



California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE
MINUTES**

DATE: December 17, 2008

LOCATION: Department of Consumer Affairs
Hearing Room, First Floor
1625 North Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Susan L. Ravnan, PharmD, Chairperson
Kenneth Schell, PharmD, President
James Burgard, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Schieldge, Senior Staff Counsel
Tina Thomas, Analyst

President Schell called the meeting to order at 9:30 a.m.

During the meeting, President Schell recognized board staff inspectors in attendance of the meeting, as well as past board member, Dr. Ruth Conroy.

1. Emergency and Disaster Response Planning

- *Request from San Diego County for Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency*

In 2007, the board received 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 ciprofloxacin to first responders, that would be stored in their homes for their and their families' use, with the remainder being stored somewhere (unmentioned) else. The county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers. This request was later withdrawn.

In September 2008, the board received a new request from San Diego County. This plan calls for Doxycycline 100mg #20 to be prescribed to approximately 100,000 First Responders and Critical Access Employees and their family members. Each prescription will be written by the Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing.

Following our September meeting, San Diego County was contacted and advised of the committee's request to appear in person at a committee meeting. In response, San Diego County submitted a letter seeking confirmation that this model satisfies the requirements in pharmacy law. The letter was provided in the committee meeting materials. Whereas budget restrictions prevented them from attending the committee meeting in December, representatives will attend the January Board Meeting to make this request directly to the board.

Dana Grau (California Dept of Health Services - Emergency Preparedness Office) explained that their office is involved with various projects, including response planning. He stated that their mission is to support and coordinate activities at the local level.

Dr. Grau provided background on the request by San Diego County. He explained the types of emergencies, specifically those of a bio-chemical terrorism nature, which would require dispensing of the general population within 48 hours of a catastrophe. Dr. Grau explained the "strategic national stockpile" and 12-hour push packages, as well as the type and quantity they provide in terms of pharmaceutical products. He further explained that CDH looked at first responders who will be primarily responsible for coordinating and dispensing the high volume of medications.

Dr. Grau indicated that medications are typically stored in the first responders' homes. He stated that the goal of San Diego County is to allow first responders access to needed prophylaxis, including their family members. Dr. Grau also noted that the intent is to provide those medications before the event is declared an emergency.

Dr. Grau stated that a trial program was conducted by the Center for Disease Control in St. Louis, Missouri three years ago. The test group was provided the emergency medications and were instructed how to store the medications in homes. The test group was thoroughly screened. Results were reviewed at the end of the program, reflecting 98% of the test group individuals complied with storage instructions.

Dr. Grau reiterated the request of San Diego County to include the families of the first responders. He stated that San Diego County representatives will be prepared to attend the full board meeting and answer questions at that time.

Board Comments:

President Schell asked if the test program in St. Louis was extended to the family members.

Dr. Grau responded that it was.

President Schell stated his concern over what to do with the medications once they are expired, as they can not be flushed or reused. He pointed out that the request for larger quantities of emergency prophylaxis drugs, due to the inclusion of family members, causes security issues for pharmacies, as well as questions by the general public over some individuals getting medications and others who are not.

Dr. Grau responded that a large piece of the planning involves how the information is disseminated. Additionally, a significant amount of planning time was involved in identifying modes of dispensing so that they can distribute the medication very rapidly by setting up specific dispensing units.

Virginia Herold, Executive Officer, questioned the quantity being requested. She noted that the request of 500,000 pills for the first responders is one-fifth of the population of San Diego County.

Dr. Grau responded that the DPH would need a more specific definition from San Diego County of who is a "first responder".

Ms. Herold referred to the public information piece. She asked if San Diego is developing that piece currently and if they will be modeling it after the program in St. Louis.

Dr. Grau responded that San Diego County is developing a public information piece and that they have completed quite a bit already with regards to the modes of dispensing.

Ms. Herold stated that it would be helpful to the board if that information was provided for the January 2009 Board Meeting. She also asked if the DPH supports San Diego County's program, specifically with regard to pre-emergency dispensing, as proposed currently.

Dr. Grau responded that they support the concept, but would like to review the specifics in collaboration with the board. He stated that it does look feasible.

