



California State Board of Pharmacy

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**Licensing Committee
Summary of the Meeting of December 6, 2006**

Hilton Airport Hotel and convention Center
2500 Hollywood Way
Burbank, CA 91505

Present: Ruth Conroy, PharmD, Chair and Board Member
Clarence Hiura, PharmD, Board Member
Susan Ravnar, PharmD, Board Member

Virginia Herold, Interim Executive Officer
Anne Sodergren, Legislation Coordinator
Robert Ratcliff, PharmD, Supervising Inspector

Chairperson Conroy called the meeting to order at 9:35 a.m.

Proposal from the California Schools of Pharmacy to Identify Professional Competencies that Should be Obtained by the End of the Basic Internship Experience

Barbara Sauer, PharmD, provided information about a project recently initiated by California's pharmacy schools to review the basic intern experience earned by California pharmacy students. The group will examine both the required and elective components of ACPE approved intern experience at the basic (IPPE) and advanced (APPE) levels. The project will be called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience besides simply the accrual of hours.

One concern of the educators is that requiring a specific duration of experience (i.e., 1,500 intern experience hours) but without specifying the components to be gained from the experience is not beneficial.

The California schools are collaborating on this new initiative to determine and assess the competencies that should be achieved by the end of introductory pharmacy practice experiences (IPPEs) before students start their advanced experiences.

President Powers has appointed Board Member Ravnan as the board's representative to this group.

Dr. Sauer stated that the schools of pharmacy believe it would be educationally sound for interns to pass an objective exam to assess performance at the end of the basic phase of internship. The benefits of such an assessment are:

- Students know what they need to learn at the basic level
- Schools know what should be learned and instructed

The assessment will include identification of some of the skills listed on the prior intern experience skills affidavit developed by the board in the early 1990s.

The 1,500-hour intern requirement would not be eliminated, but added would be an assessment when the basic skills have been mastered.

The goals of the initiative are to:

1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during intern experiences.
2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
3. Develop a validated and standardized OSCE-based examination to assess achievement of the basic competencies.
4. Develop a mechanism to assure replenishment of the OSCEs and exam security in the future.
5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

Motion: Recommend that the board support and participate in this initiative

The project will be completed by mid-2007.

Request to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy

Students from California pharmacy schools returned to the committee to advance a proposal seeking changes in board regulation section 1728 regarding the maximum number of intern hours that an intern pharmacist may earn outside a pharmacy from 600 to 1,000 of the total of 1,500 intern experience hours.

The students indicated that pharmacy practice is no longer confined to pharmacy environments and students would benefit by gaining experience performing services in the pharmaceutical industry, managed health care, regulatory affairs and association management. However the students cannot earn intern hours for this experience, which impedes their experience as students and future development as pharmacists. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth years in both community and hospital pharmacy. In the fourth year,

pharmacy experience is more clinical. If the intern hour requirements were changed, a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. However, those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The students, Jonathan Watanabe, Tom Wang, David Truong and Jennifer provided a Power Point presentation highlighting the additional areas that interns could pursue if the intern hours experience requirement was more flexible. They cited statistics indicating the benefit that redirected students could provide to health care and that the proposal fits the board's mission.

Discussion during this meeting included a possible increase of 400 hours to the intern experience requirement, to total 1900 hours, to permit such additional experience. Discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is so important to a pharmacist's future as a supervisor of pharmacy functions and personnel. Without a solid understanding and actual experience in such environments, pharmacists will have a difficult time because core experience in a pharmacy is lacking.

The committee concluded that it is premature to move forward with the students' proposal at this time. Instead the committee wants to wait for the results of the pharmacy schools' project discussed earlier at this meeting that will establish a competency assessment of basic pharmacy intern skills before considering any changes in the ratio of intern hours.

Proposed Regulation Requirements for Compounding by Pharmacies

The committee reviewed proposed regulation language that would establish parameters for pharmacies that compound medication for patients. This language was developed two years ago as a work product following completion of the board's Workgroup on Compounding. Legislative proposals were also developed as another work product of this workgroup, but the legislation containing these provisions was dropped during the final stages of the 2006 legislative session due to opposition that could not be resolved. The regulation proposals are being submitted to the committee for refinement and presentation to the board to ensure basic standards for public safety when pharmacies compound medicine.

Dan Wills, Grandpa's Pharmacy, made several comments on segments of the regulation. He stated that it is impossible to ensure a compound is free from any contaminants. He also had questions regarding unit dose containers.

Comments were also made by those present at the meeting on various provisions. Comments included that adding flavoring to a medication should not be included in the regulation's requirements, and reconstitution of ocular products also should be excluded from definition of compounding. Other comments included that obtaining components from suppliers for some items, such as sugar, should not be required by the record

keeping requirements of section 1735.2(c), and a better definition of container needs to be developed, including a definition of a unit-dose container. Concern was also expressed about the meaning of section 1735.7(b) regarding the required quality assurance plan.

