California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE
MINUTES

DATE: June 23, 2008

LOCATION: Department of Consumer Affairs
El Dorado Meeting Room
1625 North Market Boulevard, Suite N220
Sacramento, CA 95834

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

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer

Chairperson Ravnan called the meeting to order at 1:00 p.m.

Request for Board Recognition of Schools of Pharmacy (16 CCR §1719) for School with Accreditation Council for Pharmacy Education (ACPE) Precandidate Status

- **Sullivan University, College of Pharmacy**
- **California Northstate College of Pharmacy**

Virginia Herold noted that the board can only act on one of the two requests.

Chairperson Ravnan indicated that the Sullivan University College of Pharmacy was granted pre-candidate status by ACPE in January of 2008, to admit their first class in July of this year. They are in the middle of their 2008-2009 review period for advancement to candidate status. The letter from Sullivan University requesting board recognition was provided in the committee packet prior to the meeting.

Chairperson Ravnan advised the committee, that California Northstate College of Pharmacy also submitted a request for board recognition, however, unlike Sullivan

University, California Northstate College still under consideration for pre-candidate status. At the time of the committee meeting, the board was not yet advised if this status was granted. As such, no committee action could be taken on California Northstate's request, rather it was a discussion item only.

Executive Officer Herold detailed the reason for these letter requesting board recognition. Specifically a school must be accredited by the American Council on Pharmaceutical Education (ACPE) under California Law in order for the student to receive an intern card. If the school is not accredited, ACPE approved candidate status will be accepted. In the case of these two schools, neither has received candidate status at this point. Pre-candidate status is granted to allow a college to enroll their first class.

The board has contacted ACPE and has confirmed that Sullivan University is moving appropriately in the process towards candidate status. Board staff is recommending that the committee recommend to the full board approval of the Sullivan University's request, thereby granting the ability of its student to apply for an obtain intern cards.

Bob Graul asked if this is typical to do for out-of-state schools. Ms. Herold answered that it is, because many of their students may be California residents, thus allows them to pursue internships when they return.

Lorie Rice (UCSF, School of Pharmacy) asked why the approval is a recommendation only. Ms. Herold explained that it must be approved by the full board, so the committee is deciding today on whether to recommend to the Board to act on this.

Ms. Rice asked if Sullivan has a campus in California. Ms. Herold indicated that they do not, but many students may be California residents.

Ms. Herold noted that, in the case of Northstate, they are still working with ACPE to obtain pre-candidate status. That decision should be made sometime this week, but the board does not have that information.

Ms. Rice asked if Northstate will have a campus in California and when the first students will be enrolled.

Ms. Herold responded that the campus will be in California and that students will be enrolled for the Fall of 2008 semester. Consideration for intern cards can be approved by the board at the next board meeting if appropriate.

MOTION: To recommend board recognition of Sullivan University to allow students the ability to obtain intern cards so that they may earn intern hours towards licensure.

M/S: BG/SW

SUPPORT: 4 OPPOSE: 0

Discussion of Licensure of Ambulatory Surgical Clinics by the Department of Public Health under Health and Safety Code §1204 that are Owned by Physicians

Chairperson Ravnan referred to an attachment provided in the committee packet, a letter from the California Ambulatory Surgery Association (CASA) requesting guidance from the board to rectify regulatory consequences from *Capen v. Shewry (2007) Cal. App 4th 378* (Capen Decision) as it relates to the board's ability to issue clinic permits to ambulatory surgical clinics.

Chairperson Ravnan explained that current law allows the board to issue a clinic license only to an entity also licensed by the Department of Public Health (DPH). The Capen Decision determined that DPH does not have jurisdiction over surgical clinics owned in part, or wholly by a physician. The ramifications of this decision is that DPH can no longer issue surgical clinic licenses to such entities, nor can such current licenses be renewed. The Capen Decision determined that regulation of such clinics falls under the purview of the Medical Board. Without a license from DPH, the board is unable to issue a clinic license to allow such clinics to purchase drugs at wholesale as well as commingle medications. Without the board issued license each prescriber must maintain a separate drug supply or the drug supply must be wholly owned by the professional director or some single prescriber.

CASA has pursued legislation that would have, among other things, expanded the board's authority to issue a clinic license to those surgical clinics that were operating either under a DPH issued license or are accredited by an approved agency or are Medicare certified. The board has consistently had a support position on such legislation.

Anne Sodergren introduced Bryce Docherty who represents CASA.

Mr. Graul asked if this is referring to the Plescia bill.

Ms. Sodergren confirmed that it is.

