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 18, 2009

LOCATION: First Floor Hearing Room

Department of Consumer Affairs

1625 N. Market Boulevard Sacramento, CA 95834

BOARD MEMBERS

PRESENT:

Stanley C. Weisser, RPh, Treasurer, Chair

Randy Kajioka, PharmD Susan L. Ravnan, PharmD

BOARD MEMBERS PRESENT IN THE

AUDIENCE: Kenneth Schell, PharmD, President

STAFF

PRESENT: Virginia Herold, Executive Officer

Anne Sodergren, Assistant Executive Officer

Robert Ratcliff, Supervising Inspector Judi Nurse, Supervising Inspector Kristy Schieldge, DCA Staff Counsel Debbie Anderson, Licensing Manager

Tessa Fraga, Staff Analyst

Call to Order

Chair Weisser called the meeting to order at 9:44 a.m.

1. <u>Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)</u>

Chair Weisser provided that when disasters strike California, people need emergency care, and those not injured in the event often are relocated from their homes without

their medicines. He stated that in both cases, board licensees are called upon to aid these people in ways law may not specifically provide for. Mr. Weisser advised that in the early to mid 2000s, the board sponsored legislation to ensure the public would not be deprived of necessary medicines when disasters occur and emergency response teams are making efforts to care for the public.

Chair Weisser referenced Section 4062 of the California Business and Professions Code and read the following:

4062. Furnishing Dangerous Drugs During Emergency

- (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
- (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

Chair Weisser provided that California law also provides that in patient care emergencies (not just declared disasters), that a pharmacist may provide medicine to care for patients. He referenced Section 4064: Emergency Refill of Prescriber without prescriber authorization.

Chair Weisser provided that by late 2006 (following Hurricane Katrina), the board developed an emergency response policy to aid pharmacies with knowledge about what the board expected pharmacies, pharmacists, wholesalers and other licensees to do in the event of a declared disaster. He stated that the emergency response plan boils down to once an emergency is declared, use sound judgment, but "take care of patients."

Chair Weisser provided that staff from the Department of Public Health emergency response unit, who oversaw California's HINI response earlier this year, will provide an update of their planning, their roll out and deficiencies in the plan that need correction before the next declared disaster. He advised that the board may want to ultimately take action on some of these discussion items.

Chair Weisser provided that one problem the board is aware of is the delivery of flu medicines from the national stockpile did not contain sufficient quantities of oral dosage forms of Tamiflu and Relenza to provide to infants and young children. Chair Weisser indicated that compounding these dosage forms in the future may be one way to correct this.

Chair Weisser provided that the board placed the antiviral protocols released by the Department of Public Health in response to the HINI emergency on its web site and sent a subscriber alert at the end of May.

Presentation to the Committee

Dana Grau, representing the California Department of Public Health (CDPH), thanked the board for posting the antiviral protocol documents on its web site. He provided an overview of the Interim Guidance on Distribution and Dispensing of State and Federal Antiviral medicaitons. Dr. Grau advised that CDPH is responsible for the distribution of federal stockpiles of antivirals to local health departments who then distribute to local dispensing sites. He reviewed the H1N1 response plan implemented by the CDPH and the recent distribution of antiviral medications. Dr. Grau also provided an overview of the Interim Guidance on Antiviral Recommendations for Novel Influenza A (H1N1) Virus Infection. He indicated that this document provides interim guidance on the use of antiviral agents for treatment and chemoprophylaxis of novel influenza a (H1N1) virus infections in individuals, nursing homes and non-medical institutions.

Dr. Grau provided that CDPH has learned a variety of important lessons and has focused on areas that need to be addressed in response to the H1N1 outbreak. He reviewed several issues including the significant shortage in pediatric antivirals, reimbursement and compensation for the services of pharmacists who fill and order compound antiviral prescriptions, the dissemination of the guidance for prescribing and dispensing antiviral medications during a pandemic, the difference between intended use of public versus private antiviral medications, the identification by local health departments of long-term storage sites, and the emergency use authorizations that were issued for Tamiflu and Relenza.

Dr Grau provided that California has access to 9 million courses of antiviral medication for fall 2009. He indicated that this supply would supply treatment for 25% of Californians. Dr. Grau advised that the Department of Public Health and the Federal Government also have reserve stockpiles. He stated that distribution plans are ready and that plans are being developed for a mass vaccination campaign.

Committee Discussion

Susan Ravnan sought clarification on whether Tamiflu comes in a suspension and if a protocol has been developed.

Dr. Grau responded that Tamiflu does come in a suspension; but; in limited supplies. He advised that a protocol has been published.

Randy Kajioka expressed that more structure for how doses are efficiently administered to patients and how pharmacists can be more of an integral part of the process should be provided.

Dr. Grau provided that each local health department is developing a pandemic response plan to address mass vaccination and dispensing campaigns. He confirmed that more work needs to be done to better organize these plans.

Executive Officer Virginia Herold provided that the board is willing to help with subscriber alerts. She advised that all pharmacists and pharmacies will be required to subscribe to the e-mail alert system by January 2010. She indicated that the board has encouraged pharmacists to pre-register to respond to disasters. Ms. Herold sought clarification regarding the number of number of pharmacists who have registered at the local level. She also asked if a better coordination system could be implemented.

Dr. Grau provided that he is unaware of this number. He advised that better coordination is needed and indicated that CDPH would like a pharmacist to work as an agency representative to facilitate this effort.

Ms. Herold discussed the idea of generating a self-identified list of pharmacies that would be willing to help compound in the event of an emergency.

Chair Weisser expressed concern regarding timeframes and the possibility of a "tiddlewave" that may be created due to the onset of a new outbreak.

Dr. Grau provided that timeframes are uncertain. He advised that the CHPH is evaluating the pattern from the 1918 Spanish Flu and anticipates that the next occurrence is likely to occur during the next flu season.

Dr. Ravnan suggested that the development of a course to provide compound training.

