



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE

Meeting Summary

DATE: December 14, 2005

TIME: 9:30 a.m. – 12 noon

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

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.

Competency Committee Report

Assistant Executive Officer Virginia Herold provided the statistics for the California Pharmacy Jurisprudence Examination (CPJE) from April 1, 2005 to September 30, 2005. The overall pass rate was 77.5%. She noted that the data from this time frame captures the recent 2005 graduates from the California schools of pharmacy. The NAPLEX scores associated with any candidate who took the CPJE during this six-month period as reported to the board are also displayed, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period as noted). The board reports the CPJE performance data at six-month intervals and the schools of pharmacy are provided copies of this report. The report is also posted on the board's web site.

Ms. Herold also reported that at the October meeting, the Board of Pharmacy approved the new content outline for the CPJE, which will be used beginning April 2006. All questions for the CPJE are developed according to this outline. The new content outline has been released publicly and is on the board's web site. It will also be published in the January 2006 board newsletter. The board's CPJE content outline does not include tasks tested by NAPLEX; these tasks were removed via analysis of the NAPLEX content outline.

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

Committee Chair Ruth Conroy reported that 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. The board encouraged the Committee to develop a concrete proposal 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.

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, June and September 2005 meetings.

The Committee defined and discussed three primary areas in which clarification and possible statutory change was substantially 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 pharmacist-in-charge (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.

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., drug utilization review (DUR), medication therapy management (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. The draft assumed that the three types would not be mutually exclusive, i.e., a given facility could overlap.

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 the proposal did not. It was argued that the public is adequately protected by licensure of the pharmacist and additional licensure as a pharmacy was not necessary. The recommendation provides pharmacists with an option to be licensed as an “advice/clinical care pharmacy.”

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 does not 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.

The Licensing Committee recommended that the Board of Pharmacy update the definition of pharmacy to include prescription processing and review, patient consultation, drug utilization review, medication therapy management, and or other cognitive pharmacy services for patients in this state. Moreover, a pharmacy would not be required to store and dispense dangerous drugs. It would be an option for pharmacists practicing pharmacy independently to be licensed as a “pharmacy.” The Committee determined that this was the best approach because it was consistent with other states and would not impede the independent practice of pharmacists in California.

The Committee then discussed 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 discussions of this issue, there was 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. However, the definition of a nonresident pharmacy needs to be updated to include all pharmacy services not just the distribution of prescription drugs. The definition would be updated consistent with the definition for California pharmacies.

While it appears that there 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. Because of this, other considerations arose from the Committee’s discussion, 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 committee meetings seemed to acknowledge a possibility of choosing between (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 Committee considered a draft statutory proposal that provided 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 that the statutory proposal 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.

The NABP model rules 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. Telepharmacy is defined as the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

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 Licensing Committee recommended that the Board of Pharmacy update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. The committee also recommended that B&P § 4303 be amended to

strengthen the board's authority to discipline a nonresident pharmacy and not rely on the state where the pharmacy is located to take action first.

The Committee did not recommend that the pharmacist-in-charge of the nonresident pharmacy be licensed in California nor require a pharmacist whether practicing as an employee of a nonresident pharmacy or practicing independently and providing cognitive pharmacy services to California patients be licensed in California. The Committee concluded that there has not been a compelling argument or public need to change the current licensing structure. The Committee stated that if an out state pharmacist harms a California patient, then the board would rely on that state to take action. Currently the Board has such authority to take action against a California pharmacist should he or she harm a patient in another state. The committee did recommend that board amend B & P § 4301(j) and (o) to clarify the law to include violations of other state laws and regulations as unprofessional conduct.

The Licensing Committee discussed proposed amendments to update the 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.

Many of the 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 licensed professional pharmacists can practice both within and outside the four walls of a traditional pharmacy.

In addition, the Committee discussed additional revisions to B&P 4052, which essentially reduces the size of section 4052 and relocates subparts to sections 4052.1-4052.3. These changes should be non-controversial.

The Committee recommended to the board that it amend the law to update the definition of pharmacist practice to reflect existing practice and the professional development of pharmacists, amend the law to reflect the recordkeeping requirements for pharmacists that practice outside a pharmacy and to pursue the suggested changes to section 4052, which are technical in that subparts are being relocated to other sections of law, and amend B & P 4306.5 regarding the unprofessional conduct of pharmacists.

2006 Meeting Dates

The Licensing Committee selected the following meeting dates for 2006: March 22 (Oakland), June 15 (Burbank), September 20 (Oakland), and December 6 (Burbank).

Adjournment

Licensing Committee Chair Ruth Conroy thanked everyone for participating and adjourned the meeting at 12 noon.