients whose refilled medications are available in the Scriptcenter. The PIC stated that patients are provided a choice of obtaining their medications through the Scriptcenter or not. An enrollment form is stored on the Scriptcenter that patients can read and complete if they are interested in obtaining their routine refilled medications from the device. Patients are asked to provide a unique security

password and a login identification code for access to their medications from the Scriptcenter. There is a written acknowledgement on the application form that is signed by the patient who authorizes Longs to place their refilled prescriptions into the Scriptcenter and further advises the patient that not all of their prescriptions may be eligible for the service. The patient signs the completed form that is given to the pharmacist and the patient's confidential information is entered into the computer system. The patient keeps the bottom portion of the form, which contains their password and login identification code (which is not provided to the pharmacy). There is also an additional advisement at the bottom of the portion retained by the patient that states, *"Prescriptions that are oversized, unusually shaped, or that require refrigeration or consultation will not be available for pick-up in the Scriptcenter. These items will be available at the pharmacy counter."*

It was reported to Supervisor Ming that since the program's inception on December 2, 2004, Longs has enrolled approximately 600 patients and has dispensed over 1,000 refilled prescriptions from the Scriptcenter. There have been approximately 15 patients who have since dropped from the program. The reasons cited were varied and some were related to the inconvenience of utilizing their ATM or credit card twice in the store for purchases not related to the Scriptcenter. The PIC provided a copy of the in-store patient satisfaction survey questionnaire and a copy of the survey results. A review of the results showed that many of the patients found the Scriptcenter to be a convenience and were satisfied with the service.

Dr. Ming explained that he also conducted separate interviews with customers utilizing the Scriptcenter during the inspection. Statements from these patients were similar to the survey results in claiming convenience for obtaining the medications. One patient stated that a "not-so computer literate person" might have difficulty early on but did not feel it was a major issue. Patients felt that they had ample opportunity to talk to a pharmacist during and after hours if the need arose. There is a sign next to the ScriptCenter, which listed two telephone numbers for 24-hour pharmacies that could be called.

The Scripcenter is located at one end of the pharmacy cashier counter. The front of the device is accessible to the patients. The rear of the device where the drugs are loaded is in the back of the pharmacy cashier counter and directly accessible by the pharmacy staff during operational hours. Immediately behind the Scriptcenter is the will-call or pick-up shelf for medications not suitable for the Scriptcenter or for patient not enrolled in the program. During off hours, a retractable door descends to block off the prescription area; however, the Scriptcenter is then located outside of the secured area during off hours. Access to the rear of the cabinet is only done by pharmacy staff and requires computer access to unlock the cabinet. No keys are used.

The PIC demonstrated the process to access the Scriptcenter to load and unload the device with medication. The PIC stated only the pharmacy staff can access the device and it is computer controlled requiring the pharmacist or pharmacy technician to enter an individual specific log-in identification code and password. According to the PIC and consistent with Dr. Ming's observation, no one outside the pharmacy staff and only the licensed pharmacy staff have access codes into the device. The Scriptcenter is constructed of steel with steel rear doors that are unlocked only by the correct computer access codes. The doors cannot be pulled opened to gain

access. Once opened, the bin boxes containing the medications are accessible. The doors are manually closed and an audible click is heard when the doors are relocked and made secure. The Scriptcenter weighs 1300 pounds unloaded. There are two large bolts visible from the back of the device and under the rear doors, which attach the Scriptcenter to the floor for seismic safety purposes and to prevent intentional removal. There is an additional security feature located at the front of the Scriptcenter, which is a video unit that is activated each time an access code is entered onto the keyboard and creates a video record of the person accessing the device. Also, the keyboard screen on which the patient enters their access code and prescription number can only been seen by the user.

