



LICENSING COMMITTEE
Meeting Summary

DATE: June 15, 2005

TIME: 9:30 a.m. – 3:00 p.m.

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

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
Richard Benson, Public Member

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

Proposed Statutory Changes to the Licensure and Regulation of Clinics

Licensing Unit Manager Anne Sodergren reported that at the last Licensing Committee meeting, the committee was provided with proposed changes to the licensing requirements for clinics. Because of comments that were received, the proposal was tabled for further discussion with the interested parties. Based on these discussions, the proposal was revised accordingly.

Ms. Sodergren explained that a board-licensed clinic is authorized to purchase dangerous drugs at wholesale and owns the dangerous drugs. This means that the authorized prescribers of the clinic can dispense from one central stock. Otherwise, each prescriber

must dispense from his/her own stock of dangerous drugs and these drug stocks cannot be commingled.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The committee was provided with proposed changes to statute that would streamline the application process, better define who is accountable for the license and make license and regulatory requirements consistent between the two types of clinic licenses. Other than some minor clarification of the language, no other comments have been received.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed statutory changes to the clinic requirements. The statutory changes would be introduced in 2006 as omnibus provisions.

Pharmacist Self-Assessment Mechanism (PSAM)

The National Association of Boards of Pharmacy (NABP) announced in May 2005 the availability 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 at www.nabp.net.

The PSAM, which is applicable to general pharmacy practitioners in all practice settings, 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 3 hours per section is allowed. Pharmacists may take all three sections in one sitting, 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 beginning the first section. The fee for the PSAM is \$75.

The PSAM does not report scores to any person or group other than the testing pharmacist. Once the pharmacist has completed the mechanism, he or she will receive a confidential achievement report indicating the percentage of questions answered correctly in each of the five content areas as well as the overall percentage of questions answered correctly. The achievement report is separate from the record of completion and has no identifiers of the test taker.

It was noted that the Idaho State Board of Pharmacy will award pharmacists 4 hours of continuing education to complete the assessment. The Licensing Committee directed that staff determine if other states also award continuing education for the PSAM or any other pharmacist self-assessment mechanism for professional development and to report back to the committee with its findings. Also, it was suggested that the California Pharmacy Education Foundation or perhaps ACPE may accredit self-assessment mechanisms as another option for pharmacists to obtain continuing education credit.

Accreditation Council for Pharmacy Education (ACPE) No Longer Recognizes Drug and Device Manufacturers as ACPE Accredited CE Providers

The Licensing Committee was provided with an announcement from ACPE that it will no longer recognize drug and device manufacturers as ACPE accredited continuing education providers. This will become effective July 1, 2005.

Infusion Services/Suites

The Licensing Committee was provided a copy of a letter that was jointly issued by the Department of Health Services (DHS) and Board of Pharmacy in 1997. The letter addresses whether or not a pharmacist who operates an infusion service or suite where patients receive intravenous drug therapy is exempt from licensure as a primary care clinic. Health and Safety Code section 1206(a) exempts from clinic licensure any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the scope of their license.

It was determined that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. However, the pharmacist must comply with the protocol requirements set forth in Business and Professions Code section 4052. Since 1997, when the letter was first issued, Business and Professions Code section 4052 was changed.

DHS has requested that the Board of Pharmacy review this 1997 letter to determine if the board's interpretation is still the same and whether or not the letter should be updated. Since the letter was first issued in 1997, Business and Professions Code section 4052 has been changed, but these changes have not substantively altered the analysis. Consistent with the board's previous interpretation, under current law a pharmacist would be authorized to provide infusion services to a patient of any physician with whom the pharmacist has established a protocol.

Ms. Harris stated that she would advise DHS that the board's interpretation on this issue has not changed and will update the law provisions referenced in the letter.

Competency Committee Report

Pharmacist Licensure Examination

Assistant Executive Officer Virginia Herold reported that the board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since this time, the board has received 3,580 applications to take the California license exams; 1,605 individuals have become licensed as pharmacists since mid-June and 2,692 individuals have been made eligible to take the licensure examinations; 2,028 individuals have been verified to the NABP as qualified to take the NAPLEX for California (includes score transfers); 2,268 CPJE examinations have been administered and 488 have failed the CPJE examinations. Also, 96 regrades of the CPJE have been performed (resulting in no change in score). The CPJE's current pass rate is 81.5 percent.

