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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: September 29, 2008

LOCATION: Department of Consumer Affairs
Sequoia Meeting Room
2420 Del Pas Road, Suite 109 A/B
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Susan L. Ravnan, PharmD, Chairperson
Stanley C. Weisser, RPh
Henry "Hank" Hough, Public Member
James Burgard, Public Member

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

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1. Emergency And Disaster Response Planning

- California Dept. of Public Health: Request from San Diego County for Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency

Chairperson Susan Ravnan explained that 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 regiment 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. Chairperson Ravnan noted that this request was later withdrawn.

Chairperson Ravnan indicated that, in September 2008, the board received a new request from San Diego County. She explained that 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 would be written by the

Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing.

Chairperson Ravnan stated that San Diego County is seeking confirmation that this model satisfies the requirements in pharmacy law. A copy of the First Responder and Critical Access Employee Home Emergency Prophylaxis Kit Plan was contained within the committee packet provided.

Stan Weisser asked if it is legal for someone to prescribe “mass” prescriptions for each family member without a doctor-patient relationship.

Executive Officer, Virginia Herold, responded that that is a question for the Medical Board. She stated that in this case, the First Responders are county employees, and that Health Officers have in the past filled those prescriptions as the employer of those first responders. She reiterated that it would be up to the Medical Board to determine whether it would be a viable prescription when it is being dispensed to the family members, rather than the First Responder employees.

Kristy Schieldge, board counsel for DCA, stated her concerns as to whether the pharmacists are in the scope of their practice by not reviewing medical history on every patient they are dispensing for. She also cautioned the board in giving any legal opinion pertaining to the request, as it could be seen as giving approval.

Ms. Herold indicated that the initial request by San Diego County was to dispense the drugs without a label. This subsequent request, however, does have some degree of control. She also noted that Doxycycline has contraindications with a lot of other drugs.

There was discussion on where the medication supply would be dispensed and how it would be funded.

Mr. Weisser stated that he is not comfortable with the request and would need more information.

Hank Hough shared concern about the drugs expiring while sitting on the shelf in the First Responders’ homes.

Ms. Herold stated that the intent is to make sure that the First Responders and their families are taken care of, so that they can respond to the emergency needs of the community. She added that the counties are trying to find ways to assist with accomplishing this. Ms. Herold stated that Orange County dispensed medications in a similar manner (without advising the board), but the drugs were only provided to the First Responders, not their family members. In that case, they were labeled patient-specific.

Jim Burgard shared the concern in dispensing to family members when medical history is unknown and contraindications are an issue.

Public Comment:

Lynn Rolston (CPhA) stated that they have received a lot of feedback from organizations in other counties. She indicated that the issue may need to be addressed with a more global approach, and that a solution is needed that would apply statewide. She reiterated that it would need to be addressed at some point, whether it is for this county or for another county with another drug, and that it would helpful to know what the parameters will be for situations of dispensing mass amounts of drugs to First Responders.

Steve Gray (Kaiser Permanente) stated that Kaiser has been approached to get involved in a similar situation because of their large dispensing facilities. He stated that it is important to determine who will conduct the dispensing. He pointed out that physicians can dispense in California, and that the Medical Board has been "loose" on the interpretation of dispensing guidelines. Dr. Gray stated that the law does not require a "good faith" physical exam in order to dispense certain medications. He used the example where a drug is prescribed based on information collected by experienced personnel. He also added that it is unlikely that those 100,000 prescriptions would be provided as written prescriptions, as the cost would be significant. He also noted that it is indicated that such prescriptions would not be covered under insurance programs, as it is not a current medical need.

Ms. Herold suggested that the board invite San Diego County to the next committee meeting and, in the interim, board staff will contact the Medical Board and other counties for input.

Mr. Burgard suggested that the board provide a letter to San Diego County, indicating some of the parameters of concern prior to their attendance at the next meeting.

Ms. Herold stated that she suspects San Diego County already anticipates this as outside of the normal course of business for dispensing a prescription to a pharmacy. She added that they would provide parameters for the county as suggested. She noted that the intention is to ultimately have a "drive by" type arrangement for dispensing of the medication to the public in order to avoid large amounts of people arriving in the hospitals during a natural disaster, for example, who are not seeking medical treatment.

Mr. Burgard requested a copy of the letter that will be sent to San Diego County.

- **New Name for ESAR-VHPS**

In August board staff received notification that the ESAR-VHPS was renamed to Disaster Healthcare Volunteers of California.

