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

Licensing Committee Report

Members:

Stan Weisser, RPh, Chairperson
Randy Kajioka, PharmD
Susan Ravnar, PharmD
Ramón Castellblanch, Public Member

LICENSING COMMITTEE REPORT AND ACTION

The Licensing Committee met on June 18, 2009, in Sacramento. Minutes of this meeting are provided in **Attachment 11**, near the back of this tab section.

A. Subcommittee to Evaluate Drug Distribution within Hospitals

FOR INFORMATION and DISCUSSION: Meeting Summary of the Meeting Held June 2, 2009

Attachment 1

Background:

During the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. However, because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Nevertheless, the recall system is not working, and staff is pursuing identification of problems with the recall system with the California Department of Public Health, the California Society of Health-System Pharmacists, The California Hospital Association and the FDA. We are hoping to develop California-specific solutions.

President Schell established a two-board member task force to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. The first meeting of this subcommittee was March 2, 2009, at the Crowne Plaza Hotel in Irvine, California, and was well attended. During this first meeting, the FDA and Department of Public Health discussed recall requirements at both the state and federal level and participants discussed best practices related to drug recall process within hospitals.

The second meeting was held June 2, 2009, at University of California San Francisco. Again, attendance was good, although not as many attended as had attended the March meeting. This meeting focused on recall best practices and the needs of hospitals to change practices to provide patient care. Minutes of this meeting are provided in **Attachment 1**.

The board may wish to discuss how it wishes to proceed with future meetings. Tentatively the next meeting will be held in the Inland Empire area on September 17, 2009. However, budget restrictions for 2009-10 may limit where the board can hold this meeting.

At the next meeting the committee will continue to focus on developing recall best practices and examine statutory and regulation requirements that may impede patient care in inpatient settings.

B. Summary and Discussion for June 18, 2009 Meeting of the Licensing Committee

1. FOR INFORMATION: Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health

Attachment 2

When disasters strike California, people need emergency care, and those not injured in the event often are relocated from their homes without their medicines. In both cases, board licensees are called upon to aid these people in ways law may not specifically provide for. 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.

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. The emergency response plan boils down to once an emergency is declared, use sound judgment, but "take care of patients." A copy of this policy and the newsletter article that accompanied it are provided in **Attachment 2**.

During the committee meeting, attendees heard a presentation from Dr. Dana Grau, the Department of Public Health Emergency Response Unit, who oversaw California's H1N1 response earlier this year. Dr. Grau shared the department's response as well as deficiencies identified in the disaster response plan that need correction before the next declared disaster.

One problem discussed during the meeting 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. Compounding these dosage forms in the future may be one way to correct this. 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. To facilitate the creation of such a list, the July 2009 issue of The Script will include an article requesting that pediatric compounding pharmacies to join the Board's emergency notification list.

Also, provided in **Attachment 2**, are the antiviral protocols released by the Department of Public Health in response to the H1N1 emergency. The board placed these items on its web site and sent the following subscriber alert at the end of May:

The Board of Pharmacy added to its website today antiviral documents released by the California Department of Public Health.

To view the antiviral documents go to:
http://www.pharmacy.ca.gov/about/antiviral_documents.shtml

2. FOR INFORMATION: Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiencies

Attachment 3

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. In general, a pharmacy technician can perform nondiscretionary tasks such as packaging, manipulative and repetitive tasks while under the direct supervision and control of a pharmacist.

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).

All applicants for licensure must submit an application to confirm eligibility for licensure and must also undergo a fingerprint background check. 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. During the committee meeting Debbie Anderson, Licensing Unit Manager, provided an overview of the application process as well as information on how to avoid common deficiencies.

Over the last five fiscal years, the board has realized over a 25% increase in the number of pharmacy technician applications. In addition the number of pharmacy technicians continues to increase. 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. Statistics are provided below.

FY	2004/05	2005/06	2006/07	2007/08	2008/09
Applications Received	6514	6665	6810	7609	8271*
Total Current Licensees	41,068	44,713	50,510	54,219	57,002**

* As of June 11, 2009

** As of May 3, 2009

A copy of the pharmacy technician application is in **Attachment 3**.

3. FOR INFORMATION: Release of the National Association of Boards of Pharmacy's Report of the Task Force on Standardized Pharmacy Technician Education and Training

Attachment 4

In September 2008, the National Association of Boards of Pharmacy (NABP) convened a task force meeting to evaluate standardized pharmacy technician education and training. The task force established a resolution which was approved by the NABP membership at the Association's 104th Annual Meeting.

The resolution contained seven recommendations, including changes to the Model Rules for the Practice of Pharmacy. As updated, the Model Rules specify that to be registered as a Certified Pharmacy Technician in a state, an application shall meet the following requirements (Recommended revisions are denoted by underlines and strikethrough.):

- Graduated from a high school or obtained a Certified of General Development (GED) or equivalent.
- Graduate from a competency-based pharmacy technician education and training program approved by the board or been documented by the pharmacist-in-charge where the applicant is employed as having successfully completed a site-specific, competency based education and training program approved by the board.
- Have successfully passed an examination developed using nationally recognized and valid psychometric and pharmacy practiced standards approved by the board.

Attachment 4 includes the report of the task force as well as an article from the *Association News* published in October 2008.

4. FOR INFORMATION: Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams

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). Board staff initiated the process; however, because of a recent Executive Order signed by the Governor, we are unable to proceed.

The psychometric assessment of the examination is needed to ensure for 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.

Board staff will pursue the necessary contract for services when allowed.

5. FOR INFORMATION: Discussion of the Reporting and Accounting of Intern Hours for California Pharmacy School Students

Attachment 5

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. Most other states have similar requirements, although the total number of hours that interns must earn in several states is slightly different.

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

For students who earn their experience in other states, it is virtually impossible to obtain this distinction in where an intern has gained experience as the board accepts intern hours verified by the state board in the state where the hours were earned. However, the distinction upon whether these hours have been earned in a pharmacy under the supervision of a pharmacist cannot be discerned.

At various Licensing Committee Meetings over the last few years, various proposals have been suggested by different proponents to amend the intern hour requirements. Some of these proposals and discussions included:

Pharmacy students from CA pharmacy schools requested 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.

Discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is 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.

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. These new requirements added hours to the educational requirements students need as part of their intern training. 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. It is our understanding that this examination is no longer being proposed as a model.

The committee considered several questions, including if clarification was needed on the definition of "obtained in a pharmacy" in section 1728(a)(1)(A). Staff counsel advised that clarification was not required.

The committee suggested that the board seek input from community pharmacist regarding the adequate preparation and training of new graduates and heard testimony that the practice of pharmacy has changed substantially since the establishment of the intern hours required.

The committee did not take action on this item. Major provisions establishing California's Intern Requirements are provided in **Attachment 5**. Also included is the form used by California to collect intern hours.

6. FOR INFORMATION: Private/Public Partnerships to Add Health Care Practitioners to California's Work Force

Attachment 6

In May, 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. The purpose of the event was to share promising practices in public-private partnerships in allied health workforce education and training.

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.

Provided in **Attachment 6** is a Press Release from the Office of the Governor, announcing a \$32 million public-private partnership to add health care professions to California's Work Force. Also included is information from the Labor and Workforce Development Agency that provides additional information on how this money will be allocated and for what specific allied health programs. The first phase included engagement by 28 California Community Colleges. According to the information provided, the program will be expanded at the UC, CSU and CCC through a competitive grant process.

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

Attachment 7

During the committee meeting, Debbie Anderson, made a presentation on the application process for obtaining a community pharmacy license. Ms. Anderson discussed pharmacy ownership structures and associated application requires as well as outlined the process for receiving a temporary pharmacy license if the event of a pharmacy of location or change of ownership.

Ms. Anderson stated that about 80% of all pharmacy applications are deficient when initially submitted.

Attachment 7 includes a portion of the application for a pharmacy license as well as two articles published in recent board newsletters on the process for purchasing a pharmacy from other owner.

8. FOR INFORMATION: Impact of State Furloughs on Processing Timelines and Workflow of the Board

During the committee meeting, attendees were advised of the impact to the twice-monthly furlough days. The committee was advised 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 but that it is becoming more difficult as the work of this unit continues to increase.

Since that time, a new Executive Order was issued by the governor. This new order imposes a third furlough day each month and closes state offices three Fridays each month through June 2010.

Board and executive staff is evaluating our most mission critical functions. To allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff previously authorized a temporary stop in responding to applicants calling on the status of a pending application. 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.)

We have 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. Given the new executive order, we may again stop responding to such inquiries to remain current with other mission critical functions.

A more comprehensive discussion on the executive order and its impact will be held during the organization development committee report.

9. FOR INFORMATION: Pharmacies Refilling Orders for Other Pharmacies with Prescription Drugs Owned by Neither Pharmacy

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. 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. This in turn allows the neighborhood pharmacy to focus on filling first time or immediate need patients' medications, and allow the others to be delivered in.

The board's requirements authorizing such practice are contained in Title 16 CCR §1707.4.

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 is employed by the chain store, but the technicians are employed by the owner of the drugs.

This information was presented to the committee need 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.

During the meeting, the committee heard a presentation from representatives from McKesson. McKesson filed an application to open a refill pharmacy located in Southern California. This refill pharmacy would offer refill pharmacy services to independent pharmacies in Southern California and will operate in compliance with Title 16 CCR § 1707.4. According to the presentation, the refill pharmacy will not take title to any drug, rather the title would remain with McKesson Wholesale until transferred to the dispensing pharmacy when a prescription is filled. 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.

The committee voted to direct board staff to further evaluate this issue and to report back to the full board.

10. FOR INFORMATION: Accreditation of Internet Pharmacies by the National Association of Boards of Pharmacy

Attachment 8

Internet pharmacies often operate in violation of state and federal pharmacy law. Yet consumers, often unaware of the dangers of Internet purchase of drugs, will buy from these Web sites that may not be pharmacies at all. As a result, they may not be getting the medication they intend. They may also seek to obtain medication without the supervision of a prescriber.

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. This created a "Good Housekeeping Seal" of approval. The certification is called VIPPS (Verified Internet Pharmacy Practice Sites. They also recently established a similar approval for veterinary pharmacies (Vet-VIPPS).

Recently the NABP researched whether a number of Web sites met or did not meet these criteria. Attachment 8 provides information on the VIPPS survey and the Vet VIPPs program.

11. FOR INFORMATION: Competency Committee Report

Attachments 9 & 10

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

Included in **Attachment 9** is a breakdown of the passing rates for the CPJE and NAPLEX exams. 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

Included in **Attachment 10** is a 10-year comparison by exam type. In general the overall passing rate on the previous pharmacist licensure exam (administered through June 2003) range from 41.1% to 59.8%.

Beginning in 2004, when the exam changed to the CPJE and NAPLEX, the overall pass rates are higher. 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.

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. 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. We anticipate releasing this survey to a random sample of pharmacists before the end of year. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

12. FOR INFORMATION: Meeting Summary of the Licensing Committee Meeting Held on June 18, 2009

Attachment 11

Attachment 11 contains a summary of the Licensing Committee Meeting held on June 18, 2009.

C. FOR ACTION: Strategic Plan Update for the Licensing Committee for 2009/10 and Discussion for Future Activities of the Committee

Attachment 12

Attachment 12 contains the recommended strategic plan update for the Licensing Committee for 2009/10.

D. FOR INFORMATION: Fourth Quarterly Report on Licensing Committee Goals for 2008-09

Attachment 13

Attachment 13 contains a copy of the board's licensing statistics and the fourth quarter's status of Licensing Committee Goals.

Attachment 1

Meeting Summary of the Subcommittee to Evaluate Drug Distribution with Hospitals

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SUBCOMMITTEE TO EVALUATE DRUG DISTRIBUTION WITHIN HOSPITALS
MINUTES**

DATE: June 2, 2009

LOCATION: UCSF Laurel Heights Conference Center
3333 California Street
San Francisco, CA 94118

BOARD MEMBERS PRESENT: Kenneth Schell, Pharmacist Member, President
Randy Kajioka, Pharmacist Member

STAFF PRESENT: Virgina Herold, Executive Officer
Anne Sodegren, Assistant Executive Officer
Caroline Kline, Legislation and Regulation Coordinator
Tessa Fraga, Administrative Analyst

CONSULTANTS PRESENT: Val Sheehan, Meeting Facilitator
Carmen Fraser, Senior Associate

The meeting was called to order at 9:45 a.m.

1. Welcome, Meeting Overview, Introductions

Board President Ken Schell welcomed everyone and remarked that this was the second in a series of meetings to evaluate drug distribution in hospitals. Dr. Schell noted that in the twenty years since the regulations have been formally reviewed, many issues regarding drug distribution in hospitals have changed. Dr. Schell emphasized how important these meetings were in terms of examining and better understanding current issues.

Val Sheehan, Meeting Facilitator, introduced herself and associate Carmen Fraser and welcomed the group to the subcommittee meeting. Ms. Sheehan then introduced Board of Pharmacy staff and board members who were in attendance. She reviewed the purpose of the subcommittee and pointed out that the ultimate goal was to ensure safe and effective patient care. Secondary goals included helping to inform decisions regarding pharmacy law and regulations and providing input and guidance on recommendations to the Board.

Ms. Sheehan briefly summarized the proceedings from the first subcommittee meeting held on March 2, 2009. The March 2nd meeting focused primarily on issues related to drug recall in hospitals/health systems. The impetus for the series of meetings stemmed from difficulties faced by hospitals in removing recalled heparin product after receiving numerous recall notices. The heparin recall revealed larger, more systemic issues regarding effective drug distribution in hospitals. The Board of Pharmacy felt it was important to convene the subcommittee to better understand these larger issues and discuss various ways to improve the drug distribution system in California.

As part of an effort to examine and address these issues, the first meeting agenda covered the following:

- An overview of the role and jurisdiction of state and federal regulatory agencies involved in drug recall;
- A detailed timeline and summary of key events related to the heparin recall;

- Group discussions about best practices and suggestions for improvement related to drug recall; and
- Potential discussion topics for future subcommittee meetings.

Ms. Sheehan noted that today's meeting agenda was formed by topics generated at the March 2nd meeting. For example, issues pertaining to: 1) the role and accountability of the pharmacy director and 2) the quality and safety of drug distribution and clinical services were raised at the last meeting and will be addressed during today's meeting. Ms. Sheehan noted that the March 2nd meeting was well-received and participants appreciated the opportunity to increase their knowledge, provide feedback, and interact with regulators. Ms. Sheehan shared that minutes for that meeting were available online.

Ms. Sheehan reminded the audience that today's meeting was being recorded and that the minutes will be available one week before the July 15, 2009 Board meeting. She invited meeting participants to introduce themselves and then reviewed the agenda, meeting values, and meeting courtesies. Ms. Sheehan noted that a section of the agenda towards the end of the meeting had been set aside for public comment.

2. Revisiting Drug Recall Practices

Virginia Herold, Executive Officer of the Board of Pharmacy, stated that one of the goals for the series of meetings was to develop a list of best practices related to drug recalls, specifically for the inpatient setting with some modifications for the outpatient setting. At the March 2nd meeting, over 100 participants worked in small groups to develop a series of best practices. [The full summary of the recommended drug recall best practices is included as Appendix A and can be found on the Board of Pharmacy's website.] Best practices were organized into the following major categories:

ACTIONS:

- Procedural
- Know Drug Storage Areas in Hospital
- Wholesalers
- Technology-Based

IMPROVEMENTS:

- Notification System for Recalls Needs Improvement
- Tracking of Drugs Throughout the Hospital
- Staffing/Lines of Authority
- Geographic Issues – Where Drugs are Stored

Ms. Herold asked for comments from audience members periodically while reviewing the draft recommended best practices.

- Under the section on procedures, a participant commented that the list did not have a requirement for timelines for the hospitals. The participant added that wholesalers also needed a deadline expectation beyond which they will no longer ship recalled drugs. Ms. Herold responded that timelines will be considered with further editions of the recommendations.
- Another participant commented on designating specific people who are accountable in procedural and diagnostic areas where medications are also sequestered. These people need to share responsibility for complete evaluation of all possible drug storage areas and communication to their respective departments. Even though there may be specific authorized drug storage areas in the hospital, the reality is that drugs are often found outside these areas.
- Ms. Herold continued by reviewing the remaining sections under ACTIONS and asked participants for any additional comments that would benefit recall in hospitals. A participant asked if there was regulatory or legal

authority for the Board of Pharmacy or the California Department of Public Health (CDPH) to ask for a list of authorized storage areas and cite hospitals if drugs are found outside of designated storage areas. Ms. Herold commented that while there is no current regulation specifically focusing on storage, it is an area that the Board of Pharmacy is reviewing, particularly with regards to satellite pharmacies that are currently not authorized. She added that CDPH focuses on facilities, not specific drug storage areas. Dr. Loriann DeMartini added that there is no requirement under Title 22 specifically regarding drug storage areas.

- The participant added that without that regulatory or legal authority, it is left to the authority of the Pharmacy Director to ensure that others are accountable, and that hasn't worked well historically. Ms. Herold responded that these meetings were hoping to address that very issue. She added that a single model may not meet everyone's needs and perhaps various models need to be examined.
- Another participant noted that the FDA currently requires wholesalers to sequester recalled product upon receipt of a notice from the manufacturer, which typically comes through the mail. Because of the time gap between electronic notices to hospitals and mail notices to wholesalers, wholesalers continue to distribute recalled product up to a week following electronic notification of recall. She added that the State needs to narrow that period of time so that the wholesaler is held to a similar standard as the hospital. Electronic notification should be required for wholesalers. This may not be done nationally, but it could certainly be done in California.
- A participant representing wholesalers remarked that once they receive a recall notice from the manufacturer via email or regular mail, they notify their distribution centers to sequester the recalled product. Typically, within an hour of receiving a manufacturer's recall notice the wholesaler notifies its distribution centers via email and the recalled product is sequestered. She acknowledged that there can be a delay because manufacturers still send recall notices through the mail. She added that manufacturers have email addresses for wholesalers are able to contact wholesalers via email. Ms. Herold pointed out that having a situation where the end user is aware of a recall and a wholesaler has to wait to get an official notice before acting upon the recall notice, highlights a very serious gap in the system.
- A participant suggested having sites check inventory with the understanding that the wholesaler may not have received the recall notice yet. This can be done for a period of time following the issuance of a recall notice. Ms. Herold acknowledged that continuing to check inventory, for a week or two after a recall notice has been issued, was a good addition to the list of suggested best practices.
- A participant commented that the list of suggested actions relied on the fact that the notification system is in tact and that you get timely notification. She added that the list of suggestions did not include anything targeting notification. She said that she had a pilot program with her wholesaler where the wholesaler electronically notified them directly about recalls. She acknowledged that she gets more notification from her wholesaler than from the FDA. She felt that wholesalers were doing a good job of notifying them about recalls.
- Ms. Herold responded by saying that the Board of Pharmacy did not believe that any hospital or wholesaler deliberately shipped or dispensed recalled drug product. However, the reality was that recalled drug product was made available to patients. She added that the Board of Pharmacy is considering using subscriber alerts to connect all pharmacies to the Board of Pharmacy. She acknowledged that the Board of Pharmacy may not get information as quickly as hospitals and encouraged participants to forward suggestions about how the Board can share information about recalls most effectively and efficiently. She added that once a hospital is notified about a recall, even if the manufacturer has not given explicit directions about what to do with the recalled drug product, that hospital is expected to sequester and quarantine the recalled drug product until it receives instructions about what to do with the drug.
- A participant commented that manufacturers often send recall notices just to their purchasers and don't share the information more broadly. In many communities, hospitals share drugs because of shortages or

borrowing and a situation may arise where a secondary hospital does not receive a recall notice. The participant suggested creating a regulation whereby the Board of Pharmacy will have to be notified directly by wholesalers about any drug recall. The Board of Pharmacy can then broadcast the notice more widely.

