California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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

LICENSING COMMITTEE
Meeting Summary

DATE: December 1, 2004

TIME: 1:30 p.m. – 3:00 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Legal Counsel

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 1:30 p.m. She explained that committee members John Tilley and Richard Benson were unable to attend the meeting.

Workgroup on Compounding – General Compounding Proposal

Dr. Schell reported that the Workgroup on Compounding was initially formed in part to respond to a request from the Department of Health Services – Food and Drug Branch to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer. The goal was to work with the compounding profession to respond to this request as well as identify and address "gaps" in pharmacy law related to pharmacy compounding. At each workgroup meeting, there have been over 30 participants that have provided valuable input into the process.

Dr. Schell explained that at the September meeting a concept draft to regulate general compounding by pharmacies was presented and discussed. Based on the discussion and the comments that were provided, proposed statutory and regulatory amendments were drafted for

the workgroup's review. The Workgroup on Compounding met on December 1st (prior to the Licensing Committee meeting) for final review and discussion of the proposal. It was noted that the workgroup members would have the opportunity to address any concerns regarding the proposal to this committee and ultimately to the board.

Dr. Schell explained that the proposal that is being recommended for the Licensing Committee's consideration includes a definition of compounding, which currently is not defined in pharmacy law. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications.

Dr. Schell reiterated that at the September workgroup meeting, there was considerable discussion regarding the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s). As stated previously, one of the initial requests from DHS was for the board to identify the criteria it uses to determine when a compounding pharmacy would be considered a manufacturer. While one of the workgroup subcommittees updated the list of factors that the board developed many years ago, board counsel explained that the proposed "factors" for distinguishing compounding from manufacturing would at best be considered "guidelines," and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

Further, counsel advised that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer.

While compounding is included in the definition of manufacturing, a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner).

Therefore, Dr. Schell concluded that based on counsel's advice the Board of Pharmacy's priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. This proposal provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed statutory and regulatory changes relating to general compounding. The statutory changes would be introduced in 2005 and upon successful enactment; the regulation proposal would be pursued.

Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients

Executive Officer Patricia Harris explained that she prepared a background document for the Licensing Committee that gave an overview on the many issues and questions that the Board of Pharmacy has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin discussion on how the board should address these many issues that don't fit the traditional statutory definition of pharmacy practice and the independent practice of pharmacists as health care providers.

The background document provided for five issues. The first issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

In the second example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

At least one central prescription processing facility in California has been licensed as a pharmacy. The reason for licensure as a pharmacy is two-fold. First, the prescriptions are faxed

to the facility for central processing. Because there is a fax copy of the prescription, it has been reasoned that the facility must be licensed as a pharmacy to accept the faxed prescription document. (Cal. Code Regs., tit. 16, section 1717, subd. (e)). It can be argued that Business and Professions Code section 4051, subdivision (b)(2) authorizes the pharmacist to have access to the prescription, patient profile or other relevant medical information. This section doesn't require that this information be electronic only. However, does this central facility have the authority to maintain the faxed copy of the prescription record once it has been processed and the pharmacist has approved it for filling? Does the pharmacist? What happens to the faxed prescription document? What are the record-keeping requirements for each prescription recipient?

The second reason that this facility is licensed as a pharmacy is so that it can employ non-licensed pharmacy personnel to process prescriptions as authorized by California Code of Regulations, title 16, section 1793.7.

However, this central prescription processing facility doesn't dispense prescription drugs, so the question is raised whether this central facility is appropriately licensed as a "pharmacy." California pharmacy law defines a "pharmacy" in part as "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded." (Bus. & Prof. Code, § 4037, subd. (a)). This definition also states that a pharmacy includes, but is not limited to, "any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (*Ibid.*). Possession, storage, and sale of dangerous drugs or devices are therefore a central part, though not an explicitly necessary part, of the definition of a California "pharmacy."

California pharmacy law does not specifically define the scope of practice for the profession of pharmacy. That scope of practice has been defined in other sources. For instance, the National Association of Boards of Pharmacy in its *Model Act* defines the "Practice of Pharmacy" as: the interpretation, evaluation, and implementation of Medical orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews, the Practice of Telepharmacy within and across state lines; Drug or Drug-Related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices and maintenance of proper records for them.

The issue before the Licensing Committee is whether or not the Board of Pharmacy should license a "central prescription processing facility" located in California that does not dispense prescription drugs or devices as a "pharmacy."