Mr. Docherty stated that he is the lobbyist for CASA. He indicated that they have been pursuing licensure of ambulatory surgery centers for the last three years, which the board has supported. CASA felt that is was important to clarify and expand those settings that would fall under the purview of the Board of Pharmacy for the purposes of drugs that are being dispensed and utilized in a non-inpatient environment. Their first two pursuits were vetoed by the Government, but not because of the drug dispensing aspect. These bills were vetoed because of the piece that spoke to the DPH authority to license ambulatory surgical centers. He noted that right now state licensure by the DPH to operate as a surgical clinic is permissive and not mandatory. Mr. Docherty explained that there are two legislative pursuits involved. The first is the surgical center piece, where they are trying to standardize the licensure criteria for surgical centers, as

there is currently none within the state law. In regards to the pharmacy aspect, CASA has been asking for the Board of Pharmacy's authority to issue a license to a surgical center, including those who are accredited by one of the four accrediting bodies approved by the Medical board, as well as those who are Medicare certified. Mr. Docherty noted the recent court ruling on Sept. 19th (Capen vs. Shewry) that determined that the Department of Public Health (DPH) has no jurisdiction over the licensure od surgical clinics in the state if they have some form of physician ownership. Mr. Docherty explained that the purpose of the letter submitted was to seek clarification from the board on the following:

- What are centers going to do if they want to seek a license from the board and they are no longer eligible for licensure?
- What are we going to do with those surgical clinics who have been licensed and who have obtained the clinic license from the board but are no longer eligible for licensure based on this recent court decision.

Mr. Docherty stated that currently the DPH is not renewing those licenses. He also noted that it is not only a requirement for the board issued clinic permit, but also a requirement in order to see Medi-Cal patients and for third party reimbursement.

Mr. Docherty explained that the letter was also submitted to advise the Licensing Committee that CASA is pursuing the current pharmacy-related portion of the bill AB 1574. The bill will be heard in Senate Health on June 25th. They are guardedly optimistic and are requesting support from the board.

Ms. Herold clarified that, by law, the board cannot issue a new permit, and can only renew a clinic that is already licensed with us.

Stan Weisser asked if there are many clinics affected by this issue. Mr. Docherty indicated that it is affecting many clinics.

Mr. Graul asked for clarification that AB 1574 is only addressing the pharmacy portion of the prior bill, and was concerned that the board would be issuing permits to unlicensed facilities.

Mr. Docherty explained that the board issued clinic permits is only currently to a DPH state-licensed surgical clinic, and they are attempting to gain obtain authority so that the board can provide clinic permits to those who are accredited by one of the four accrediting agencies or Medicare certified in lieu of being state licensed with DPH.

Steve Gray (Kaiser Permanente) asked how many accredited and/or Medicare certified clinics there are.

Mr. Docherty explained that it is unknown at this time.

Mr. Docherty stated that some accredited and Medicare certified ambulatory surgical clinics are wholly physician-owned entities and their clinics are regulated by their medical license.

Mr. Graul clarified whether the bill would make it mandatory for the surgical clinics to gain permits. Mr. Docherty stated that they would not.

Mr. Docherty stated that CASA is looking for an official response from the board on how the Capen decision will affect board issued clinics.

Ms. Herold stated that those currently licensed would not lose their ability to renew their permit, as we do not have grounds to remove them. She reiterated that we cannot address the issue of licenses for new clinics until there is a legislative fix.

Mr. Docherty requested written confirmation that the board will continue to renew the clinic permits.

Ms. Herold stated that the clinics are already aware of this, and that anyone with questions or issues can contact her.

Peter Kellison (Surgical Care Affiliates) stated that it is a very complicated environment and appreciates the board's support.

Ms. Herold noted that a clinic will still be able to operate regardless of the board's decision or ability to address the permit issue, and that it is simply a bit more complicated with physicians bringing in their own pharmaceuticals. It was noted that the item would be placed on the agenda for the July board meeting.

Dr. Gray asked when the permits of the surgical clinics expire.

Ms. Herold and Ms. Sodergren explained that the permits are renewed on a cyclical basis.

Dr. Gray pointed out that the Board of Pharmacy permit also entitles a clinic to obtain a separate DEA registration number, DEA forms, etc. Without that, it causes issues at a federal level as well. He also noted that a separate DEA registration is required for every facility where the drugs are stored, causing even more complication. Dr. Gray asked Mr. Docherty who will be issued the board-issued clinic license.

Mr. Docherty stated that the permit would be issued to the clinic, based on the ownership structure.

Discussion with the California Pharmacists Association and California Society of Health-Systems Pharmacists on a Task Force to Evaluate Pharmacy Technician Qualifications

Dr. Ravnan reported that this year the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licenses in California as a pharmacy technician. This bill was pulled due to concerns vetted by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

CSHP will be sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. The first stakeholder meeting is scheduled for June 25, 2008. Board staff will attend the meeting and report to the board at the July board meeting.

Mr. Docherty (representing CSHP) provided comments to the board on the topic. He stated that CSHP currently sees this as their "top" legislation priority. He indicated that there are approximately 50,000 licensed pharmacy technicians, and that the amount of licenses being issued is increasing rapidly. They feel that the requirements to obtain a technician license need to be strengthened. CSHP had proposed a bill that would require a pharmacy technician to pass the Pharmacy Technician Certification Board (PTCB) exam or other exam that is psychometrically sound, rather than it being one of four options as is the current law in order to obtain a license. The bill would also establish the requirement of 20 units of continuing education every two years for pharmacy technicians. Mr. Docherty stated that CSHP wants to ensure that pharmacy technicians are maintaining competency. CSHP also wants to ensure the bill encompasses all "houses" of pharmacy as well. CSHP is having their first stakeholder meeting on June 25th for further discussion. Mr. Docherty thanked the board for their involvement of the bill and indicated that CSHP is requesting the board to co-sponsor the bill next year.