This system, coordinated by the Emergency Medical Services (EMS) Authority, is to allow for health care professionals to sign up to serve as a volunteer in response to a disaster. The EMS will continue to work diligently to increase the number of volunteers in this program.

A copy of the memo provided by EMS Authority was contained within the committee packet provided.

2. Patient Privacy Issues Arising From Abandonment Of Records – The Abandoned Records Project Of The California Office Of Privacy Protection

Chairperson Ravnan stated that the California Office of Information Security and Privacy Protection recently convened a meeting to discuss abandoned records. She explained that abandoned records could involve health information, financial information or other personal information. She further explained that abandoned records include personal information for which no responsible owner or custodian can be located, but does not include improperly disposed of records, such as records being placed in a dumpster.

Chairperson Ravnan stated that the problem arises when records containing personal information are left behind by a professional or business. She indicated that sometimes these records are stored in self-service storage areas. The responsible party may have died, gone out of business or otherwise abandoned the premises, practice or records. Chairperson Ravnan said that the abandoned records pose a risk to the individuals whose personal information is compromised and could make them victims of identity theft, physical harm, etc. She stated that one possible solution is to notify the regulatory agency that licenses the professional who abandoned the records to take care of such records.

Chairperson Ravnan indicated that at this meeting, which is envisioned to become a series of meetings, the board shared their current records retention requirements for both current businesses as well as those that discontinue business. It appears that pharmacy law appropriately addresses several aspects of this issue, however it was clear from the meeting that not all professions have similar requirements to protect consumer information. Chairperson Ravnan did note, however, that pharmacy law does not address certain types of abandoned records such as those stored on unwanted computer equipment or offsite storage that becomes abandoned. She stated that the committee would develop a proposal to address this in the future.

Ms. Schieldge asked how this issue applies to the pharmacy board.

Ms. Herold provided background on an incident where a disposal issue arose because of tax records being stored in a private storage entity by a member of the board of accountancy who passed away. The Board of Pharmacy requires the completion of Discontinuance of Business form in the case of a deceased owner or close of business. Within that document, the location of the stored documents must be provided. The

location is required to be a licensed facility, with documents retained for at least three years. If that requirement is not followed, a citation and fine will be issued. Ms. Herold stated that the issue lies within the computer storage of documents when those computers are replaced and disposed of. She added that the board wants to ensure the proper storage of patient documents in all types of media, as they are highly confidential and contain sensitive material.

Ms. Schieldge referenced that there is a separate requirement under California Law, outside of the Information Practices Act, which states that records must be properly destroyed once they have completed use of the documents. She added that it does not address how the documents are to be destroyed, however, when the patient relationship no longer exists.

Ms. Herold stated that the issue at hand relates to a multi-disciplinary meeting and the various types of sensitive records being used. She indicated that the board needs to be cognizant of this concern over the highly confidential documents in reference

Mr. Burgard stated that he attended a meeting of an organization where legal disposal of hard drives are done in order to control the transfer of records when a computer is no longer used and discarded. He suggested this as an option.

Public Comment:

Dr. Gray stated that Centers for Medicare and Medicaid Services requires prescription records to be stored for 10 years. He further explained that those records need to be kept on paper for three of those years, and can be kept electronically after that. Dr. Gray also pointed out the frequent change of computer systems due to rapid technology, and noted that Kaiser changes computer systems approximately once every three years. He stated that computerized records are often stored by a service for practicality purposes and to reduce the cost impact. He added that the problem with contracts for such services often involves seizing the records when payment of services is not provided. Dr. Gray suggested that regulation be put in place which requires records to be returned to the pharmacy, regardless of payment of services.

Cookie Quandt (Long's Drugs) suggested that the board provide an article in the *Script* newsletter regarding the retention of records. She noted that as pharmacies are being acquired by Long's, they are educating them on what to do with records. Dr. Quandt stated that a refresher would be helpful.

Ms. Herold responded that the board does have the records retention information on the self-assessment form and the discontinuance of business form, but agreed that it could be included in the newsletter as well. She indicated that there will be additional meetings by the California Office of Information Security and Privacy Protection, and stated that they will bring the issue to the board for further discussion as well.

3. Update On The 2007 Compromise Of The NAPLEX Examination

Chairperson Ravnan stated that the board was recently provided an update on the litigation against the Board of Regents of the University System of Georgia and two University of Georgia (UGA) College of Pharmacy professors. She explained that the litigation alleges that the University offered, and the professors conducted, a pharmacy examination review class in which the participants were provided with actual test questions from the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE).