Mr. Weisser sought clarification regarding whether interns could be used as a possible labor force.

Ms. Herold provided that the use of an intern without the oversight of a pharmacist during a declared disaster would be permitted.

Discussion continued regarding disaster response and preparedness.

Dr. Kajioka sought clarification regarding the definition of an emergency.

Dr. Grau reviewed the three elements that warrant the declaration of a pandemic including the number of individuals infected, the transmission of the virus from person to person, and the severity.

Ms. Herold provided that the business and professions code allows the board to wave pharmacy law in the event a disaster is declared. She advised that licensees are often reluctant to participate in a disaster response because they may fear discipline. Ms. Herold encouraged licensees to act responsibly and to use their best professional judgment to provide patient care.

Ms. Herold requested that the CDPH ask Dr. Mark Horton to provide a letter to be included in the board's newsletter to encourage pharmacists to participate in disaster response. She also expressed concern regarding the expiration date of the supply.

Dr. Grau provided that the expiration date on the initial lot expired June 30, 2009. He advised that this lot has been tested by the Federal Drug Administration FDA and the expiration date has been extended to 2011. Mr. Grau indicated that the supply distributed from CDPH warehouse has been appropriately relabeled.

Dr. Ravnan discussed the lack of current training options and recommended the development of pharmacist training programs at the county level.

Dr. Grau provided that a pharmacist training program needs to be developed at the state level. He advised that a variety of courses are available in mass dispensing.

Dr. Kajioka sought clarification regarding whether the mass dispensing courses are available electronically and was confirmed.

President Schell provided that San Diego County has developed a pharmacist training program. He proposed that this program could provide support for other counties seeking to develop their own programs.

Public Comment

Steve Gray, representing Kaiser Permanente, expressed concern regarding the notification, interpretation, and implementation of extensions for expiration dates.

Dr. Grau provided that the current expiration date only applies to the supply stored at the CDC warehouses and is lot specific.

Mr. Gray suggested that all significantly sized hospitals can participate in the compounding of pediatric doses. He recommended that this be discussed during a special session at the California Society of Health-System Pharmacists (CSHP) seminar in October 2009. Dr. Gray encouraged that clarification be provided regarding the target for the H1N1 vaccine and the Tamiflu treatment in order to discourage hoarding and better supply the demand.

Dr. Grau indicated that the CDPH will need to do a better job of advertising and communicating what it is publishing. He advised that the CDPH must be careful when requesting how the private sector will perform its duties.

Chair Weisser discussed the issue of acute institutions attempting to sway the public from coming to the institution with a suspected flu.

Dr. Gray provided that community pharmacies can have products compounded by a hospital pharmacy through a process called "depoting." He advised that it will need to

be clarified and clearly communicated to pharmacists that a patient specific order for the flu vaccine is not required.

Chair Weisser encouraged that this discussion be continued at the July 2009 Board Meeting.

There was no additional committee or public comment.

2. <u>Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiencies</u>

Chair Weisser provided that as defined in pharmacy law, a pharmacy technician is an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties as specified. He stated that a pharmacy technician can perform nondiscretionary tasks such as packaging, manipulative and repetitive tasks while under the direct supervision and control of a pharmacist.

Presentation to the Committee

Debbie Anderson, Licensing Manager, provided an overview of the pharmacy technician application process as well as information on how to avoid common deficiencies. She stated that Business and Professions Code Section 4202 specifies the requirements for licensure as a pharmacist technician in California. Specifically, an applicant must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

- 1. Possess an associate's degree in pharmacy technology.
- 2. Complete a course of training specified by the board in regulation.
- 3. Graduate from a school of pharmacy recognized by the board.
- 4. Be certified by the Pharmacy Technician Certification Board (PTCB).

Ms. Anderson provided that all applicants for licensure must submit an application to confirm eligibility for licensure and must also undergo a fingerprint background check. She advised that it is estimated that about 50% of all pharmacy technician applications are deficient when initially received usually because either the applicant or technician training program fail to complete a portion of the application or completed it incorrectly.

Ms. Anderson provided that over the last five fiscal years, the board has realized over a 25% increase in the number of pharmacy technician applications and the number of pharmacy technicians continues to increase. Ms. Anderson indicated that as the number of applications continues to grow, board staff remain dedicated to processing applications timely, however this is becoming increasingly more difficult as the workload increases, but the staffing remains unchanged. Ms. Anderson provided the following applicant statistics:

FY	2004/05	2005/06	2006/07	2007/08	2008/09
Applications Received	6514	6665	6810	7609	8271*

* As of June 11, 2009

Committee Discussion

Dr. Kajioka suggested that a list of common application deficiencies be created and submitted to pharmacy technician schools to help reduce the number of deficiencies.

Ms. Herold provided that the processing of applications creates a demanding workload and is currently done by one staff member. She advised that the board is hoping to add an additional position to help with this workload. Ms. Herold explained that fingerprint errors generate delays in the processing of applications. She encouraged applicants to ensure that all information submitted with their fingerprints is correct.

Chair Weisser discussed the timeframe for the processing and verification of rolled fingerprint cards and fingerprints via LiveScan.

Ms. Anderson provided that the Department of Justice requires California residents to use LiveScan. She explained that LiveScan provides efficient and electronic submission of fingerprints; but, it does not completely eliminate all errors and delays.

Chair Weisser thanked Ms. Anderson and the board's licensing staff for their hard work.

There was no additional committee discussion. No public comment was provided.

3. Release of the National Association of Boards of Pharmacy's Report of the Task Force on Standardarized Pharmacy Technician Education and Training

Ms. Herold provided that on September 2008, the National Association of Boards of Pharmacy (NABP) convened a task force meeting to evaluate standardized pharmacy technician education and training. She stated that the task force established a resolution which was approved by the NABP membership at the Association's 104th Annual Meeting. Ms. Herold indicated that the resolution contained seven recommendations, including changes to the Model Rules for the Practice of Pharmacy. She advised that it is the board's discretion as to whether they would like to adhere to this resolution.