Mr. Graul asked who is participating in the stakeholder meetings. Mr. Docherty indicated that it includes CSHP, CPHA, Kaiser, California Retailers Association (CRA), United Food and Commercial Workers Union, as well as anyone else who would like to attend. Assembly Member Bill Emmerson is sponsoring the bill and requested the meeting be held at the capitol so that he could be present for its first meeting.

Mr. Graul asked who is participating from the board.

Ms. Herold indicated that Ms. Sodergren would be attending, as Ms. Herold is unavailable.

Mr. Graul and Mr. Weisser both noted that they would be unable to attend the first meeting, but would like to be kept updated on the progress.

Chairperson Ravnan asked if work experience was discussed as part of the legislative proposal, since competency and technical skills are best obtained through repetition and hands-on work experience.

Mr. Docherty stated that there are numerous issues that need to be addressed related to standardized education and training, however their focus right now is on the licensing requirements as discussed.

Mr. Graul asked if there is still a shortage of pharmacy technicians in the state. Mr. Docherty indicated that there is a shortage of pharmacists, but was unsure if there is still a shortage of technicians.

Hank Hough shared an example of a case in Florida where a death resulted from pharmacy technician error. He stressed how this highlighted the needs for continuing education, as the consequences can be disastrous.

Ms. Rice asked what prompted the need for a bill. She also stated that studies have shown that continuing education does not necessarily enhance a technician's performance, and that work experience rather creates increased competency. She stated that required continuing education only increases the profits of the provider of the continuing education, and stressed that the board place serious consideration over the need for such standardized requirements before putting such requirements in place for technicians who make considerably less money than pharmacists. She stated that the bottom line on continuing education is that it is a good way of having a discussion amongst your peers, but she has yet to see anything that shows conclusively that continuing education increases and enhances performance. She feels that it shouldn't be something that is put in place simply because everyone else is doing it. She noted that this opinion is her own, and not necessarily that of UCSF.

Ms. Herold responded that the board did not take a position on the issue in one direction or the other.

Mr. Docherty provided a response to address the issue. He explained that CSHP and CPhA represent a fair amount of pharmacy technicians and that there was a lot of discussion from the technicians themselves regarding education. He pointed out that the technician involved in the Florida case was someone who did not pass the PTCB and was awaiting another opportunity to take the exam when the incident occurred. He noted an incident in Ohio, as well as the incident at Cedars-Sinai involving the Quaid twins, and the procedures neglected and errors made by the technicians involved. In terms of continuing education, it is a need for CSHP to "get ahead of a curve" in case something else like this should happen in California.
Ms. Rice responded with her concern over pharmacy technicians being trained or supervised by other pharmacy technicians, and questions the involvement and responsibility of the pharmacist.

Mr. Docherty responded that those comments speak to the need for the bill as well, as pharmacists need to be able to place more responsibility on the technicians and know that there is a certain level of competency there as well, rather than trusting on one of the four requirement options having been completed.

Ms. Rice responded by requesting that CSHP look at the literature regarding continuing education.

Dr. Steve Gray stated that CPhA is also concerned about the issue discussed and lack of competency requirements of technicians at this time. They do not find any evidence to support that passing the PTCB improves performance, and that there may be better ways to ensure performance. He also suggested to the board to look at the ratios as well as the varying environments technicians are employed in and how they are supervised. Dr. Gray suggested the consideration of having different types of technicians and/or how the technicians are utilized within the various entities and work environments they are employed in. He also brought up the issue of a lack of minimum age requirements with regard to technicians, including the fact that background checks cannot be conducted when technicians are under the age of 18, which often includes minors who have dropped out of high school for various reasons that are unknown. Dr. Gray also discussed technicians being utilized outside of pharmacy settings.

Mr. Weisser discussed the interaction between technicians and customers, and that enhanced education would be a benefit to the pharmacies as a whole. He stressed that he can only see benefits to providing the need for those technicians to gain the continuing education that they may not otherwise have and enhance their performance with relation to customer interaction.

Ms. Rice responded that the technicians that voluntarily pursue continued education are the ones who want to learn and will succeed in their education, and that those who are forced to attend continued education will not necessarily see the benefit and take advantage of it.

Heidi Barsuglia (CRA) stated that they are attending the stakeholders meeting. She pointed out the differing views on this proposal, and stated that it is premature for the committee to recommend to the board to co-sponsor this legislation until we see what the legislation may look like.

Ms. Herold advised the board not to pursue sponsorship at this time, as it is premature. She stated that the board should wait for the stakeholders to work out the details of the proporsal. She pointed out that she felt it was a wise decision by the author to pull the bill back.

“Cookie” Quandt (Long’s Drugs) stated that there is a shortage of technicians, especially in very rural areas. She also commented on the technician schools mentioned by Dr. Gray. She stated that they have not had success in gaining

technicians from those schools, as they are often high school drop-outs and end up with drug diversion incidents within their pharmacies when employed.

Mr. Weisser asked if their program has an ongoing education program for their technicians.

Ms. Quandt stated that it involved classroom training as well as on-going training provided by pharmacy managers. There are also manual requirements, which the technicians must review on an annual basis. She concluded by saying that training is required before they go into the pharmacy in order to understand the requirements.