Chairperson Ravnan indicated that the National Association of Boards of Pharmacy (NABP) continues to gather information related to this matter, which calls into question whether participants of the review course met the qualifications for licensure to practice pharmacy competently and safely. The NABP also indicated that they believe that this course was offered at other schools and colleges of pharmacy. Chairperson Ravnan stated that the NABP is taking steps to identify relevant students and will communicate any and all score invalidation and cancellations to the Board of Pharmacy, as well as the affected candidates.

Chairperson Ravnan noted that if any California licensed pharmacist is identified, the board will be required to pursue disciplinary action against the pharmacist to remove them from practice.

Chairperson Ravnan further explained that the board received a copy of a formal complaint filed by the NABP with the Accreditation Council for Pharmacy Education (ACPE) in regards to the accreditation status of the University of Georgia College of Pharmacy. This notification states that at the ACPE Report of Proceedings for June 18-22, 2008, Meeting of the ACPE Board of Directors, the University of Georgia College of Pharmacy was placed on probation (Spring 2009). Chairperson Ravnan stated that NABP is requesting the immediate revocation of the University of Georgia's accreditation.

A copy of NABP's update on the compromise as well as a copy of the formal complaint filed with the ACPE is contained within the committee packet provided.

Ms. Herold explained that the board has already been given names of four students from UGA involved with the compromise. Fortunately, they were not licensed in California. She indicated that NABP is seeking ACPE to verify the accreditation of UGA. If that occurs, graduates of that school would not be able to take the exam for licensure in California. She noted that UGA does send students to California for licensure. She also noted that a similar incident occurred in 1995 as well, and was to have been corrected then.

Anne Sodergren stated that NABP is also investigating other schools, as similar review courses may have been provided elsewhere.

Public Comment:

Dr. Quandt asked if there are any interns currently licensed in California that would be associated with UGA. She noted that the board would have to consider the licensure of those individuals as well.

Ms. Herold confirmed that would be the case, but only if the school loses their accreditation. If that occurs, those interns' licenses would need to be revoked.

4. Fact Sheets On Application Procedures For Pharmacist Applicants

Chairperson Ravnan indicated that approximately 50 percent of the pharmacist examination applications which the board receives are deficient. She stated that, in an effort to improve applicant understanding of the requirements for licensure, board staff has developed fact sheets that will be placed on the board's Web site. Chairperson Ravnan noted that the fact sheets are specific to each of the three groups of applicants who qualify for the pharmacist examination: recent graduate, foreign graduate and licensed pharmacists from out of state. She stated that the board hopes the end result of these fact sheets will be a reduced number of deficient applications and fewer inquiries to board staff.

Chairperson Ravnan also explained that, for the last several years, board staff has made site visits to California Schools of Pharmacy to provide presentations on the application process. These presentations reduce the number of deficient applications received from California graduates. She pointed out that the board cannot complete this type of outreach to out of state schools; however, they are hopeful that these fact sheets will have a similar affect.

Draft copies of the fact sheets were provided at the committee meeting for review and discussion.

Ms. Herold stated that the board has a detailed set of instructions for application to the pharmacy examination. She explained that when completing the application, applicants often don't read those instructions. Additionally, when applicants have deficiencies, they often don't refer back to those instructions. As a result, the board is providing the fact sheets as another piece of information for applicants to refer to. Ms. Herold indicated that the current budget constraints have caused significant reduction in staff size, especially in the licensing unit. Because of this, the board is unable to respond to the high volume of application status inquiries as the priority within licensing is to process applications. In order to assist applicants with monitoring the status of their applications independently, board staff has developed the U-Track form. Ms. Herold explained that this is an interim solution until I-licensing is in place. She indicated that the board staff is ready to place U-track on line, along with the fact sheets as discussed.

Mr. Weisser asked about the turnaround time for application processing.

Ms. Herold stated that the board is doing fairly well. She indicated that they have extended the timeframe for status calls to 60 days before contacting the board. She noted, however, that this is a slower time of year for examinations being taken.

Ms. Sodergren stated that exam applications are being processed at approximately 15 days from the time of receipt. She noted, however, that there is currently a large volume of intern applications.

Ms. Herold noted that Long's Drugs would potentially be purchased. She explained that when that occurs, the board estimates the cost at approximately 200 hours to process those applications. This is equivalent to labor hours of one full-time employee for one month. However, the board is unable to hire staff or allow overtime. Ms. Herold stated that they are being instructed by potential buyers to complete the applications within 24 hours, which is not a feasible request. She added that management would attempt to construct a team to expedite. Ms. Herold noted that a Quality Assurance exam is in process as of August, and results are expected to be released by next week. She explained that notification of those exam results will result in additional workload as well.