Committee Discussion

Dr. Kajioka sought clarification regarding section 309 (a)(5) of the NABP report. Ms. Herold provided that this section and the NABP model may not fit or pertain to California law.

There was no additional committee discussion. No public comment was provided.

^{**} As of May 3, 2009

4. <u>Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy</u> Technician Exams

Chair Weisser provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He advised that board staff initiated the process; however because of a recent Executive Order signed by the Governor, we are unable to proceed.

Chair Weisser provided that the Executive Order prevents state agencies from entering into new contracts until agencies submit a budget plan detailing a reduction in contracts for services and other expenses by 15%. Chair Weisser stated that until such a plan is submitted and approved, board staff cannot continue to pursue the necessary contract to complete this evaluation.

Chair Weisser provided that the psychometric assessment of the examination is needed to ensure compliance with Section 139 of the Business and Professions Code and is the first step to allowing the use of the ExCPT exam as a qualifying method for licensure as a pharmacy technician.

Committee Discussion

Ms. Herold provided that the assessment is temporarily delayed until further clarification regarding contracts is provided from the department. She reviewed several challenges with implementing the 15% reduction in contracts and related expenses. Ms. Herold discussed that the entities responsible for the PTCB and ExCPT may have to cover the costs to have their exam assessed by an independent psychometric expert identified by the board.

There was no additional committee discussion. No public comment was provided.

5. <u>Discussion of the Reporting and Accounting of Intern Hours for California</u> Pharmacy School Students

Chair Weisser provided 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 in California. He stated that most other states have similar requirements, although the total number of hours that interns must earn in several states is slightly different.

Chair Weisser provided that board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. He indicated that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy,

but not specifically earned within a pharmacy. Chair Weisser explained that California pharmacy students typically earn the 600 "discretionary" hours for school-related experiential training (clinical clerkship).

Chair Weisser stated that at various Licensing Committee Meetings over the last few years, various proposals have been suggested by different proponents to amend the intern hour requirements. He provided an overview of these proposals and discussions.

Chair Weisser provided that coupled with this discussion is the major change to intern experience requirements established by the Accreditation Council for Pharmacy Education in the last few years. He stated that these new requirements added hours to the educational requirements students need as part of their intern training. Chair Weisser explained that as these new requirements were being put in place nationally, California pharmacy schools were undertaking an initiative to establish core competency assessment (via an exam) of pharmacy intern skills. He advised that it is the understanding of the board that this examination is no longer being proposed as a model.

Chair Weisser posed the following question: given the ACPE requirements for domestic pharmacy schools that all intern hour experience must include a minimum of 300 hours of basic training and 1,450 hours of advanced training (ACPE has guidelines describing this experience), is there a need to require submission of intern hours from any domestic graduate? He provided that while this would greatly simplify the processing of applications for the California pharmacist licensure examinations, others have questioned whether such a modification would result in pharmacists who lack essential pharmacy experience in a pharmacy.

Chair Weisser provided that Board President Schell has expressed interest in revisiting the intern hours requirements.

Committee Discussion

Kristy Schieldge, DCA Staff Counsel, provided that California pharmacy law clearly defines what is meant by "obtained in a pharmacy" in §1728(a)(1)(A).

Dr. Ravnan discussed the 300 hours of basic training requirement. She expressed concern regarding the adoption of the ACPE requirements. Dr. Ravnan suggested that the board seek input from community pharmacists regarding the adequate preparation and training of new graduates.

President Schell discussed the challenges faced by pharmacy students. He provided the practice or pharmacy has changed substantially since the establishment of the intern hours requirement. He advised that pharmacists need training and experience inside the pharmacy to understand the practice of pharmacy.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that based on his experience many recent graduates who are licensed to dispense drugs are not adequately prepared to do so. He advised that experience and competency expectations needs to be more clearly defined. Dr. Gray indicated that Kaiser Permanente supports the requirement for experience inside of a pharmacy and provided that it should be maintained.

There was no additional committee or public comment.

6. <u>Private/Public Partnerships to Add Health Care Practitioners to California's Work Force</u>

Chair Weisser provided that in May 2009, the California Hospital Association (CHA) and The California Endowment sponsored a one-day conference focused on promising practices in partnerships that address the need for qualified, diverse allied health professionals. He stated that the purpose of the event was to share promising practices in public-private partnerships in allied health workforce education and training.

Chair Weisser provided that several speakers presented during the conference, including Victoria Bradshaw, Cabinet Secretary of the Labor and Workforce Development Agency and Stephanie Leach, Assistant Secretary, Policy and Program Development, California Labor and Workforce Development Agency.

Chair Weisser provided that a Press Release from the Office of the Governor, announced a \$32 million public-private partnership to add health care professions to California's Work Force. He advised that information from the Labor and Workforce Development Agency provides additional information on how this money will be allocated and for what specific allied health programs. Chair Weisser stated that the first phase included engagement by 28 California Community Colleges. He indicated that according to the information provided, the program will be expanded at the UC, CSU and CCC through a competitive grant process.

Committee Discussion

Dr. Kajioka sought clarification regarding information provided in the Press Release.

Ms. Herold provided that the initiative calls for the development of effective allied health partnerships. She explained that this could potentially increase the number of pharmacy technicians.

There was no additional committee discussion. No public comment was provided.

7. Obtaining a Pharmacy License in California: An Overview of the Process

Presentation to the Committee

Debbie Anderson, Licensing Manager, provided an overview of the process for obtaining a community pharmacy license in California. She stated that several sections within the Business and Professions Code grant the board's authority and specifies the requirements for community pharmacy licensure. Ms. Anderson reviewed pharmacy ownership types and application requirements. She also outlined the processes for temporary permits, change of location, and change of ownership.