Mr. Graul indicated that he agrees with the continuing education (CE) proposal, but wants to study the details of the proposal further before having an opinion. He did note that if there is a formalized CE requirement, it generates more technician centered CE, which there isn't much of right now. He added that as a consumer protection agency, the board should look at the quality of technicians and assist the legislature in coming up with some requirements that ensure the quality of technicians in California is superior.

Mr. Weisser agreed with the comments given by Mr. Graul.

Bill Young (Alameda County Pharmacists Association) provided feedback from local pharmacy owners and managers. He stated that that there does not appear to be a shortage of licensed pharmacy technicians looking for employment, however there is a shortage of qualified, promising technicians that pharmacists want to hire.

The board has no recommendation on the proposal at this time. Two members of the committee would like to be a part of the task force. Ms. Herold commented on the need for numerous meetings to work through the details of the bill and address the concerns by all stakeholders. Mr. Docherty stated that they would have as many meetings as needed in order to exhaust all the issues.

Discussion to Amend 16 CCR Section 1728 to Increase the Number of Intern Hours that Can Be Earned Outside of a Pharmacy

Dr. Ravnan stated that 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 if 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) that 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 firs the board's mission.

Discussion at the December 2006 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 pharmacist 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 establish core competency assessment 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.

As the development of these core competencies were completed, President Schell requested that the Licensing Committee revisit the request to amend the intern hours requirement.

President Schell commented that this issue that was brought to him from a student at Loma Linda University practicing at an ambulatory care pharmacy site, and was told his hours would not be included because he was not practicing at a licensed pharmacy as the law requires. President Schell pointed out that he has not necessarily been in support of this concept in the past because he does not feel intern hours should be included from certain entities such as manufacturers, etc. The example provided of this student, however, where someone is under the supervision of a licensed pharmacist, seems

appropriate. He highlighted that pharmacists no longer have to be working in a licensed pharmacy in order to practice pharmacy, and that the board should alter the intern hour requirements to match what we've done with licensed pharmacists and allow students to obtain those types of experiences.

Ms. Herold asked how the board would be able to determine whether someone's experience in a non-pharmacy is substantially related to the practice of pharmacy. She gave examples of recent inquiries of pharmacologists requesting intern hours for preparing lectures for students in the area of pharmaceutical education. In that situation, that would be within the board's discretion, but they are not working within a pharmacy or in the direct supervision of a pharmacist. She stated that a lot of these will become "line calls" for the board and that, without clear regulations, would become difficult to decide upon fairly and consistently. Ms. Herold noted that the board does their due diligence with regard to acquired intern hours and proper authorized signature of licensed pharmacists for those hours, but they also accept the out-of-state intern hours with no knowledge of where they were truly obtained.

President Schell remarked on the protocol from the past, which was to require affidavits indicating specific activities that must be completed by the intern in order for the pharmacy supervisor to approve, and encouraged the board to consider revisiting the need for those again so that the board had clear guidance on what was required for the legitimacy of intern hours. President Schell felt that there are ways to work around the situation and find solutions, and to not allow intern hours to work in environments such as ambulatory surgical clinics could create disparity in what should be considered an important pharmaceutical education.

Dr. Gray stated that Kaiser has had a lot of discussion around this subject over the last few years. Kaiser feels that the board needs to consider recharacterizing what it means by "under the supervision of a pharmacist" and what type of practice of pharmacy should be included. He noted that also means the board would need to know what to exclude in that definition process, which is not always an easy or painless thing to do. He gave examples of where and how the 900 versus 600 intern hours could be accumulated and "right versus wrong" ways to gain those hours. Dr. Gray stated that they have found that too many of their graduates are not ready to become dispensing pharmacists when they leave school. Due to the pharmacist shortage and the economy, Kaiser often sees the new graduates working alone and during late evening hours, without the proper supervision and mentoring opportunities that they need. They are now implementing their own intern rotation process within Kaiser, allowing them a more complete experience over two to three years during their internship.

Ms. Rice stated that the board should include the new American Council on Pharmaceutical Education (ACPE) requirement of an additional 300 hours of Introductory Pharmacy Practice Experience (IPPE) into the continued discussion and regulation as well. She also agreed with Dr. Gray's comments regarding flexibility in the regulations. She pointed out that a student can graduate with six weeks in a community

setting, and that we should take thorough consideration with regards to lowering that requirement.

Mr. Weisser reiterated that it is critical that they have experience in working with the patients.

Chairperson Ravnan discussed her thoughts with the 900 hours and stated that she does not feel that it is too much time to require. She pointed out that there are advantages for students to be working directly with patients and using their cognitive skills, as well as the unique experience within the practice of pharmacy of which they can learn from other professionals. She stated that she would hate to see them lose the opportunity to gain those skills as well as skills assessments.

Mr. Graul asked if the 300 hours of IPPE is within the first year. It was clarified that it is within the first two years, and that they would have their intern license by then. Mr. Graul asked if the 300 hours could be used for the 1500 hours.

Ms. Rice clarified that they cannot be paid for the 300 hours, whereas the 1500 hours of intern hours are paid.

Mr. Graul asked how difficult it is for the intern to obtain their 1500 hour requirements.

Chairperson Ravnan asked for clarification on the 900 hours and if they are non-paid. It is not clarified within the law. It is concluded that the school can thus approve the hours if they were earned in early experience in a pharmacy. An affidavit would be required, signed by the pharmacy in which they earned the hours.