Ms. Herold suggested that the DPH, San Diego County, and board members meet prior to the January 28, 2008 board meeting so a complete proposal is prepared to present to the board at that full board meeting. She added that they want to be supportive, but that the proposal is larger than has been requested in the past by a county. She reiterated her concern over the quantity of drugs being requested within the plan.

President Schell noted that further questions will be withheld for San Diego County to be able to respond to.

- *Emergency Pharmaceutical Assistance Program*

The California Department of Public Health recently shared information about a federal government program intended to assist persons affected by disasters, who do not have any type of prescription drug coverage, to obtain necessary medication without charge from a local pharmacy while providing pharmacies with a method to recoup their expenses in providing medicine.

According to the California Department of Public Health, "This program could go a long way toward helping fill the gap identified in previous disasters where people without health insurance had to rely on community pharmacy to essentially give away medications and medical supplies. This program could also help manufacturers appropriately donate drugs without adding to the chaos."

Dr. Grau added that this new program will close the gap between those who have public and private health insurance. The program is designed to assist those with no health insurance, and would involve screening by the American Red Cross in order to receive a 30-day supply of medication in direct response to an emergency in the area of their residence. Dr. Grau indicated that there appeared to be specific guidelines in place in regards to donations of pharmaceuticals by manufacturers, but that he has not received the details.

2. Formation of Subcommittee to Evaluate Drug Distribution Within Hospitals

Board staff is pursuing identification of problems with the recall system in conjunction with the California Department of Public Health, the California Society of Health-System Pharmacists, The California Hospital Association and the FDA. The board is hoping to develop California-specific solutions.

President Schell stated that he appointed a two-board member task force, himself and Robert Gaul, to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital.

President Schell stated that they will be working in concert with another committee already in existence in an attempt to address and evaluate the drug distribution in hospitals, and to ensure that the regulations in place are in concert with current practice. He added that the board recognizes that regulations can become outdated, and hopefully the committee will be able to align regulations with current practice where practice.

This topic bridges both enforcement issues and licensing issues, but because there may be a list of legislative changes identified that involve licensing issues, the task force has been moved to the Licensing Committee

Public Comments:

Steve Gray (Kaiser Permanente) stated that it would be helpful if the board would publish a list of topics that will be addressed in order to allow public to provide input. He noted that the topics, as listed, can be perceived as either very narrow or quite broad. Dr. Gray explained the current response process when a disaster occurs, and raised the question over what the hospital pharmacies, pharmacists, and others dispensing emergency medications are supposed to do with the drugs when they end up not being needed for the emergency as originally planned.

Bryce Docherty (California Society of Health-system Pharmacists (CSHP)) stated concern over the drugs as they leave the pharmacy, as well as within “the walls of the hospital setting”, with relation to potential diversion. He stated that there are CSHP members who would be interested in joining the subcommittee if it is feasible.

3. Discussion Regarding Intern Hours That Can Be Earned Outside a Licensed Pharmacy

Under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations.

More specifically, board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. The remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically within a pharmacy. California pharmacy students typically earn the 600 “discretionary” hours for school-required experiential training (clinical clerkship).

At the March 2006 Licensing Committee Meeting, pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its requirements that allow for an additional 400 hours (for a total of 1,000 hours of the required 1,500 hours required) which an intern can earn for pharmacy-related experience (under the supervision of a pharmacy) outside a pharmacy.

According to the students, opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience, which impedes their experience as students and future development as pharmacists.

At the December 2006 Licensing Committee Meeting, pharmacy students provided a 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 at this meeting included a possible increase of 400 hours of 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 and that without a solid understanding and actual experience in such environments, pharmacists will have a difficult time because core experience in pharmacy is lacking.

At the conclusion of the December 2006 meeting, the committee determined that it was premature to move forward with the students' proposal given that concurrent with this request, the Schools of Pharmacy in California were undertaking an initiative to establishing core competency assessments of basic pharmacy intern skills. (The ACPE guidelines detail the advanced pharmacy intern skills competencies.) At the request of UCSF, the board sent a letter supporting the results of the initiative.

The committee more recently discussed this topic at the June 2008 Licensing Committee Meeting. At that time the committee's recommendation was to table any action to alter the intern hours' requirement. However, after the July 2008 Board Meeting, it was referred back to the Licensing Committee to further explore the issue.