Public Comment:

Dr. Quandt stated that the most common question she receives from applicants relates to fingerprint scanning. She asked for an explanation of the delay due to scanning issues.

Ms. Herold indicated that that is a question for the Department of Justice (DOJ), as they are the agency who regulates fingerprint scanning.

Ms. Sodergren provided information on a recent challenge with scanning results where the DOJ has changed their requirements. She explained that there was a prior process that would allow for correction of errors (key entry, etc.) which has since been eliminated. She further explained that the DOJ has included an additional key indicator in order to process and provide results to the Board of Pharmacy, which is the applicant's social security number. Ms. Sodergren explained that the livescan operators are located throughout California, and often do not input the Social Security number as it is not a required field in the data entry, even though it is a required piece of information from the DOJ. Ms. Sodergren indicated that board staff is creating a specific set of instructions for applicants regarding the data required, so that the applicant ensures that the livescan operator includes all the information needed when inputting their data. She further explained that the board needs to be confident that they are licensing applicants who have properly identified themselves, which cannot be done if the social security number is not appropriately verified and documented as such by the Department of Justice.

Ms. Herold stated that they have encouraged DCA to create a task force to work with the DOJ, but it has not been pursued. She explained that many of the board licensed interns often continue to become pharmacists. She stated that those licensees are required to submit prints each time they apply for those classifications. Ms. Herold noted that the DOJ has also lost staff that cannot be replaced. She also stressed that it is not feasible for staff to follow-up on print results as they receive over 1000 prints a month.

Dr. Quandt asked when a candidate should follow-up with the board if they have completed a second livescan because of a deficiency.

Ms. Sodergren responded to wait for 30 days, as that is the timeframe DOJ requests the board to wait before requesting a follow-up with them. She added that the board continues to try to advocate with the DOJ.

Ms. Herold noted that the Board of Pharmacy is a “small user” with respect to the amount of prints that are processed at the DOJ.

Chairperson Ravnan asked if the board needs to approve the fact sheets.

Ms. Herold responded that they are only provided to the board for their review and board members are welcome to comment on them, but it is not required for approval.

5. Licensing Unit Workload Adjustments Made To Accommodate Budget Restrictions

Chairperson Ravnan explained that, effective August 1, 2008, the Governor signed Executive Order 09-08, which required the board to dismiss several non-permanent employees and to furlough one additional staff member. She further explained that, as a result, the board lost six key staff responsible for, among other duties, assisting with the processing of applications and other licensee maintenance processes such as change of pharmacist-in-charge applications, change of designated representative-in-charge forms, discontinuance of business forms, etc.

Chairperson Ravnan noted that, the board additionally lost its licensing manager to another state agency in the first week of August. Unfortunately, also pursuant to the Executive Order, the board has been unable to fill this vacancy.

Chairperson Ravnan stated that, when faced with the challenge and the limited resources, board executive staff directed staff to suspend responding to status inquiries. She explained that this allowed board staff to focus on the most mission critical functions for licensing, which is processing applications.

Chairperson Ravnan provided a report of the workload statistics for August 2008. The application types were provided, with statistics for completion of licenses for each.

Chairperson Ravnan indicated that currently board staff is again responding to status inquiries. She noted, however, that these inquiries result in several staff losing the equivalent of at least one day per week in responding to such inquiries rather than processing applications, deficiencies, etc.

Chairperson Ravnan stated that, should board staff have to continue to operate with these limited resources, the board may need to permanently suspend status inquiries. The board recognizes that this creates frustration with applicants as well as board staff who pride themselves on providing excellent customer service. Chairperson Ravnan stated however, that until staffing levels return to appropriate levels, the board cannot continue to complete all tasks and respond to such inquiries without resulting in significant workload backlogs.

Ms. Herold commended the board staff on the volume of licenses processed.

Public Comment:

Dr. Gray referred back to a prior situation where the Board of Pharmacy budgeted funds were taken to bolster the General Fund. He asked if this may result in a similar situation.

Ms. Herold responded that the board has made the argument that fees are intended to pay for the services provided by the Board. She stated that there is consideration being given by the administration as to whether special funded agencies should be exempt from hiring freezes, etc. She added that the board did contribute $1 million to the state's General Fund this year as a loan.