Dr. Gray discussed the wording of a form in the past with reference to the phrase “employed”, which gave the impression that the hours then needed to be paid. Clarification has been provided by the board since then, indicating that the hours do not need to be paid hours. There has been argument by ACPE on whether it is appropriate to be paid for their IPPE hours, but legal action has been taken by them on a school of pharmacy.

Ms. Herold pointed that there is a cap in the pharmacy law that you can only issue the intern permit for six years, but the board is seeing some candidates entering in with programs that are longer than six years.

Mr. Weisser stated that the introduction of pharmacy practice experience does not involved students with patients and isn’t sure it’s very experiential.

Ms. Rice stated that it depends on the environment and type of training the student has had. She reiterated that it is still a burden for the first and second year students.

Bob Ratcliff made the comment that it doesn’t seem to make sense to have the students put so much effort into earning up the 900 experiential hours, and not focus on the 600

hours offered by the school. Mr. Ratcliff suggested to place more ownership on the school to incorporate the training they feel is needed for more well rounded students within the 600 hours the school provides. He stated that part of the issue for the graduates coming out of school is that they haven't worked long enough in drug distribution in order to understand all the nuances that are involved.

Chairperson Ravnan added that when she was teaching, her students did a regulatory rotation and received credit for that towards their 600 school hours, pointing out that the schools do in fact have that discretion to offer such electives.

Mr. Graul commented on the possibility of increasing the hours to an additional 400 hours as previously suggested.

Ms. Rice raised the issue of the additional 300 hours for IPPE as discussed prior.

Chairperson Ravnan pointed out that the 300 hours can be included in the 400 total, and can be paid or unpaid. She clarified that it would not be an additional 700 hours, but only 100.

Dr. Gray stated that the board should be cognizant of the changes at the national level. He said that there are discussions involving mandatory one-year of post-graduate residency being required by law. He questioned whether the required hours in place today are enough for the board to grant a license and allow students to go to work in pharmacies. He stated that he would rather see a student earning their 600 hours in an environment working side-by-side with a pharmacist in a critical care setting.

Mr. Graul responded that it comes down to a balance between a student getting a lot of patient care experience in a non-traditional environment, yet still needing the experience to handle the setting of being alone after-hours in a dispensing pharmacy setting.

Dr. Gray clarified that he is still in favor of the 900 hours in a dispensing pharmacy setting. He doesn't feel that those 900 (or even 1500) hours in a dispensing pharmacy (only) may not be enough to prepare them.

It was clarified that Dr. Gray is in favor of increasing the intern hours requirement or ensuring that the current hours are obtained in appropriate settings that allow for well-rounded experience and competency needed.

Ms. Herold stated that the discussion could go to the board with or without a recommendation.

Ms. Rice reiterated that the board should be monitoring the activity and decisions at the national level before moving forward.

Mr. Burgard stated that it is unenforceable as the law reads now. He shared his concern over the lack of specifics with how interns are required to gain their hours.

Ms. Weisser suggested that we take no action at this time and look to the direction of the board and chair for further input.

MOTION: Table any action at this time to alter the intern hours requirement.

M/S: JB/HH

APPROVE: 4 OPPOSE: 0

Discussion of the Ability for Pharmacy Applicants to Pursue Board Licensure Concurrent with Department of Health Care Services (DHCS) Provider Recognition and Drug Enforcement Administration (DEA) Registration

Christine Soto provided a presentation on the subject by outlining the application process and discussing how applicants can file applications with other agencies simultaneously.

Ms. Soto provided the board Web site and explained that applicants download a pharmacy application at the site. She indicated that applicants should copy their application and include it with concurrent applications submitted to the Department of Health Care Services (DHCS) and Drug Enforcement Administration (DEA) demonstrating that the entity is also seeking board licensure. This will allow applications to be processed concurrently by all three agencies in order to minimize impact and avoid delays.

Ms. Soto reviewed the licensing application process, including the time frame for each stage of the process. She made note of the reasons for delay in some applications, which can be due to deficiencies in the application, research of an applicant's criminal history, etc.

Ms. Sodergren added background on the reason for the topic as an agenda item for discussion. She explained that there has been some concern by some applicants because they are unable to get their DEA registration number or Medi-Cal provider number from the DHCS until they are licensed by the Board of Pharmacy. It was brought to the board to have the Licensing Committee and board staff review the current process and determine the reason for the delay for some applicants versus others. The recommendation by the licensing staff is for applicants to provide a copy of the application submitted to the board when submitting their applications to DHCS and DEA. The DHCS and DEA will to process their registration number and provider number applications with the knowledge that a license is being sought by the Board of Pharmacy as well. However, it is important to note that the DHCS and DEA will still wait to provide the numbers until the license is approved by the Board of Pharmacy. Applying concurrently to all three agencies, however, will help to avoid delays with DEA and DHCS.

Ms. Herold explained that this is very routine but found that some entities were unaware of the process and ability to apply concurrently. She stated that the board would include this information in a future Script newsletter.

Mr. Graul asked if this information is included in the FAQ section of the website. Ms. Soto stated that it is not, but should be included.

There was brief discussion on pre-opening inspections conducted prior to licenses, registration and provider numbers in place.