Committee Discussion

Chair Weisser sought clarification regarding the percentage of deficiencies for these applications.

Ms. Anderson provided that about 80% are deficient. She advised that applicants are issued deficiency letters to address deficient application requirements.

Ms. Herold discussed several challenges that are encountered with issuing this type of license.

Public Comment

Steve Gray, representing Kaiser Permanente, sought clarification regarding the term "trade style."

Ms. Herold responded that "trade style" refers to the name of the business or operation name.

Dr. Gray asked if there is a mandatory connection between the trade style and a pharmacy prescription label.

Ms. Herold provided that the trade style and the label should match. She advised that transition issues do exist when a major chain buys another chain with respect to information provided on the label.

Dr. Gray sought clarification regarding a timeframe for a transition scenario.

Ms. Herold provided that this transition would require a change in permit. She advised that this is not the highest priority with respect to processing.

Ms. Anderson provided that board staff is currently working on the 2008 change in permit backlog.

Discussion continued regarding the processing of change in permits and the possible impacts of SB 470.

Dr. Gray suggested that information regarding hospital pharmacy licensure be provided at a future meeting. He requested clarification regarding the requirements for including a pharmacy inside of a psychiatric hospital.

There was no additional committee or public comment.

8. <u>Impact of State Furloughs on Processing Timelines and Work Flow of the</u> Board

Ms. Herold provided that board operations continue to be impacted by the twice-monthly furlough days. She stated that the board's licensing unit is working extremely hard to process all applications within 30 days and process all incoming mail on a weekly basis. Ms. Herold advised that this is becoming more difficult as the work of this unit continues to increase.

Ms. Herold provided that to allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff authorized a temporary stop in responding to applicants calling on the status of a pending application. She explained that this temporary stop allowed staff to focus on reducing the backlog of new applications as well as complete a file inventory. (The board's licensing manager was available and responded to several applicants that could not wait.)

Ms. Herold provided that the board has resumed responding to status inquiries, however, workload studies show that on average, board most staff spends about 1.5 days each week responding to status inquiries. Ms. Herold advised that should this trend continue, the board may again stop responding to such inquiries to remain current with other mission critical functions.

Ms. Herold provided that workload often limits board staff's availability to answer phone calls regarding the status of a pending application or licensing requirements. She advised that responses will be provided to status inquiries for applications that the board has had for more than thirty days. Ms. Herold encouraged applicants to email or call the board if they have not been contacted by the board or have not received a license 60 days after submitting their application.

9. <u>Pharmacies Refilling Orders for Other Pharmacies with Prescription Drugs</u> <u>Owned by Neither Pharmacy</u>

Chair Weisser provided that for many years, chain store pharmacies and entities such as Kaiser Permanente have established specialized, centralized refill pharmacies to refill medications for delivery to patients of their multiple pharmacies in an efficient manner. He advised that typically these medications are maintenance meds that are telephoned in, filled at the refill pharmacy and then delivered to the patient's neighborhood pharmacy overnight. Mr. Weisser indicated that this allows the neighborhood pharmacy to focus on filling first time or immediate need patients' medications, and allow the others to be delivered in.

Chair Weisser provided that the board's requirements authorizing such practice are contained in Title 16 CCR §1707.4.

Chair Weisser provided that the board was recently asked about a derivation of this model where:

- 1. A refill pharmacy prepares medications for other community pharmacies not owned by the same owners as the refill pharmacy. Each neighborhood pharmacy is owned by a different owner. The drugs are not owned by either pharmacy, but a third party who will bill the dispensing pharmacy once the patient-specific drugs are delivered to the neighborhood pharmacy. The drugs in the refill pharmacy are not owned by the pharmacy, but by another entity.
- 2. A refill pharmacy is owned by a pharmacy chain. The refill pharmacy is owned by the chain, but the drugs are owned by another party until they are delivered to the neighborhood chain store. The billing is from the owner of the drugs to the neighborhood pharmacy. The staff of the pharmacy are employed by the chain store, but the technicians are employed by the owner of the drugs.

Chair Weisser provided that the committee needs to determine whether these models are compliant with California pharmacy law, and whether safeguards are needed to protect the quality of the drugs and patient privacy.

Guest Speaker

Roger Morris, attorney on behalf of McKesson Corporation, provided that McKesson has filed an application to open a refill pharmacy located in Southern California. He stated that the McKesson refill pharmacy will offer refill pharmacy services to independent pharmacies in Southern California and will operate in compliance with Title 16 CCR § 1707.4.

Mr. Morris provided an overview of the McKesson refill pharmacy business model. He reviewed the refill process with respect to the transfer of title and physical possession of the drugs. Mr. Morris advised that the refill pharmacy will not take title to any drug. He explained that title will transfer from McKesson directly to the dispensing pharmacy when a prescription is filled. He indicated that the refill pharmacy will be responsible for

the safety, effectiveness, and integrity of all drugs in its possession until such drugs are received by the dispensing pharmacy.

Committee Discussion

Ms. Herold sought clarification regarding record keeping issues with respect to the refill pharmacy.

Mr. Morris provided that McKesson Wholesale will maintain the title of the drugs. He explained that the drugs will be in the inventory of the McKesson refill pharmacy. Mr. Morris indicated that an invoice and a packing slip will be generated when the refill pharmacy fills a prescription for an independent pharmacy. He stated that the independent pharmacy will receive a bill for the cost of the drug and the service fee.

Discussion continued regarding the McKesson model and the refill pharmacy process. Concern was expressed regarding the consumers knowledge of what entity filled their prescription. The committee agreed that consumers would want some form of notification regarding this information.

Robert Ratcliff, Supervising Inspector, asked who would decide what prescriptions are filled at a refill pharmacy. He expressed concern regarding patient rights and the tracking system.

Mr. Morris responded that the independent pharmacy would decide to have a prescription filled by the refill pharmacy. He advised that a patient can request that their prescription be filled by the independent pharmacy instead of the refill pharmacy.