- Another participant shared her positive experience using RASMAS, a web-based subscription service that provides comprehensive notification, distribution, and management of product alerts and recalls for all healthcare and consumer products used in healthcare facilities. She added that RASMAS constantly searches multiple websites for recall information. Her hospital had several coordinators who receive electronic notification through RASMAS.
- A participant suggested that since wholesalers are saying that they cannot act until they receive official notice from a manufacturer, wholesalers may want to consider putting an asterisk or other denotation on a shipment invoice indicating that a shipment may contain recalled drug product. This way a hospital that receives the shipment has some way of knowing that a shipment may contain recalled drugs and can act accordingly.
- Another participant countered that she didn't understand why wholesalers who are licensed in the State of California are held to different standards than hospitals. She added that if the hospital can get access to the information through RASMAS and other services, why can't the wholesaler get that same information? The result would mean that all entities would be on the same timeframe and the level of due diligence would be equal.
- A participant cautioned everyone about the reliability of products like RASMAS. For a wholesaler to create a drug shortage based on information that may not be reliable could be devastating. The key would be to have an early and reliable recall notice system in place.
- Ms. Herold asked participants for clarification regarding recalled lot numbers. A participant confirmed that any recall notice sent has to have a lot number. However, invoices do not have to go out with lot numbers, which means hospitals often don't know what lot numbers are in their facilities. Another improvement would require wholesalers to provide lot numbers on every invoice.
- Ms. Herold pointed out that an electronic tracking system or e-pedigree would address some of these issues. The coding would contain information which would allow hospitals to know exactly what lot numbers they have in their possession. In addition, Ms. Herold pointed to the suggested use of bar codes and radio-frequency identification (RFID) on the list of best practices document as other potential tracking mechanisms. Ms. Herold stressed that while the systems are not in place right now to implement e-pedigree or RFID, the Board of Pharmacy is working towards finding effective solutions in the future.
- Ms. Herold closed by thanking participants for their comments on the document. She informed the group that the Board will continue to collect feedback and comments at this meeting and will collect more feedback once the document is posted on the Board's website. For the next meeting, a more finalized version of the suggested best practices will be distributed, hopefully in advance of the meeting. Ms. Herold also addressed the issue of having more disciplines, Boards and organizations represented at future meetings (e.g., nursing, California Hospital Association, etc.). She stressed the importance of gaining clarity and consensus as pharmacists before opening up the discussion more broadly to other professional groups.

3. Overview of Pharmacy Law Related to Hospitals/Health Systems

Robert Ratcliff, PharmD, Supervising Inspector at the Board of Pharmacy, and Joshua Room, Deputy Attorney General gave a presentation on pharmacy law related to hospitals and health systems. Major points from Dr. Ratcliff's and Mr. Room's presentation included:

- The goal of the presentation was not to make each Pharmacist-in-Charge (PIC) fit into every requirement that applies to the pharmacy or to the PIC. The goal of the presentation and of the subcommittee in general was to communicate what's expected of a PIC and empower PICs with information to help them be more proactive about their roles as leaders within their organizations.
- Each Pharmacy Director has pharmacy departments that look very different in terms of size and complexity, but each director has similar tools at his/her disposal. These tools include:
 - Knowledge, Training & Experience
 - Staff – knowledge
 - Training & experience
 - Policies & Procedures
 - Associations guidance
 - Board of Pharmacy
 - Pharmacy Law
 - Self Assessment
 - CA Dept. of Public Health
 - Title XXII
 - Joint Commission
- The Hospital Pharmacy Self-Assessment tool is extremely helpful in knowing what is expected by the Board of Pharmacy. PICs are encouraged to share the assessment tool with staff as a public document.
- From the Board's perspective, PICs have a similar "authority, responsibility and accountability" as nurses have for the nursing service within a facility per 22 CCR § 7021 (c).
- A participant commented that a PIC's area of responsibility is much broader. PICs are responsible for all medication management throughout a hospital.
- The purpose of reviewing a PIC's areas of responsibility per various regulations and statutes is to ensure that PICs have the appropriate authority within their organizations to influence policies and procedures and effect the necessary changes that have to be made to ensure that the hospital is in compliance with relevant laws. It is also to ensure that when they are held accountable, they've had the power and authority up until that point to make the necessary changes. In addition, subverting this authority by a non-pharmacist owner can constitute a misdemeanor.
- A participant commented that even though all of this is in the law, administrators prioritize risks. It is not often seen as a risk when a pharmacist is not reporting to the right person.
- Another participant pointed out that influence is the key element to make change happen. If there are no consequences for the administrator for not ensuring the proper level of authority for a PIC, then things are not likely to change.
- Mr. Room reiterated that one of the purposes of the subcommittee is to determine what can be done to address whether or not PICs have authority to do their jobs effectively. From the Board of Pharmacy's perspective, there are enough statutes and regulations to bolster a PIC's authority. Mr. Room added that if that's not the case, the Board would like to hear from participants about what needs to change.
- The Board of Pharmacy has at its disposal the ability to create regulations to support effective pharmaceutical care in California, but only has the power to hold the PIC accountable. From the Board's perspective, a citation is a public record of the problem and a proposed remedy.
- Another participant commented that through regulation, nursing is required to sit at the C-Suite level which gets them to the table earlier regarding allocation of resources. Getting the resources and tools to

make things happen requires early participation. Resource allocation and decision-making depend on where pharmacists sit in the organization.

- Dr. Loriann DeMartini added that there is another Title 22 requirement that addresses the lines of communication and authority between the Chief Nursing Officer and other disciplines – medical, administration, and governing body. She stated that there isn't similar language for the PIC who has similar overall responsibilities for the pharmaceutical services within a hospital.

4. Models of Drug Distribution in Hospitals/Health Systems: A Panel Discussion

In an effort to better understand various models of drug distribution in hospitals, the Board of Pharmacy invited four pharmacy directors to present on their respective hospital's model for drug distribution. Panelists were asked to briefly discuss some of the challenges they face in terms of drug distribution and if possible, comment on where pharmacy law or lack of pharmacy law and contributed to their challenges.

The presenters were:

- Elaine Levy, Sharp Healthcare, San Diego
- Tom Dotts, Pomona Valley Hospital
- James McNulty, Kaweah Delta Medical Center, Visalia
- Terry Nishizaki, UC Davis Medical Center, Sacramento

The main points from the presentations are as follows:

Elaine Levy, Sharp Healthcare

- Sharp is a health system composed of six hospitals, their own health plan, home infusion department and hospice.
- As a team across the hospitals, they discovered that they were doing repetitious and duplicative work in their IV rooms and at the same time evaluated their home infusion services. As a way to increase efficiency and save costs, they developed the Sharp Central Pharmacy Services (SCPS).
- In addition to the efficiency and cost savings, the USP Guidelines were an impetus for creating the centralized pharmacy. They performed evaluations for each site through a GAP analysis. They also did a full business development project to assess what it would take to open up SCPS.
- They met with the Board of Pharmacy early on because they knew it would be challenging with separately licensed pharmacies and having the infusion pharmacy.
- Sharp Healthcare internal consultants used the process improvement framework called Lean Six Sigma (Define, Measure, Analyze, Improve, and Control) and were instrumental in helping to create the SCPS. The framework helped the team make good decisions about process improvement.
- The project took a year. A key lesson learned was that when they created an off-site facility and took work outside the hospital pharmacy, they couldn't do it without redesigning how business was done.
- One of the biggest challenges was information technology (IT). Everything pharmacy does centers around IT. They had to be able effectively code information for each of the hospitals they were serving.

- They used several tools to improve work flow, including many borrowed from Japanese business settings including the Heijunka and the Kan Ban.
- Since opening, they are still working out many issues such as recycling and reporting from two systems that had to be combined. They continually measure as part of the Lean Six Sigma framework and look at expense per unit of service (UOS) as a way to measure success.
- They are currently mostly still manual, but are considering using Intellifill, an automated robot that produces syringes. They are also considering Intelliflow to manage the IV room workflow. Some advantages include recording and storing data for regulatory compliance and standardizing practices.

Tom Dotts, Pomona Valley Medical Center

- Pomona Valley is one of the few remaining stand-alone hospitals in California. They have 456 beds and have the third largest number of deliveries in state. Last year, they had over 8000 deliveries. They have a 65-bed ICU and a very busy emergency department.
- Dr. Dotts commented on the previous discussion regarding pharmacy director leadership. Dr. Dotts expressed that the issue had more to do with the pharmacists themselves rather than the administrators. Mr. Dotts added that he thought pharmacists may be hesitant to take on the challenges of the position and that he had not come across an administrator who wouldn't be more than happy to have a PIC take on more authority and accountability.
- Dr. Dotts sits on the medical executive committee, which he acknowledged may not be the norm. At his hospital, pharmacy is highly integrated with every aspect of nursing and they work well with the medical staff in general. Outside consultants validated that the hospital was near benchmark in terms of drug utilization. Staffing analyses also revealed that they were very productive in the area of pharmacist and tech staffing.
- They have a centralized model and they use automated drug dispensing cabinets. In excess of 90% of the administered medications come out of cabinets. Dr. Dotts added that the key aspect for medication distribution is to be proactive and not let things go on auto pilot. He added that it was important to have someone on top of issues every day.
- They conduct continuous quality improvement (CQI) processes on a quarterly basis and the information collected often can help PICs continue to raise the bar.
- They are planning to institute bedside bar coding.

James McNulty, Kaweah Delta Health Care District

- They are a 500 bed licensed facility in Central California. A current expansion will push them to 630 beds. They are spread out over multiple cities and multiple campuses.
- Most of their drug distribution challenges are related to having 630 beds on three campuses. Most of those beds are in the main hospital; the challenges are distributing drugs to the other two campuses.
- Some of their services include a dialysis center, oncology, skilled nursing facilities, home infusion and hospice. They also have an acute care hospital for adult, peds. and NICU.
- They have five pharmacies including two outpatient pharmacies, an employee pharmacy and infusion pharmacy. In addition, there are inpatient and operations. When other pharmacies close, all orders are sent to the main hospital.

- The main hospital pharmacy is open 24 hours a day. More than 98% of their drugs are in Pyxis machines. They are scheduled for bedside patient/drug bar code verification in February 2010 and computerized provider order entry in November 2010.
- Their main challenge came down to implementing new technology or bar code strategies within current laws or lack of current laws. Some additional challenges to bar coding included:
 - Bar coding of product for all campus areas.
 - Because they prefer to package at one campus and transfer to other campuses, they are considered a manufacturer and are held to different standards. One suggestion is to work with CDPH to get a manufacturing license.
 - Use of Pharmacy Order Management System (POMS) from remote location.
 - Because they work with pharmacists in remote locations, the expectation is to notify the Board of Pharmacy and the Drug Enforcement agency when operating under this scenario.
 - Replenishment of Automated Dispensing Cabinets (off campus)
 - One of their biggest challenges is filling of Pyxis units for off-campus areas when pharmacy areas are closed. Sending bulk product can mean that a pharmacy becomes a wholesaler.
 - Pharmacist oversight of drug areas
 - Oversight continues to be a challenge, particularly regarding drug recall management and management of IV solutions at off campus locations.
- Dr. McNulty concluded by saying that he hoped that the subcommittee would take a hard look at current practices and determine whether current law was appropriate. As more technology is implemented, it is more important than ever to work collaboratively with the Board of Pharmacy, CDPH and other pharmacists to ensure safe and effective patient care.

Terry Nishizaki, UC Davis Med Center

- UC Davis Med Center in Sacramento has a central pharmacy and three satellites. They get their physician orders through computerized physician order entry (CPOE). Dr. Nishizaki commented that in all his years of practice, CPOE has been the greatest change to utilize their pharmacy and pharmacy staff much better.
- They are a 577 bed facility. They are a major teaching hospital; they have a Level 1 trauma center, burn center and children's hospital.
- They have decentralized drug distribution through automated dispensing machines (ADMs). They have over 100 Pyxis machines throughout the institution. Medications are accessible and secure and there's accountability.
- They refill the Pyxis machines centrally and deliver them daily to the automated dispensing machines. They dispense 250,000 doses per month out of Pyxis machines.
- They have been able to drop their error rate substantially through the use of bar coding.
- They have a centralized IV preparation area. First and miscellaneous doses are done from the satellite to catch up between batches. They do over 1,000 IVs per day.
- They are moving toward compliance with USP 797, Pharmaceutical Compounding: Sterile Preparations, the first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP). USP Chapter 797 describes the procedures and requirements for compounding sterile preparations

and sets the standards that apply to all settings in which sterile preparations are compounded. Some strategies they are using to be in compliance include 12-Hour BUDs in the satellites, central IVs and containment hoods.

- The IV compounding requirements have definitely changed the way all the UC hospitals do business. The regulations need to reflect both manual and automated compliance strategies. In the future, they are looking at robots to do IV compounding to help with efficiency and worker safety. Bar coding has also brought a whole new level of patient safety.
- Some suggestion for the Board of Pharmacy include:
 - All of their sites are signed up for the Board of Pharmacy email alerts, but one suggestion would be to have a similar mechanism as JCAHO where you can send in a question via email and receive an answer within a couple of days.
 - Better communication around change in interpretation of existing regulations. For example, PICs were cited during the heparin recall. It would have been beneficial to get more advance warning about that change.
 - Better communication regarding licensure status and better advance warning about recalls.
 - More education around the new manual of disciplinary guidelines and how it will impact practice and incorporation of technology in regulations with timelines.
- The pharmacist is just one part of a very complex system that is ultimately trying to deliver effective patient care.

The panelists took questions from the audience. Ms. Herold asked the panelists if they could have any law on the books modified, changed or developed, what would it be and why?

- One of the panelists suggested having more centralized control with the ability to radiate out. Another added that they needed flexibility to adapt because changes happen so fast.
- An audience member asked, in recent years have regulatory agencies helped or hindered your practice? Elaine Levy responded that conversations with the Board of Pharmacy in the conceptual stages of creating the centralized pharmacy were extremely helpful. She added that she received very valuable guidance about licensing.
- Another panelist added that even though the JCAHO process can be difficult, it has made it possible to make significant changes in the health care setting. The accreditation process has brought better understanding and more visibility to the fact that medication management is a very complex issue. In particular, there is better understanding from the C-Suite.
- A participant asked how one goes about changing laws when you have Title 22 on the books and you run the risk of contradicting what is outlined by the laws that the govern hospitals.
- Dr. DeMartini confirmed that there is no plan to revise Title 22. To clarify about the issue of conflict, Dr. DeMartini added that statutes specifically covering scope of work will usually trump Title 22. She added that whenever you have two regulatory bodies that have jurisdiction, the more stringent one will apply. At any point in time if you want to flex a regulation in Title 22, you can submit a program flex request to your district office for licensing and certification. A request is usually sent with the understanding that a proposed alternative will still meet the intent of the regulation.

- Ms. Herold responded by saying that the Board of Pharmacy does not have the authority to flex regulations in the way that the CDPH does. The Board of Pharmacy tends to go to the legislature more often. One of the potential outgrowths of the subcommittee meetings is to examine where statutory regulations are needed. For example, over the years the Board has done statutory modifications to allow the use of technology. She added that if you can make a compelling case that the patient's interests will be served by doing a particular modification, the Board has been known to carry that particular modification through the legislature. The Board is sponsoring six bills this year.
- Dr. Schell acknowledged the number of regulations that have been enacted in the last 20 years to improve the quality of products and services produced in hospital pharmacies and asked the panelists if they've seen any demonstrable improvement in the types of sterile products they produce or the ways the provide services.
- Dr. McNulty from Kaweah Delta responded by saying that they evaluated a product long before USP 797, clean room standards. They have seen no significant difference after being fully compliant with USP 797 and spending \$1.2 million. The consensus was that the medical literature supported Dr. McNulty's observation.
- Dr. Schell also asked the panelists if they have seen a decrease in medication errors.
- Dr. Nishizaki responded that CPOE and bar codes have been very effective in decreasing medication errors. Another participant commented that the use of smart pumps has also helped decrease medication error.
- Dr. Dotts shared his frustration with the scenario of roving nurses who commit drug theft in one hospital and end up working at new hospital the next day. He posed to the Board the question about how consumer protection can truly happen when the process to suspend nurses is so slow.
- Ms. Sodegren responded that there is a diversion process in place at the Board of Nursing. If a pharmacist submits a report to the Board of Pharmacy about a theft, the BOP takes it directly to the Board of Nursing. Ms. Sodegren's understanding is that if a nurse is in the diversion program, that nurse is restricted from practice for 90 days. Any board's enforcement process can take time because of due process. Ms. Herold added that an admission by a colleague that a professional is under the influence can help speed up the process. Another alternative is to involve the police, although the police may only arrest under petty theft or embezzlement. The key would be to make sure that the police are aware of the violations of the business and professions code, so that the penalties are stronger and the provider can be removed from practice.

5. Providing Safe and Effective Patient Care: Oversight and Management of Drugs in Hospitals/Health Systems

For this part of the agenda, Ms. Sheehan asked participants to form pairs and interview each other about drug oversight and management in their respective practice settings, using an interview form [See Appendix B – Providing Safe and Effective Patient Care: Oversight and Management of Drugs in Hospitals/Health Systems]. The goal was for the Board of Pharmacy to gain a more comprehensive understanding of drug oversight and management practices. The interview questionnaire focused on two major categories: acquisition and storage/management. Following the interviews, the group discussed the responses.

- When asked about whether or not drugs are brought in from other staff, a participant shared that dialysis staff bring in their own medications, but with pharmacy oversight. It doesn't work well, but pharmacy tries to make it work.

- Another participant commented that this dialysis scenario was very significant during the heparin recall. They realized that the dialysis staff who bring in their own drugs did not have a consistent standardized notification process. To remedy the situation, their facility included dialysis staff in the notification process.
- A participant commented that organ procurement staff bring in their own medications and another participant added that samples are also a problem
- The Veteran's Administration Hospital in San Francisco has a "no outside source, no sample" policy. There is a disciplinary policy to support this policy. One difficult enforcement area is providers who carry medications in their pockets.
- With a patient's own insulin pump, there is no way to identify what's inside. Surgery kits pose similar challenges. Surgery kits are tricky because are they a drug or device? Are they considered under the regulations?
- A participant commented that physicians are not employees of hospitals and hospitals are at the mercy of doctors. Taking away a physician's privileges because he or she violated a no outside drugs policy may compromise the care provided by that hospital. This can be even more complicated in small communities with fewer doctors, where doctors practice at multiple hospitals or there are just too few doctors for the community.
- Anesthesiology and emergency room services are contracted out, so they have their own their policies that don't always match the hospital's policies. The group agreed that they have the option to spell out specifics in the contract.
- A participant pointed out that no administrator has his or her name on a license, so there isn't the same level of personal responsibility like nurses, lab directors, and pharmacists. A skilled nursing facility has a professional on the license; in general, licensed professionals have more to lose.
- Dr. DeMartini from CDPH confirmed that a nursing home has to have a licensed administrator and she added that an administrator's name does appear on a hospital license as well. She also clarified that if you have 100 beds or more, there's a hospital license that has to be used with a Pharmacist-in-Charge. A hospital with 99 or fewer beds still requires a pharmacist to run services, but there's a difference.
- A participant noted a trend with decentralized pharmacies (satellites) with centralized distribution. She added that rampant use of satellites throughout the hospital may not be the best use of resources especially in light of technology and pyxis storage units.
- A participant commented that the main problem with satellites was the belief that the same rules that apply to centralized pharmacies, apply to satellites. The main problem with satellites is that people grab their own drugs. There was a consensus that drugs need to be centralized and pharmacists need to be decentralized.
- Satellites initially were a way to have more control over the drugs and get pharmacy out of the basement, but now there is no need to have a satellite to justify having a pharmacist on the floor.