Dr. Gray asked about a lawsuit against the state for such acts.

Ms. Herold confirmed the lawsuit with another department and explained that it is because the funds cannot be a permanent transfer. She further explained that it is acceptable to loan the funds, which is what the board has done.

Dr. Gray stated that he has been meeting with the schools of pharmacy and referenced the increased experiential hours now being required of their students. He indicated that he was concerned about the quantity of intern licenses being issued, and added that the schools can not increase hours if the students cannot get a license.

Ms. Sodergren responded that they have not received very many applications as of yet, but there will be over 400 coming at the end of the month.

Ms. Herold added that the priority is to process applications for pharmacists, followed closely in turn by interns.

Ms. Sodergren indicated that the board will most likely need to cease responding to status inquiries again, as they need those staff members to process applications due to the staffing shortage. Ms. Herold added that the receptionist staff has also become more knowledgeable and is able to field many of the calls when they can.

Mr. Weisser asked about the specifics surrounding the licensing manager vacancy.

Ms. Sodergren explained that if a state agency has already made a "good faith" hire, they can proceed with hiring that individual regardless of the Executive Order and budget constraints. She stated that that was the situation with the agency that the board's licensing manager transferred to. Unfortunately, however the board did not have a tentative offer in place for a replacement licensing manager and recruitment efforts were ceased because of the Executive Order.

Ms. Rolston referred to the loan previously discussed and asked what the terms were.

Ms. Herold responded that because of the deficit, the state can keep the funds until they determine that the board needs the funds returned to them. She noted that the board is planning for a fee increase in the future. She also stated that the loan is scheduled to be paid back the year after next.

Ms. Rolston stated that there are critical services needed by the industry which are conducted by the board, and is concerned that the fee increase will go back to a similar General Fund loan program as is currently in place.

Ms. Herold responded that the board is raising fees in order to provide additional services, and gave the example of needing a staff member to monitor fingerprinting results.

Ms. Rolston asked for clarification that the board is suspending services because they do not have the funds.

Ms. Sodergren responded that the services are being suspended because they do not have the staff due to the Executive Order.

Ms. Herold clarified that the fee increase would still be needed in order to provide additional staffing that is sorely needed.

6. The Coalition On Shortages Of Allied Health Professionals – Formation Of A Pharmacy Services Workgroup To Deal With Shortages Of Pharmacists And Pharmacy Technicians

Chairperson Ravnan indicated that the California Hospital Association recently established a coalition to examine the shortages of allied health professionals. She explained that the mission of this coalition is to create and lead a statewide coordinated

effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. She noted that this coalition is comprised of workforce committees, an advisory council and four workgroups. Chairperson Ravnan stated that the board executive staff was invited to participate on the pharmacy services workgroup, and that the focus is on pharmacists and pharmacy technicians in the hospital setting.

Chairperson Ravnan said that the first workgroup meeting was held on September 16, 2008. She noted that participants included 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 of Pharmacy staff. During this first meeting, barriers to the profession for both pharmacists and pharmacy technicians were identified. Chairperson Ravnan indicated that 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.

Chairperson Ravnan stated that 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.

Chairperson Ravnan noted that workgroup meetings will continue quarterly over the next year. She indicated that, based on the results of this workgroup as well as two others, it is the hope 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.

Information provided at the meeting as well as the meeting minutes are contained within the committee packet provided.

Public Comment:

Ms. Rolston noted that the coalition seems hospital-oriented, and asked if there is another group or association that is focused outside of hospitals.

Ms. Herold responded that the coalition is not quite ready to address the community setting. She stated that they are trying to take a collaborative effort to identify the scope of the issue and currently want to limit their focus to hospitals. Ms. Herold noted that they may expand to community settings in the future.

Mr. Weisser referenced a comment within the report which stated that there is a shortage of qualified pharmacy technicians, rather than technicians as a whole. He asked how a licensed technician is considered a “qualified” technician.

Dr. Gray commented on the discussion of non-hospital entities being included. He stated that the current lack of qualified technicians is a more significant problem within the hospitals, which is why there is a focus within that setting. He also indicated that the shortage of pharmacists creates a problem with competition, so there would potentially be a resistance if hospital groups attempt to collaborate with non-hospital groups. He explained that when students go outside of the hospitals to earn intern hours, they often find a more advantageous setting for careers. Dr. Gray noted that the task force is attempting to locate pharmacists who have intense clinical experience and identify their educational background in order to locate qualified candidates.