Alan Grover, representing McKesson Corporation, provided an overview of the McKesson inventory tracking system. He explained that title ownership and inventory are tracked separately in the tracking system.

Chair Weisser sought clarification regarding whether a wholesaler license allows for an entity to own a pharmacy filled with partially used bottles of drugs.

Mr. Morris clarified that the wholesaler would only have financial interest and title to these drugs.

Dr. Ratcliff asked if the pharmacist at the refill center would have full access to patient files.

Mr. Morris responded that the refill pharmacist would be granted full access to patient files from the independent pharmacy. He advised that all issues or problems encountered by the refill pharmacist would be referred back to the independent pharmacy.

Judi Nurse, Supervising Inspector, sought clarification regarding the record keeping and invoicing process. She expressed concern regarding refill pharmacies and not having a restriction on prescriber ownership of wholesale drugs.

Mr. Grover clarified that invoicing will be conducted on a daily basis.

Dr. Nurse expressed concern regarding the amount of responsibility placed on the pharmacist-in-charge (PIC) at the refill pharmacy.

Ms. Herold sought clarification regarding the incentives in place for the various parties involved.

Mr. Morris provided that incentives include lower cost, the ability to conduct business on a larger scale, increased efficiency, and increased consumer attention.

Ms. Herold expressed concern regarding the safeguards in place for refill pharmacies. She suggested that this matter be brought to the full board for further discussion.

Public Comment

Steve Gray, representing Kaiser Permanente, encouraged the board to support the McKesson model. He provided that the model promotes greater accuracy and safety for consumers. Dr. Gray discussed the advantages of the model and provided input from Kaiser's process for centralized refill pharmacies.

There was no additional committee or public discussion.

MOTION: To direct board staff to further evaluate this issue and to report back to the full board.

M/S: RK/SR

Support: 2 Oppose: 0

10. <u>Accreditation of Internet Pharmacies by the National Association of Boards of Pharmacy</u>

Chair Weisser provided that internet pharmacies often operate in violation of state and federal pharmacy law. He explained that consumers are often unaware of the dangers of Internet purchase of drugs and will buy from these Web sites that may not be pharmacies at all. Chair Weisser advised that as a result, they may not be getting the medication they intend. He stated that they may also seek to obtain medication without the supervision of a prescriber.

Chair Weisser provided that in the early 2000s, the National Association of Boards of Pharmacy (NABP) initiated a program to certify and accredit Internet Web site that are licensed as pharmacies and comply with guidelines of the NABP. He stated that this created a "Good Housekeeping Seal" of approval. Chair Weisser indicated that the certification is called VIPPS (Verified Internet Pharmacy Practice Sites. He advised that they also recently established a similar approval for veterinary pharmacies (Vet-VIPPS)

Chair Weisser provided that recently the NABP researched whether a number of Web sites met or did not meet these criteria. He reviewed several findings from this research and stressed the importance of this issue.

Committee Discussion

Ms. Herold discussed the solicitation of pharmacies to fill prescriptions generated by internet pharmacies. She advised that the board will issue a citation and fine to any pharmacy filling false prescriptions.

There was no additional committee discussion. No public comment was provided.

11. Competency Committee Report

<u>a. Pharmacist Exam Performance Statistics for October 2008 – April 2009 CPJE and NAPLEX Exam Administrations</u>

Ms. Herold provided that the overall passing rate during the specified time frame for the CPJE is 75.2% and 96.9% for the NAPLEX.

b. Comparison of Licensing Statistics with California's Pharmacist Licensure Examination Prior to January 2004

Ms. Herold referred to the 10-year comparison by exam type. She provided that in general, the overall passing rate on the previous pharmacist licensure exam (administered through June 2003) range from 41.1% to 59.8%.

Ms. Herold provided that beginning in 2004, when the exam changed to the CPJE and NAPLEX, the overall pass rates are higher. She stated that the pass rate for the CPJE ranges from 69.9% to 81.6% and the pass rate for the NAPLEX ranges from 90.7% to 97.6%.

c. Job Analysis for the CPJE to be understand at the end of 2009.

Ms. Herold provided that the committee will develop a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm during its annual meeting scheduled for the end of July 2009. She stated that pursuant to Business and Professions Code section 139, the board is required to complete an

occupational analysis periodically which serves as the basis for the examination. Ms. Herold advised that the analysis will be impacted by the recent Executive Order effecting all state contracts. She explained that board staff has sought an exemption to ensure that the exam job analysis is conducted.

12. Strategic Plan Update for the Licensing Committee for 2009-10

Chair Weisser provided that at the July Board Meeting, the board will update its 2009-10 Strategic Plan. He stated that the board truly manages its operations by its strategic plan. Mr. Weisser explained that all activities undertaken by the board are reported in the plan -- in the component committee reports provided quarterly to the board (in the board packets).

Chair Weisser provided that each fiscal year, the board updates its strategic plan. He indicated that the current plan was developed in 2006-07 with the assistance of a consultant. Chair Weisser advised that since then, each year the board has reviewed and as necessary revised its strategic plan. He stated that these are typically minor adjustments and additions.

Chair Weisser provided that the revision is done by each strategic committee by reviewing its portion of the strategic plan, making recommendations and then recommendations to the full board for review and approval at the board meeting.

Chair Weisser provided that the committee needs to review the plan to ensure its activities are current and reflect projects underway.

Ms. Herold suggested the following additions to the strategic plan:

- 14. Improve reporting of accounting for intern hours
- 15. Participate in initiatives to increase the number of pharmacists in California to meet future
- 16. Assess the operations of refill pharmacies

MOTION: To include the suggested additions as part of the strategic plan for the Licensing Committee for 2009-10.

M/S: SR/ RK

Support: 2 Oppose: 0

13. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:05 p.m.

Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiency Items

California State Board of Pharmacy 1625 N. Market Blvd., Suite N219 Sacramento, CA 95834

Overview

- Authority
- Pharmacy Technician Application Volume
- Qualification Methods
- Complete Pharmacy Technician Application
- Additional Review
- Avoiding Common Deficiency Items
- Process Improvements

Authority - Business and Professions Code

- Beginning of Section 4202
- (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:
 - (1) Has obtained an associate's degree in pharmacy technology.
 - (2) Has completed a course of training specified by the board.
 - (3) Has graduated from a school of pharmacy recognized by the board.
 - (4) Is certified by the Pharmacy Technician Certification Board.

Pharmacy Technician Application Volume

Fiscal Year	2004 / 2005	2005 / 2006	2006 / 2007	2007 / 2008	2008 / 2009
Applications Received	6514	6665	6810	7609	8271*
Total Current Licensees	41,068	44,713	51,510	54,219	57,002**

*As of June 11, 2209

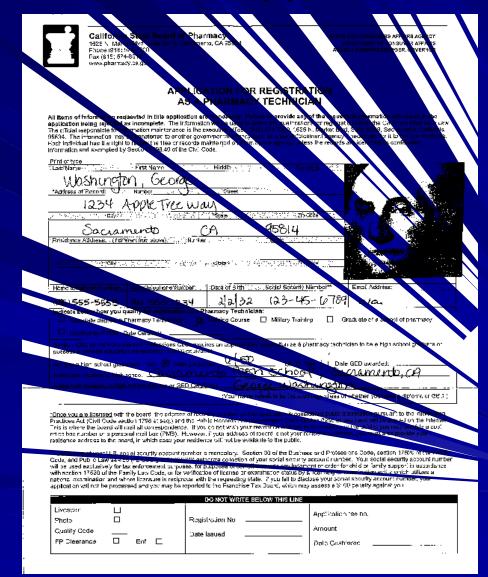
**As of May 3, 2009

Qualification Methods

- Associate Degree in Pharmacy Technology
- Training Course
 - CCR 1793.6 (c)
 - Military training
- Graduate of an ACPE School of Pharmacy
- Certified by the PTCB

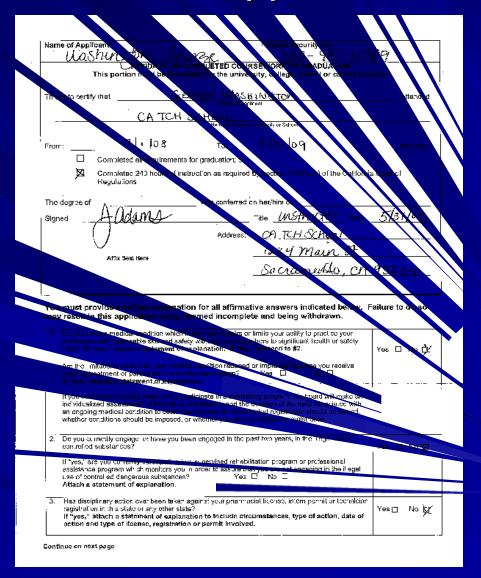
Page 1

- Personal information complete
- Photo on photo quality paper
- High school/GED information



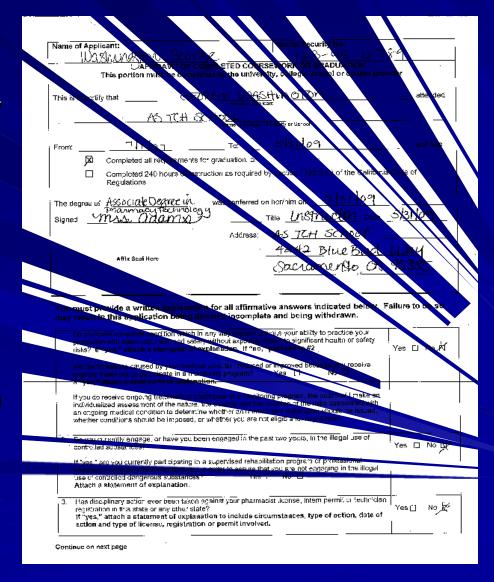
Page 2

- Questions 1, 2 and 3 answered.
- Training Course -Affidavit complete with name, dates of training, 240 hours checked, signed and dated with school seal.



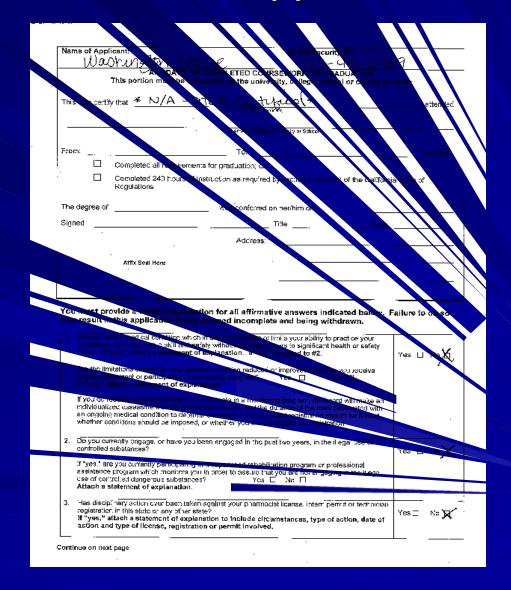
Page 2 (continued)

- Associate Degree in Pharmacy Technology – Affidavit complete with name, dates of education, Completed Requirements for Graduation box checked, signed and dated with school seal.
 - Associate Degree in Pharmacy Technology
 - BS Pharmacy or PharmD from ACPE accredited School of Pharmacy



Page 2 (continued)

- If PTCB Certified, copy of notarized current PTCB Certificate.
- Applicant must answer questions 1, 2, and 3.



Page 3

- Answer questions 4,5, 6 and 7.
- Print name, sign name and date document.