6. Additional Public Comment

Ms. Sheehan asked if there were more comments on the Best Practices Document or other comments. No further comments were offered by participants. She noted that Ms. Herold's notes will be formalized and

distributed before the next meeting. One participant commented that it is encouraging that the Board is trying to listen.

7. Closing, Evaluation, Adjournment

Ms. Sheehan closed the meeting and thanked the speakers and the Board of Pharmacy for hosting the meeting. Dr. Schell added his appreciation on the behalf of the Board of Pharmacy for everyone's time and commitment to improving patient care and safety.

The meeting was adjourned at 2:30pm

Appendix A – Summary of March 2, 2009 Recommendations for Drug Recall Best Practices

ACTIONS:

Procedural:

- Develop written procedures for recalls.
 - Include a duties or detail list with all steps needed during a recall so that any staff member can effectively carry out the steps.
 - Limit the number of people pulling the product during a recall for better accountability and control.
 - Establish a dedicated and trained recall team who knows all the policies, procedures and pertinent regulations
 - Identify individuals pulling products in each location.
 - Require individual departments to verify that they looked for the recalled product.
 - Identify avenues for notification
 - Have a centralized method to receive and interpret and disseminate information about recalls, especially Class 1 recalls.
 - Post flyers, for example on facility posted flyers saying “bad heparin” with the lot numbers. This information was shared with the nurses.
 - Offer a reward. (One facility offered a reward if \$10 per vial of recall, that was increased by the administrator to \$100 per vial.)

Know Drug Storage Areas in hospitals:

- Identify all locations where drugs are kept.
- Maintain control over drug storage everywhere in the hospital
- Set up an organized storage facility for drugs so there is just one place to go.
- Allow no drugs in the hospital that were not purchased through the pharmacy.
- Minimize the number of and maximize the quality and authority of the individuals carrying out monthly inspections. Ensure that someone is authorized to do what is necessary to secure the drug supply throughout the facility.
- Establish a method to close the loop and perform an audit. (For example, recall notices were faxed to all pharmacies and responses confirming that all drugs were removed were expected within 72 hours. After the faxes were received, an individual conducted site visits to double check.)

Wholesalers

- Have a wholesaler representative dedicated to the hospital or hospital group. (Alternatively, why not have one person be hospital’s liaison with the wholesaler.) This person can run reports and identify recalled drugs purchased by the hospital.
- Drug purchases made under the control of the pharmacy.
- Collaborate and communicate with the wholesaler

Technology-Based:

- Maintain all stock in cabinets to easily and quickly do an electronic lockout for recalls
- Implement an adverse drug reaction system that allows better tracking what occurred in relation to a recalled drug. Outcome: better communication with patients
- Obtain an electronic receipt of recall notices

IMPROVEMENTS

Notification System for Recalls Needs Improvement:

- Recall notices should state whether this is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
- Message is not always clear. Improve and simplify messages regarding recalls.
- To avoid confusion, create recall notices with more uniform language or have notice come from one source.
- Have a more effective notification system that originates in one place, listing what the issue is, what should be done, what steps should be taken, etc. Having one notice from one source with all the relevant information would minimize confusion.
- Establish a centralized method to interpret and disseminate information about recalls.
- Have a centralized system or body in a hospital that would distribute recall information through email. This would create better accountability and better response time.
- Improve coordination of recall notices especially for ubiquitous products.
- Encourage wholesalers to take more responsibility in terms of communicating recalled lot numbers

Tracking of Drugs Throughout the Hospital:

- Institute bar coding to better track drugs throughout the facility/ Hospitals need to prioritize bar coding technology.
- Electronic tracing or notification (e.g., secure email) of recall would be helpful.
- Institute RFID or bar codes and advocate to have standardized methodology in the way the information is sequenced. This should apply to the entire lifecycle of the product.
- Establish radio frequency identifiers as a way to track drugs (a non-line of sight read) this would be one way to carry e-pedigree. E-pedigree would be a way to better execute a recall.

Staffing/Lines of Authority:

- One department has to take responsibility for something that is the responsibility of the whole hospital. The emphasis needs to be placed on the CEO or president instead of the PIC; if so, a lot more action might have been taken.
- Require that drugs be stored in specific locations and institute consequences when drugs are stored out of the area.
- Expand policies to increase responsibility of other department heads during a recall
- Increase authority of PIC to better control where and how drugs are stored.
- Increase accountability. All health care providers that are touching the drug are accountable.
- At the site level, involve nurses, physicians, dialysis tech, therapists, and administrators in discussion about accountability. Pharmacists need more authority if held accountable.
- Bring together management, California Hospital Association, Medical Board, Nursing Board. Other health care providers should be willing to accept citations and fines.
- Increase accountability and collaboration among members of the health care team. There is a lack of consequences for other health care professions.

"Geographic"

- Have a better system to identify outpatient clinics that are on the facility's license. This would help clarify what a PIC is responsible for.
- Establish an authorized storage area. If something is not in an authorized storage area, then it is stored unlawfully.
- Outside medications from vendors or contractors should not be allowed in the hospital.

**PROVIDING SAFE AND EFFECTIVE PATIENT CARE:
OVERSIGHT AND MANAGEMENT OF DRUGS IN HOSPITALS/HEALTH SYSTEMS**

Name (optional): _____

Facility (optional): _____

ACQUISITION

1. Who orders drugs in your facility? (Please check all that apply.)
 - PIC
 - Pharmacy Director
 - Pharmacy Technician
 - Material Management
 - Other: _____

2. Which units of the hospital/health system order drugs directly for their use? How does the pharmacy maintain control?

3. Can contracted service providers bring in their own drugs?

4. Can professional or other staff bring in drugs for administration to patients?

5. Are there any other drug ordering or acquisition practices that you have found to be helpful? Are there ones that you have found to be more problematic?

(over)

STORAGE/MANAGEMENT

Where are drugs stored in your facility?	For each area selected, please list the title(s) of staff who manage the drugs.	Of the staff titles listed, which staff member(s) has/have the following related to drug management: (Check all that apply.)		
		Responsibility	Authority	Accountability
<input type="checkbox"/> Main pharmacy				
<input type="checkbox"/> Additional pharmacies (how many)				
<input type="checkbox"/> Satellite pharmacy				
<input type="checkbox"/> Clinics				
<input type="checkbox"/> Pyxis machines				
<input type="checkbox"/> Floor stock				
<input type="checkbox"/> Crash carts/ emergency kits				
<input type="checkbox"/> Paramedic units				
<input type="checkbox"/> Other:				

1. For satellites and Pyxis machines, what services are being provided by the pharmacy staff?

2. Are monthly inventories conducted of each identified location? Who performs the stock check? Who reconciles?

California State Board of Pharmacy

Subcommittee to Evaluate Drug Distribution within Hospitals

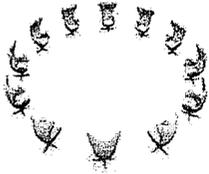
June 2, 2009

CALIFORNIA STATE BOARD OF PHARMACY

Meeting of the Subcommittee to Evaluate Drug Distribution in Hospitals

June 2, 2009
9:30am – 3:00pm

Purpose of Subcommittee



- Ultimate goal: safe and effective patient care
- Help inform decisions regarding pharmacy law or regulations
- Provide guidance on recommendations

Summary of March 2 Meeting

- Inaugural meeting – focus on drug recall processes
- Overview of federal and state regulatory agencies involved in recall
 - Alonsa Cruse, District Director, FDA
 - Daniel Seid, Chief, Drug & Safety Unit, CDPH
- Examination of heparin recall
 - Loriann DeMartini, Chief Pharmaceutical Consultant, CDPH

Summary of March 2 Meeting

- Group discussion on what's working well and not well related to recall -> captured best practices as well as suggestions for improvement of recall processes.
- Brainstorm on future topics for subctee. mtg.
 - Pharmacy Director role – authority/accountability.
 - Provision of pharmaceutical care/effective pt. care – quality and safety of drug distribution, clinical eyes, satellite pharmacies

Evaluation of March 2 Meeting

- Overall rating = 3.36 on scale of 1 – 4
- Best aspects:
 - "Opportunity to provide feedback."
 - "Chance to interact with regulators."
 - "Good information – to the point, provided by presenters."
- What would have made it better:
 - "Participation from medical, nursing and other provider boards and CHA."
 - "Larger room."

Meeting Values

- Open communication
- Collaboration
- Solution orientation

Meeting Courtesies

- Feel free to move around.
- One person speaks at a time.
- Honor time limits on breaks and lunch.
- Cell phones, iPhones, Blackberries to off/silent.

California State Board of Pharmacy
 Meeting Agenda
 Subcommittee to Evaluate Drug Distribution within Hospitals
 June 2, 2009
 9:30am - 3:00pm
 Location: UCSF

Meeting Purpose	To enhance the practice of hospital/health system-based pharmacy in California and ultimately to improve patient care and safety by exchanging information, working collaboratively and identifying best practices in pharmacy operations or areas where Pharmacy Law requires amendment. This is the second of several meetings planned throughout California during 2009 on these topics, although the agenda for each meeting will be different.
Desired Outcomes	By the end of this meeting, we will have: 1. Preliminary agreement on a best practices document related to drug recall in hospital/health systems. 2. Greater awareness of pharmacy laws related to hospital/health systems. 3. A better understanding of how different hospital/health systems acquire, store and manage drugs.

Welcome, Meeting Overview, Introduction 8:30am

Revisiting Drug Recall Practices
 Overview of Pharmacy Law Related to Hospital/Health Systems
 BREAK

Models of Drug Distribution in Hospital/Health Systems: A Panel Discussion

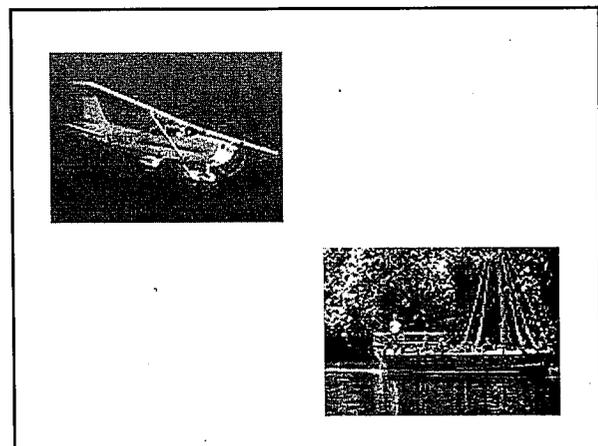
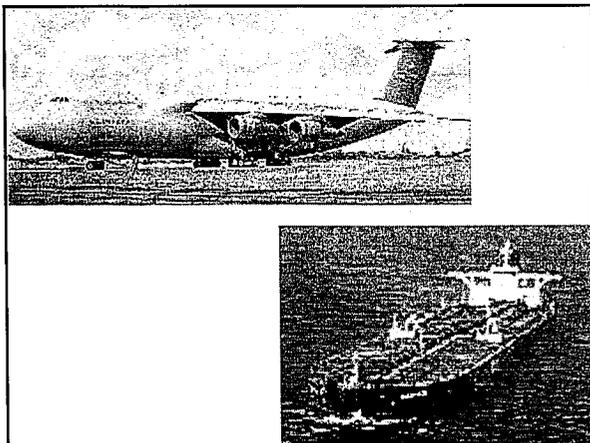
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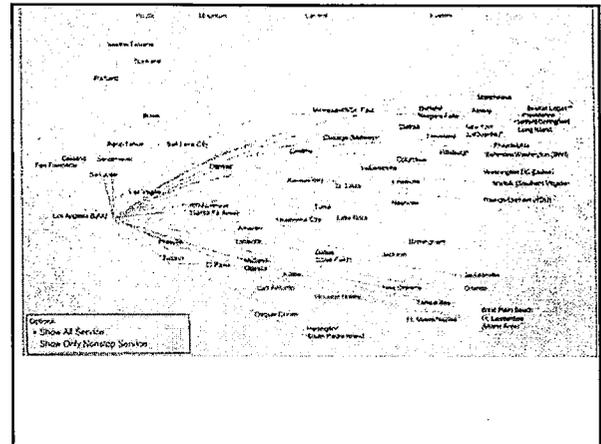
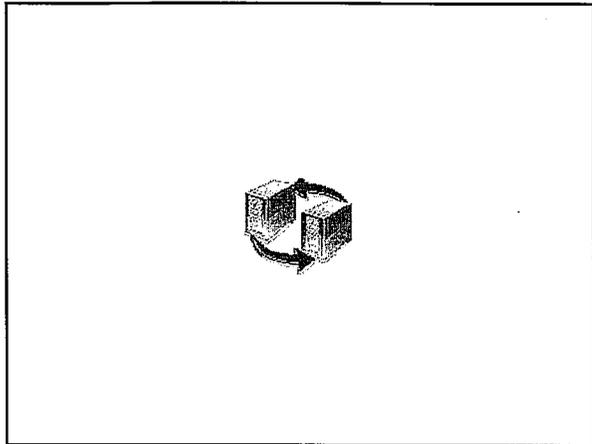
Providing Safe and Effective Patient Care: Oversight and Management of Drugs in Hospital/Health Systems
 BREAK

Additional Public Comment
 Closing, Evaluation, Adjournment 3:00pm

Authority for Pharmacist-In-Charge Oversight and Responsibility of Drug Distribution within a Hospital

Joshua Room, Deputy Attorney General
 Bob Ratcliff, Supervising Inspector





Tool Box

- Knowledge, Training & Experience
- Staff – knowledge, training & experience
- Policies & Procedures
- Associations guidance
- Board of Pharmacy
 - Pharmacy Law
 - Self Assessment
- CA Dept. of Public Health
 - Title XXII
- Joint Commission



HOSPITAL PHARMACY SELF-ASSESSMENT

The 19 of the California Code of Regulations section 1725 includes the (1) methods of change of each pharmacy licensed under section 2215 of the Business and Professions Code (2) complete self assessment of the pharmacy's compliance with federal and state pharmacy law. THE ASSessor SHALL BE LICENSED PHARMACY CLERK OR PHARMACY MANAGER. The purpose of the change form and complete self assessment under 2215 is to determine (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacy's ownership. The primary purpose of the self assessment is to identify compliance through self-examination and education.

This self assessment must be completed in privacy and may be completed online, printed and returned to the Pharmacy Division of the state board.

After it is completed, the pharmacy must file the completed form, printed and returned to the Pharmacy Division of the state board.

Each self assessment must be completed and filed in the pharmacy's records within 30 days of the assessment.

Pharmacy Name _____

Address _____ Phone _____

Outreach: Sole Retail Hospital/Inpatient Outpatient LTC Non-Quarantine Center Other (please specify) _____

Permit # _____ Exp. Date _____ Other Permit # _____ Exp. Date _____

Licensed Pharmacist Name # _____ (or Accredited by) _____

DEA Registration # _____ Fed. Reg. _____ Date of DEA Renewal _____

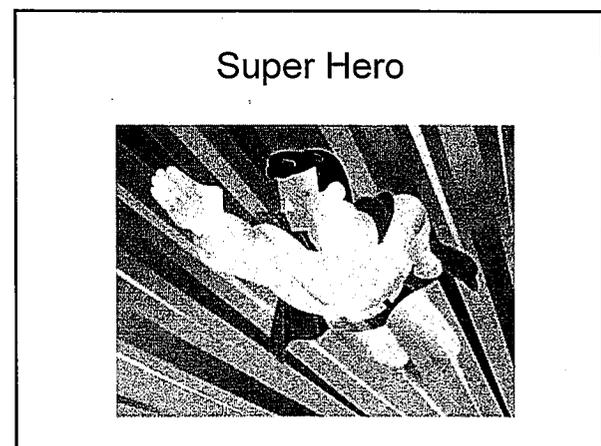
Hours: Mon _____ Sat _____ 24 Hours _____

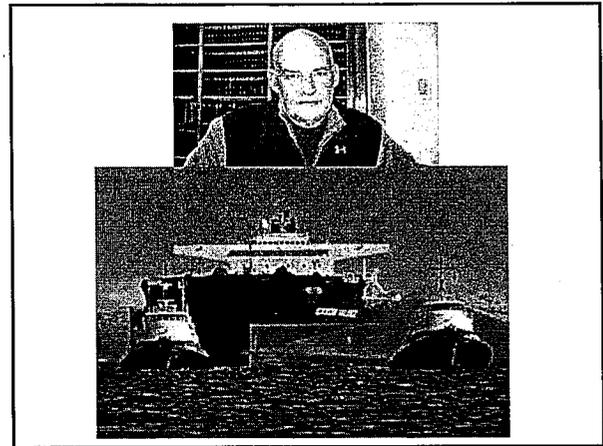
PHC _____ PHLE # _____ Exp. Date _____

Pharmacy # (if Hospital, please refunctional)

Hospital Self Assessment

- B&P 4104 – P&P for licensee theft/impairment
- B&P 4125/CCR 1711 – QA
- CCR 1714 – Pharmacy security
- B&P 4059.5(a) – RPH sign for drug deliveries
- CCR 1793.7 – P&P for TCH's
- B&P 4068 – ER prescriber dispensing
- B&P 4074(d)/CCR 1707.2 – Consultation
- CCR 1710 – Central fill
- CCR 1751 – Compounding sterile injectable drugs
- CCR 1797.8 – TCH check TCH



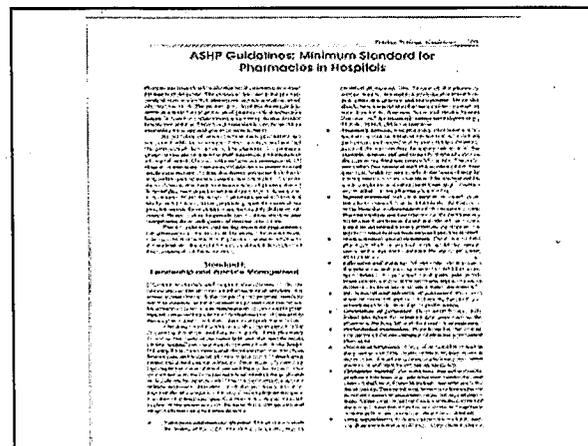


PIC Requirements - Board

- Licensed pharmacist
- Employed at the location and have responsibility for the daily operation of the pharmacy (CCR 1709.1[a])

PIC Requirements - Employer

- Varies



PIC Requirements - ASHP

- ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, 2008

ASHP Definition of a Standard of Practice
 ASHP article (Statement on Standards-Based Pharmacy Practice in Hospitals, 2008), "a standard is a statement that defines the performance expectations, or processes that must be in place for an organizations to provide safe and high quality care treatment and service." ASHP guidelines "are based on professional and scientific literature and developed with input from ASHP members, the public, regulatory bodies, other professional associations and representatives of other health care disciplines." The article continues, those guidelines "designated as ASHP minimum standards are a minimum level of practice that all hospital pharmacy departments should consistently provide."