Dr. Gray explained the process involved in obtaining a prescription order and approval within the hospital setting. He stated that currently it is difficult to get an order approved even during regular business hours, as well as after hours.

Mr. Weisser commented that radiologists who work after-hours often become staff of acute facilities and must become licensed even if they are off-site. He asked if that is true of pharmacists as well.

Dr. Gray responded that radiologists must be credentialed in order to work in acute care facilities, and that that is not the same with pharmacists. Hospital pharmacists contrac with nonresident pharmacies to review medication orders. Oregon tried to address this with a new law that is going into effect where any out of state pharmacist providing care to an Oregon resident must be licensed. He noted that a waiver is possible. He stated that if this were to become law in California as well, then other states will most likely adopt the same law. Dr. Gray noted concern as this could potentially prevent consultations with professionals who have significant expertise, but are not licensed in California.

Chairperson Ravnan commented that the pharmacist shortage within hospital settings seems like a job dissatisfaction issue, based on Dr. Gray's comments. She noted that the report from the workgroup meetings indicated the barriers were due to a workforce shortage, and that job dissatisfaction was not included. Chairperson Ravnan asked if the identified barriers to pharmacists entering the profession were based on data or opinions of the group.

Ms. Herold indicated that no research was conducted. She stated that Kathy Napp has been recruited to assist.

7. Update: Task Force to Evaluate Pharmacy Technician Qualifications

Chairperson Ravnan stated that this year 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. She noted, however, that this bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

Chairperson Ravnan indicated that CSHP is sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. She noted that the first stakeholder meeting was held on June 25, 2008, and that board member, Stan Mr. Weisser, was designated by President Schell to represent the board at these meetings.

Chairperson Ravnan shared that the discussion at both the June 2008 Licensing Committee meeting and the stakeholder meeting revealed disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualification requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. She added that there appears to be disagreement about whether continuing education is necessary for pharmacy technicians.

Chairperson Ravnan stated that CSHP is currently working jointly with the California Pharmacists Association (CPhA) to determine common outcomes and CSHP anticipates resumption of sponsoring stakeholder meetings in the future to elicit stakeholder recommendations and comments to refine the proposal for next year.

Chairperson Ravnan indicated that, on the national level, during the NABP Annual meeting, a resolution was passed to establish a task force on standardized pharmacy technician education and training. She explained that this task force would assess and recommend revisions, if necessary, to the language in *the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy.*

Public Comment:

Bryce Docherty (California Society of Health-System Pharmacists) advised the board that CSHP had an internal stakeholder meeting with CPhA last week. He stated that there was consensus to look at the standardization of training. Mr. Docherty noted that progress was made at the last meeting, and that ultimately they will have a staff member of the board attend a committee meeting to share the information. He indicated that CSHP has a meeting scheduled in mid-October and CPhA will be having a meeting in mid-November. Mr. Docherty stated that they hope to have information to share by the end of the year.

Dawn Benton (CSHP) stated that, based on earlier stakeholder meetings, it was decided that it is important for CSHP and CPhA to be on the same page before engaging other stakeholders.

8. Veterinary Food-Animal Drug Retailers - Qualification Processes for Designated Representatives

Chairperson Ravnan provided background, explaining that veterinary food-animal drug retailers (vet retailers) may distribute and label legend drugs or drugs for extra-label use prescribed by a veterinarian for use on food-animals. She further explained that a vet retailer's premises must be supervised by a registered pharmacist or a specially qualified individual approved by the board who holds a current vet retailer designated representative license. Chairperson Ravnan also noted that a vet retailer may not operate unless the pharmacist or vet retailer designated representative is physically present on the licensed premises.

Chairperson Ravnan noted that there are currently 23 vet retailers and 62 vet retailer designated representatives licensed in California.

Chairperson Ravnan explained that only a vet retailer designated representative or pharmacist may label the drugs that: (1) have been prescribed by a veterinarian, and (2) will be shipped to the veterinarian's client for use on food-animals. If the sole qualifying vet retailer designated representative or pharmacist leaves the employ of the vet retailer, the vet retailer must cease operations (and cannot perform labeling or shipping duties) until another pharmacist or vet retailer designated representative is employed and present.

Chairperson Ravnan indicated that individuals employed by a manufacturer, vet retailer, or wholesaler may qualify to become vet retailer designated representatives on the basis of specific education, training, and experience in areas covering the essential knowledge necessary to oversee operations of a vet retailer and to read, label and dispense vet food-animal drugs.

