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: September 21, 2005

TIME: 9:30 p.m. – 3:00 p.m.

LOCATION: Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
John Jones, RPh, JD

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector

Jan Perez, Legislative Coordinator
Joshua Room, Deputy Attorney General

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Request from University Compounding Pharmacy to Require Licensure of all Pharmacists that Compound

Pharmacist Joe Grasela representing University Compounding Pharmacy requested that the Licensing Committee consider a requirement that all compounding pharmacies have a special compounding license. He stated that the sterile compounding license has been in place for two years and it has raised the quality of compounded products available to the public. He is suggesting that a special license be required for pharmacies whether they compound injectable sterile products or non-sterile products.

Mr. Grasela explained that this special compounding license for pharmacies is necessary to protect the public. He stated that capsules can do as much harm as injectables. Creams

improperly used containing lidocaine can cause cardiac arrest. Oral inhalations, solutions and eye drops can be contaminated. Many other non-compounded non-sterile products can cause harm as an improperly made sterile product.

He also felt that by requiring this special compounding pharmacy license, California would be leading the way and demonstrating to the federal Food and Drug Administration (FDA) that California is regulating compounding pharmacies contrary to FDA's contention that Boards of Pharmacy are not doing enough in this area.

Pharmacist Grasela also stated that by having a special compounding pharmacy license, the board would be creating a new specialty of pharmacy. This new compounding specialty will be similar to nuclear pharmacy, home health care pharmacy, and hospital pharmacy and will provide credibility to the public and provide access to products that cannot be made by manufacturers.

The committee expressed concern regarding the compounding of inhalation and ophthalmic drug products. It was noted that both the original legislation and regulation proposals regarding sterile compounding included inhalation and ophthalmic drug products; however, because of the opposition, the legislation and regulations were limited only to compounded sterile injectable drug products.

It was explained that last year, the board's Workgroup on Compounding drafted legislation and regulations to govern compounding, which the board approved. While the bill, AB 595, was stalled this year due to opposition from the Department of Health Services (DHS), the board will eventually move forward with the regulations. The committee noted that the regulations are comprehensive and provide regulatory oversight for all compounded drug products, which includes training requirements of all pharmacy personnel who compound and a quality assurance component that guarantees that the compounded drug product meets the specified criteria of strength and quality. It was noted that the workgroup did not discuss whether a special license for all pharmacies that compounded was necessary to protect the public; however, it was the board's position that the legislative and regulatory proposals were important consumer measures and will continue to pursue them actively.

It was the committee's recommendation not to support the request that the board require a special license for all pharmacies that compound drug products and advised Mr. Grasela that the professional association may want to sponsor such legislation, at which time the board would take a position. Any proposal to require a special license would have a fiscal impact on the board and licensees. Pharmacies would have to pay an additional license fee of $500, and the board would be required to add more staff, if the same opening and annual inspection requirements were continued.

Temporary Pharmacy Permit for Pharmacies that Compound Injectable Sterile Drug Products

Chair Ruth Conroy explained that a pharmacy that compounds injectable sterile drug products is required to have a specialized pharmacy permit in addition to being licensed as a pharmacy. Under current law, when a pharmacy changes ownership, the board has the authority to issue a temporary pharmacy permit during the transition from the previous owner to the new owner. However, this same provision was not included for the injectable sterile compounding pharmacies. This has caused some difficulties for pharmacies that can obtain a temporary pharmacy permit for their general pharmacy practice, but cannot obtain temporary permit for the compounding of sterile injectable sterile products. Thus, the pharmacy must cease this service until the change of ownership is completed.

The committee recommended that the board sponsor an omnibus provision next year to allow for the issuance of a temporary pharmacy permit when a change of ownership occurs for pharmacies that compound injectable sterile drug products.

Request for Board Recognition of the School of Pharmacy at Touro University

Chair Conroy stated that Touro University College of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications for its 64 students in the Class of 2009.

Current regulation, 16 CCR § 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE). Touro University currently has pre-candidate statues.

The committee recommended that the board recognize Touro University College of Pharmacy.

Pharmacist Self-Assessment Mechanism (PSAM)

At the last Licensing Committee meeting, the committee discussed the announcement by the National Association of Boards of Pharmacy (NABP) regarding the development of the PSAM. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on NABP's web site.

The PSAM is applicable to general pharmacy practitioners in all practice settings. It consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one setting, or complete one section at a time, but once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists complete the first section. The fee for PSAM is $75.