Nursing Service

- 22 CCR § 70211(b) – The nursing service shall be under the direction of an administrator of nursing services who shall be a registered nurse with the following qualifications:
 - 1) Master's degree in nursing or a related field with at least one year of experience in administration; or
 - 2) Baccalaureate degree in nursing or a related field with at least two years of experience in nursing administration; or
 - 3) At least four years of experience in nursing administration or supervision with evidence of continuing education directly related to job specifications.

Nursing Service

- 22 CCR § 70211(c) – It shall be designated in writing by the hospital administrator that the administrator of nursing services has authority, responsibility and accountability for the nursing service within the facility.

PIC Responsibilities

- Responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy (B&P 4113[b])
- Complete self-assessment (CCR 1715)
- Notification requirements (B&P 4101)

PIC Responsibilities

- 42 CFR § 482.25(a)(1) – A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

PIC Responsibilities

- 22 CCR § 70265 – A pharmacist shall have overall responsibility for the pharmaceutical service. He shall be responsible for the procurement, storage and distribution of all drugs as well as the development, coordination, supervision and review of pharmaceutical services in the hospital.

PIC Responsible or Reports To

- CA Board has no requirements
- 22 CCR § 70265 – "...The pharmacist shall be responsible to the administrator and shall furnish him written reports and recommendations regarding the pharmaceutical services within the hospital...."

Institution/Permit Requirements

- Reporting requirements
- The pharmacist-in-charge ... shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge ... had no knowledge, or in which he or she did not knowingly participate. (B&P 4081[c])

Institution/Permit Requirements

- The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of the pharmacy. (CCR 1709.1[b])
- Any non-pharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor. (B&P 4330[b])

Questions?

Central Pharmacy Overview



SHARP Central Pharmacy Services (SCPS)

Grand Opening
November 17th
2008

~
Serving all
SHARP
Hospitals



Background

- USP Guidelines impetus as well as efficiencies and cost savings
- Evaluation of each site – GAP analysis
- Interim measures put in place to meet minimum standards

Financial Assessments

- Evaluate costs of entity renovations
- Review dollars spent in “outsourcing” products
- Cost of build out of new facility in partnership with own Home Infusion Services
- FTE transfers from hospital to Central Pharmacy

Centralized IV Location

- Evaluate hospital space – too costly
- Home Infusion space insufficient
- Warehouse space selected with facilities project manager
- Met with State Board to discussion licensing of facility
- Six Sigma “black belts” assigned to project team

Goals and Objectives

- Initially- to transfer vast majority of “medium” and “high” risk admixtures from hospitals to Central location
- Broader objective – remove all batch production from hospitals regardless of risk level to increase efficiencies, improve controls, enhance quality, reduce costs

Define

- The context of the process
- The customer
- The right metrics and targets

Measure

- Input requirements
- Output requirements
- In-process requirements

Analyze

- Cause and effects
- Determine the gap

Improve

- Ideal state
- Apply innovation
- Future state

Control

- Sustain the gains!



Central Pharmacy

Verify:

DMAIC

DFSS = Design for Six Sigma

Define

Measure

Analyze

Design

→ Verify

A product or process is not in existence and one needs to be developed

Central Pharmacy

Project Time Line:

2008-2009



	Match	May	July	Sept	Nov	Jan 09	March	May	June
Board Approval of lease	◇								
Design new lean processes									
Construction									
Move in (Weekend)					◇				
Home Infusion Operations									
TPN production for all Entities									
Hospital Pharmacy Improvements	Continuous Improvements: Cardinal Assist and IV work flows								
Production of specialty IVs									Bring in house
Patient Specific IV Batches									1 st Entity 2 nd 3 rd 4 th & 5 th

Central Pharmacy

Project Vision

Design and implement a 'Lean' centralized IV preparation and distribution process that will meet USP 797 requirements and Customer demands for timeliness and safety.

Implement Lean work flows and a Lean continuous improvement environment at Hospital Pharmacies and Home Infusion.

SCPS Manager: Bruce Schmidt
Process Owner: Elaine Levy (Pharmacy Director)
Executive Sponsors: Michele Terbet and Nancy Pratt
Sponsor: Mark Monson
Black Belts: Kurt Hanft and Erin McGlone
Steering: Jaime Santon (Facilities Project Manager), Miles Hildebrand (SCV Pharmacy), David Lauder (SCV Pharmacy), Gary Thomas (SCV Pharmacy), Blair Trotter (SCV Pharmacy), Matthew Gerlak (SCV Pharmacy)

Doors Open November 17th, 2008
 Home Infusion moved and TPN production implemented.

Central Pharmacy

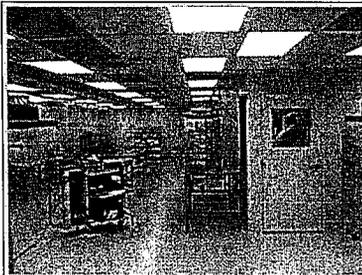
8 Work Teams formed:



Operations Oversight Team – Kurt Hanft, Elaine Levy
 Achieving project goals
 S.A.F.E Team – Lori Rhoades, Blair Frater, Erin McGlone
 To assess, plan, measure and improve a comprehensive Safety Management Program
 Finance Operation Team – Craig Dufault
 Develop go-forward business plan (Allocation, Productivity)
 Facilities Team – Jaime Santos
 Plan and coordinate construction and move
 Information Systems Team – Barbara Haskins and Rhonda Reynolds
 Provide IT Infrastructure and Software expansion
 Equipment Team – Elaine Levy
 Select pharmacy production, office, product handling, and disposal equipment.
 IV Centralization Workflow – Bruce Schmidt
 Design workflows to integrate home infusion with IV centralization
 Entity Workflow – Pharmacy managers / Operations supervisors
 Reengineer pharmacy workflow
 Implement improvements along flow from IV order to administration

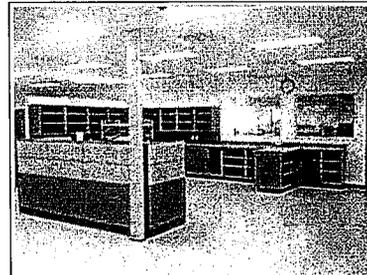
Central Pharmacy

Clean Room:



Central Pharmacy

Home Infusion Pick Area:



Central Pharmacy
Office:



Central Pharmacy
Product Anti Room:



Central Pharmacy
Improve:

Daily 9:30am Power Meeting

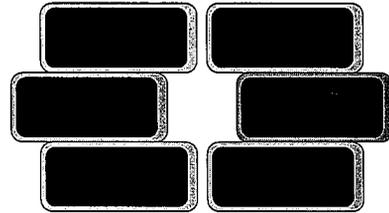
AGENDA
Review Task Board
What's New?
Round Robin
WWW Update



Central Pharmacy
Education Slides:

Each Hospital will be identified label color:

All labels printed at entity will remain all white



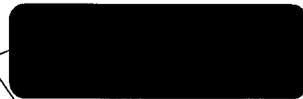
Central Pharmacy
Improve: Safe Labeling

Over Sight Team Focus:

- Limit color coding to Oxytocin
- Use Sharp Standard for Tall Man Lettering
- Box around Dose
- Label 'For IV Use Only
- Larger Label and Font

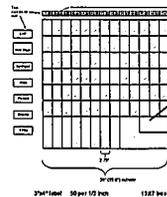


1.5 inches

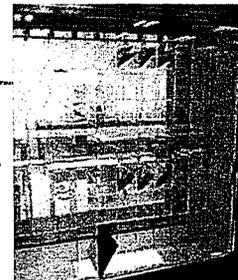


2.5 inches

Central Pharmacy
Improve: Work Flows



Level Loading Pitocin
Next Dialysis products

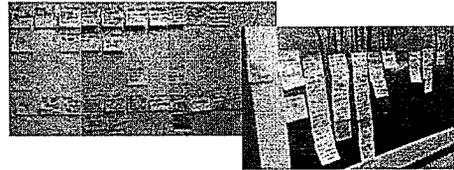


Central Pharmacy
Improve: Slappers Heijunka

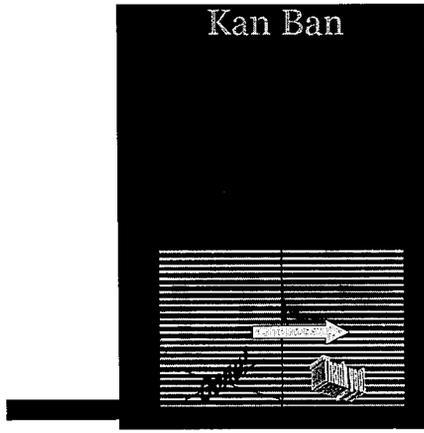
- Organizes production
- Same order every time
- Heijunka and storage shelf organized in the same order.
- Separate look-alike sound alike drugs in the order
- Visual to see if we are on track
- Easier for multiple techs to work together

Drug Order	SGP#	DOY	SNAP	SNAP#	DATE
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
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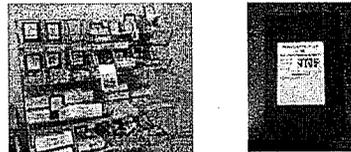
Central Pharmacy
Improve:



Kan Ban



Central Pharmacy
Improve:



Central Pharmacy
Improve: Courier Work Flow

Issue: Returning from Home Infusion deliveries in time for Hospital deliveries and reducing overtime.

Current Condition: Couriers deliver by Zone.

Root Cause: 5 Whys = Couriers wait for all deliveries for a Zone to be ready.

Counter Measure: Regardless of zone, schedule regular departure times.

WWW: Standard Work, Assign departure times and change work schedules.

- Test:**
- *Pilot and review courier availability for Hospital deliveries.
 - * Measure Miles per Patient.
 - * Review Overtime.
 - * Review third party courier charges.

- Benefits:**
- *Improve ability to deliver to hospital on time.
 - *Less courier time wasted waiting.
 - *Removed perception that couriers were standing around doing nothing.



Central Pharmacy
Control: Standard Work



Place the SGP# label under the Patient Specific Label to show:

- Same site as patient label
- Medication or patient label.

Example: 1 Shot bag put SGP# label on back.

Place the Patient Specific Label next to the syringe procedures on the control.

Visit: Add first with Patient name on the top right. Letter's 'D' on top.

Place the SGP# Label on Syringe over the 'Process Exception' tab.

Central Pharmacy Issues:



- Medication Error: Labeling error with wrong drug
- Discontinued IVs Recycling (example: Ampicillin)
- Drug Standardization / Brand differences
- Same Patient bundling issues (different patients bagged together.)
- Discontinued/Modification IS report (friendlier)
- Active IV Report used for reconciling finished IVs. (sorting issue)
- Addition drugs to add to the Hospital print list (floor stock items)
- Hospital Pharmacy time to reconcile delivery (Day 1 = 90 minutes)
- Space concerns to reconcile (opportunity for more 5S activities)

Central Pharmacy



Control: Financial Retrospective Review Measurements

Baseline Measurements

- Historical trended expense per UOS will be used as a reference when evaluating FY09 actual expense per unit
- Inflation, volume, and changes in programs or regulations will also be taken into consideration

Central Pharmacy



Control: Financial Retrospective Review Measurements

Evaluate Financial Impact of SCP Based on:

- Expenses Per UOS
 - Labor, Supply, Pharmaceutical, Purchased Service, and Total Cost per UOS (Pharmacy Adjusted Patient Days)
- Net FTE Reduction
- Capital Cost Avoidance
- Waste Savings

The final review of the metrics will take place in November-December 2009

Financial Retrospective Review Measurements- Expense Per UOS



Labor Expense Per UOS

Year	SMH	SCH	MBHW	SGH	HIT	SCV	SCO	SCO SNF
2007	41.99	23.33	28.66	35.56	32.40	41.81	65.83	7.38
2008	45.38	23.74	32.17	38.99	34.86	45.57	76.60	8.42
Budget 2009	38.31	22.60	33.14	42.34	31.97	46.15	76.70	7.01

Financial Retrospective Review Measurements- Expense Per UOS



Supply Expense Per UOS

Year	SMH	SCH	MBHW	SGH	HIT	SCV	SCO	SCO SNF
2007	89.38	31.32	40.34	95.21	25.27	68.28	65.27	14.34
2008	105.79	29.08	40.51	101.93	23.72	87.24	81.05	18.14
Budget 2009	87.97	35.60	46.61	107.23	24.30	89.96	87.11	18.03

Financial Retrospective Review Measurements- Expense Per UOS



Pharmaceutical Expense Per UOS

Year	SMH	SCH	MBHW	SGH	HIT	SCV	SCO	SCO SNF
2007	75.37	30.86	32.41	94.41	19.85	67.55	57.82	13.08
2008	84.20	28.47	32.28	100.77	17.89	85.74	74.16	16.46
Budget 2009	57.09	32.17	27.64	93.37	3.91	73.97	72.03	16.39

Financial Retrospective Review Measurements- Expense Per UOS



Total Expense Per UOS

Year	SMH	SCH	MBHW	SGH	HIT	SCV	SCO	SCO SNF
2007	136.10	56.38	74.48	135.59	90.09	116.72	145.56	21.83
2008	156.30	54.85	77.33	146.41	67.02	140.87	175.60	26.73
Budget 2009	134.66	61.29	87.29	159.33	62.48	146.86	182.49	25.19

Central Pharmacy

Verify: Financial Retrospective Review Measurements



Additional
Production 2009
\$77,000 outsourced
\$12,000/yr

Original Pro Forma (RED)

Job Code	SCP FTEs	Entity FTE Reductions							Net FTE Incr (Deer)
		SMH	SGH	SCV	SCO	MBHW	SCM	HIT	
0598 Mgr Pharmacy	0 0.46	-	-	-	-	-	-	-	(0.46)
0343 Pharmacist	1 1.90	(0.36)	(0.25)	(0.18)	-	-	-	-	(0.50)
0711 Pharmacy Tech	-	-	-	-	-	-	-	-	-
1721 Pharm Tech	4.3 5.47	(1.84)	(1.87)	(1.74)	-	(0.53)	-	-	(2.00)
0205 Pharmacy Buyer	0 1.40	-	-	-	-	-	-	-	1.40
0060 Courier	1 1.00	-	-	-	-	-	-	-	1.00
Total	10.23	(2.40)	(2.12)	(1.92)	-	(0.53)	-	-	(2.96)

New Products (67)
New products (1.23)
Current FTE Savings (1.6)

Sharp Central Pharmacy Services
Dashboard by Pillar - DRAFT

Quality	Target	Qtr 1 FY09	Qtr 2 FY09	Methodology
TPN % accuracy (output)	100%			Entity SPS entries @ 0% # QMS / # TPNs produced
TPN order entry error (input)	0%	1%		TPN SPS entries each enter Abbots and/or does not match MD order, # CIVAS / # TPNs produced
End product testing (sterility)	100%	100%		Monthly testing, Internal sampling plan per USP 797 standard.
Temperature control for delivery process	100% at 99%	99%		One month start up of daily tracking, then quarterly/seasonal tracking COPC when IV label does not match order or product compounded does not match label
End product accuracy	100%			
Environmental testing (surface, personnel, hood)	100%	100%		Monthly testing, Internal sampling plan per USP 797 standard.
Service	Target			
Percent of IV produced by SPS	70%			Reports % of class 12 produced by SPS
On-time delivery	90%			Tech signs audit courier log book. Compiled monthly.
Missing doses	TBD			How to realistically track this? Discus at oversight.
People	Target			
RWJ productivity	100%			Finance report
Workers compensation (SPS IV-related)	TBD			Report from 504 Safety Office
Finance	Target			
Entity IV waste				How to do ongoing measure? Once per quarter?
Capital cost avoidance	(\$400,000)			One time savings
Net FTE Reduction	(17)			One time savings
Total projected cost savings	(\$240,000)			Financial analysis by Gressmont finance department
Growth	Target			
Number of new products ofered	TBD			
Costs - Making target	Value - Improvement occurring			Value - Improvement occurring

The Future

- Continue to evaluate efficiencies of operation & opportunities for improvement
- Consider automation of syringe production - Intellifil
- Manage IV room workflow for Hospitals and Central Pharmacy - Intelliflow

The Future (cont'd)

- Advantages of Intelliflow:
 - Record and store all data for regulatory compliance (NDC, Exp.Date, etc)
 - Standardize processes in IV room
 - Reduce or eliminate missing doses via electronic tracking
 - Manages syringes and all products prepared in IV room

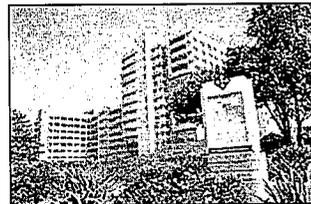
Questions



Drug Distribution at UCDMC & the Board of Pharmacy

Terry T. Nishizaki, Pharm.D., MBA, FCSHP
Assistant Manager, Inpatient Pharmacy
UC Davis Medical Center
June 2, 2009

University of California Davis Medical Center



- 577 Bed Facility
- Major Teaching Hospital
- Level I Trauma Center
- Regional Burn Center
- Children's Hospital
- Catheterization Lab

Drug Distribution

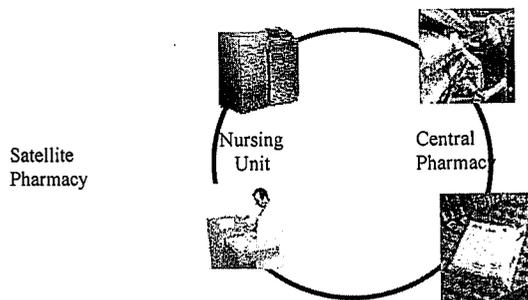
Decentralized Distribution

IV Production

Decentralized Drug Distribution

- Automated Dispensing Machines (ADMs)
- Satellite Pharmacy for 1st doses
- Central fill and delivery of ADM replenishment

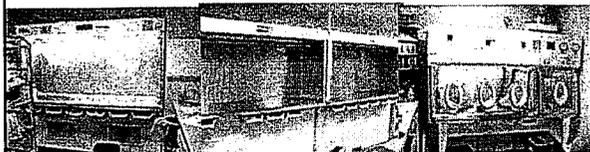
ADM Replenishment Process



IV Preparation

- Centralized IV Preparation Area
- First & Misc Doses from the Satellite

IV Preparation – USP 797



Satellite – 12 hr BUD

Central IV's

Containment Hood

- Outsourcing

IV Compounding Requirements

- Exempt IV's administered within 24 hours
- Beyond Use Date greater than 24 hours
- Business Impact
- Job Impact

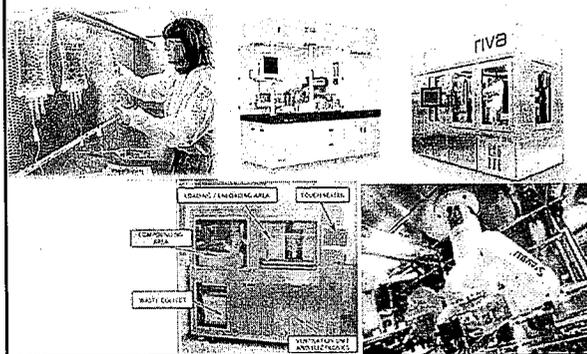
IV Compounding Requirements

Process

Manual

Automated

IV Compounding Current & Future



Board of Pharmacy Issues

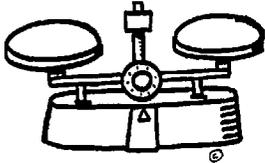
- Communication
 - E-mail alerts
 - Change in Interpretation of Existing Regs
 - Licensure status
 - Advance warning
 - » Recall

Board of Pharmacy Issues

- Manual of Disciplinary Guidelines
- Fiscal & Job Impact
- Incorporation of Technology in Regulations

Our Goal

- Patient Safety
- Future Innovations
- Regulations
- Resources
- Budget Cuts
- Decreased Reimbursement
- Increased Regulations
- Resources



Attachment 2

1. Emergency Declaration Policy
2. Newsletter Article
3. Antiviral protocols released by the DPH in response to the H1N1 emergency

Disaster Response Policy Statement

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal).

