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

Licensing Committee
Minutes of the Meeting of
May 30, 2007

Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

Present: Ruth Conroy, PharmD Chairperson and Board Member
Robert Graul, RPh, Board Member
Clarence Hiura, PharmD, Board Member
Susan Ravnan, PharmD, Board Member

Virginia Herold, Executive Officer
Robert Ratcliff, PharmD, Supervising Inspector
Dennis Ming, PharmD, Supervising Inspector
Anne Sodergren, Legislative Coordinator
Joshua Room, Attorney General Liaison and Deputy Attorney General

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

Proposed Regulation Regulations Requirements for Pharmacies that Compound

Joshua Room walked the committee through each of the provisions of proposed regulation language contained in the committee packets. Integrated into the discussion were comments from those present and the written comments submitted by NACDS, Bill Blair and CPhA. These included comments on "beyond use" vs. "expiration dates," a definition of unit dose containers, why require downloading of certificates, what is a master formula, whether compounding must occur in a pharmacy, use of the term "compounded preparation" vs. "compounded drug product."

A question was asked that if a pharmacy compounds a drug product that later comes out as a manufactured product approved by the FDA, can a pharmacy still compound it? The ensuing discussion involved several drugs that once were compounded, then became commercially manufactured drugs, for example Minoxodil. In these cases, the pharmacies could no longer compound the product.

The CSHP requested that the compounding regulations be amended to specify that they do not also apply to the board's regulations for sterile injectable compounding pharmacies. The association is concerned that there is too much required in the compounding regulations. The CSHP will put its comments in writing.

Staff will review the comments within the framework of the regulations and bring proposed language to the July Board meeting.

Request to Add the Exam for the Certification of Pharmacy of Pharmacy Technicians

Chairperson Conroy provided an update to the committee on the status of the ExCPT exam, which is a competing examination to the PTCB exam, both of which assess the knowledge of pharmacy technicians. In California the PTCB exam has been specified in law as one way to qualify for licensure as a pharmacy technician.

Since October 2006 the board has sought a psychometric evaluation of the ExCPT examination to assure this exam fits the requirements of Business and Professions Code section 139 for job relatedness. The board had hoped to use the Office of Examination Resources in the Department of Consumer Affairs to perform this function. However, since October, the department's Office of Examination Resources has been without staff possessing PhDs in psychometric evaluations disciplines. Recruitment for such positions has been difficult and no such staff has yet been hired.

In late April, Ms. Herold began a solicitation for a contractor to review materials for the ExCPT and PTCB exams to assure both are job related. At this time, the board is waiting for the bids and to develop a process by which the two exam vendors would pay for the evaluation of the respective exam.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or a regulation amendment needs to be adopted.

A comment was made that CSHP and CPhA are initiating a study of intern qualifications and experience, and whether current requirements are sufficient to adequately prepare pharmacy technicians for the responsibilities of working in a pharmacy.

California Schools of Pharmacy Proposal to Identify the Professional Competencies that Should Be Achieved by the End of Basic Intern Experience

Chairperson Conroy updated the committee on the joint project of California's pharmacy schools to develop and assess the competencies that students should achieve by the end of the introductory pharmacy experience of 300 hours. Board Member Susan Ravnan, Virginia Herold and Anne Sodergren attended the three work sessions held for this purpose since the beginning of the year.

In the committee packet were the proposed competencies. The committee reviewed them.

Ms. Herold stated that the next phase of the project will be done by the pharmacy schools and will involve developing a reliable and valid performance-based exam to assess student achievement of the basic competencies. The workgroup hopes to complete the process in time for incorporation during the 2007-08 academic year.

A problem was noted that the board's intern experience affidavit form references hours employed as an intern instead of hours obtained as an intern. Ms. Herold stated that the form would be modified.

Emergency Preparedness for California

Chairperson Conroy stated that emergency preparedness continues to be an important initiative of the Schwarzenegger Administration. She referred the committee to materials in their packet.

1. Surge Response

In late February, the state began working with PriceWaterhouseCoopers to develop a response plan for the surge response following a pandemic, a nuclear event or an earthquake. The goal is to prepare state agencies for an effective and less chaotic surge response. Chairperson Conroy stated that several inspectors from the board have attended some of the meetings, as has she. There have been at least 12 day-long meetings since February 2007.

The board's emergency response plan has been highly promoted during these meetings. However, one downside has been to minimize the need for pharmacists during emergency surge because "the board is going to waive any requirements." However, repeated clarification from board staff about what the meaning of waiving requirements means have helped to reshape the thinking of those who are developing disaster plans.

At the express request of the committee, Ms. Herold stated that the next *The Script* would include another article on disaster preparedness and the need for pharmacists to preregister for training for disaster response so they can be "first responders."

The committee reviewed a preliminary report of the "Development of Standards and Guidelines for Healthcare Surge During Emergencies, Supplies, Pharmaceuticals and Equipment."