[4. Have you everythin any toution by a pharmachallicens interpretation of techniques of states denied in this states of any other states if they are the states of the	Yes 🗆	de jaz
	 Have you ever had a phant any permit, or any professional a vocating all pense of registriction, denied or disciplined by a government authority in his state of my other sizes? If "yes," provides 	c Yes □	₹

- 6. The livest year been convicted of or personal contest to a solution of any law tile, arrange country, the brinds States or any state Issue or floor programmers? You must include all the debased when the new from the convertible all the debased was considered by the second selde under charged Code section 1203.4. That eximple times the convertible all the section to represent the "yea," attach are explanation and unding the type of visition, the later convertible to the convertible possible provide the Secret of Palargacy with contrible copies to all performs contributed an arrest reports relating to this example; time.
- 7. Are you currently or have you devicually been listed as a compality officer, puriser, own of manager, member, administration recritical director on a point in a children principle of wholesaler, medical device rotalities along other onlity floored in the state or any other state of year, provide curring any name, you of point, permit number and state types floored.

APPLICANT AFFIDAVIT

horoby attests the trace that I are the applicant whose signature of applicant and the state of the information on the form may obstitute good for donlar or revolution of the license. I hereby certify under person of popury under the two of the state of Carlon or the truth and accuracy of all statements, answers and representant is made in this application, including all statements. I also bertify that I have read and understain the instructions attacked to the application of the control of the c

MANDATORY REPORTER

Under catifornia law each person licensed by the Board of Pharmacy is a "mandated reporter" for both wild and elder abuse or neglect purposes.

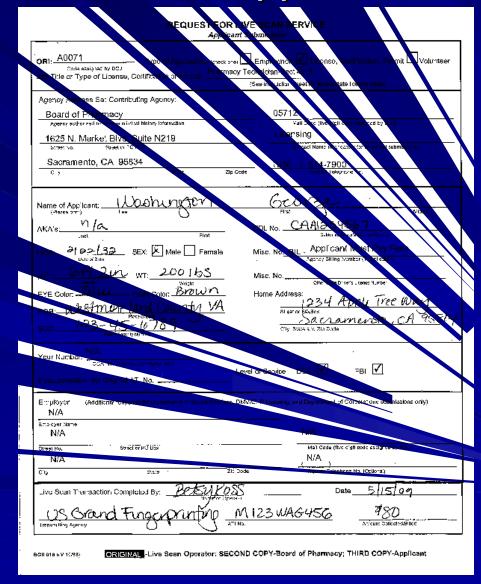
California Penal Cone section 11.06 and Welfare and Institutions Code section 15630 require that of manufated reporters make a report to an organicy specified in Panal Code section 11165.9 and Welfare and Institutions code section 15630(b)(1) penerally by enforcement, state, and/or county adult protective services agencies, etc... I whenever the mendated reporter, in his or her professional capacity or within the scope of his or her professional, that knowledge of or beconverse child, elect analysis dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by delephone immediately or as 5000 cs possible, to make a report to the appropriate agency(ies) or as soon as is practicably possible. The mandated reporter must contact by delephone immediately or as 5000 cs possible, to make a report to the appropriate agency(ies) or as soon as is practicably possible. The mandated reporter must concerning the incident.

Failure to comply with the requirements of Section 11.166 and Section 15630 is a misdemeasor, publishable by up to six months in a county jail, by a fine of one thousand dollars (\$1,000), or by both that imprisonment and fine.

For further details about these regultements, consult Penal Code sections 11164 and Welfare and Institutions Code section 15633, and subsequent sections.

Request for Live Scan Service

- Name, date of birth and US Social Security Number are correct.
- DOJ and FBI level of service completed.



- Common Live Scan Issues
 - Name, date of birth or US social security number is not correct.
 - Fingerprints rejected by DOJ for poor quality.
 - DOJ has no record of Live Scan.
 - Board has not received results.
 - CA Delay Notification received.
- Failure to provide required supporting documentation if applicant answers yes to questions #1-7.

Submit the application fee of \$50 with the application.

Attach a photo on photo quality paper.

Include all personal information – name, date of birth, telephone number, email address and US social security number.

- High School/GED Requirement
 - High School Graduate:
 - Check "Yes" for High School Graduate
 - Provide date of graduation
 - Provide name and location of high school
 - Provide name that appears on your diploma
 - GED Equivalent
 - Check "Yes" for GED
 - Provide date GED awarded
 - Provide name that appears on your GED Certificate

- Qualification Method: Associate Degree in Pharmacy Technology verified by Affidavit of Completed Coursework or Graduation
 - Name of applicant
 - Dates education received
 - Check box for "Completed all requirements for graduation"
 - Degree of "Associate in Pharmacy Technology" and date awarded included on the affidavit
 - Signed and dated by school representative with school seal and address

- Qualification Method: ASHP Training Course or non-ASHP Training Course verified by Affidavit of Completed Coursework or Graduation
 - Name of applicant
 - Dates training received
 - Check box for "Completed 240 hours of instruction as required by section 1793.6(c) of the California Code of Regulations"
 - Signed and dated by school representative with school seal and address
- If training was completed in military, provide a certified copy of DD214.

- Qualification Method: BS in Pharmacy or PharmD Degree verified by Affidavit of Completed Coursework or Graduation or transcript with degree posted.
 - School must be American Council for Pharmacy Education (ACPE) accredited.

- Qualification Method Pharmacy Technician Certification Board (PTCB) Certified
 - Provide the board with a certified copy of your current PTCB certificate

- Page 2 of the Application
 - Must answer questions 1, 2, and 3 regardless of qualification methods
- Page 3 of the Application
 - Must answer questions 4, 5, 6, and 7 regardless of qualification method
 - Applicant Affidavit: Print your name, sign your name and date the document

Avoiding Common Deficiencies

Live Scan

- Provide a copy of your Request for Live Scan Service completed at the DOJ and FBI level.
- Ensure Live Scan Operator types in your name, date of birth and US social security number correct.