The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

¹Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

²See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

DEPARTMENT OF CONSUMER AFFAIRS BOARD OF PHARMACY

Antiviral Documents

- [Interim Guidance on Distribution and Dispensing of State and Federal Antiviral Medications \(PDF\)](#)
- [Interim Guidance on Antiviral Recommendations for Novel Influenza A \(H1N1\) Virus Infection \(PDF\)](#)
- [Relenza Prescribing Information \(PDF\)](#)
- [Relenza Patient Information \(PDF\)](#)
- [Tamiflu Prescribing Information \(PDF\)](#)
- [Tamiflu Patient Information \(PDF\)](#)
- [Administration of Relenza via a Nebulizer \(PDF\)](#)

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MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

Revised: May 8, 2009

Interim Guidance on Antiviral Recommendations for Novel Influenza A (H1N1) Virus Infection

Objective: To provide 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.

Summary: CDPH recommends the limited use of treatment and prophylaxis with either oseltamivir or zanamivir to reduce the level of severe disease and mortality that may be caused by novel influenza A (H1N1) virus infection.

Antiviral treatment for five days is recommended for:

- Hospitalized patients:

Confirmed, probable and highly suspected cases: Treatment recommended

Suspected cases: Treatment recommended until PCR testing for influenza is negative or any testing for non-influenza causes of primary respiratory infection is positive.

- Non-hospitalized patients at higher risk for severe influenza:

Confirmed, probable and highly suspected cases: Treatment recommended

Suspected cases: Use clinical judgment and frequent reassessment regarding the severity and progression of illness and the fragility of the patient. For nearly all suspected cases of novel influenza A (H1N1) virus infection, the benefits of antiviral treatment will be modest and disease will not become severe if antiviral therapy is delayed or not given. Available testing for other causes of primary respiratory infection (seasonal influenza viruses and non-influenza causes) may be helpful in guiding treatment decisions. Local inventory may be insufficient to treat suspected cases.

Interim Guidance on Antiviral Recommendations

Page 2

May 7, 2009

Antiviral chemoprophylaxis for ten days after last exposure can be considered for:

- Persons who are at high-risk for severe influenza and have been household close contacts of a confirmed, probable or highly suspected case.
- Health care workers or public health workers who were not using appropriate personal protective equipment during close contact with an infectious case that is confirmed, probable, or highly suspected.
- Patients at high-risk for severe influenza who have had close contact with an infectious health care worker or patient who is a confirmed or probable case.

These recommendations also apply to educational, residential and correctional facilities.

Antiviral treatment and prophylaxis of residents and employees are recommended during outbreaks of confirmed novel influenza A (H1N1) virus infection in nursing homes and related medical facilities.

In localities of California where seasonal influenza caused by oseltamivir-resistant human A (H1N1) viruses is still occurring, consider using zanamvir monotherapy or a combination of oseltamivir and either rimantadine or amantadine.

Prevention of the spread of novel influenza A (H1N1) virus infection relies on non-pharmacologic infection control measures. Therefore, persons with mild influenza should be directed to remain at home rather than visit health care facilities. Medical care providers can be contacted by telephone or email for questions about treatment.

Patients should seek medical care for symptoms of more severe influenza, such as:

- difficulty breathing
- unable to take adequate fluids
- confusion or altered mental status; severe headache or other pain that is clearly not controlled by usual medications; sudden weakness, or change in vision
- rapid worsening of symptoms

These interim recommendations are currently more restrictive than those of the federal Centers for Disease Control and Prevention. Recommendations may change as additional data on antiviral effectiveness, clinical spectrum of illness, adverse events from antiviral use, and antiviral susceptibility become available.

Interim Guidance on Antiviral Recommendations

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Principles: As novel influenza A (H1N1) virus infection currently appears to be no more severe than seasonal influenza, this guidance on the use of antiviral medications reflects the current

- Policies on antiviral medications for seasonal influenza viruses.
- Possibility that the novel influenza A (H1N1) virus might become increasingly resistant to antiviral medications, especially if the medications are heavily used.
- Possibility that the novel influenza A (H1N1) virus may become increasingly virulent in the future.
- Absence of a vaccine for the novel influenza A (H1N1) virus.

The priority for the use of available supplies of antiviral medications is to reduce the level of severe disease and mortality that may be caused by novel influenza A (H1N1) virus infection.

The need to protect individuals from infection with novel influenza A (H1N1) virus must be weighed with existing information on disease severity, treatment efficacy, current and future antiviral resistance, current and future supplies of medications, and other factors.

Case Definitions for Infection with Novel Influenza A (H1N1) Virus

A **confirmed case** is defined as a person with influenza-like illness who has novel influenza A (H1N1) virus infection confirmed by real-time RT-PCR or viral culture.

A **probable case** is defined as a person with influenza-like illness who is positive for influenza A, but negative for H1 and H3 by influenza RT-PCR.

For the purposes of this guidance, a **highly suspected case** is defined as a person with influenza-like illness with onset within 7 days of close contact with a person who is a confirmed or probable case.

For the purposes of this guidance, a **suspected case** is defined as a person with influenza-like illness who does not meet the other case categories and who does not have laboratory evidence of a primary infection other than influenza (e.g., parainfluenza virus, respiratory syncytial virus, etc.).

The **infectious period** is defined as 1 day prior to illness onset to 7 days after onset.

Close contact is defined as having cared for or lived with a confirmed, probable or suspected case of novel influenza A (H1N1) infection, or having been in a setting where there was a high likelihood of contact with respiratory droplets and/or body fluids of such

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a person. Examples of close contact include kissing or embracing, sharing eating or drinking utensils, physical examination, or any other contact between persons likely to result in exposure to respiratory droplets. Close contact typically does not include activities such as walking by an infected person or sitting across from a symptomatic patient in a waiting room or office.

An ***influenza-like illness*** is defined as fever greater or equal to 37.8°C (100°F) and either cough or sore throat.

High-risk groups: Persons who are at high-risk for severe complications infection with novel influenza A (H1N1) virus are defined as:

- Children younger than 2 years old
- Adults 65 years of age and older
- Residents of nursing homes and other chronic-care facilities.

Persons with the following conditions:

- Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), or metabolic disorders (including diabetes mellitus);
- Immunosuppression, including that caused by medications or by HIV;
- Pregnant women;
- Persons younger than 19 years of age and receiving long-term aspirin therapy;
- Any condition (e.g., cognitive dysfunction, spinal cord injuries, severe seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration.

See MMWR: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008.

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Antiviral Treatment of Novel Influenza A (H1N1) Virus Infection

Recommendations for use of antiviral medications may change as additional data on antiviral effectiveness, clinical spectrum of illness, adverse events from antiviral use, and antiviral susceptibility data become available.

Antiviral Treatment for five days is recommended for:

- Hospitalized patients:

Confirmed, probable and highly suspected cases: Treatment recommended

Suspected cases: Treatment recommended until PCR testing for influenza is negative or any testing for non-influenza causes of primary respiratory infection is positive.

- Non-hospitalized patients at higher risk for severe influenza:

Confirmed, probable and highly suspected cases: Treatment recommended

Suspected cases: Use clinical judgment and frequent reassessment regarding the severity and progression of illness and the fragility of the patient. For nearly all suspected cases of novel influenza A (H1N1) virus infection, the benefits of antiviral treatment will be modest and disease will not become severe if antiviral therapy is delayed or not given. Available testing for other causes of primary respiratory infection (seasonal influenza viruses and non-influenza causes) may be helpful in guiding treatment decisions. Local inventory may be insufficient to treat suspected cases.

Once the decision to administer antiviral treatment is made, treatment with zanamivir or oseltamivir should be initiated as soon as possible after the onset of symptoms. Evidence for benefits from treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of treatment of seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset.

Antiviral doses recommended for treatment of novel influenza A (H1N1) virus infection in adults or children 1 year of age or older are the same as those recommended for seasonal influenza (Table 1). Oseltamivir use for children < 1 year old was recently approved by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA), and dosing for these children is age-based (Table 2).

Note: Providers in areas that continue to have seasonal influenza activity, especially those with circulation of oseltamivir-resistant human A (H1N1) viruses, might prefer to use either zanamivir monotherapy or a combination of oseltamivir and rimantadine or amantadine to provide adequate empiric treatment or chemoprophylaxis for patients who might have seasonal human influenza A (H1N1) infection.

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Antiviral Chemoprophylaxis

Antiviral chemoprophylaxis with either oseltamivir or zanamivir (Table 1) can be considered for:

- Persons who are at high-risk for severe influenza and have been household close contacts of a confirmed, probable or highly suspected case.
- Health care workers or public health workers who were not using appropriate personal protective equipment during close contact with an infectious case that is confirmed, probable, or highly suspected.
- Patients at high-risk for severe influenza who have had close contact with an infectious health care worker or patient who is a confirmed or probable case.

Antiviral chemoprophylaxis typically should be given for 10 days. If additional exposure occurs after chemoprophylaxis has started, continue until 10 days after last confirmed exposure with an infectious case. Chemoprophylaxis is not necessary if contact with an ill case occurred more than 7 days after the onset of illness.

Oseltamivir can also be used for chemoprophylaxis in children <1 year of age under the EUA (Table 3).

Antiviral Use for Control of Novel H1N1 Influenza Outbreaks in Nursing Homes

The use of antiviral medications has been a cornerstone for the control of seasonal influenza outbreaks in nursing homes and other long term care facilities. For outbreaks of confirmed novel influenza A (H1N1) infection in these settings, prompt initiation of zanamivir or oseltamivir are recommended for:

- Treatment of ill patients
- Chemoprophylaxis of employees and well residents for a minimum of two weeks. If surveillance indicates that new cases continue to occur, chemoprophylaxis should be continued until approximately 7 days after illness onset in the last patient.

In addition to antiviral medications, other outbreak-control measures include appropriate infection control, establishing cohorts of patients with confirmed or suspected influenza, restricting staff movement between wards or buildings, and restricting contact between ill staff or visitors and patients, and active surveillance for new cases. Medical directors of long-term care facilities should review their plans for outbreak control of influenza. Additional guidance for infection control measures in long-term care facilities can be found at <http://www.cdc.gov/flu/professionals/infectioncontrol/institutions.htm>.

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See MMWR: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008.

Non-medical Institutions

The following recommendations apply to persons working, residing in or attending non-medical institutions, including educational, residential and correctional facilities:

Confirmed, probable or highly suspected cases of novel influenza A (H1N1) virus infection associated with these settings should be considered for treatment, especially if at higher risk for influenza complications.

Contacts who have shared the same bedroom or cell of a confirmed or probable case and who are at high-risk for complications of influenza (e.g., persons with certain chronic medical conditions, persons 65 or older, children younger than 2 years of age, and pregnant women) can be considered for antiviral chemoprophylaxis.

Additional institutional contacts of a confirmed or probable case can be considered for treatment once symptomatic, especially if at high risk for severe influenza.

Children Under 1 Year of Age

Children under one year of age are at high risk for complications from seasonal human influenza virus infections. The characteristics of human infections with novel H1N1 viruses are still being studied, and it is not known whether infants are at higher risk for complications associated with novel H1N1 infection compared to older children and adults. Limited safety data on the use of oseltamivir (or zanamivir) are available from children less than one year of age. Oseltamivir is not licensed for use in children less than 1 year of age (although use for children < 1 year of age was recently approved by the FDA under an EUA ([Table 2](#))). Available data come from use of oseltamivir for treatment of seasonal influenza. These data suggest that severe adverse events are rare, and the Infectious Diseases Society of America recently noted, with regard to use of oseltamivir in children younger than 1 year old with seasonal influenza, that "...limited retrospective data on the safety and efficacy of oseltamivir in this young age group have not demonstrated age-specific drug-attributable toxicities to date." (See <http://www.idsociety.org/content.aspx?id=9202#flu> for IDSA guidelines for seasonal influenza).

Because infants typically have high rates of morbidity and mortality from influenza, infants with novel influenza A (H1N1) infections may benefit from treatment using oseltamivir ([Tables 2 and 3](#), <http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>).

Healthcare providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed novel H1N1

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influenza or who has been exposed to a confirmed case novel influenza A (H1N1) virus infection and carefully monitor infants for adverse events when oseltamivir is used. See <http://www.cdc.gov/h1n1flu/eua/> for additional information on oseltamivir for this age group.

Pregnant Women

Oseltamivir and zanamivir are "Pregnancy Category C" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. Because of the unknown effects of influenza antiviral drugs on pregnant women and their fetuses, oseltamivir or zanamivir should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus; the manufacturers' package inserts should be consulted. However, no adverse effects have been reported among women who received oseltamivir or zanamivir during pregnancy or among infants born to women who have received oseltamivir or zanamivir. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women. The drug of choice for prophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.

Adverse Events and Contraindications

For further information about influenza antiviral medications, including contraindications and adverse effects, please see the following:

- [Antiviral Agents for Seasonal Influenza: Side Effects and Adverse Reactions](#)
- [MMWR: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\), 2008](#)
MMWR August 8, 2008 / 57(RR07);1-60
- Harper SA, Bradley JS, Englund JA, et al. Infectious Diseases Society of America Guidelines. Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America: at <http://www.idsociety.org/content.aspx?id=9202#flu>

Adverse events from influenza antiviral medications should be reported through the [U.S. FDA Medwatch website](#).

- Links to non-governmental federal organizations are provided solely as a service to our users. These links do not constitute an endorsement of these

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organizations or their programs by the State of California, and none should be inferred. The State of California is not responsible for the content of the individual organization Web pages found at these links.

Tables

Table 1. Antiviral medication (oseltamivir and zanamivir) dosing recommendations for treatment or chemoprophylaxis of novel influenza A (H1N1) infection. (Table extracted from IDSA guidelines for seasonal influenza .)			
Agent, group		Treatment – 5 day Course	Chemoprophylaxis –
Oseltamivir			
Adults		75-mg capsule twice per day for 5 days	75-mg capsule once per day
Children (age, 12 months or older), weight:	< 15 kg	60 mg per day divided into 2 doses	30 mg once per day
	15-23 kg	90 mg per day divided into 2 doses	45 mg once per day
	24-40 kg	120 mg per day divided into 2 doses	60 mg once per day
	>40 kg	150 mg per day divided into 2 doses	75 mg once per day
Zanamivir			
Adults		Two 5-mg inhalations (10 mg total) twice per day	Two 5-mg inhalations (10 mg total) once per day
Children		Two 5-mg inhalations (10 mg total) twice per day (age, 7 years or older)	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older)

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Table 2. Dosing recommendations for antiviral treatment of children younger than 1 year using oseltamivir

Age	Recommended dose for 5 days
<3 months	12 mg twice daily
3-5 months	20 mg twice daily
6-11 months	25 mg twice daily

Table 3. Dosing recommendations for antiviral chemoprophylaxis of children younger than 1 year using oseltamivir

Age	Recommended prophylaxis dose for 10 days
<3 months	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg once daily
6-11 months	25 mg once daily

Application for a Pharmacy Technician License



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

PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

A PHARMACY TECHNICIAN is an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other non-discretionary tasks related to the processing of a prescription in a licensed pharmacy, but excludes all functions restricted to a registered pharmacist. To work as a pharmacy technician in California, you must possess and keep current a registration as a pharmacy technician.

Effective January 1, 2004, experience as a pharmacy clerk or pharmacy technician can no longer be used to qualify for registration as a pharmacy technician in California.

HOW TO APPLY TO BECOME A PHARMACY TECHNICIAN

To be considered complete, your application must include:

1. **FEES:** A check or money order in the amount of \$50, made payable to the **Board of Pharmacy**. This is a non-refundable fee. If you reside outside California, see Fingerprint Instructions on next page for additional fees required.
2. **APPLICATION:** A pharmacy technician application (17A-5). The application must be completed in its entirety-- with all questions answered. Failure to do so will delay processing and may result in the application being returned without processing. A 2" x 2" photo must be taped to the front of the application.
3. **QUALIFYING METHOD SUBSTANTIATION:**
 - A. If you are qualifying by one of the following methods, the **Affidavit of Completion of Coursework or Graduation** portion of the application must be completed by the university, college, school or course provider.
 - ♦ An Associate degree in pharmacy technology
 - ♦ Completion of a training course accredited by the American Society of Health-System Pharmacists (ASHP);
 - ♦ Any other course that provides a minimum of 240 hours instruction as specified in section 1793.6 (c) of Title 16 of the California Code of Regulations.
 - ♦ Graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE).
 - B. If you are qualifying by training provided by a branch of the federal armed services, you must submit the original or a certified true copy of your DD214 **with your application**. (A certified true copy is a copy that has been certified or notarized as a true copy)
 - C. If you are certified by the Pharmacy Technician Certification Board (PTCB), you must submit a certified true copy of your PTCB certificate **with your application**. (A certified true copy is a copy that has been certified or notarized as a true copy)

4. **FINGERPRINT SUBMISSION** (See "Fingerprint Requirements"): A copy of **Request for Live Scan Service Form** verifying that your fingerprints have been scanned and all applicable fees paid.

The board requires the applicant to have their fingerprints resubmitted at the time a pharmacy technician application is submitted to the board regardless of any prior fingerprint submission for other applications with the board.

A. If a California resident:

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit to the board.

Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://ag.ca.gov/fingerprints/publications/contact.pdf>

Note to Applicants Submitting Fingerprints Via Live Scan: While the Live Scan forms contained in the board's application package are pre-slugged to indicate level of service at the DOJ and FBI level, please ensure at the time of Live Scan transmission that the Live Scan operator selects both the DOJ and FBI levels of service. If FBI is not selected at the time of original transmission, you may be required to have your Live Scan redone at another time and have to repay for the DOJ and FBI levels of services again. The board has been notified by the DOJ that effective 9/1/07, if the FBI level of service is not requested at the time of original transmission both DOJ and FBI levels of service will have to be redone. Any issue of cost for resubmission should be handled at the Live Scan Site level.

B. Non California Residents:

If you reside outside California, you must submit rolled fingerprints on cards together with a fee of \$51 made payable to the Board of Pharmacy (\$32 California Department of Justice (DOJ) fee and \$19 FBI fingerprint processing fee). You may contact the board to request the fingerprint cards at (916) 574-7900. You may also request cards at www.pharmacy.ca.gov.

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take longer than the Live Scan process, by approximately six weeks. Poor quality prints may result in rejection of the card and will substantially delay licensing since additional fingerprint cards will be required from you for processing.