The pharmacy is open Monday thru Friday from 8am to 10pm, Saturday from 9am to 7pm and Sunday from 10am to 6pm. During these hours, the PIC stated that a pharmacist is always available to answer any questions regarding medications obtained from the Scriptcenter. A notification is provided to the patient at the time of enrollment that advises drugs requiring consultation would not be available in the Scriptcenter. The PIC also stated that a new access window is planned immediately adjacent to the Scriptcenter that will be used by patients who have difficulty obtaining their prescriptions or have questions regarding their Scriptcenter refilled medications. In the event that a refill medication requires patient consultation or discussion, a message would appear on the screen notifying the patient to contact the pharmacist in order to obtain their medication(s).

During after hours, there are two 24-hour Longs pharmacies nearby that will answer questions. There is a large information board next to the Scriptcenter that identified the two pharmacies and their telephone numbers. It was explained that Longs was planning to attach a telephone onto the Scriptcenter that will provide direct access to the other pharmacies during off hours. The intent of the Scriptcenter is to provide access to refill medications that patients must take on a chronic basis and are unchanged from refill to refill. Current pharmacy rules and regulations do not require consultation for these types of refilled medication; however pharmacy rules and regulations state that any changes in refill medication directions, strength, dosage etc. are considered "new" medications and require consultation. According to the PIC, none of these drugs are eligible for the Scriptcenter refill dispensing process.

Supervising Inspector Ming confirmed that refill medications and new prescriptions that require consultation are not placed in the Scriptcenter for automated dispensing. These prescriptions are filled and placed in the will-call/pick-up area and consultation is provided at the time the patient or the patient's representative asks for the prescription(s).

Dr. Ming concluded that Longs Drugs #247 is in compliance with the waiver provisions that authorizes its use of the Scriptcenter automated refill-dispensing device. It was his recommendation that the term "close proximity" used in granting the waiver for CCR 1717, be more defined to mean "within the immediate vicinity" of the licensed location. Locating the device within the pharmacy with the front in the public area and the back accessed only from the licensed area, or at the very least located at the pharmacy cashier counter as observed at the Longs pharmacy maintains the professional relationship between the patient and the pharmacist, and allows the staff to answer and resolve problems associated with obtaining the refilled

medications without leaving the pharmacy area unattended. In addition, patients should have the expectation that the device would be located in the pharmacy area and not in some remote location in another part of the business.

Request from the University of California San Diego (UCSD) for Waiver of California Code of Regulations section 1717(e) to Install and Use an Automated Dispensing Device

The Board of Pharmacy has received a request from UCSD for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit at its hospital outpatient pharmacy.

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 Asters ScriptCenter, at various Long Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway Inc. to install and utilize these same units at its Safeway and Vons pharmacies

The board granted the waivers pursuant to 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).

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients. SSPPS plans to provide the information regarding the study to the board at its April meeting.

The waiver request will be presented to the Board of Pharmacy at its April meeting.

Centers for Medicare and Medicaid Services (CMS) Implementation of the Medicare Drug Improvement and Modernization Action (MMA) of 2003 – Proposed Electronic Prescribing Standards

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS) issued proposed regulations regarding electronic prescribing. The regulations propose to adopt standards for an electronic prescription drug program under Title 1 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Of interest to the state boards is the area

in the regulations that addresses the federal preemption of state law. The MMA language that addresses the preemption is Section 1860D-4(e)(5).

In the proposed regulations, CMS has interpreted this section of the Act as preempting state law provisions that conflict with the federal electronic prescription program drug requirements that are adopted under part D. The deadline to submit comments to CMS on the proposed regulations is April 5, 2005.

Board counsel has advised the California law doesn't conflict with the federal electronic prescribing regulations.

The National Association of Boards of Pharmacy (NABP) is also requesting input as to whether or not the state boards will be implementing different requirements for the e-prescribing and transmission of prescriptions for controlled substances. To date, the U.S. Drug Enforcement Agency (DEA) has not released any final requirements on the electronic transmission or e-prescribing of controlled substances. NABP is asking states the following question:

> "Do you think that the security and privacy provisions for the electronic transmission or e-prescribing of non-controlled substances and C-III to C-V controlled substances prescriptions should be equivalent and more stringent requirements in place for C-II controlled substances prescriptions only?"