The third scenario is related to a prescription that originates in California. It is sent

electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

Questions that need to be considered are: Does an out-of-state central prescription processing facility have the authority to process prescriptions for California patients? Is this authority increased if the review process is performed or overseen by a pharmacist licensed in California? Does a non-California licensed pharmacist have the authority to perform drug utilization review and/or other pharmacist's services for California patients? Also, what authority or ability does the Board of Pharmacy have to protect the public if the out-of-state pharmacist is unprofessional in providing pharmacist's care to California patients? What would be the record-keeping requirements for each prescription recipient?

Under current law, a California licensed nonresident pharmacy may perform all these services for California patients without requiring California licensure for the pharmacist.

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

While the regional call center is licensed as a pharmacy in its domestic state, it doesn't appear to meet the definition of a California nonresident pharmacy (e.g., it does not ship, mail or deliver drugs into California). Based on the information provided, it is a California licensed pharmacist who makes the determination whether or not a therapeutic interchange is appropriate for the California patient and if so, then the California prescriber is contacted to approve the change. Can a pharmacy not licensed in California, such as this regional call center (e.g., licensed in Texas) maintain and make use of a pharmacy database for California patients?

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

The last situation that was discussed is a new provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments, medication "brown bag" reviews, formulating/monitoring/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, NABP was not clear on how states will view the provision of MTMP's across state lines. Similar to the situations presented above, California needs to decide how it wishes to address pharmacists not licensed in California providing MTM to California patients.

Another possible issue is whether California should alter, expand or refine its scope of practice and/or provisions dealing with collaborative practice/medication management to respond to the MMA and the existence of the MTM reimbursement protocols. As noted above, for example, the definition of "pharmacy" in the NABP *Model Act* addresses the propriety of collaborative practice and provision of drug management services explicitly.

There was considerable discussion by the Licensing Committee about the changes to pharmacy practice and how these many changes don't fit the traditional definition of pharmacy. The committee agreed to address these issues through its committee meetings in 2005.

Status on the Licensing of Pharmacists in California

The Assistant Executive Officer Virginia Herold reported that the Board of Pharmacy transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. She reported that as of November 19, 2004, the board has received over 2,500 applications to take the California license examinations, and since June 2004, over 1,200 applicants have been licensed as pharmacists. She also noted that the pass rate for the California Pharmacy Jurisprudence Examination (CPJE) is 85%.

Ms. Herold stated that the job analysis survey for the CPJE was mailed 3,000 pharmacists. The job analysis is done every 5 years and its purpose is to develop the content outlines of the CPJE. Pharmacists who complete the survey will be awarded continuing education credit for their participation.

Implementation of AB 2682 (Chapter 887, Statutes of 2004) Regarding the Licensure of Wholesalers and Nonresident Wholesalers

Ms. Harris reported that Assembly Bill 2682, signed by Governor Schwarzenegger on September 29, 2004, makes changes to several Business and Professions Code sections specific to the licensing requirements for wholesalers located outside of California who ship, mail or delivers dangerous drugs or devices into California. Because of the significant changes, the requirements will be phased in over the next two years. The following is a brief description of these changes.

- B & P 4043 – Changes that the name of a wholesaler shipping drugs into California from an out-of-state distributor to a nonresident wholesaler. This change is effective January 1, 2006.
- B & P 4161 – Requires any out-of-state distributor who ships, mails, or delivers dangerous drugs or devices into California to be licensed with the board. Previously any business that that shipped into California to another California licensed wholesaler was exempt from obtaining a California license. This changed is effective January 1, 2005. Effective January 1, 2006, B & P 4161 is again amended to change the name from out-of-state distributor to nonresident wholesaler and to change the title of "exemptee-in-charge" to "designated representative-in-charge."
- B & P 4162.5 – Requires an applicant for licensure or renewal to submit a surety bond of $100,000 for each nonresident wholesaler site licensed or to be licensed. The board may accept a surety of bond of $25,000 if the annual gross receipts of the previous tax year, as a nonresident wholesale is $10,000,000 or less. This section takes effect January 1, 2006.

To facilitate the implementation of these changes, board staff, along with DAG Joshua Room, has reviewed and revised the application forms, requirements and processes for both the wholesaler and nonresident wholesalers. It is anticipated that the new forms will be available on the board's website by mid-December.

Committee Meeting Dates for 2005

The Licensing Committee set its meeting dates and locations for 2005: March 16th – Oakland, June 15th – Burbank, September 21st – Oakland and December 14th – Burbank.

Adjournment

Licensing Committee Chair Ruth Conroy adjourned the meeting at 3:00 p.m.