YOU MUST SATISFY ALL REQUIREMENTS FOR LICENSURE AT THE TIME OF APPLICATION



California State Board of Pharmacy
 1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
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STATE AND CONSUMERS AFFAIRS AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

APPLICATION FOR REGISTRATION AS A PHARMACY TECHNICIAN

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for registration under the California Pharmacy Law. The official responsible for information maintenance is the executive officer, (916) 574-7900, 1625 N. Market Blvd, Suite N219, Sacramento, California 95834. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

Print or type

Last Name	First Name	Middle	Former	<p>TAPE A PHOTOGRAPH TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION</p> <p>NO POLAROID</p>	
*Address of Record: Number		Street			
City		State	Zip Code		
Residence Address: (if different from above) Number		Street			
City		State	Zip Code		
Home telephone number:	Work telephone number:	Date of Birth:	Social Security Number**		Email Address:
()	()				
<p>Indicate below how you qualify for registration as a Pharmacy Technician:</p> <p><input type="checkbox"/> Associate degree in Pharmacy Technology <input type="checkbox"/> Training Course <input type="checkbox"/> Military Training <input type="checkbox"/> Graduate of a school of pharmacy</p> <p><input type="checkbox"/> Certified by PTCB - Date Certified: _____</p>					
<p>Section 4202 of the Business and Professions Code requires an applicant for registration as a pharmacy technician to be a high school graduate or possess a general education development (GED) equivalent.</p> <p>Are you a high school graduate? Yes <input type="checkbox"/> Date graduated _____ GED? Yes <input type="checkbox"/> Date GED awarded: _____</p> <p>Name and location of high school _____</p> <p>Name that appears on high school diploma or GED Certificate _____</p> <p style="text-align: center;">(Your name needs to be included regardless of whether you have a diploma or GED.)</p>					

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

** Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

DO NOT WRITE BELOW THIS LINE				
Livescan	<input type="checkbox"/>		Registration No. _____	Application fee no. _____
Photo	<input type="checkbox"/>		Date Issued _____	Amount _____
Qualify Code	_____			Date Cashiered _____
FP Clearance	<input type="checkbox"/>	Enf <input type="checkbox"/>		

Name of Applicant: _____	Social Security No: _____
---------------------------------	----------------------------------

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION
This portion must be completed by the university, college, school or course provider

This is to certify that _____ attended
Name of Applicant

_____ Name of College, University or School

From: _____ To: _____ and has

Completed all requirements for graduation; or

Completed 240 hours of instruction as required by section 1793.6 (c) of the California Code of Regulations

The degree of _____ was conferred on her/him on _____

Signed _____ Title _____ Date _____

Address: _____

Affix Seal Here

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

<p>1. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? If "yes," attach a statement of explanation. If "no," proceed to #2.</p> <p>Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If "yes," attach a statement of explanation.</p> <p>If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted registration should be issued, whether conditions should be imposed, or whether you are not eligible for registration.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>2. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?</p> <p>If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach a statement of explanation.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<p>3. Has disciplinary action ever been taken against your pharmacist license, intern permit or technician registration in this state or any other state?</p> <p>If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Continue on next page

<p>4. Have you ever had an application for a pharmacist license, intern permit or technician registration denied in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>5. Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state? If "yes," provide the name of company, type of permit, type of action, year of action and state.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>6. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States or any state laws or local ordinances? You must include all misdemeanor and felony convictions, regardless of the age of the conviction, including those which have been set aside under Penal Code section 1203.4. Traffic violations of \$500 or less need not be reported. If "yes," attach an explanation including the type of violation, the date, circumstances, location and the complete penalty received. . In addition to this written explanation, please provide the Board of Pharmacy with certified copies of all pertinent court documents or arrest reports relating to this conviction.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

APPLICANT AFFIDAVIT	
----------------------------	--

I, _____, hereby attest to the fact that I am the applicant whose signature appears below. I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I have read and understand the instructions attached to this application.

Signature of Applicant

Date

MANDATORY REPORTER

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

California Penal Code section 11166 and Welfare and Institutions Code section 15630 require that all mandated reporters make a report to an agency specified in Penal Code section 11165.9 and Welfare and Institutions Code section 15630(b)(1) [generally law enforcement, state, and/or county adult protective services agencies, etc...] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or 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 telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as is practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable 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 requirements, consult Penal Code sections 11164 and Welfare and Institutions Code section 15630, and subsequent sections.

Attachment 4

1. Report of the NABP task force
2. Article from the *Association News* published in October 2008



Report of the Task Force on Standardized Pharmacy Technician Education and Training

NOTE: The NABP Executive Committee accepted all the recommendations of this task force with the following exceptions:

- **Recommendation 3** was made more specific to assert that NABP will encourage states that certify technicians to recognize certification by the Pharmacy Technician Certification Board (PTCB). The basis for this decision by the Executive Committee is that PTCB certification and, specifically, the Pharmacy Technician Certification Examination have been reviewed and approved by NABP pursuant to Resolution 96-1-2000, adopted by the member boards of NABP at the 96th Annual Meeting in 2000.
- **Recommendation 5** was accepted in part and rejected in part. Rejected was the Task Force's recommendation to incorporate the term *Certified Pharmacy Technician Trainee* into the Model State Pharmacy Act and Model Rules of the National Associations of Boards of Pharmacy. Although the Executive Committee agreed to the concept, they felt a more appropriate, less-confusing term would be *Candidate for Certified Pharmacy Technician*.

Members Present:

Susan Ksiazek (NY), *chair*; Wendy L. Anderson (CO); Lee Ann Bundrick (SC); Gay Dodson (TX); Jacqueline L. Hall (LA); Jeane A. Johnson (NM).

Members Not Present:

Jerry Wiesenbahn (OH)

Others Present:

Gregory Braylock, Sr, *executive committee liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Christine Siwik, Gertrude Levine, *NABP staff*.

Guest Participants:

Douglas Scheckelhoff, *American Society of Health System Pharmacists*; Melissa Murer Corrigan, *Pharmacy Technician Certification Board*; Jan Keresztes, *Pharmacy Technician Educators Council*, Kevin Nicholson, *National Association of Chain Drug Stores*.

Introduction:

The Task Force on Standardized Pharmacy Technician Education and Training met September 9-10, 2008 at NABP Headquarters.

This task force was established in response to Resolution 104-4-08, Task Force on Standardized Pharmacy Technician Education and Training, which was approved by the NABP membership at the Association's 104th Annual Meeting in May 2008.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Review and analyze the present state requirements for pharmacy technician licensure, registration, and certification.
2. Review and analyze the present state requirements for pharmacy technician education and/or training.
3. Assess the feasibility, in regard to the protection of the public health, of the states implementing standardized state requirements for technician education and/or training.
4. Recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing this issue.

Recommendation 1: NABP Clarify the Terms Used for Pharmacy Technicians

The task force recommends that NABP clarify for the states the meanings of the words *licensure*, *registration*, and *certification* as they relate to the regulation of pharmacy technicians in order to promote standardized use of these terms among the states.

Background:

Task force members discussed the status of pharmacy technician regulation among the states, particularly the fact that the words *licensure*, *registration*, and *certification* are often used interchangeably for essentially the same designation of pharmacy personnel. Members concluded that in order for pharmacy technician education and training to be standardized there should be a consensus among the states in the nomenclature. Members agreed that states should strive to mirror the *Model Act* for uniformity by recognizing two tiers of non-pharmacist personnel: pharmacy technicians and certified pharmacy technicians.

Recommendation 2: NABP Continue to Support the Recommendation that States License or Register Pharmacy Technicians

The task force recommends that NABP continue to support its position that states should license or register pharmacy technicians in the interest of the public health and improved patient care and safety, and to address the growing problem of diversion by unlicensed pharmacy personnel.

Background:

Task force members agreed that a crucial step towards standardization would be for all states to license or register pharmacy technicians. Upon obtaining and reviewing compiled data, members recognized that pharmacy technicians were one of the few ancillary personnel in the health care field that remained unlicensed in several states. Members noted that pharmacy technician-attributable medication errors have increasingly gained national media attention and voiced

concern that this has shed a negative light on the regulation of pharmacy practice, particularly in states lacking licensure or registration of pharmacy technicians.

Members also discussed the role that licensure and registration play in decreasing diversion of controlled substances. Several task force members relayed their states' increases in diversion-based disciplinary actions subsequent to the establishment of pharmacy technician licensure or registration requirements. They indicated that such requirements effectively precluded violators from obtaining employment in other pharmacies through license or registration revocation. Members also discussed the importance of applicant criminal background checks and how they keep potential diverters from obtaining access to pharmacies. Members felt that states should proactively conduct criminal background checks and not rely on the veracity of applicants to disclose past criminal convictions.

Recommendation 3: NABP Encourage States to Require Pharmacy Technician Certification from an Organization that Utilizes a Nationally Recognized Competency Assessment Examination

The task force recommends that states, subsequent to implementing a pharmacy technician registration or licensure system, require technicians to obtain certification from an organization that utilizes a nationally recognized competency assessment examination as a means to provide further assurances that pharmacy technicians possess necessary knowledge and skills to assist in the practice of pharmacy.

Background:

Task force members discussed information provided by the guest participants and concluded that certification would be a progressive step only if competency was measured. It was agreed that, to provide the most accurate measure of competence, any examination used had to be developed using nationally recognized and validated psychometric and pharmacy practice standards. It was acknowledged that NABP directly verified the standards and processes of the Pharmacy Technician Certification Board (PTCB) examination for certification and that NABP's *Model Act* recommends that boards of pharmacy utilize that certification program as part of their assessment of pharmacy technician competency.

Recommendation 4: NABP Encourage States to Continue to Report Pharmacy Technician Disciplinary Information to the NABP Disciplinary Clearinghouse and Expand the NABP Licensure Transfer Program to Include Pharmacy Technicians

The task force recommends that NABP encourage states to continue to report pharmacy technician disciplinary information to the NABP Disciplinary Clearinghouse. The task force further recommends that NABP expand its licensure transfer program to include pharmacy technicians who have been certified by a pharmacy technician certification program that utilizes a nationally recognized competency assessment examination.

Background:

Task force members discussed the importance of board of pharmacy reporting of pharmacy technician disciplinary information to the NABP Disciplinary Clearinghouse, especially in light of the prevalence of diversion cases. Members stressed that disciplinary reporting will make it more difficult for disciplined individuals to relocate to another state and obtain pharmacy employment.

Members also discussed how the expansion of NABP's licensure transfer program to include pharmacy technicians and the utilization of a certification process would positively impact the pharmacy profession by guaranteeing a national pool of pharmacy technicians that have achieved a level of competency and professionalism. Members agreed that pharmacy technicians must be certified in order to participate in the NABP licensure transfer program.

Recommendation 5: Amend *Model Act*

The task force recommends the following changes to the *Model Act*, including changes to the Model Rules for the Practice of Pharmacy. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.

**Model State Pharmacy Act and Model Rules
of the National Association of Boards of Pharmacy**

Article I Title, Purpose, and Definitions

Section 105. Definitions.

- (r) "Certified Pharmacy Technician" means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as receiving new Prescription Drug Orders; prescription transfer; and Compounding but excluding Drug Regimen Review; clinical conflict resolution; prescriber contact concerning Prescription Drug Order clarification or therapy modification; Patient Counseling; and Dispensing process validation.

- (dddd) "Pharmacy Technician" means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as assisting in the Dispensing process; processing of medical coverage claims; stocking of medications; cashiering but excluding Drug Regimen Review; clinical conflict resolution; prescriber contact concerning Prescription Drug Order clarification or therapy modification; Patient Counseling; Dispensing process validation; prescription transfer; and receipt of new Prescription Drug Orders.

Section 105(dddd). Comment.

The term Pharmacy Technician will continue to be utilized until 2015. At that time, the *Model State Pharmacy Act and Model Rules* will be amended to require that all Pharmacy Technicians be certified. The *Model Act* will also be amended at that time to replace the term Pharmacy Technician with the term Certified Pharmacy Technician Trainee, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Certified Pharmacy Technician Trainee registration will be allowed.

Article III

Licensing

Section 308. Registration of Certified Pharmacy Technicians.

- (a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:
- (1) have submitted a written application in the form prescribed by the Board of Pharmacy;
 - (2) have attained the age of _____;
 - (3) have good moral character;
 - (4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
 - (5) have:
 - (i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy; or
 - (ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board;
 - (6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards ~~or examinations~~ approved by the Board of Pharmacy; and
 - (7) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.
- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.
- (c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

Section 309. Registration of Pharmacy Technicians.

- (a) In order to be registered as a Pharmacy Technician in this State, an applicant shall:
- (1) have submitted a written application in the form prescribed by the Board of Pharmacy;
 - (2) have attained the age of _____;
 - (3) have good moral character;
 - (4) have paid the fees specified by the Board; and
 - (5) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Pharmacy Technician.
- (c) The Board of Pharmacy shall, by rule, establish requirements for registration of Pharmacy Technicians.

Section 308(a)(5)(i). Comment.

It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

Section 308(a)(5 and 6). Comment.

In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 308(a)(5)(i), 308(a)(5)(ii), and 308(a)(6).

Section 309. Comment.

In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to remove the term Pharmacy Technician and incorporate the term Certified Pharmacy Technician Trainee, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Certified Pharmacy Technician Trainee will be allowed.

Model Rules for the Practice of Pharmacy

Section 2. Personnel.

- (a) Duties and Responsibilities of the Pharmacist-in-Charge

- (2) The Pharmacist-in-Charge has the following responsibilities:

- (B) a Pharmacy Technician Training Manual ~~for the~~ that is site-specific to the practice setting of which he or she is in charge. He or she shall supervise a site-specific training program conducted pursuant to the Pharmacy Technician Training Manual for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Pharmacy Technicians successfully completing the Pharmacy's Technician site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board;

Background:

Members reviewed the *Model Act* and the Model Rules for the Practice of Pharmacy and concluded:

1. the terms Pharmacy Technician and Certified Pharmacy Technician should continue to be utilized until 2015 and at such time NABP should modify the *Model Act* to require that all Pharmacy Technicians be certified. Also at that time, the term Pharmacy Technician should be replaced with the term Certified Pharmacy Technician Trainee and redefined to provide a path by which all pharmacy technicians can become certified. A one-time renewal of the Certified Pharmacy Technician Trainee registration will be allowed;
2. requirements for certification should include a high school diploma, a Certificate of General Educational Development, or equivalent, and should incorporate provisions for grandfathering;
3. requirements for certification should include board-approved, competency-based training and educational programs; and
4. the term "site-specific" should be added to pharmacy technician and certified pharmacy technician training program references.

Members also discussed whether the boards of pharmacy should recognize specific accrediting bodies, such as the American Society of Health-System Pharmacists (ASHP) in their regulations regarding board-approved, competency-based training and educational programs. Members concluded that ASHP or other accrediting bodies need not be mandated but certainly could be provided for by policy.

Recommendation 6: NABP Develop an Interactive Educational Session at the 105th Annual Meeting

The task force recommends that NABP develop an interactive educational session at the 105th Annual Meeting that addresses the issues related to the standardization of pharmacy technician education and training.

Background:

Members suggested that NABP conduct an open discussion at the 105th Annual Meeting. Further discussion ensued regarding the logistics of such an event and it was determined that an interactive continuing education session would be most appropriate for the boards of pharmacy as well as meeting participants.

Recommendation 7: Request a Second Meeting of the Task Force and/or Create a Standing Committee

The task force requests that the Executive Committee approve funding for a second meeting of the task force and/or create a standing committee on pharmacy technicians to review existing state requirements for educational and training programs and national accrediting organizations'

core competencies to recommend a national standard for the educational and training requirements for pharmacy technician certification.

Background:

Members agreed that standardization of pharmacy technician education and training has been, and will continue to be, an ongoing issue and, as such, should be addressed on a regular basis until at least such time that all states license or register pharmacy technicians and that a national license transfer program is operational.

Task Force Examines Standard Requirements for Pharmacy Technicians

In the last five years, the number of pharmacy technicians recognized by the state boards of pharmacy has more than doubled, from 139,560 reported by 27 states in 2003 to 284,421 reported by 36 states in 2008, according to census data provided in the *Survey of Pharmacy Law*. Currently, requirements for the training and licensing or registration of pharmacy technicians vary from state to state. An NABP task force met in September 2008 at NABP Headquarters to consider whether uniform standards would be in the best interest of patient health and safety.

The charge of the Task Force on Standardized Pharmacy Technician Education was to review and analyze the present state requirements for pharmacy technicians in regard to licensure, registration, and certification, and in regard to education and training; and to assess the feasibility, in regard to the protection of the public health, of the states implementing standardized requirements for technician education and training. In addition, based on these discussions, the task force recommended revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing this issue.

NABP Supports Technician Regulation

NABP first formally recognized pharmacy techni-

cians in 1993 with amendments to the *Model Act* that called for state registration procedures, required site-specific training, and called for the establishment of a national technician competency examination and disciplinary clearinghouse. In 2000, NABP expanded its recognition of pharmacy technicians. Task forces and committees explored the issue and encouraged states to modify or eliminate ratios in pharmacy settings with quality assurance programs in place, and recognized two levels of pharmacy support personnel: pharmacy technicians and certified pharmacy technicians.

Certified pharmacy technicians were required to be registered with the state board of pharmacy, have completed a certification program approved by the board, and could, under the supervision of a pharmacist, perform certain activities, such as receive new prescription drug orders, handle prescription transfers, and perform drug compounding. Pharmacy technicians were also required to be registered with the state board of pharmacy, and could under the supervision of a pharmacist, perform certain activities such as assist in the dispensing process, process medical coverage claims, stock medications, or serve as cashier. They could not, however, participate in the receipt of new prescription drug orders or prescription transfers. Neither

pharmacy technicians nor certified pharmacy technicians, according to regulations recommended in the *Model Act* could participate in drug regimen reviews, clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification, or patient counseling or dispensing process validation.

Also in 2000, in response to requests from member boards, NABP evaluated technician examinations and programs to ensure that they effectively assess technician competencies and to determine whether they could be used as one means for boards to determine eligibility of technicians to assist in the practice of pharmacy. This evaluation process resulted in an official partnership in January 2002 with the Pharmacy Technician Certification Board (PTCB). NABP assists in development and management of the PTCB examination and officially recognized the examination in the *Model Act*. As amended to reflect this change, the *Model Act* encourages use of the PTCB examination for technicians by the state boards. The primary purpose of credentialing and licensure examinations is to assure the public that key professional standards have been met.

Based on the trends of the last five years, it seems clear that the future of pharmacy practice includes increased and expanded use of technicians, further rec-

ognition of PTCB by states, and further recognition of technicians by the states.

State Regulations

According to the 2008 *Survey of Pharmacy Law*, 40 jurisdictions (38 states plus Guam and Puerto Rico) currently license, register, and/or certify pharmacy technicians, whereas 13 jurisdictions (12 states plus the District of Columbia), do not. Of the latter group, the boards of pharmacy in two jurisdictions (Kentucky and District of Columbia) are in the process of developing regulations, and Florida has adopted regulations that will take effect in 2010.

Twenty-nine jurisdictions have some form of technician training requirements, with variations ranging from on-the-job training by the pharmacist-in-charge appropriate to the technician's duties, to successful completion of a board of pharmacy-approved certification program. Thirteen states specify continuing education requirements for technicians, ranging from three hours per year to 20 hours every two years. Fourteen states have technician examination requirements, and several of these states require certification by PTCB or other board-approved organization. The boards of pharmacy in 39 jurisdictions have the authority to deny, revoke, suspend, or restrict technician registration.

(continued on page 168)

nabp newsletter

Standard Requirements for Pharmacy Technicians

(continued from page 167)

States Pass, Explore Legislation

Florida: On June 23, 2008, Florida Governor Charlie Crist signed into law Senate Bill (SB) 1360, which outlines new requirements for training, certification, and registration of pharmacy technicians. The new law requires the Florida Board of Pharmacy to adopt rules establishing the registration of the more than 40,000 pharmacy technicians currently working in the state by 2010. In 2011, Florida technicians will need to either complete a Board-approved training program with 1,500 hours of work as a technician under a Florida licensed pharmacist, or become certified by a program accredited by the National Commission for Certifying Agencies, such as the PTCB program.