Chairperson Ravnan stated that, in addition to the training required for designated representatives, designated representatives for vet retailers must also have either a course of training that includes as least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

- Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers
- Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian
- Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian
- Understanding of cautionary statements and withdrawal times
- Knowledge and understanding of information contained in package inserts

<u>OR</u>

- Possess a registration as a registered veterinary technician with the California Veterinary Medical Board

OR

- Be eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination

OR

- Have worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer designated representative. Part of the 1,500 hours of work experience shall include knowledge and understanding of information contained in package inserts. A vet retailer designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Chairperson Ravnan stated that the ability to read prescriptions and prepare and label containers for food animals without the oversight of a pharmacist requires specific training.

Chairperson Ravnan explained that, in the past, the University of California Davis had a 40-hour training course that satisfied the requirements for licensure as a vet retailer designated representative. Chairperson Ravnan stated, however, that the board received information that this program is no longer offered. She advised that the board staff is unaware of any other program in California that complies with the requirements in law.

Chairperson Ravnan stated that the board staff is requesting that the committee consider changes in the vet retailer program, specifically to either ask the Veterinarian Association or the Veterinarian Board to offer the 40-hour course, or to consider eliminating the program. Further, board staff is requesting that, given the nature of the work being performed by such individuals, the committee discuss if the requirements as framed in law are appropriate.

A copy of a letter from Greg Evans, PharmD, a Los Angeles Times article entitled, "Antibiotics in Our Livestock" , and a copy of Title 16, California Code of Regulations Section 1780.1 is contained within the committee packet provided.

Ms. Herold explained that the program has been with the board since 1998. She stated that it was set up in part because the US Department of Food and Agriculture requires a prescription when dispensing drugs to animals being used to produce food or are a food product. She further explained that, in the case of food-animals, the animals are considered property. Owners/ranchers provide drugs to a large amount of food-animals, and law states that they must have appropriately labeled containers on the premises. Ms. Herold stated that there is concern of less-than-adequate training provided to those who would be labeling the prescriptions.

Public Comment:

Dr. Michael Karle (California Veterinary Medical Association) provided background on the issue. He emphasized that that this is a consumer safety training issue, and

ultimately a food safety issue. He stated that CVMA has had two reports where drugs were mislabeled by vet retailers. Dr. Karle stated the current issues, which are:

- Selling drugs to clients without a valid prescription
- Not copying the indications onto the label
- Selling clients the wrong prescription drug
- Selling clients wrong quantities and refills
- Not placing prescription labels on over-the-counter drugs
- Selling more of the drug than prescribed
- Mishandling oral medications
- Not forwarding invoices appropriately
- Promoting drug use without consulting with the Veterinary Medical Association

Dr. Karle commended the board of pharmacy for discussion on the topic and pursuing site visits to the vet retailers. He noted that visits have not been done in past, and appreciates the boards attention to the issue. He stated that more will need to be done in order to raise the standards.

Dr. Karle commented on the board report, and stated that he doesn't think that eliminating the course requirements is the right action. In fact, he feels that even more education is needed by the vet retailers.

Chairperson Ravnan asked how many drugs are used in food-animals.

Dr. Karle responded that there are 40-50 prescription drugs. He noted that it is tightly regulated as to which drugs can be used and on which species.

Dr. Karle stated that there are several antibiotics that are available over-the-counter. He stated that all prescribed drugs must have a prescription from a licensed veterinarian. Dr. Karle indicated that part of the issue at hand is veterinarians are not good whistleblowers. CVMA is attempting to educate veterinarians on how to report the issue when they are aware of it, noting that there is no way that the Board of Pharmacy can take action unless a complaint is received.

Ms. Nurse stated that the veterinarians were unaware that they could report filling errors to the board. She noted the significance of the issue as the drugs are used in large amounts of food-animals and ultimately ends up in food consumed by the general public.

Ms. Herold stated that the board appreciates Dr. Karle's assistance in educating their staff of inspectors on the drugs used, appropriate laws, process for prescription fills, etc. within the veterinary food-animal arena.

Public discussion included possible solutions to the issue raised by Dr. Karle. Solutions discussed included:

- Implementation of a 40-hour course provided by CVMA
- Veterinarians labeling medications for the pharmacy
- Drugs dispensed by specific pharmacies properly trained on the use of such drugs on animals
- Restricting drug dispensing by vet retailers and requiring those drugs to be provided by veterinarians directly
- Continuing education for vet-retailers (it was noted that currently there is no option for continuing education coursework)
- Recertification of vet-retailers every 2-3 years

Ms. Herold stated the board understands the difficulty for veterinarians in reporting inappropriate dispensing by vet-retailer designated representatives. Ms. Herold clarified the issue of concern with allowing a group of individuals with little training to read prescriptions, label containers, and dispense drugs into the food supply. She added that the individuals working within the facilities are often less than properly trained.