In June 2008, a letter was received from Landon Dean, a student from Loma Linda University. This letter was brought to the committee for consideration. Mr. Dean is suggesting modification to California Code of Regulations (CCR) section 1728. Mr. Dean's letter, minutes from this topic of the June 2008 Licensing Committee meeting, as well as a copy of CCR section 1728 are included in the committee meeting materials.

President Schell stated that he thinks there is room to have discussion with regards to extending intern hours earned outside a licensed pharmacy. He stated that this is a fairly broad topic but the committee will ultimately need to make some decisions.

Chairperson Ravnar noted she has read the proposal. She stated that it is important to recognize that the pharmacy setting is changing. She added that the 900 intern hours requirement within a pharmacy setting is minimal. She stated concern over decreasing the hours even more, and feels that the pharmacist interns may then not be fully prepared to practice in a pharmacy.

Jim Burgard stated his agreement with Chairperson Ravnar. He explained that he has been exposed to experts in the training profession. He stated that 900 hours of training may not be enough to place a pharmacist into their profession. Mr. Burgard added that he would be more inclined to add hours and require more exposure within the

pharmacy, and believes that a highly disciplined structure for training should be followed.

President Schell noted that he has read the proposal several times. He stated his support in extending pharmacy interns to be able to work and earn hours outside of the standard pharmacy setting. President Schell noted, however, that extending the hours would be a challenge to the education programs that exist currently. He indicated an issue with regard to facilities with coagulation services where, currently, intern hours cannot be earned. He stated that he does not agree with that, and it is one reason why he is in support of the proposal.

Public Comments:

Dr. Gray (Kaiser Permanente) recognized the sincerity of the Loma Linda student who proposed the language change in regulation. He stated that the language of the regulation, as proposed, should indicate that the intern hours are to be earned under direct supervision of a pharmacist. Additionally, training should be provided by a licensed pharmacist.

Dr. Gray also suggested additional changes in regulation language with regard to the 900 intern hours and how “in a pharmacy” relates to hospital practice and activities specific to pharmaceutical and hospital care. He gave an example of hospitals who now staff their emergency rooms with a licensed pharmacist on a 24-hour basis, and that would not be considered “in a pharmacy”.

Dr. Gray discussed a prior accreditation standard proposed, which would require additional practical hours as part of their curriculum, and would be a burden to the pharmacy schools and students. He explained that schools of pharmacy responded by implementing a program to determine whether the additional knowledge had ultimately been gained by the additional proposed hours as intended. The program included an option to be exempt from the additional hours by taking a “challenge exam”. Dr. Gray suggested requiring a similar program where students would demonstrate whether they had gained the knowledge as intended by completing the hours in another pharmacy-related setting rather than “within a pharmacy”.

Barbara Sauer (UCSF School of pharmacy) stated her agreement with Dr. Gray that the practice of pharmacy is changing. She stated that she was responsible for much of the effort to develop the California Pharmacy Coalition, with the cooperation of the Board of Pharmacy, to meet the new accreditation standard.

Dr. Sauer stated that the coalition was underfunded, and underestimated the resources needed to develop a state-wide competency based exam. She added, however, that they were successful in adopting a document, a set of competencies that all pharmacists should be able to conduct, which is being used in the California schools of pharmacy. Dr. Sauer stated that UCSF is using the competencies to collect data and

determine what students are doing for their internship. Dr. Sauer stated that there are new accreditation standards which require schools of pharmacy to provide 1440 hours of advanced practice experience, and 300 hours of introductory practice experience to expand over the first three years of internship. She added that many schools count on the 900 hours within the pharmacy to support the nature of the experiential programs. Dr. Sauer indicated that there is a lot of experiential training within the school's curriculum, but not necessarily in the pharmacy setting. She encouraged the committee to review the regulations to clarify what must be done during internship and what "in a pharmacy" specifically means. She referred to the need for clarification relating to the accreditation standards as well.

Dr. Sauer stated that the schools of pharmacy have an ambitious goal, and that UCSF was not successful thus far in reaching theirs. She added that the schools of pharmacy will need to collaborate to create a set of competencies, as well as a competency exam, that will improve the quality of internship.