Ms. Herold ask those who had comments on the language to please submit them in writing to the board.

Motion: Bring the regulation to the board for future adoption as a regulation.

Request to Add the ExCPT Exam as an Additional Qualifying Method to Become a Pharmacy Technician

Ms. Herold updated the committee on the status of the review of the ExCPT exam, which has been developed by the Institute for the Advancement of Community Pharmacy Technicians (ICPT) as a means to assess the knowledge of applicants for a pharmacy technician registration. The National Community Pharmacists Association and the National Association of Chain Drug Stores support use of the exam. Five states currently authorize the use of this exam as a qualifying route to technician registration.

Currently California uses the Pharmacy Technician Certification Board examination as one route that individuals can use to qualify for pharmacy technician registration. Until recently, this was the only pharmacy technician certification examination available.

At the last committee meeting, the board directed staff to develop a plan to review the ExCPT exam to determine if it meets the requirements of the California Business and Professions Code section 139 regarding a valid examination.

Ms. Herold explained that within the Department of Consumer Affairs is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards within the department. Any review of any licensing examination considered by the board should likely include staff from this office as part of the review process. However, at the current time this office is undergoing recruitment for a new chief. Ms. Herold suggested that until such time as a new chief is hired, the board should delay the review of the ExCPT exam because professional expertise and objectivity are needed. Moreover, legislation will be needed to authorize use of the examination, and should the board sponsor such a proposal, the board will need to submit evidence of psychometric validation.

However, there are other options to perform this review that the committee discussed – including suggesting that the NABP form an independent task force to determine if the exam is psychometrically valid as the ICPT insists. This is a bit sensitive as the NABP is one of the owners of the currently used competing exam – the Pharmacy Technician Certification Board Examination.

Alternatively, the board could direct what organization the ICPT could submit its exam to for independent evaluation. This is a process suggested by the American Society of Health System Pharmacists (which is also an owner of the Pharmacy Technician Certification Board Examination). The committee reviewed a letter from this association expressing concern whether the ExCPT exam has been appropriately validated, and recommending an independent organization to evaluate the exam.

The committee took no action on this agenda item.

Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists

The committee reviewed a request from the Commission for Certification in Geriatric Pharmacy to award continuing education credits to those pharmacists who pass the certification examination to become a Certified Geriatric Pharmacist. According to the association, there are 1,300 certified geriatric pharmacists in the US, Canada, Australia and other countries. To become certified, the individual must pass a 3-hour, 150-question examination covering three areas: patient specific, disease specific, and population specific activities. Two states, Ohio and Washington, do award CE units for passing this examination.

The committee wanted to know more about the examination and qualifying process. However, there was no one from the commission present at the committee meeting, so the committee voted not to approve the item until someone from the commission could appear.

Motion: Table the item until someone from the Commission for the Certification in Geriatric Pharmacy can meet with the committee.

Ms. Herold will contact the commission to assure someone will attend before this item is rescheduled for a future Licensing Committee Meeting.

Emergency Preparedness for California Pharmacy – Review of the Board's Proposed Disaster Response Policy

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California could proceed. The policy encourages pharmacists, interns and technicians to seek out disaster response training in advance of an emergency so qualified individuals are available to assist in disaster response.

Staff made several additions to the text requested by the board following the adoption of the policy.

The committee reviewed the modifications and agreed they met the minor additions sought by the board.

Motion: Publish the modified policy in the next *The Script* newsletter.

Ms. Herold added that in the coming months, staff will continue to work with the Emergency Preparedness Office of the Department of Health Services on matters relating to the distribution of medicine when a state of emergency has been declared.

National Provider Identifier (NPI)

The committee reviewed materials regarding the National Provider Identifier (NPI) number, which is a unique identifier for health care providers, including pharmacies and pharmacists. The NPI was developed by the federal Health and Human Services Agency as part of HIPAA. All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA-covered, HIPAA standard transactions. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes.

Pharmacists and pharmacies can obtain this number from CMS. All covered entities must have the NPI in place by May 23, 2007.

Competency Committee Report

Ms. Herold advised the board about current matters involving the California Pharmacist Jurisprudence Examination (CPJE).

The test administration contract for the Department of Consumer Affairs, which the board uses to administer the CPJE, will again need to be reissued for bids for examinations that will be administered starting June 2007. This is the second time the request for proposals has been cancelled in the last few years.

The pass rate on the CPJE for 2005/06 was 80 percent: during the fiscal year 1,633 attempts to pass the exam were made, and 1,308 individuals passed the exam.

The board's Competency Committee was split into two divisions in August to decrease the heavy meeting schedule associated with examination development and administration. The committee also developed its meeting schedule for 2006-07.

Adjournment

There being no additional business, Chairperson Conroy adjourned the meeting at 1 p.m.