Ms. Soto stated that the licensing department does make efforts to assist applicants who experience delays in the process by contacting DHCS and DEA as needed.

Dr. Gray suggested that the board include information in the newsletter and FAQ website section indicating that you cannot obtain your NPI number at the same time.

Status Report to the Committee on Continuing Education Audits

Chairperson Ravnan indicated the Business and Professions Code section 4231 requires that the board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has completed 30 hours of approved continuing education during the two years preceding the application for renewal. This section also exempts this requirement for the first renewal of a pharmacist license. Effective in 2006, this section was amended to state that the board would not renew a license if proof is not provided and instead requires the board to issue an inactive pharmacist license.

Since 2006, the board has used its enforcement discretion and has not fully implemented this requirement. Rather, the board is randomly conducting continuing education audits on a monthly basis. Over the last year, these audits have revealed that approximately 12% of pharmacists audited provide false information on their renewal. As a result, the board completes an investigation substantiating the violation and a citation and fine is issued.

In addition to these audits, the board sends an average of 20–25 letters to pharmacists monthly who fail to certify the completion of the required continuing education. Because of delays in the programming changes necessary to fully implement the changes made to these requirements in 2006, the board has been handling much of this process manually. Board staff continues to advocate for the necessary programming changes required to the system. Absent the programming changes, board staff will begin to manually issue inactive pharmacist licenses to those individuals who fail to provide proof of their continuing education as required.

Ms. Herold explained that CE audits have been consistently conducted over the last year based on pharmacist license renewals. The audits are done at least six months

after the renewal period, to avoid confusion about when the audit was completed. Cite and fines are issued to those who are unable to provide proof of completing their CE. Ms. Herold pointed out that 12% non-compliance is about half of the prior years' audit. The prior audit of 2005-2007 conducted reflected 33% non-compliance. She noted that the law allows the board to change their pharmacist license to inactive if compliance of CE cannot be proven. Ms. Herold is advising pharmacists that the board will be diligently taking action as is appropriate on those non-compliant pharmacists.

Ms. Sodergren noted that, in addition to the audit process, the board would send a notice when CE has not been included on the renewal application. If a notice is sent, and the pharmacist does not respond with documented proof, the pharmacist will be changed to inactive status.

Mr. Weisser asked how a pharmacist could then be removed from inactive status.

Ms. Herold responded that the pharmacist would need to pay the fine and then provide proof of 30 hours of CE since the time of the last renewal.

Mr. Weisser asked about pharmacists that do not have their full CE completed.

Ms. Herold responded that the board wants the pharmacists in compliance, but that there will be a consequence.

Mr. Weisser asked why pharmacists are not required to send copies of their CE completion to the board. Ms. Herold responded that the paperwork would be overwhelming for the board and staff, and would require an increase in fees to accommodate the paper overload.

Ms. Quandt asked for clarification that the board audits 20-25 pharmacists at least six months after their renewal. She confirmed that it is only 1% of the total pharmacists.

Ms. Herold agreed that it is extremely low, but that it is just enough to keep the pharmacists alert.

Ms. Quandt asked about advice for those pharmacists who failed to sign the affidavit indicating that they have completed their CE and want to be able to renew as soon as possible.

Ms. Herold responded that the pharmacists should download the renewal form on the Web site and be sure to sign the statement under penalty of perjury that they have in fact completed their 30 units of CE. She indicated that they should also include their documented proof of CE as well, as it will ultimately be requested.

Ms. Quandt asked if it is appropriate to recommend to the pharmacists in this situation to go to the board office to submit their documents.

Ms. Herold indicated that it would be appropriate as well, but that the documents may or may not be reviewed immediately at that time.

Discussion also included the specifics of how a pharmacist can verify the status of their records in relation to their CE, as well as how an employer can determine whether a license has been cleared by viewing the board website.

Ms. Herold reiterated the importance of making sure all pharmacists are earning their CE.

Dr. Gray asked for clarification regarding whether a pharmacist is employable when inadequate CE is indicated.

Ms. Sodergren provided an explanation, indicating that the CE inadequate status occurs when it is time for the pharmacist to renew their license. The license could be changed to an inactive state if the pharmacist fails to submit continuing education are required.

Dr. Gray asked about the situation where a pharmacist is renewed and is later audited. He asked what action is taken if it is determined that the pharmacist does not have adequate CE completed.

Ms. Herold stated that the board would issue a notice to the pharmacist of the shortage in CE and provide 30 days for the pharmacist to complete their missing CE hours, as well as provide proof of the completed hours. A fine will also be issued for non-compliance.

Ms. Sodergren added that SB 1779 does allow the board to change a pharmacist's license to inactive if they are found to be non-compliant of CE hours at the time of an audit.

Ms. Herold added that there would still be a notification process prior to any action taken. She reiterated again that the focus is to get the pharmacist in compliance and completing their CE hours.

Dr. Gray asked for clarification that a pharmacist may complete their deficient hours during the 30-day allotted period.

Ms. Herold confirmed.

Ms. Sodergren noted that those hours, however, cannot be counted for the current renewal period, and would only apply to the prior renewal period where the hours were missing.

Ms. Quandt raised the concern over needing to monitor the pharmacist's license status on a monthly basis in order to verify any pharmacists that may have been converted to inactive status due to inadequate CE.

