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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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Licensing Committee Report

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Report of March 16, 2005

NO ACTION

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

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

The committee agreed to address the various issues through its quarterly meetings and was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists 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.

Based on the discussions at the last meeting, staff drafted a proposal from which the committee could begin addressing the many issues. **(Attachment A)** It was explained the proposal is a means by which to begin the discussions. For better understanding, the concepts were written as statutory changes. The proposal:

- Updates the definition of a pharmacist.

- Revises the definition of a pharmacy to include an “intake/dispensing pharmacy,” a “prescription processing pharmacy,” an “advice/clinical care pharmacy” and “nonresident pharmacy.”
- Acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.
- Updates pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist.
- Requires that a pharmacist who performs cognitive services for California patients be licensed in California.
- 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 were also made to the pharmacist scope of practice sections, 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 change to the scope of practice for pharmacists, the protocol specifications or the emergency contraception drug therapy requirements.

Other changes updated the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

In addition, there is a change to require a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also 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. The definition of unprofessional conduct for a pharmacist is amended to include those acts or omissions that involve the failure to exercise or implement his or her 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. It also includes the 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 may 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.

There was considerable discussion and concern expressed regarding the draft statutory proposal. The greatest concern raised was the requirement that pharmacists practicing outside of California and providing cognitive services to California patients would be required to be licensed

pharmacists in California even if these services are being provided under the auspices of a nonresident pharmacy permit. Another concern was the proposed requirement that the pharmacist-in-charge for nonresident pharmacies would be required to be licensed California pharmacists. These are major deviations from the current regulatory framework for nonresident pharmacies. There were also questions as to the expanded definitions of pharmacy and the need for these types of facilities to be licensed as pharmacies.

It was noted that the proposal was comprehensive, complex and overwhelming. This proposal will be the focus of roundtable discussions at future Licensing Committee meetings. It is the committee's goal to have a proposal for action at the October board meeting.

Competency Committee Report

Pharmacist Licensure Examination

The Board of Pharmacy transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since February 28, 2005, the board has received 2,778 applications to take the California license exams; 1,341 individuals have become licensed as pharmacists since mid-June and 2,195 individuals have been made eligible to take the licensure examinations; 1,731 individuals have been verified to the National Association of Boards of Pharmacy (NABP) qualified to take the North American Pharmacist Licensure Examination (NAPLEX) for California (includes score transfers); 1,990 CPJE examinations have been administered and 357 have failed the CPJE examinations. Also, 82 regrades of the CPJE have been performed (resulting in no change in score). The CPJE's pass rate is 85 percent.

At this meeting, the board will be given a report on the demographic characteristics and the performance of candidates who have taken the NAPLEX and CPJE, from March 29, 2004 – March 31, 2005. This report will be provided every 6 months.

Restructure of the Competency Committee

Last year the Board of Pharmacy agreed with the recommendation from the Licensing Committee to restructure the Competency Committee. The Competency Committee develops and scores the CPJE. The committee is to be restructured into 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.

To activate this restructuring, the board needs additional pharmacists to serve as item writers and committee members. The board is now aggressively recruiting individuals for these important duties. There was an article in the board's January 2005 newsletter, (the first since the restructuring was approved) requesting interested individuals to submit applications. All board members are asked to assist in recruiting for these positions.

The item writers will meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline will be assigned. There will be no other meeting for this group of individuals.

The core committee will be slightly smaller than the current Competency Committee (if the current Competency Committee was fully appointed, there would be 29 members). The new structure is:

<u>Composition:</u>	<u>19 members</u>
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance of the core committee meetings will be a requirement, and those who miss a certain number of committee meetings each year will be asked to become item writers, where attendance at meetings is not necessary. There will be six two-day meetings annually.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed. Newer pharmacists are sought because the examination measures practice at the entry level with two years' pharmacist experience, not after 20 years of experience.

Appointment to the committee or as an item writer is an honor and an opportunity to give back to the profession. It is also a good opportunity to learn more about Pharmacy Law. Committee members are paid \$30 per hour to perform committee duties.

The board's president appoints the members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

Job Analysis

The Board of Pharmacy 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

The administration of the CPJE is through Experior Assessments, LLC, at test centers nationwide. 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 April 4th. Review of the responses to the RFP by the evaluation team will be completed by May 4. The new contract should be awarded on June 20, 2005, leaving four months to implement a transition to the new contract before the end of the current contract.

Delays in this process could impact the ability of applicants to take the CPJE after November 30, 2005. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems in December.

Petition Process for Intern Hours

For a number of years, pharmacist interns have been required to earn 1,500 hours of intern experience as a requirement for pharmacist licensure. The only exception was for pharmacists licensed in other states who could meet this requirement by providing evidence of licensure and working as a pharmacist for one year in another state.

Last year's board omnibus bill (SB 1913, Chapter 695) contained provisions that moved key intern requirements from board regulations to statutes. At the January 2005 board meeting, the board approved adoption of a related rulemaking to streamline the requirements for earning intern hours. Several changes were made, including one to eliminate a cap of 250 hours on maximum intern hours earned during the first year of pharmacy school. This regulation should be in effect about July 1, 2005.

Since before 1990, the board has had an informal process to allow pharmacists from foreign countries to petition for 600 intern hours for experience they earned in the foreign country as an intern or pharmacist. To petition for the 600 hours, the applicants had to have earned 250 hours of intern experience in California, and provide experience affidavits attesting to their experience in the foreign country. The board used the old intern experience affidavits and required an estimate of how many hours the applicant spent performing the specific duties in the foreign country.

The core of this evaluation was the assumption that the time spent performing the duties on the experience affidavit in the foreign country (e.g., processing prescriptions) would be the same as when performed in California. There was no other validation for this assessment. Members of the Competency Committee would review these experience petitions. Anyone who worked with the individual from the foreign country could sign the affidavit, although the board preferred that a pharmacist do it. Typically fewer than 10 of these petitions were received annually.

The problem is that the petition process outlined above was an underground regulation, and the board cannot continue with this process unless a regulation is promulgated to permit it. The committee did not take any action on this item.

Accreditation Council for Pharmacy Education (ACPE) Site Visits

Over the last few months, the ACPE has visited the new schools of pharmacy at Loma Linda University and the University of California San Diego. Chairperson Conroy participated in the review at the Loma Linda School of Pharmacy, and Board Member Schell participated in the review at UCSD. More recently Board Member Dave Fong participated in the pre-candidate review at the University of Touro.

Meeting Summary of March 16, 2005 (Attachment B)

Quarterly Status Report on Committee Strategic Objectives for 2004/05 (Attachment C)