Illinois: Beginning on January 1, 2010, within two years after being employed as a registered technician, a pharmacy technician must become certified by successfully passing the PTCB examination or another Board-approved pharmacy technician examination in order to continue to perform pharmacy technician's duties. This requirement does not apply to pharmacy technicians hired prior to January 1, 2008.

Ohio: On May 29, 2008, the Ohio State Senate approved SB 203. The legisla-

tion requires pharmacy technicians to work only under the direct supervision of a pharmacist, to be 18 years of age or older, possess a high school diploma or GED, submit to a criminal records check that is submitted to the employer, have no felony convictions, and successfully pass competency examination approved in rule by the Ohio State Board of Pharmacy. Those employed as pharmacy technicians on the effective date of the bill will have one year from that date to pass Board-approved competency examination. New hires will have 210 days from the date of hire to pass Board-approved competency exams. Under the bill, only a pharmacist, a pharmacy intern, or a qualified pharmacy technician, as defined by the law, may engage in the compounding of any drugs, package or label any medication, or prepare or mix any intravenous medication to be injected into a human being.

Known as Emily's Act, the legislation is named after 2-year-old Ohio girl Emily Jerry, who died on March 1, 2006, after a pharmacy technician mixed her IV solution incorrectly. The pharmacist on duty at the time lost his license and is currently facing felony charges of involuntary manslaughter and reckless homicide in Ohio. The technician was not charged criminally or sanctioned by the Ohio State Board of Pharmacy because Ohio has no statutes regarding pharmacy technicians. Emily's Act has also been introduced federally (HR 5491) by Representative Steven

C. LaTourette. (See Federal Legislation Proposed.)

Kentucky: On July 15, 2008, the Kentucky Board of Pharmacy has adopted draft legislation for the registration of pharmacy technicians. The legislation states that, effective April 1, 2009, pharmacy technicians in Kentucky must be registered with the Board.

South Carolina: South Carolina SB 1156 proposes to increase the pharmacy technician-to-pharmacist ratio from 3:1 (with two technicians being state certified) to 3:1 (with one technician being state certified) and 4:1 (with two technicians being state certified).

Washington: On May 29, 2008, the Washington State Board of Pharmacy adopted a rule that resulted in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a Board-approved national standardized examination and complete a Board-approved technician training program. Individuals who have obtained a pharmacy technician credential before January 1, 2009, will not be required to meet the new standards.

Task Force to Reconvene

The task force is recommending a second meeting to review existing state requirements for educational and training programs and national accrediting organizations' core competencies to recommend a national standard for the educational

Federal Legislation Proposed

In February 2008, US Representatives Steven C. LaTourette of Ohio and Stephen F. Lynch of Massachusetts introduced federal legislation, HR 5491, that would assist in the implementation of training, education, registration, and certification requirements for pharmacy technicians nationwide. The Pharmacy Technician Training and Registration Act of 2008, or Emily's Act, allows the Secretary of Health and Human Services to make grants to states to establish pharmacy technician registration programs that include passing the national PTCB examination, and subsequently complete mandatory continuing education and renewal every two years. The bill would also provide for states that accept grants to comply with the act and to report pharmacy technician errors to the Secretary annually. ③

and training requirements for pharmacy technician certification.

The following individuals served on the task force: Susan Ksiazek, RPh, chairperson; Jacqueline Hall, Gay Dodson, RPh; Jerry Wiesenbahn, RPh; Wendy Anderson, RPh; Lee Ann Bundrick, RPh; Jeane Johnson, RPh; and Gregory Braylock, Sr, RPh, Executive Committee liaison. ③

Major provisions establishing California's Intern Requirements

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

- (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
- (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
- (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.
- (c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

1726. Supervision of Intern Pharmacists.

- (a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.
- (b) The pharmacist supervising an intern pharmacist shall provide the experience necessary for the intern pharmacist to become proficient in the practice of pharmacy.

1727.1 Intern Pharmacist Address.

The board shall not make an intern pharmacist's address publicly available on the "Internet," as defined by Business and Professions Code section 17538.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, 4030, 4100 and 4208, Business and Professions Code.

1728. Requirements for Examination.

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
 - (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
 - (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
 - (4) A signed copy of the examination security acknowledgment.
- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Attachment 6

1. Press Release from the Office of the Governor
2. Information from the Labor and Workforce Development Agency



Office of the Governor

ARNOLD SCHWARZENEGGER
THE PEOPLE'S GOVERNOR**PRESS RELEASE**

04/13/2009 GAAS:158:09 FOR IMMEDIATE RELEASE

Gov. Schwarzenegger Announces \$32 Million Public-Private Partnership to Add Health Care Professionals to California's Work Force

As part of his commitment to creating jobs in California, Governor Arnold Schwarzenegger today announced his Allied Health Initiative - a \$32 million public-private partnership aimed at reducing California's critical health care worker shortage by adding thousands of additional professionals to California's hospitals and health care facilities over the next three years. This partnership is being led by the Labor and Workforce Development Agency and includes several state agencies, the California Community Colleges, along with the University of California and California State University systems, and the California Hospital Association and its member teaching hospitals. The Initiative will begin in the fall with 25 community colleges enrolling more than 700 additional allied health students in their classes.

"Today we are taking some great action to put Californians in jobs and pump up the economy, and at the same time, improve the quality of health care for Californians," said Governor Schwarzenegger. "The health care industry is one of the bright spots in our economy continuing to add jobs, and still our hospitals and community clinics struggle with massive shortages because our colleges and medical training program can't keep pace with the rising demand. This public-private partnership will expand the number of pharmacists, lab technicians, imaging specialists and more - giving thousands of Californians the opportunity to pursue their dreams while making our state a healthier place to live."

With this Initiative, regional industry and education leaders will work together to develop effective allied health partnerships. An allied health professional is a licensed individual that works in support of a nurse or doctor, such as lab technicians, dental hygienists and pharmacy technicians.

Funding for the three-year program consists of \$16 million from the state, including \$8 million federal Workforce Investment Act funding and \$8 million Recovery Act federal stimulus funding. Private partners, such as schools and hospitals, will provide \$16 million in matching funds or in-kind contributions.

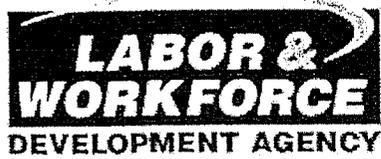
"We are grateful that Governor Schwarzenegger has once again put his full faith in California Community Colleges to help train the workers of tomorrow," said California Community Colleges Chancellor Dr. Jack Scott. "California Community Colleges have over 72,000 students enrolled in health occupation programs, and we expect that this Initiative will increase our ability to educate even more students in the healthcare field. "

According to a [Health Workforce Solutions study](#), more than 60 percent of the health occupations in California are in allied health and we are already experiencing shortages. According to the most recent employment numbers available from California Labor Market Information Division and Federal Bureau of Labor Statistics, California only has 73 percent of the pharmacists, 65 percent of the Medical Lab Technologists, and 62 percent of the Radiation Technologists and Technicians of the national average per 100,000 people. In spite of the economic downturn, the health care industry continues to grow in California, adding more than 27,000 jobs between February 2008 and February 2009.

By the year 2030, more than one million Californians will be 85 years of age or older which is going to increase the demand for health care services. As California's population continues to age, more and more workers - including healthcare workers - are beginning to retire at a faster rate. The California Labor and Workforce Development

Agency and the Employment Development Department workforce projections include the need to educate over 206,000 additional healthcare professionals by 2014.

The Allied Health Initiative is going to be structured after Governor Schwarzenegger's successful California Nurse Education Initiative created in 2005. That initiative was a \$90 million, five-year public-private partnership, which has so far seen an increase of more than 54 percent in the number of Registered Nurse (RN) graduates (9,526 graduated in 2008), an increase of more than 56 percent new faculty members (over 1,240 new faculty members), an increase of more than 68 percent new student enrollments in RN programs and 22 new public and private RN programs since its inception.



**Governor's Allied Health Initiative
California Community Colleges
Fall 2009 Program Expansion**

List of Campuses and Participating Allied Health Programs

The following 28 California Community College campuses will participate in the initial roll out of the expansion of allied health programs in Fall, 2009. It is anticipated that additional allied health program expansions will be added at UC, CSU and CCC through a competitive grant process in partnership with the Governor's Allied Health Initiative.

College	Program(s)
Allan Hancock	DA
American River College	SP
Antelope Valley	RADT
Cabrillo College	DA
Cañada College	RADT, MA
Citrus College	DA, LVN, NA EMT
College of the Sequoias	HCA
College of the Siskiyous	LVN, NA
Consumnes River College	P, EMT
Cypress College	DA, DH
Feather River College	LVN, NA, PCA
Fresno City College	RADT
Long Beach	LVN
Los Angeles Trade Tech	NA
Los Medanos	LVN
College of Marin	DA
Merced College	RT, NA
Mt. San Antonio	NA
Orange Coast College	RT
Reedley College	DA
Riverside College	MA, NA, SLA
Saddleback College	MLT
Santa Monica College	RT
Taft College	DH
Ventura College	MA, NA
West Hills Coalinga	PT
West Hills Lemoore	LVN
Yuba College	PT

Legend:

- LVN: Licensed Vocational Nurse
- NA: Nursing Assistant
- PCA: Personal Care Attendant
- SP: Speech Pathologist
- P: Pharmacy Tech
- EMT: Emergency Medical Technician
- RADT: Radiology Technology
- MA: Medical Assistant
- DA: Dental Assistant
- PT: Psychiatric Technicians
- HCA: Home Care Attendant
- DH: Dental Hygiene
- RT: Respiratory Therapy
- MLT: Medical Lab Technologist

GARY W. REICHARD

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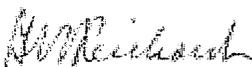
Fax: (562) 951-4986

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www.calstate.edu

Date: April 29, 2009

To: CSU Provosts

From: Gary W. Reichard 
Executive Vice Chancellor and Chief Academic Officer

Subject: COVER MEMO REGARDING Code: AA-2009-09
RFP: Matching Funds Grants to Expand Allied Health Degree Programs

The California Labor and Workforce Development has asked us to encourage our campuses to coordinate with local Workforce Investment Boards and health care industry and biotechnology partners for the match-funding required for the grant proposals announced in Coded Memorandum AA-2009-08, issued on April 27, 2009 and superseded by AA-2009-09 (attached).

I wish you success in establishing successful partnerships.

Attachments

GWR/cmh

c: Chancellor Charles B. Reed
Dr. Elizabeth Ambos
Ms. Sue DeRosa
Dr. Jeronima Echeverria
Dr. Christine Hanson
Ms. Stephanie Leach, Assistant Secretary, Policy and Program Development
California Labor and Workforce Development Agency
Dr. Lorie Roth
Mr. Robert Turnage
Deans of Health and Human Services
Deans of Science

CSU Campuses
Bakersfield
Channel Islands
Chico
Dominguez Hills
East Bay

Fresno
Fullerton
Humboldt
Long Beach
Los Angeles
Maritime Academy

Monterey Bay
Northridge
Pomona
Sacramento
San Bernardino
San Diego

San Francisco
San José
San Luis Obispo
San Marcos
Sonoma
Stanislaus



April 29, 2009

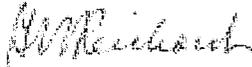
Code: AA-2009-09

Supersedes AA-2009-08

CODED MEMORANDUM

To: CSU Provosts

**Submission Deadline:
May, 15, 2009**

From: Gary W. Reichard 
Executive Vice Chancellor and Chief Academic Officer

**Subject: REQUEST FOR PROPOSALS
Matching Funds Grants to Expand Allied Health Degree Programs**

Governor Schwarzenegger has announced a multi-front Allied Health Initiative patterned after the Nursing Education Initiative, which has been successful in increasing the production of RNs for the state's workforce. Through this initiative, the California Labor and Workforce Development Agency has made available \$1 million to expand CSU allied health academic programs and has asked the Chancellor's Office to request proposals for 1:1 matching partnerships that would expand existing allied health academic programs. Consideration will be given to proposals to expand enrollment in and student completion of high workforce-demand allied health certificate programs, options and concentrations, and full degree programs. Priority will be given to proposals for existing clinical laboratory science and medical laboratory technology programs, as the biotechnology and health care industries have indicated their interest in partnering with higher education to expand the production of graduates prepared for careers in these fields. Campuses are encouraged to coordinate with local Workforce Investment Boards and health care industry and biotechnology partners for the match-funding required for the grant proposals.

The source of this project is federal economic stimulus funding made available by the American Recovery and Reinvestment Act (ARRA). ARRA requires that all expenditures be made between June 2009 and June 30, 2011. Programs may be of a shorter duration, however. Additional funding from other sources may become available to support programs beyond June 2011. Grants may be used to elevate existing options and concentrations to full degree programs (procedures for carrying out such elevations are described at http://www.calstate.edu/app/documents/program_modification/Option_Elevation.pdf).

Proposals may include funding for faculty assigned time, and in-kind matching support is allowed. State FTES funding and student self-support fees will not be considered "partnership" funding. Projects are allowed 10% for indirect administrative charges. Partnerships are encouraged to include provision for internships and clinical placements, and may include support for laboratory supplies, equipment, and staffing, as appropriate. Campus proposals will be reviewed at the Chancellor's Office, and funding will be recommended to the California Labor and Workforce Development Agency, which will award the grants directly to the campuses. ARRA reporting requirements will be in effect.

Please submit by May 15, 2009 your completed proposal and a provost's letter of support via e-mail to Dr. Christine Hanson, State University Dean, Academic Program Planning. The proposal form is provided as an attachment to this memorandum. Please direct questions to Dr. Hanson at chanson@calstate.edu or (562) 951-4672.

Attachment

GWR/cmh

c: Chancellor Charles B. Reed
 Dr. Elizabeth Ambos
 Ms. Sue DeRosa
 Dr. Jeronima Echeverria
 Dr. Christine Hanson
 Ms. Stephanie Leach, Assistant Secretary, Policy and Program Development
 California Labor and Workforce Development Agency
 Dr. Lorie Roth
 Mr. Robert Turnage
 Deans of Health and Human Services
 Deans of Science

Campus:

Project administrator's e-mail address:

Please submit to chanson@calstate.edu a Provost's cover letter of support and this completed application form (please retain this format).

GRANT PROPOSAL
Expanding CSU Allied Health Programs

I. SUMMARY

- A. PI/Project administrator name and contact information**
- B. Project start and end dates**
- C. Amount of funding requested**
- D. Brief description of matching support from partner(s)**
- E. Academic program (degree program, certificate program, minor, or option or concentration within a degree program)**
- F. Current program enrollment**
- G. Expanded program enrollment target**
- H. Current annual program degree production**
- I. Projected annual program degree production**

II. NARRATIVE

- A. Purpose of project**
- B. Indicators of project success** Please describe how you project outcomes will be measured.
- C. How will this project benefit California's allied health workforce and the healthcare for Californians?**

Attachment 7

1. Portion of the application for a pharmacy license
2. Articles published in recent board newsletters on the process for purchasing a pharmacy from other owner

I'm opening a Pharmacy—What do I do?

That's a big question, and the following simplified steps are detailed to help you get through all the necessary application processes.

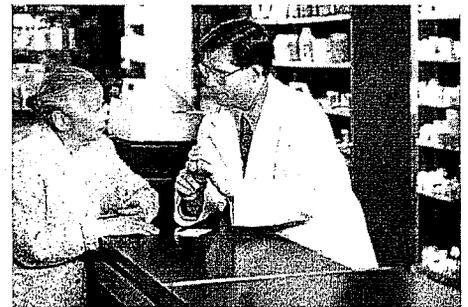
Step 1.

Apply for a Board of Pharmacy pharmacy license by downloading the application and instructions for its completion at www.pharmacy.ca.gov/forms/phy_app_pkt.pdf.

Step 2.

DEA registration is required for the purchase and distribution of controlled substances, but you may not apply for registration until **after** the pharmacy license number is issued. A DEA registration application may be obtained by downloading www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm.

Note: Although the DEA will **not** begin processing the registration application until a Board license number has been issued, applying for DEA registration online greatly reduces DEA's processing time.



Step 3.

A National Provider Identifier (NPI) number is required when applying for a Medi-Cal provider number. To apply for the NPI, download the application at www.med.umich.edu/medschool/gme/mpi/NPI_Form_cms.pdf.

Step 4.

To obtain a Medi-Cal provider number from the Department of Health Care Services, download the application at http://files.medi-cal.ca.gov/pubsdoco/provappsenroll/05enrollment_DHCS6205.pdf.

Step 5.

The National Council for Prescription Drug Programs (NCPDP) Provider ID assists pharmacies with 3rd party reimbursement. To obtain the NCPDP Provider ID information and/or application, call (480) 477-1000.

Step 6.

Check with the city or county of your area to determine whether a business license is required for your operation.

I'm closing my Pharmacy—What do I do?

A very large part of closing a pharmacy, whether due to retirement, sale, or bankruptcy, is determining what to do with the inventory and hard copy and electronic records. Section 1708.2 of Title 16 of the California Code of Regulations (16 CCR) directs pharmacies to contact the Board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and to follow all other instructions provided in this section. You must also contact the DEA for their instructions regarding your registration.

In the cases where a pharmacy files a bankruptcy petition or enters into a liquidation arrangement that would result in the sale or transfer of inventory, the Board must be notified in writing of the following, if known:

- Date of sale or transfer of drugs, poisons, devices or appliances;
- Name and address of purchaser;
- Inventory of dangerous drugs and devices showing their disposition; and

- Location of records of acquisition and disposition of dangerous drugs and devices (16 CCR section 1705).

Additionally upon closing a pharmacy, the pharmacist-in-charge and pharmacy owner must complete, sign, and submit to the Board a Discontinuance of Business (DOB) form. The form can be downloaded at www.pharmacy.ca.gov/forms/17m8.pdf. The large wall license, current pharmacy license renewal certificate, and an inventory of dangerous drugs and devices must be submitted to the Board with the DOB form.

When a pharmacy discontinues business, all prescription records, electronic files (patient profiles, invoices and prescriptions), a current inventory of dangerous drugs and devices, and acquisition and disposition records must be maintained in a board-licensed facility for at least three years (Business & Professions Code sections 4081, 4105 and 4333). Again, this information is required on the DOB form.

Answers to Estate Planning Questions Related to Pharmacy

Pharmacy inheritance questions may arise occasionally, and the following is offered as an example.

Smith's Pharmacy has been family owned for 40 years and is currently owned by the surviving wife, Mary, who is 83 years old. The family wants to assure that they can maintain control of the pharmacy when Mary dies. The family does not intend to sell the pharmacy, nor do they wish to acquire partners. Two sons, John (a licensed pharmacist) and Tom, currently operate the pharmacy and will continue to maintain control.

Q. If no further estate planning is done, upon Mary's death all her shares of Smith's Pharmacy, Inc. will pass to the Smith Family Trust, with beneficiaries John and Tom. Will the Board of Pharmacy conclude that a transfer of ownership has occurred?

A. Yes. The Smith Family Trust is a new entity in the Board's records. This change needs to be reported as soon as possible when the change occurs, because the Trust is not able to operate the pharmacy as the new owner until the new owner is approved (California Code of Regulations section 1709[c]). It may be possible to obtain a temporary permit for the new owner. Again, this must be done before the pharmacy continues operation.