Ms. Herold noted that it may be a disciplinary action for the employer.

Ms. Sodergren indicated that this is the case for any pharmacy and that a pharmacist can voluntarily make changes to affect their pharmacist license as well. She noted that the pharmacist license status on the Web site is only a snapshot in time.

Quality Assurance Review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Ravnan stated that during the public comment portion of the April 2008 board meeting, the board heard comments from Jennifer DeLany regarding the board's Quality Assurance (QA) review of the California Practice Standards and Jurisprudent Examination for Pharmacists (CPJE). Counsel advised the board that no action could be taken during that meeting and as such the board decided to place this discussion on a future agenda to allow for board discussion. As this matter is related directly to licensing, it is being brought before the Licensing Committee for discussion.

The board contracts with a psychometric firm who provides the board with expert guidance on the appropriate administration and scoring of the CPJE, including quality assurance assessments. The contractor determines the criteria that need to be met in evaluating the examination's performance before candidate scores are reported. Board staff recognizes the consequences that such reviews have on candidates that work closely with the contractor to release scores as soon as possible.

The CPJE is an essential function of the board's licensing program and decisions are not done arbitrarily or capriciously but with deliberate care and with consultation from experts in the field of exam review, testing and validation.

Ms. Herold added that the exam vendor determines when the board can release the exam scores. This is done to protect the integrity of the exam process. It is also done because the exam consultant is responsible for defending the validation of the exam in the case of a lawsuit.

Dr. Gray asked when the results of the exams were released from the most recent QA period.

Ms. Herold responded that the results were released by June 3, 2008.

Mr. Graul asked how often the QA period occurs.

Ms. Herold indicated it is typically done about three or four times per year, but not necessarily quarterly.

Mr. Graul asked about the time delay involved.

Ms. Herold says it is typically conducted until 400 applicants have completed the exam, but that the board allows the vendor to determine the time it feels necessary to complete the validity. It was noted that during the "off season" where less applicants are taking the exam, the QA period might take longer.

Bill Young (Kaiser Permanente) indicated that students are highly anxious when their test results are held for the extended period, and asked if it is possible to work with the vendor to allow for advance notice of the QA period for the consideration of the students.

Ms. Herold noted a similar incident last year when the board was changing exam vendors. The students were advised of the vendor change, which resulted in a "rush" of students trying to take the exam before the vendor change. This caused a major reduction in exams being taken after the vendor change, thus delaying the next QA period even more. Ms. Herold stressed the negative effects of providing forewarning of a QA, including a significant shift in students being willing to take the exam.

President Schell reminded everyone that, prior to 2004, the board could only offer exams twice a year.

Ms. Herold stated that the board is sympathetic to the anxiety and stress of the students. The board however, needs to ensure that, with public protection as the core, the exam is a valid assessment of whether or not each pharmacist applicant is minimally competent.

Competency Committee Report

Chairperson Ravnan stated that the Competency Committee has had regular meetings, and has provided a proposal to the Licensing Committee.

Request to Grant Continuing Education Credits for Participation on the Competency Committee

Chairperson Ravnan noted that the Competency Committee is a subcommittee of the board's Licensing Committee. 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). A committee member term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day committee meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination

development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments.

The Competency Committee requests board approval of six hours of CE earned annually for Competency Committee member participation.

A comment was included that a regulation change will be necessary to allow the board to award the CE should it approve this request.

Chairperson Ravnan noted that she was a member of the competency committee prior to joining the board. She indicated that it was a grueling task at times, and although there was compensation for the duties, it was a humbling experience. She added that the experts on the panel are in fact true experts who had to do above and beyond the CE credits required in order to have the discussions involved for exam preparations. Chairperson Ravnan stated that she was perplexed that they would request almost half of their CE hours to be counted by way of the competency committee participation, as there is a need for additional higher education in their level of expertise required as the members of the committee are held at a higher standard. Chairperson Ravnan strongly disagreed with recommending the approval of the six hours of CE to the board.

Ms. Sodergren spoke on behalf of the committee and noted that the committee would be open to the number of hours granted, and that the quantity of six only came from being consistent with the amount of hours earned for pharmacists who attend a public board meeting.

Ms. Herold publicly acknowledged the hard work and efforts of the Competency Committee members. She explained how diligently the committee works on the exam questions and process. She noted, however, that the committee members do agree to serve on the panel and receive compensation for doing so. She added that, by giving them CE for doing something they would otherwise do, we are exempting them from a requirement to earn CE. Ms. Herold also agreed with Chairperson Ravnan's comments in that the committee members are expected to be subject matter experts who need to maintain the higher education level expected of them by way of higher level learning. Ms. Herold suggested that, if moving forward with the recommendation, compensation then be reduced in lieu of the credits.

Mr. Weisser asked what the compensation is.

Ms. Herold responded that it is $30 per hour plus reimbursed state travel expenses.

Chairperson Ravnan added that being on the committee and being able to conduct discussion with other panel experts is a benefit and a rewarding experience, and that it is an honor to be on the committee.

Mr. Burgard agreed that the tasks performed by the committee are very grueling in terms of the extensive process involved in determining exam questions. He stated that he is in favor of whatever can be done to assist and support the members of the committee.