Public discussion continued regarding the issues surrounding vet-retailer designated representatives, enforcement issues and what role other regulatory agencies play in protecting food-animals.

Ms. Herold stated that this is a program in which the Board of Pharmacy is not prepared to adequately monitor and administer, and that the professionals working in this area need to be properly educated and skilled. She noted that there is a need to expedite action on the issue as many retailers are not able to access the needed training at this point.

Dr. Gray suggested contacting Western University, as they have a veterinary program as well. He stated that they also have a relationship with Cal Poly Pomona, which is a multi-disciplinary campus and may have some contacts to consult and assist with developing a solution.

Ms. Herold commented on the possible change to require recertification of a vet-retailer or continuing education as a possible solution and stated it would be a statutory change, but agreed that it could be a possible option. She clarified, however, that it would be very difficult for the Board of Pharmacy to justify the additional regulation. She stressed the importance of providing the board with complaints, so that there is evidence of the need for such requirements and legislation.

Ms. Herold stated that the board would be willing to assist the CVMA in exploring the options discussed. She added that CVMA may be able to get demand simply by having the course available.

9. Continuing Education for Competency Committee Members

Chairperson Ravnan explained that the Competency Committee is a subcommittee of the board's Licensing Committee. She further explained that the Competency

Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). She also noted that a committee member term is generally about eight years.

Chairperson Ravnan indicated that annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. She stated that each two-day committee consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Chairperson Ravnan explained that committee members also participate in 2-4 writing assignments based on the examination development need. She added that committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments, and noted that they are compensated for time and travel.

Chairperson Ravnan stated that current pharmacy law requires pharmacists to earn 30 hours of approved continuing education (CE) every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Chairperson Ravnan reported that in June 2008, the Licensing Committee considered a request from the Competency Committee to earn 6 hours of CE annually for participation in this committee. She advised that the Licensing Committee decided to request additional information on this topic and did not take action.

Chairperson Ravnan said that, based on further discussion with the Competency Committee during its annual retreat, the committee is revising and resubmitting its request. Specifically, one of the core functions of this committee is to complete on-line review of all test questions prior to administration. Chairperson Ravnan explained that, as the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that questions and answers are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically committee members are not compensated for their time to complete this function. If a committee

member is seeking reimbursement for this time however, continuing education will not be awarded.)

Chairperson Ravnan indicated that if the committee and board vote to approve this request, a regulation change will be necessary to implement the change.

Ms. Schieldge clarified that this would apply to those who do not seek monetary compensation.

The committee discussed the total actual hours involved in completing the on-line review, including the ability to monitor completion of those hours.

MOTION: To recommend to the board to award six hours of continuing education to Competency Committee members, no more than annually, to complete the on-line review of all test questions prior to administration.

MOTION: SW/JB

SUPPORT: 5 OPPOSE: 0

10. Competency Committee Report

a) Update of the CPJE

Chairperson Ravnan reported that since the June 2008 Licensing Committee Meeting, the Competency Committee as a whole held its annual meeting to discuss examination development as well as other emerging issues.

Chairperson Ravnan stated that each Competency Committee workgroup was scheduled to meet this fall, however the meeting scheduled in September was cancelled because of the Governor's Executive Order. She indicated that a meeting is also scheduled in October and board staff is hopeful that this meeting will continue on as planned. She noted that the workgroup meetings focus primarily on examination development.

Chairperson Ravnan advised that the board anticipates the completion of the current Quality Assurance assessment.

b) Report To The Legislature On The Impact Of Requiring Foreign Graduates To Take Remedial Education After Failing The Pharmacist Licensure Examinations Four Times

Chairperson Ravnan reported that Business and Professions Code 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.

Chairperson Ravnan stated that 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.

The draft report was contained within the committee packet provided. Chairperson Ravnan advised that this report is due to the legislature on September 30, 2008.

Ms. Herold commented that the data reflects a benefit to retaking the exam.

11. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Mr. Hough commended Ms. Herold and Ms. Sodergren for their efforts during the budget restraints, specifically in the area of licensing.

No public comment was provided.

The meeting was adjourned at 12:07 p.m.