Restructure of the Competency Committee

Ms. Herold reported that President Goldenberg has appointed 8 new members to the Competency Committee. She anticipates that with these new appointments, the board will be able to move forward in restructuring the committee as approved by the Board of Pharmacy last year. It will be a two-tier structure – a core committee and a group of item writers. The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination. She added that the board is continuing its efforts to recruit pharmacists to participate as members of the committee.

Job Analysis

Ms. Herold explained that the board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline. The board completed its last job analysis in 1999/00.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses will be tallied by the board's examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

Administration of the CPJE – New Vendor Contract

Ms. Herold reported that the board's CPJE is administered through Experior Assessments, LLC, at test centers statewide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because each agency is not required to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years.

At this time, the tentative RFP release date is July 5th. Review of the responses to the RFP by the evaluation team will be completed by September 20th. The new contract should be awarded by October 7th, leaving four months to implement a transition to the new contract before the end of the current contract (which can be automatically extended to February 2006).

Delays in this process could impact the ability of applicants to take the CPJE after February 2006. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems.

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

For the December 2004 Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacists' care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin a discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and which are part of the growing and developing independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner rather than later in anticipation of the provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act that are expected to take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists (or other health care providers) to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

For the March 2005 Licensing Committee meeting, board counsel and staff drafted a proposal, including draft statutory changes, as a vehicle through which the committee could begin addressing the many issues. It was explained that the proposal is merely a means by which to begin the discussion. To spur discussion, the concepts were written as proposed statutory changes, but these were not presented as finished recommendations. As drafted, the proposed statutory changes update the definition of a pharmacist, and the definition of a pharmacy (to include an "intake/dispensing pharmacy," a "prescription processing pharmacy," an "advice/clinical care pharmacy" and a "nonresident pharmacy") and also refine and expand the acknowledgment that pharmacy is an evolving profession that now includes more sophisticated and comprehensive patient care activities.

The proposal also updates pharmacy law to more accurately reflect current pharmacy practice and the current functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that

a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Statutory changes are also proposed to the pharmacist scope of practice sections (Bus. & Prof. Code, § 4052), which are technical clean up to make the statutes easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no substantive change to the scope of practice for pharmacists, the protocol requirements, or the emergency contraception drug therapy requirements.

Other proposed statutory changes update the definition of a nonresident pharmacy to include entities performing prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. The proposal would require that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. The proposal would further require that only a California licensed pharmacist be able to perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

In addition, to the proposal would require a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also documentation of inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management. The board is also given authority to investigate matters related to the performance or provision of cognitive services. It is proposed that the definition of unprofessional conduct for a pharmacist be amended to include those acts or omissions that involve the failure to exercise or implement a pharmacist's best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services, and also those acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct would further be amended to include acts or omissions that involve the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

The committee and members of the industry and the public in attendance at the meeting discussed the proposal at length. There appear to be three primary areas of philosophical debate regarding the proposal, and/or regarding the question of whether and how to regulate entities and/or pharmacists performing pharmacy services other than drug dispensing, whether inside or outside of California. During this discussion, counsel repeatedly advised that pursuant to Business and Professions Code section 4001.1 the Board of Pharmacy's primary duty is public protection, and opined that it seemed there was little if any disagreement that the surest way to assure public protection was through licensure and control, over both in-state and out-of-state entities or individuals providing services to patients in California. The Board would need to be persuaded that the public could still be adequately protected.

1. Definition of a “pharmacy”

The proposal updates the definition of pharmacy to include a “dispensing pharmacy” that stores and dispenses dangerous drugs, a “prescription processing pharmacy” that physically processes the prescription document but doesn’t dispense dangerous drugs and an “advice/clinical center pharmacy” that provides cognitive pharmacy services such as clinical advice or information, telephonic or in-person consultation, drug utilization review, and medication therapy management but doesn’t dispense dangerous drugs.