Health and Safety Code section 11164.5 specifies that a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Business and Professions Code section 4071.1, for Schedules II-V if authorized by federal law and in accordance with regulations promulgated by the DEA.

There was discussion that the DEA is studying the Public Key Infrastructure (PKI) for use for e-prescribing of schedule II drugs; however, the American Medical Association (AMA) is opposed to this system because it has its own system for electronic prescriptions.

Information on the Prescribing Authority for Naturopathic Doctors

On February 28, 2005, the board requested a legal opinion from staff counsel Dana Winterrowd regarding the prescribing authority for naturopathic doctors. An article appeared in the board's January 2005 newsletter regarding the authority of Naturopathic Doctors to prescribe; however, since the article appeared, the board has been working with the Bureau of Naturopathic Medicine to further clarify this authority. Due to the short timeframe for the request, counsel was unable provide the opinion for this meeting but will make an effort for the April Board meeting.

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

Supervising Inspector Robert Ratcliff reported that as of 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 took 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 prepared a series of articles that appeared in the January newsletter and on the board's Web site. Another series of questions has also been prepared that will be added to the board's Web site.

A question that is not on this recent updated series of questions but was asked at a recent SB 151 presentation is regarding prescriptions for Schedule III-V medications that are not on the new security forms. The board's direction to pharmacies is to treat these prescriptions as "oral" prescriptions and for the pharmacist to initial and date under Health and Safety Code 11164(b)(1). The pharmacist should always use his or her professional judgment when filling the prescription, contact the prescriber to verify if necessary and to advise the prescriber that for future written prescriptions, security forms are required.

Supervising Inspector Ratcliff emphasized that the direction board inspectors are giving to pharmacists is to take care of the patient. It is not the board's position that pharmacists be the "forms police." It is the responsibility of the prescriber to have the correct legal forms.

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, 2006 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.

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.

At the April board meeting, Acerity Corporation will present its security software program, which is an electronic authentication process. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications. At the last enforcement committee meeting, there was a presentation by T3Ci. As stated with that presentation, it is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

At the invitation of the National Association of Boards of Pharmacy (NABP), California participated on its task force to develop recommendations for electronic pedigree requirements. The recommendations of the task force will be made public in early March. Again at the invitation of NABP, California has participated in two wholesale distributors regulatory meetings. The purpose of the these meetings is to work with the industry to established the prescription drug pedigree requirements so that the industry can identify its business solutions and technology standards to capture the pedigree data.

Implementation of SB 1159 (Vasconcellos)

Executive Officer Patricia Harris reported on the implementation of SB 1159. She noted that this agenda item was not noticed but is being provided for information purposes. With the recent signing and enactment of Senate Bill 1159 (SB 1159, Vasconcellos), local cities and counties can now legally authorize the establishment of the Disease Prevention Demonstration Project (DPDP), allowing pharmacies to sell syringes without requiring a doctor's prescription. The new legislation stipulates that the California Department of Health Services (DHS) must convene an uncompensated Evaluation Advisory Panel and, in coordination with this panel, design and implement a comprehensive evaluation that will assess the impact that SB 1159 has on HIV and HCV risk behaviors as well as the health and well-being of surrounding communities and stakeholders.

SB 1159 requires that the panel include the following:

- Infectious disease control specialists
- California State Board of Pharmacy representative(s)
- Representative(s) of independent pharmacies
- Representative(s) of chain pharmacies
- Law enforcement representatives
    - Executives, such as police chiefs and sheriffs
    - Rank and file officers
- Specialist(s) in hazardous waste management from DHS
- Waste management industry representative(s)
- Local health officers

SB 1159 requires that DHS evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010.

The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

President Goldenberg and Vice-President Powers will be the Board of Pharmacy representatives.

Adjournment

President Goldenberg ended the discussion at 11:45 a.m.