2. NABP Recommendations for Disaster Response

Chairperson Conroy referred the committee to information published in the May 2007 NABP Newsletter on guidelines for boards to use in preparing for disaster response. Chairperson Conroy was one of the members of the NABP task force that developed the NABP recommendations.

The board has already accomplished or is working on most of the 11 recommendations.

She also referred the committee to other NABP-prepared materials including the "Emergency and Disaster Preparedness and Response: Roles of Federal, State and Local Governments."

Chairperson Conroy reiterated her concern that in the initial federal disaster plan, pharmacists were not listed as a critical health care provider, as were physicians, nurses and EMTs. Pharmacists need to become trained in disaster response so that the public health can be better served with respect to appropriate drug therapy during disasters.

3. County of San Diego's Request for Dispensing Doxycycline or Ciprofloxacin

Chairperson Conroy referred the committee to a request from San Diego County to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regimen of doxycycline or ciproflocacin to first responders, that would be stored in their homes for their and their families use, with the reminder being stored somewhere (unmentioned) else. The county seeks an exemption from patient-specific labeling because "it would be difficult, if not impossible" to label these containers.

Ms. Herold stated that whereas the board could exempt such labeling after an emergency had been declared, the board has no authority to exempt it in advance of a disaster unless the board promulgated a regulation or obtained statutory authority to authorize this.

Since no one from San Diego County was in attendance at the meeting, the committee took no additional action.

Mobile Community Clinics and Licensing by the Board of Pharmacy

Chairperson Conroy asked Paul Drogichen, PharmD, Director of Pharmaceutical Services, Los Angeles County, to provide information to the committee regarding his request that the Board of Pharmacy alter its licensing requirements to issue clinic permits to mobile clinics, and not just to the brick and mortar administrative office. She referred to the committee to material in the packet submitted by Dr. Drogichen.

Dr. Drogichen stated he was concerned with the differing licensing policies of the board and the Department of Health Services, since the DHS will issue a unique clinic license to a mobile clinic, and the board will not.

Dr. Drogichen stated he was recently advised that some DHS mobile clinics have been denied a board clinic license.

Dr. Ratcliff and Ms. Herold explained that the board only issues a permit to a clinic at a brick and mortar location. Such a location can have multiple mobile clinics, but the main location, typically the main and administrative office, is what actually holds the board's license. Dr. Ratcliff stated that there should be no problem with a mobile clinic having the benefits of a board license so long as a brick and mortar address is used as the licensed location. He asked Dr. Drogichen to contact him if he has additional questions.

Legislative Proposal for Establishment of a State Protocol for Immunizations

Chairperson Conroy reminded the committee that at the April Board Meeting, the board voted to propose a statutory modification to California Pharmacy Law to allow pharmacists to administer immunizations pursuant to a state-adopted protocol.

The board's action was based in part on information provided at the last committee meeting, where Dr. Jeff Goad, Professor at the USC School of Pharmacy, made a presentation on establishing state protocols for immunizations by pharmacists. He stated that pharmacists can administer immunizations in 44 states. In California this authority exists under section 4052 of the Business and Professions Code pursuant to a protocol by a prescriber. According to testimony provided by Dr. Goad, physicians are reluctant to accept the liability for this action, even though it has wide support.

Since the April Board Meeting, staff has developed a statutory modification, based in part on Health and Safety Code section 1261.3, that allows a pharmacist to administer influenza and pneumococcal immunizations for a certain patient population in skilled nursing facilities pursuant to standing orders.

The committee reviewed the proposed modification to amend Business and Professions Code section 4052(a)(9):

> Administer immunizations pursuant to a protocol with a prescriber <u>or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.</u>

Motion: Hiura/Graul: Propose to the Board to seek amendment to Business and Professions Code Section 4052(a)(9) to add: <u>or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.</u>

Approve: 4 Oppose: 0

The committee considered various limits on the protocols and what kind of training would be required of pharmacists before they could provide immunizations under the proposed amendment. Dr. Ravnan agreed to work with Dr. Goad and board staff to refine the requirements and bring this to the July Board Meeting.

Competency Committee Report

Ms. Herold stated that on June 1, the board would have a new test administrator for the CPJE. She distributed a just-released *Candidates Handbook* to the committee members. This handbook provides information about how to sign up for the CPJE. It also provides test preparation information, the exam's content outline and sample test items.

Psychological Services, Inc., (PSI) will mail the handbook to candidates once they are made eligible by the board.

Ms. Herold also noted that during a two-week period in April, board staff qualified over 400 new graduates of California schools who were being processed so they could take the exam with the prior vendor (on or before May 31, 2007).

Ms. Herold stated that things were going OK for a transition being rushed into place in insufficient time. She stated that she hoped that the transition to the new vendor would be invisible to candidates.

Adjournment

There being no additional business, Chairperson Conroy adjourned the meeting at 1:30 p.m.