It was expressed by some at the meeting that the definition of “pharmacy” should refer only to those entities that store and dispense dangerous drugs. These participants asserted that an entity providing related “pharmacy” services such as prescription processing and advice/clinical care should not be licensed as a “pharmacy.” Others argued that the entities providing these services should not be licensed at all, but if they were should be called something other than a “pharmacy.” It was also discussed that the advice/clinical care “service center” should not be required to be part of a licensed entity. Pharmacists should be allowed to perform such services as part of their California (or other state) pharmacist license.

In reviewing the laws from other states, it was observed that most states do include the related “pharmacy” services in the definition and licensure of a “pharmacy.”

It was explained that currently the board does license those entities that are only processing prescriptions as “pharmacies” and the primary reason for this is so that the pharmacy can use a pharmacy technician and/or clerk to enter the prescription into a pharmacy computer system. It was argued that licensure as a pharmacy isn’t necessary in order to use a pharmacy technician because Business and Professions Code section 4071.1 authorizes this practice, but there is not complete agreement since this section only authorizes a “pharmacy technician” to process a prescription as the agent of the prescriber.

It was also suggested that the definition of a pharmacy should be clarified to expressly exclude a physician’s office or clinic. In addition, clarification should be sought that allows a pharmacist to perform services for a physician as part of the physician’s practice, without requiring that the physician’s office be licensed as a “pharmacy.”

2. Nonresident Pharmacy

The proposal updates the definition of nonresident pharmacy to include not only those out-of-state pharmacies that dispense prescription medications to California patients, but also those that perform drug utilization review, patient consultation, medication therapy management and/or other cognitive services for California patients (or providers).

Many of these types of nonresident pharmacies are currently licensed with the board. Often times, the “call center” of a mail order pharmacy is located in one state, while the dispensing pharmacy is located in another. It was suggested that we not license the individual site but the organization that is providing the service. It was also noted that the Call Center may be required

to be registered with the Telephone Medical Advice Services Bureau as required by Business and Professions Code section 4999 et seq.

Though there was much spirited discussion on this point, as to whether non-dispensing cognitive service “sites” need to be licensed, or licensed as nonresident pharmacies, there did appear to be a rough consensus that some form of registration or licensure of these sites is appropriate.

3. California Licensure of Out-of-State Pharmacist

As part of the discussion regarding the “out-of-state call centers,” it was noted that the pharmacists providing the drug utilization review, consultation and medication management therapy (and even those pharmacists that dispense medications) to California patients are not presently required to be licensed as California pharmacists. The proposal would require that the pharmacist providing these services be a licensed California pharmacist.

There was concern that this licensure would be burdensome to the nonresident pharmacy and out-of-state pharmacists. Various other options were discussed such as a “registration program” for the nonresident pharmacist, some type of national certification by the National Association of Boards of Pharmacy (NABP), reciprocity, 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 (see below).

The NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to patients as a “licensed pharmacist,” notify patients of the jurisdiction in which he or she is currently licensed to practice pharmacy, and register (with the respective state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction’s Board of Pharmacy address and/or telephone number.

It was explained that the current “nonresident pharmacy” model has been in place for close to 20 years and that out-of-state pharmacists are not currently required to be licensed in California if practicing within the framework of a California nonresident pharmacy. The board needs to decide if the current model is acceptable, while acknowledging that should a California patient be harmed, under the current system the board’s jurisdiction is solely over the licensed entity, and the board must rely on the state where the pharmacist is licensed to take appropriate action against the individual license (on referral).

Consistent with the requirement that pharmacists providing pharmacist care to California patients be licensed California pharmacists, the proposal would also require that the pharmacist-in-charge of a nonresident pharmacy be licensed in California. As specified above, requiring California licensure for out-of-state pharmacists-in-charge and requiring that all pharmacists providing services to California patients be affiliated with an entity with such a PIC was discussed as a possible compromise to licensing all such out-of-state pharmacists.

Committee Chair Conroy thanked the participants and encouraged them to submit any suggested proposals on the policy issues and proposals discussed in writing for consideration at the next meeting in September. She added that it is important that barriers are not erected that would impact good pharmacist care for California patients, while balancing and understanding the board's fundamental role of public protection.

Adjournment

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