4. Update on the Coalition on Shortages of Allied Health Professionals – Workgroup to Address Shortages of Pharmacists in Hospitals

The California Hospital Association established a coalition whose mission is to create and lead a statewide coordinated effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition is comprised of workforce committees, an advisory council and four workgroups. Board executive staff was invited to participate on the pharmacy services workgroup. The focus is on pharmacists and pharmacy technicians in the hospital setting.

This workgroup, comprised of staff and members of the California Hospital Association, the California Society of Health-Systems Pharmacists, a representative from academia, representatives from various hospitals and health systems as well as board staff, has met on at least three occasions. Based on the results of this workgroup as well as two others, it is the hope that the coalition will develop and implement solutions to eliminate barriers, foster collaboration among CHA member hospitals and health systems, promote a long-term vision for the allied health workforce in California and develop links with workforce partners and stakeholders.

During the first meeting, barriers to the profession for both pharmacists and pharmacy technicians were identified, however further discussion resulted in the group concluding that there is not a shortage of pharmacy technicians; rather it is a shortage of qualified pharmacy technicians. Subsequent meetings continue to further define the barriers as well as a ranking of the top barriers. Some of the barriers identified for pharmacists included a limited number of student slots for individuals looking to enter the profession, the pharmacist examination and reciprocity, losing potential candidates to other healthcare professions, e.g., medical school, and untested new schools of pharmacy. The most recent meeting focused on a draft issue statement.

Board statistics show that 2061 applicants took the board's examination between June 1, 2007 and July 31, 2008; 890 of those applicants were graduates of California Schools of Pharmacy.

Board staff will continue to update the committee on the progress of the workgroup as well as any outcomes.

Ms. Herold explained that this item is part of a subcommittee and integrates with other projects underway, including a strategic plan by the Department of Consumer Affairs to ensure an ongoing supply of practitioners within the healing arts. The California Hospital Association (CHA) is, however, not yet ready to present the report and its details. She stated that the group focused on the ongoing supply of pharmacists, not technicians, working in the hospital setting. The intent by CHA is for the report to be released in the near future.

Public Comments:

Dr. Gray (Kaiser Permanente) stated that he has not seen the report. He stated concern that the group may be looking at the issue in a very broad perspective. Specifically, the review should include barriers to lack of pharmacist care, as well as pharmacists. Dr. Gray explained the process for call centers in obtaining pharmacy approval on prescriptions, as well as the procedure for backup call centers when an overload in a pharmacy occurs. He stated concern over barriers being established for the call centers which would exacerbate the current shortage issue. Dr. Gray stated that he has been told that the hospital pharmacy shortage is currently worse than the nursing shortage. He noted that hospitals with 99 beds or less are still not required to have a pharmacist on staff, which reduces patient care. Dr. Gray noted that Oregon adopted regulations which require pharmacists to be licensed in Oregon if providing care to an Oregon resident, which is causing problems for them as well. Dr. Gray concluded by stating that California has to be open to ensuring quality of care by going outside of traditional thinking.

5. Update: Task Force to Evaluate Pharmacy Technician Qualifications

Chairperson Ravnar stated that, during the last legislative cycle, the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. This bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

Mr. Docherty (CSHP) gave a brief background on legislation they have sponsored to create requirements for technician licensure, which was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

Mr. Docherty indicated that, since the last update to the committee and board, additional stakeholder meetings have occurred. He stated that the task force has been reestablished in order to move forward with recommendations and comments and refine the proposal for next year. At the most recent meeting earlier in the month, discussion involved the redraft of the proposal and, more specifically, the ratio requirement for the community pharmacy setting, as well as potentially limiting the proposal to hospital based or inpatient pharmacy technicians only.

Mr. Docherty stated that CSHP would be interested in comments from the board on the subject as they are considering moving forward. He stated that they have been unable to reach consensus within industry to strengthen the education and training requirements. Mr. Docherty emphasized that the training component in many facilities is not at the quality that it should be because of limited time by the pharmacists-in-charge. He summarized CSHP's concern over standardizing what the training is, as well as having pharmacy technicians responsible for maintaining their competencies on an ongoing basis in terms of continuing education.