For applicants residing outside of CA

- Fingerprints professionally rolled on fingerprint cards provided by the board.
- All personal information included on fingerprint cards included.
- Fingerprint processing fee of \$51.

Process Improvements

- The Licensing Unit constantly reviews processes to improve efficiencies
 - Quarterly Pending Inventory Review
 - Ongoing review of applications and instructions
 - Ongoing review of processing of applications to reduce bottlenecks

Obtaining a Community Pharmacy License in California An Overview of the Process

California State Board of Pharmacy 1625 N. Market Blvd., Suite N219 Sacramento, CA 95834

Overview

- Authority
- Ownership Types
- Application Requirements All
- Application Requirements by Ownership Types
- Application Requirements Others
- Temporary Permit
- Change of Location
- Change of Permit
- Processing the Application
- Process Improvements

Authority - Business & Professions Code

- Section 4037 Definition of a Pharmacy
- Section 4110 License Required
- Section 4111 Restriction on Prescriber
 Ownership
- Section 4201 Application Form: Required Information; Authority Granted by License;
 Reporting Changes in Beneficial Ownership
- Section 4400 Fees

Ownership Types

- Individual Owner
- Partnership
- Corporation For Profit, Non-Profit, Publicly Traded
- Limited Liability Company (LLC)
- State, City or County Owned Pharmacy and City or County Owned Jail Pharmacy
- Native American Tribe Owned Pharmacy
- Non-Native American Owned but Operating on Tribal Lands

Application Requirements – All Types

- Application (17A-4)
- Fee
- Ownership Form
 - Corporation or LLC (17A-33)
 - Partnership or Individual (17A-34)
- Financial Affidavit in Support of Application (17A-2)

Application Requirements — All Types (continued)

 Approved Wholesaler Credit Application or Wholesale Agreement

Copy of the Lease Agreement or Grant Deed if owned

Seller's Certification if applicable (17A-8)

Application Requirements – All Types (continued)

Documents Required based on Organizational Structure:

Certification of Personnel (17A-11)

Individual Personal Affidavit (17A-27)

Individual Financial Affidavit (17A-26)

Fingerprinting Requirements at DOJ/FBI Level

- Individual Owner Owner
- Partnership Each Partner
- Corporation For Profit Corporate Officer, Major
 Shareholder and Director
- Limited Liability Company (LLC) Each Member/Manager

Application Requirements - Individual Owner not Incorporated

Certification of Personnel for Pharmacist-in-Charge (PIC) (17A-11)

Application Requirements - Partnership

Certification of Personnel for PIC (17A-11)

Signed Partnership Agreement

Application Requirements – Corporations

- First line corporation over pharmacy must complete Corporation or Limited Liability Company Ownership Information Form (17A-33)
- Each remaining parent corporation must complete Parent Corporation or Limited Liability Company Ownership Information (17A-33A)
- Corporations include: For Profit, Non-Profit and Publicly Traded Corporations

Application Requirements – Componations For **Profit**

Certification of Personnel for PIC (17A-11)

Articles of Incorporation endorsed by Secretary of State

Application Requirements — Componations For Profit (continued)

- Statement of Information endorsed by the Secretary of State
 - Statement of Foreign Corporation endorsed by Secretary of State if incorporated outside California

Bylaws

Application Requirements – Componations Nom-Profit

- Statement of Information endorsed by Secretary of State
- Bylaws
- Articles of Incorporation endorsed by Secretary of State
- Certification of Personnel (17A-11) for each corporate officer, shareholder, director and the PIC

Application Requirements – Corporations Publicly Traded

- Copy of the corporations 10K filing with the Securities Exchange Commission (SEC)
- A list of the top five shareholders who own 5% or more stock which requires a filing with the SEC
 - If shareholder is an individual, include name, title and professional license
- Identification if shareholder is bank, trust company or financial institution

Application Requirements – Limited Liability Company (LLC)

Corporation or Limited Liability Company
 Ownership Information Form (17A-33A)

- First line limited liability company over pharmacy; and
- Each remaining company

Application Requirements – Limited Liability Company (LLC) (continued)

Certification of Personnel for PIC (17A-11)

 Articles of Incorporation and Statement of Information endorsed by Secretary of State

Copy of limited liability agreement

Application Requirements - Others

State, City or County Owned Pharmacy

Native American Owned

Non-Native American Owned but Operating on Tribal Lands

Temporary Permit Requirements

- Community Pharmacy Application (17A-4)
- Fee
- Ownership Form
 - Corporation or LLC (17A-33)
 - Partnership or Individual (17A-34)
- Financial Affidavit in Support of Application (17A-2)
- Certification of Personnel (17A-11) for People Listed on Ownership Information
- Live Scan Receipt or Fingerprint Cards and Fees

Change of Location ONLY (Does not include ownership change)

- Application (17A-4) and Fee
- Ownership Form
 - Corporation or LLC (17A-33)
 - Partnership or Individual (17A-34)
- Copy of lease agreement or grant deed
- Each corporate officer, shareholder, and director must submit:
 - Certification of Personnel (17A-11)
 - Individual Personal Affidavit (17A-27)
 - Copy of Live Scan Receipt
- PIC must submit Certification of Personnel (17A-11)

Change of Permit

- Change of Permit must be filed 30 days after the following occurs:
 - Change of corporate officers/administrators
 - Change of medical director (clinics only)
 - Transfer of 10% to 49% of stock
 - Change of street name or number made by the US
 Post Office
 - Change of tradestyle name or corporate name

Processing the Application

- Applications are processed by the initial processing analyst.
- If an application is missing a requirement, a deficiency letter is sent.
- If an application is complete, the file is forwarded to a final reviewing associate analyst for issuance.

to improve efficiencies

Quarterly Pending Inventory Review

Implement triage system effective //1/f Letter processing of applications

Ongoing review of applications and instructions