Ms. Weisser stated that granting the 6 hours of CE would seem to be a “small perk”, although the compensation is also significant.

Chairperson Ravnan is concerned that this will open the floodgates for other professionals in the pharmaceutical industry to request CE. She gave the example of educators requesting CE for hours placed in instruction.

Mr. Graul stated that the reason individuals choose to sit on committees is not for the purpose of acquiring CE. He added to Chairperson Ravnan’s concerns about other committee members then being able to earn CE for their time spent on a committee as well. He acknowledged the hard work conducted by the committee.

President Schell asked how difficult it is to obtain members to sit on the committee.

Ms. Herold responded that it is not too difficult, but has varied in terms of recruitment results in the past. She noted the requirements to qualify for the committee, as well as the need to limit the candidates to varying types of professional background and areas of specialty.

President Schell brought up the issue of retaining and recruiting members for the committee for the future.

Ms. Herold suggested the topic of CE to the October Board Meeting agenda. In the interim, the Competency Committee members will be surveyed (at their August committee meeting) to determine how many are in favor of the CE credit as well as any issues that may need to be addressed. She felt that it is important to determine how crucial the issue of CE units is to the committee before pursuing any further.

Dr. Gray suggested the board to research what other boards do regarding CE credits and their competency committee.

Ms. Herold pointed out that there isn’t necessarily a comparable structure because other boards do not necessarily have state exams.

Review and Discussion of “Standards and Guidelines for Healthcare Surge During Emergencies” Report

Ms. Sodergren informed the committee of standards developed by the Department of Public Health Services to be used as training material by local agencies, government,

and health care providers to get them thinking about disaster planning. The board is sharing this as an available tool for disaster response. The memo that was provided to the committee provides a link to the DPH website where the materials can be downloaded.

Ms. Herold added that the Governor's office spent millions of dollars creating the report as well as extensive training in conjunction with preparing for natural disasters.

Ms. Herold discussed the current state with regard to the large fires currently spreading throughout California. She stated that a pharmacy in Santa Cruz requested that the board activate the emergency response plan out of concern over patients presenting at the pharmacies needing medications filled due to leaving their prescriptions when evacuating their homes.

Ms. Herold asked the committee for guidance on when the board's emergency response plan should be put into affect.

Chairperson Ravnan asked about the form of communication in the event of enacting the emergency response plan.

Ms. Herold indicated that it would be advised via a subscriber alert. She also added, however, that if the alerts occur too frequently they can lose their impact of seriousness.

Dr. Gray asked if there is a bill that will address the issue.

Ms. Sodergren and Ms. Herold confirmed that AB 2756 will address this.

Dr. Gray pointed out the complexity of how to provide guidelines in the event of the response being enacted, including the geographics involved based on where the disaster is taking place versus where the patient goes to fill the prescription. He also indicated that there is confusion over how emergency refills are to be handled, including the fact that a patient can have a prescription filled at a pharmacy different than where it was originally filled.

President Schell noted that the confusion was an issue last October in San Diego during the fires in that area.

Ms. Herold added that the board did send out three subscriber alerts at that time.

Mr. Weisser asked how a pharmacist finds out about the emergency response plan during the time of a disaster.

Ms. Herold responded that it would be from the Office of Emergency Services.

Mr. Graul shared his experiences with having difficulty trying to get prescriptions filled for patients at various pharmacies during the fires last October. He also pointed out the

amount of time before residents are sometimes allowed back into their homes during disasters such as fires, and suggested not to place an arbitrary time frame on the emergency response plan.

Ms. Herold stated that it may be time for the board to discuss the need to redefine the specifics of the disaster response plan.

Discussion continued regarding the evacuation of small groups of residents in remote areas and issues with those families obtaining needed medication refills with various situations (no bottle, can't reach doctor, etc).

Mr. Hough stated that this highlights the importance of reminding patients to keep the name of their medications they are taking within their purse or wallet.

Dr. Gray shared information on a new program where patients can have their medical history and list of prescriptions on a database to access from any computer anywhere.

Mr. Hough responded that it still would not resolve the problem when they do not have access to a computer in a large disaster situation.

Mr. Graul emphasized that each situation will require pharmacists to exercise professional judgment on a case-by-case basis. The pharmacist can always follow-up with the prescribing doctor once the emergency is over.

Mr. Weisser noted that after many years in the industry, pharmacists are often skeptical.

Discussion ensued regarding needed specifics and parameters for pharmacists in the case of a natural disaster.

Mr. Graul stated that pharmacists may need direction to make judgment calls within reasonable professional limits, as long as they document their actions properly.

Ms. Herold responded that it is clearly documented in the disaster response policy in that sense.

Mr. Hough reiterated the need to place responsibility on the patient to carry their prescription information with them. He felt that this would eliminate a lot of the issues discussed today. He suggested a card that prescription information would be written on so that it is easy to carry in a purse or wallet.

Mr. Graul suggested continuing to remind the pharmacists on an ongoing basis of the guidelines to make professional judgment in emergency situations, document the incident, and follow up.

Review of Strategic Plan for 2008/09 for the Licensing Committee Goals

There was no discussion on the 2008-2008 Licensing Committee Strategic Plan.

Public Comment for Items Not on the Agenda

No public comments were provided.

The Meeting was adjourned at 4:07 p.m.