Public Comments:

Dr. Gray (Kaiser Permanente) commended CSHP for creating a broad base of representatives to come together and discuss the issue. He referenced previous discussions of pharmacy students in relation to the skills needed in order to perform the functions in a particular setting "category". He suggested the need for higher standards for technicians who perform certain functions, regardless of the setting they work in. Dr. Gray stated that he hopes the board would consider regulations which address the functions conducted by technicians, rather than regulations being "setting-based". He stressed to the board the concept that technicians are valuable assistance to pharmacists who may not be practicing in a standard pharmacy setting.

Ms. Herold asked Mr. Docherty if the proposal is wholly supported by the hospital environment.

Mr. Docherty responded that they will be meeting with them separately. He noted that there was a hospital representative at their last stakeholder meeting. When the representative was asked what direction the hospitals take with regard to the policies in the pharmacy setting, her response was that they follow the direction of the pharmacist-in-charge. Mr. Docherty added that CSHP will continue to engage in conversations with the hospitals.

Ms. Herold asked if they are aware of any problems by the hospitals with the current proposal.

Mr. Docherty responded that they are unaware of any problems.

6. Florida NAPLEX Rule Change

Chairperson Ravnar stated that the board received notification that the Florida Board of Pharmacy recently amended its law which had required license transfer applications (by endorsement) to have passed the North American Pharmacist Licensure Examination (NAPLEX) within 12 years.

Applicants for licensure in Florida must meet all other Florida endorsement criteria before they can become eligible for licensure in that state.

Numerous state boards of pharmacy implemented restrictions or similar requirements for applicants utilizing a Florida license as the basis for seeking licensure in another state. NABP is encouraging all board's to review state requirements and laws that may warrant modification to support uniform licensure requirements.

Chairperson Ravnar explained that in 2003, as a result of the board's Sunset Review process as well as the completion of a review of the NAPLEX examination by a psychometric expert which determined the examination to be psychometrically sound, the board pursued a legislative change to alter the testing requirements for pharmacist licensure. Chairperson Ravnar indicated that, as part of a negotiated agreement when the legislature considered this proposal in 2003, the law was written to include that the board would not accept any NAPLEX score that was earned prior to January 1, 2004.

Business and Professions Code section 4200 detailed the requirements for licensure in California as a pharmacist. The requirements include the following:

1. 18 years of age
2. Graduation from an ACPE accredited school or certification by the Foreign Pharmacy Graduate Examination Committee
3. 1500 hours of intern experience as specified
4. Passage of the NAPLEX and CPJE examination

A memo from the NABP regarding the change in Florida's law as well as Business and Professions Code section 4200 were provided in the committee meeting materials.

7. Competency Committee Report

Chairperson Ravnar stated that each Competency Committee workgroup is scheduled to meet early in 2009 and will focus on examination development and item writing. She added that, later in the year, the committee will begin to develop a job survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically, which serves as the basis for the examination.

8. Final report to the Legislature on the Impact of Requiring Foreign Graduates to Take Remedial Education After Failing the Pharmacist Licensure Examinations Four Times

Business and Professions Code (B&PC) section 4200.1 establishes a requirement in law that an applicant who fails either the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) or the North American Pharmacist Licensure Examination (NAPLEX) four times, must complete 16 units of pharmacy education prior to being eligible to take either examination again.

In addition, this section also requires the board to collect specified data and submit a report to the legislature detailing the findings. The reporting elements include:

- The number of applicants taking the examination and the number who fail the examination for the fourth time,
- The number of applicants, who after failing the examination for the fourth time, complete a pharmacy studies program in California or in another state to satisfy this requirement,
- To the extent possible, the school from which the applicant graduated, the school's location and the pass/fail rates on the examination for each school.

The report includes data from January 1, 2004 through July 1, 2008.

Chairperson Ravnar stated that the final report, which was sent to the legislature, is included in the committee meeting materials. She added that, based on the report findings discussed and a subsequent motion during the October Board meeting, board staff will seek legislation to repeal the sunset date in B&PC section 4200.1.

9. Establishment of Meeting Dates for 2009

The committee selected committee meeting dates for 2009.

10. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 11:06 a.m.