During the meeting in June, the committee learned that the Idaho State Board of Pharmacy would grant 4 hours of Board-approved CE to pharmacists for completing the PSAM. More recently, Tennessee will grant 3 hours of CE. NABP did pursue accreditation of the PSAM by the Accreditation Council for Pharmacy Education (ACPE), but the accreditation was denied. It was also suggested by the California Pharmacists Association (CPhA) that the Pharmacy

Foundation of California approve the PSAM as another CE option for California pharmacists. However, it not clear whether or not CPhA had pursued this suggestion.

The committee recommended that a pharmacist that completes the PSAM be granted 6 hours of continuing education.

Request for Comments on the Definition of Pharmacist's Scope of Practice Consistent with Pharmacy Law for Disaster Response Teams

Assistant Executive Officer Virginia Herold stated that since 2005, a group of individuals from various state and local agencies and some private associations have been meeting to design an advance registration system to prescreen and identify medical providers for quick deployment in response to disasters and bioterrorism events.

The group has been meeting under the authority of the state Emergency Medical Services Authority under a Health Resources and Service Administration Hospital Bioterrorism grant. This project is the "Emergency System for Advanced Registration of Volunteer Health Professionals" (ESAR-VHP). She stated that she has been participating as the board's representative.

One item that has been requested is the scope of practice for pharmacists in emergency situations. She and Supervising Inspector Robert Ratcliff have developed a preliminary scope of practice that they seek comment and input.

The final version will state in layperson's terms the duties pharmacists can perform under emergency conditions. For example, a draft version of the emergency scope of practice for dentists envisions the ability to suture outside the mouth or set bones in faces.

The committee was provided a draft and suggested revisions were provided.

Request from the Accreditation Council for Pharmacy Education (ACPE) for Comments by November 1, 2005 on the Draft PharmD Standards and Guidelines

The Licensing Committee was provided a copy of the revised ACPE standards and guidelines. ACPE is requesting comments by November 1, 2005.

Development of Proposal to Update the Definition and Requirements for Pharmacy, Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists

Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The committee agreed to address these issues through its quarterly meetings. However, the committee was encouraged to develop a concrete proposal sooner rather than later in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act, which are expected to take effect in 2006.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March and June 2005 meetings.

Based on discussions and feedback at the March and June 2005 meetings, liaison counsel with the Attorney General's Office, DAG Joshua Room drafted statutory changes to frame the previous discussions in terms of the various policy choices presented. As always, the primary concern for the board is protection of the California public.

As the committee has defined and discussed them, there are three primary areas in which further specification and possible statutory change has been debated: (1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise; (2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a PIC licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance; (3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board?

The committee was provided with possible responses that were not intended to be comprehensive.

1. Definition of "Pharmacy"

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. It also provided for "nonresident pharmacies" that could be any of these three types. The draft assumed that the three (four) types would not be mutually exclusive, i.e., a given facility could overlap. Various statutory options were provided that accomplished the same goal.

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and this proposal doesn't. The public is adequately protected by the pharmacist licensure.

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law doesn't allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon. None of these alternatives would require statutory revisions.

2. Out-of-State Pharmacists (and Pharmacies)

A second primary topic for discussion has been whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussion(s) of this issue, there has been acknowledgment of a need to balance

the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. Now, however, there apparently has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Secondary and tertiary considerations arise from this discussion as well, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the March and June 2005 meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The March 2005 draft statutory chose a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed at the March and June 2005 meetings that this requirement of licensure would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

As was discussed at the June 2005 Committee meeting, NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two were presented as possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services.

The third and final primary topic for discussion has been whether and/or how to amend or expand statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

The statutory proposals pertaining to this subject area made along with the others for the March 2005 Licensing Committee meeting have not generated comment on specifics of the proposed language so much as they have inspired discussion about whether (and how) it is a good idea to expand and/or specify the practice definitions in this way. Therefore, the committee was provided with a verbatim reiteration of those statutory amendments pertaining to this subject that were presented in March 2005. Except as already specified above, at least some of these (particularly revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial. Others have not yet been fully debated.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

The committee discussed this final section and there was support for these changes and updates to pharmacy law. It was suggested that this section be separated from the first two sections of the proposal and be pursued legislatively.

The committee agreed to continue discussion of the proposal at the December Licensing Committee meeting. The committee will report to the board at the October meeting the progress of its discussions.

Adjournment

Licensing Committee Chair Ruth Conroy thanked everyone for participating and adjourned the meeting at 3:00 p.m.