Q. Additional estate planning may include the gifting of fractional shares and possibly the sale of additional shares to family members. At what point, if any, will the Board of Pharmacy conclude that a transfer of

ownership has occurred? The pharmacy wants to avoid any possibility of losing the current pharmacy permit, thereby causing a disruption of billing with Medi-Cal.

A. In all likelihood, small changes in ownership may be covered as a change of permit where the ownership changes less than 10 percent. Any new owners added on would also trigger a change of permit notification (CCR section 1709[b]), until a change of 50 percent in ownership occurs, at which point a change of ownership application must be submitted.

Specifically:

California Code of Regulations section 1709(a) requires that any changes in a pharmacy's owner(s) must be reported to the Board within 30 days. Section 1709(b) states: "Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days." Section 1709(c) states: "The following shall constitute a transfer of permit and require application for a change of ownership: any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license."



California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8617
www.pharmacy.ca.gov

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

REQUIREMENTS FOR FILING A COMMUNITY PHARMACY APPLICATION

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items will delay the processing of your application. If the number of forms provided is not sufficient, please make photocopies. You will be notified of any major deficiencies in your application. Please allow approximately 60 days from the time your application packet is complete before calling the Board of Pharmacy.

Any forms that have been previously submitted with another application will not be pulled from the file. You must complete and submit all of the requested information.

If you would like notification that the board has received your application, please submit a stamped postcard addressed to yourself.

SUMMARY OF CHECKLIST

- | | |
|-----------|---|
| Section A | Requirements for all applicants except government owned, Indian tribe owned, or change of location. Note: All pharmacy change of ownership applications will be considered for temporary permits. Whenever a change of ownership occurs, either a temporary permit will be pursued or operation must stop. In addition to the regular items required for this application, a \$250.00 temporary permit fee must also be submitted. |
| Section B | Forms required for an applicant who is filing as an individual owner |
| Section C | Forms required for an applicant whose ownership is a partnership |
| Section D | Forms required for an applicant who is filing as a corporation |
| Section E | Forms required for an applicant who is filing as a limited liability company |
| Section F | Requirements for state, city or county owned pharmacy and city or county owned jail pharmacies |
| Section G | Requirements for Native American tribe owned pharmacy |
| Section H | Requirements for non-Native American owned but operating on tribal lands |
| Section I | Requirements for change of location only (no ownership change) |

CHECKLIST FOR FILING A COMMUNITY PHARMACY APPLICATION

Section A All Applicants

- 1. Application (17A-4) and the non-refundable processing fee of \$400.
- 2. Ownership form
 - a. Corporation OR Limited Liability Company (17A-33)
 - OR**
 - b. Partnership or Individual (17A-34)
- 3. Financial Affidavit in Support of Application (17A-2)
(NOTE - Not needed for a change of location or non-profit organization)

AND
- 4. Approved wholesale credit application or wholesale agreement
(NOTE - Not needed for a non-profit organization)
- 5. Copy of the lease agreement
- 6. Seller's Certification for a Pharmacy (17A-8) (If applicable)
This is only required for an application for a change of ownership and it must be submitted by the prospective owner(s).

Section B Individual Owner who is not incorporated

In addition to items listed in Section A, the following must be submitted:

- 1. Certification of Personnel (17A-11)
- 2. Individual Personal Affidavit (17A-27)
- 3. Individual Financial Affidavit (17A-26)
- 4. Copy of *Request for Live Scan Service Form* verifying that your fingerprints have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 7.
- 5. Certification of Personnel (17A-11) for the pharmacist-in-charge

Section C Partnership

In addition to items listed in Section A, the following must be submitted:

- 1. Each partner must submit:
 - Certification of Personnel (form 17A-11)
 - Individual Personal Affidavit (17A-27)
 - Individual Financial Affidavit (form 17A-26)
 - Copy of *Request for Live Scan Service Form* verifying that your fingerprints have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 7.
- 2. Certification of Personnel (17A-11) for the pharmacist-in-charge
- 3. Signed Partnership Agreement

If the partners are a corporation or a limited liability company (LLC), then complete and provide the same documents required of corporations (see section D).

Section D Corporations

In addition to items listed in Section A, the following must be submitted:

The first line corporation over the pharmacy needs to complete a form 17A-33. Each remaining parent corporation, over the first line corporation, needs to complete a form 17A-33A.

For Profit

For the named corporation on the application, or person(s) who owns an interest in, the corporation named on the application the following is required:

- 1. Each corporate officer, major shareholder, and director must submit:
 - Certification of Personnel (17A-11)
 - Individual Personal Affidavit (17A-27)
 - Individual Financial Affidavit (form 17A-26)
 - Copy of *Request for Live Scan Service Form* verifying that your fingerprints have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 7.
- 2. Certification of Personnel (17A-11 for the pharmacist-in-charge)
- 3. Articles of Incorporation **endorsed** by the Secretary of State.

4. Statement

- a. Statement of Information **endorsed** by the Secretary of State. An endorsed copy must be requested from the Secretary of State.

OR

- b. Statement by Foreign Corporation **endorsed** by the California Secretary of State. **This is only required if the named corporation on the application is incorporated outside of California.**

5. By-laws

Non-Profit

For the named corporation on the application, or person(s) who owns an interest in, the corporation named on the application, the following is required:

1. Statement of Information **endorsed** by the Secretary of State.
2. By-laws
3. Articles of Incorporation **endorsed** by the Secretary of State.
4. Each corporate officer, shareholder, and director must submit:
- Certification of Personnel (17A-11)
5. Certification of Personnel (17A-11) for the pharmacist-in-charge

Publicly Traded Corporation

1. A copy of the corporation's 10K filing with the Securities Exchange Commission.
2. A list of the five largest shareholders who own 5% or more of stock which requires a filing with the Securities Exchange Commission.

If the shareholder is an individual, include name, title and professional license (if applicable). Also, identify if the shareholder is a bank, trust company or financial institution to which a license is issued in a fiduciary capacity.

Section E Limited Liability Company (LLC)

In addition to items listed in Section A, the following must be submitted:

The first line limited liability company over the pharmacy needs to complete a form 17A-33A. Each remaining company over the first line limited liability company also needs to complete a form 17A-33A.

- 1. Each member/manager must submit:
 - Certification of Personnel (17A-11)
 - Individual Personal Affidavit (17A-27)
 - Individual Financial Affidavit (form 17A-26)
 - Copy of *Request for Live Scan Service Form* verifying that your fingerprints have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 7.
- 2. Certification of Personnel (17A-11 for the pharmacist-in-charge)
- 3. Articles of Organization **endorsed** by the Secretary of State
- 4. Statement of Information endorsed by the Secretary of State
- 5. Copy of limited liability company agreement

Section F State, City or County Owned Pharmacy

In addition to items listed in Section A, the following must be submitted:

- 1. Application (17A-4)
- 2. Completed Certification of Personnel (17A-11) for:
 - a. Administrator
 - b. pharmacist-in-charge
- 3. A letter of verification from the county public health department or the board of supervisors indicating that the facility is government owned
- 4. The name of the Director of Public Health or the responsible party for the pharmacy operation
- 5. A copy of the organizational structure

Correctional facilities/city or county owned jail facilities

- 1. Application (17A-43)
- 2. Completed Certification of Personnel (17A-11) for:
 - a. warden
 - b. medical director
 - c. pharmacist-in-charge

Section G Native American Owned

In addition to items listed in Section A, the following must be submitted:

- 1. Application (17A-4) and the non-refundable processing fee of \$400.
- 2. Official documents from the U.S. Department of Interior, Bureau of Indian Affairs, identifying the official tribe.
- 3. A copy of the constitution and by-laws establishing the tribal council that will be the governing entity of the pharmacy.
- 4. Tribal council members and the administrator/CEO must submit:
 - Certification of Personnel (17A-11)
 - Copy of *Request for Live Scan Service Form* verifying fingerprints for the tribal council and the administrator/CEO have been scanned and all applicable fees have been paid. Please refer to fingerprint instructions on page 7.
- 5. Certification of Personnel (17A-11) for the pharmacist-in-charge.

Section H Non-Native American Owned but Operating on Tribal Lands

In addition to items listed in Section A, the following must be submitted:

If the non-Native American owner is a corporation:

- 1. All requirements listed in Section A.
- 2. Articles of incorporation endorsed by the Native American tribe.
- 3. Statement of Information **endorsed** by the Native American tribe.
- 4. **AND all other requirements** of corporate owners listed in section D, (except the articles of incorporation and the statement by domestic stock must be endorsed by the Native American tribe and not by the Secretary of State).

If the non-Native American owner is a sole owner or partnership:

- 1. All requirements listed in Section A.

- [] 2. Documents describing the agreements with the Native American tribe to operate the pharmacy on tribal land.
- [] 3. **AND all other requirements** of sole owners or partnership listed in Section B or Section C respectively.

Section I Change of Location ONLY (no ownership change)

- [] 1. Application (17A-4) and the non-refundable processing fee of \$100.
- [] 2. Ownership
 - a. Corporation or Limited Liability Company (17A-33)

OR

 - b. Partnership or Individual (17A-34)
- [] 3. Copy of the lease agreement.
- [] 4. Each corporate officer, shareholder, and director must submit
 - a. Certification of Personnel (17A-11)
 - b. Individual Personal Affidavit (17A-27)
 - c. Completed fingerprint card and \$51 fingerprint processing fee.
- [] 5. Pharmacist-in-charge must submit a Certification of Personnel (17A-11)

Fingerprint Requirements

California Residents

The board will only accept Live Scan Service Forms from California residents.

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://ag.ca.gov/fingerprints/publications/contact.htm> or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit to the board.

Non California Residents

If an owner, partner, corporate officer, major shareholder or director reside out of state they must submit rolled fingerprints on cards provided by the board and include a separate fee of \$51 (\$32 California Department of Justice (DOJ) fee and \$19 FBI fingerprint processing fee). (Live Scan processing fees are paid directly at the Live Scan site.) You may contact the board to request fingerprint cards at (916) 574-7900. You may also request cards on our website at www.pharmacy.ca.gov.

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take approximately six weeks (live scan is faster). Poor quality prints may result in rejection and will substantially delay licensing as additional fingerprint cards will be required from you for processing.

The board will only accept fingerprint cards from residents outside of California.



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

COMMUNITY PHARMACY PERMIT APPLICATION

Please print or type **ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A**

Name of Pharmacy:		Pharmacy Telephone Number ()		
Address of Pharmacy:	Street and Number	City	State	Zip Code
Indicate type of pharmacy practice: (check all that apply)				
<input type="checkbox"/> Retail		<input type="checkbox"/> Home Health Care		<input type="checkbox"/> Nuclear
<input type="checkbox"/> Mail Order		<input type="checkbox"/> Skilled Nursing Facility		<input type="checkbox"/> Board & Care
Indicate whether this application is for:				
<input type="checkbox"/> New pharmacy		<input type="checkbox"/> Change of Location of an existing pharmacy		<input type="checkbox"/> Change of Ownership of an existing pharmacy
If this is a change of ownership or change of location , indicate previous name, address and license number of pharmacy.				
Date of proposed change of ownership or location _____				
Please indicate type of ownership:				
<input type="checkbox"/> Individual		<input type="checkbox"/> Partnership		<input type="checkbox"/> Corporation
		_____ Not-for-profit		<input type="checkbox"/> Limited Liability
<input type="checkbox"/> Government owned				
Will this pharmacy dispense replacement contact lenses to patients?				
<input type="checkbox"/> Yes		<input type="checkbox"/> No		
By your affirmative answer above, your pharmacy name will be provided to the California Medical Board and you will be in compliance with section 4124 of the California Business and Professions Code.				

CONTINUE ON REVERSE

FOR OFFICE USE ONLY		
STAFF REVIEW		CASHIER LOG
<input type="checkbox"/> Articles of Incorporation <input type="checkbox"/> Financial Aff <input type="checkbox"/> Partnership agreement <input type="checkbox"/> Stock certificate <input type="checkbox"/> Seller's certificate <input type="checkbox"/> By-laws <input type="checkbox"/> Whlse agreement <input type="checkbox"/> Lease	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

Premises leased/rented <input type="checkbox"/>				Premises owned <input type="checkbox"/>			
If the premises are leased/rented, are they leased/rented from a person who is licensed in California to prescribe?							
Yes <input type="checkbox"/>		No <input type="checkbox"/>					
Name of lessor/rentor or owner		Address		City/State/Zip		Telephone number	
						()	
Name of lessee or renter		Address		City/State/Zip		Telephone number	
						()	
Monthly Rental \$				Expiration date of lease:			
A copy of the lease agreement <u>must</u> accompany this application.							

Anticipated first day of business:			
Name and address of pharmacist-in-charge		Pharmacist license number	
Name and telephone number of contact person to clarify information provided on this application			e-mail address
			()

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a pharmacy permit will be issued. If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Any application not completed within 60 days of receipt may be deemed withdrawn by the Board of Pharmacy. Fees applied to this application are not transferable and are not refundable.**

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the executive officer, (916) 574-7900, 1625 N. Market Blvd, Suite N219, Sacramento, California 95834. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted by section 1798.3 of the Civil Code.

CONTINUE ON NEXT PAGE

Certification of Applicant

ALL OWNERS AND OFFICERS MUST SIGN BELOW

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies and says that: (1) he/she is the owner or an officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant(s) business to be conducted under the license(s) for which this application is made; (4) all supplemental statements are true and accurate; and (5) the transfer application may be withdrawn by either the applicant or the licensee with no resulting liability to the Board of Pharmacy.

Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date



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

CERTIFICATION OF PERSONNEL

INSTRUCTIONS: Must be completed by each owner, director, officer, major shareholder and pharmacist-in-charge.
 All blanks must be completed; if not applicable, enter N/A. Failure to furnish a complete explanation or any omissions **will delay** the processing of your application.

1. Full name (last, first, middle)	
2. Residence address (street, city, state, zip code)	Residence telephone number ()

3. Are you currently licensed as a physician, podiatrist, dentist, optometrist or veterinarian in this state or any other state? If the answer is "yes," please list each license number, license type, and the state(s) where you are licensed. Yes No

License Type	License Number	State	Expiration Date

4. Is your spouse, child, parent, or other relative or any person with whom you share a financial interest, licensed in this state or any other state, as a physician, podiatrist, dentist, or veterinarian? If the answer is "yes," list the name of each person, their relationship to you, the license type, number and state. (Use additional sheets if necessary.) Yes No

Name	Relationship	License Type	License Number	State

5. Are you currently, or have you previously been, listed as a corporate officer, partner, owner, manager, limited liability company member, administrator or medical director on a permit to sell, store or possess dangerous drugs or dangerous devices in this state or any other state? If "yes," please list the company name, permit type and number, position(s) held, state and expiration date. Please include information regarding cancelled permits. (Use additional sheets if necessary.) Yes No

Name of company	Type of permit	Permit number	Position held	State	Expiration date

6. Have you ever had a pharmacy permit, or any professional or vocational license or registration denied, suspended, revoked, placed on probation or other disciplinary action taken by this or any other governmental authority in this state or any other state? If "yes," please provide permit type, action, company name (if applicable), year of action and state. (Use additional sheets if necessary.) Yes No

Name of person or business	Type of permit	Type of Action	Year of Action	State

7. Are you currently, or have you previously been, associated in business with any person, partnership, corporation, or other entity, or shared a financial or community property interest with any person whose pharmacy permit, or any professional or vocational license was denied, suspended, revoked, or placed on probation or other disciplinary action taken, by this or any other governmental authority in this state or any other state? If the answer is "yes," please list the company name, permit type, action, year of action and state. (Use additional sheets if necessary.) Yes No

Name of person or business	Type of permit	Type of Action	Year of Action	State

8. Have you ever been in violation of any provisions of pharmacy law, in this or any other state? If "yes," please list each type of violation, license type, type of action, year of action and state. (Use additional sheets if necessary.) Yes No

Name of person or business	Type of permit	Type of Action	Year of Action	State

9. Have you ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, any state or local jurisdiction? You must include all misdemeanor and felony convictions, regardless of the age of the conviction, including those which have been set aside and/or dismissed under Penal Code section 1000 or 1203.4. (Traffic violations of \$500 or less need not be reported.) If "yes," please attach an explanation which must include the type of violation, the date, circumstances and location, and the complete penalty received. Yes No

10. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health and safety risks? Yes No

If "yes," attach a statement of explanation. If "no," go directly to question 12.

11. Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes No
If "yes," please attach a statement of explanation.

(If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition so as to determine whether an unrestricted license should be issued, or whether conditions should be imposed).

12. Do you currently engage in, or have been engaged in the past two years, in the illegal use of controlled substances? Yes No
If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to ensure that you are not engaging in the illegal use of controlled substances? **Please attach a statement of explanation.**

13. Will you work as an employee of this business? If yes, what will your responsibilities and duties be with this business? Yes No

You must provide a written explanation for all affirmative answers to questions 3 - 12. Failure to do so may result in this application being deemed withdrawn as incomplete.

If you are a non-pharmacist owner, partner, corporate officer, corporate director or administrator of the business, you should be aware that:

- (a) any non-pharmacist owner who commits any act which would subvert or tends to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor;
- (b) you may not order a pharmacist to perform any act which is prohibited by law;
- (c) any violation of the Federal Food, Drug & Cosmetic Act, the Federal Controlled Substance Act or any law or regulation relating to the practice of pharmacy in the State of California is grounds for suspension or revocation of the permit for which you are applying;
- (d) committing any act prohibited by law, or neglecting to perform any duty required by law, could result in proceedings against the personal license of a pharmacist or could result in an action against your permit.
- (e) you are not permitted to assist in any phase of compounding or dispensing of prescriptions, or to perform any of the duties which are required by law or regulation to be done by a pharmacist;
- (f) only a pharmacist may possess the key to the pharmacy or to the permanent barrier separating the pharmacy;
- (g) you may enter the pharmacy for the purpose of performing certain specified duties only when the pharmacist is present; and the pharmacist is responsible for any non-registered person allowed to enter the pharmacy. (This does not apply to hospital pharmacies or limited permits under Business and Professions Code section 4117, or Title 16, California Code of Regulations section 1714);
- (h) dangerous drugs and/or devices as defined in Business and Professions Code sections 4022 and 4023 may only be sold on prescription or to persons who are licensed to handle, sell and possess such drugs.

All items of information requested on this form are mandatory. Failure to provide any of the requested information will result in the application being deemed withdrawn as incomplete. This information will be used to determine qualifications for licensure under California pharmacy law. The officer responsible for information maintenance is the executive officer, telephone (916) 574-7900, 1625 N. Market Blvd, Suite N219,, Sacramento, California 95834. This information may be transferred to another governmental agency, such as a law enforcement agency, if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted by Civil Code section 1798.3.

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in the foregoing certification of personnel form, including all supplementary statements ,and I personally completed this certification of personnel form.

I also certify that I have read and understand the rules of professional conduct and have retained a copy on file.

Signature

Date



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 CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

Financial Affidavit in Support of Application

All items of information in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for registration under the California Pharmacy Law. The official responsible for information maintenance is the executive officer, (916) 574-7900, 1625 N. Market Blvd, Suite N219, Sacramento, California 95834. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by section 1798.3 of the Civil Code.

Please print or type **All blanks must be completed; if not applicable, enter N/A**

Name of Corporation, Partnership or Individual Owner:				
Address of Corporation, Partnership or Individual Owner:				
Name of Pharmacy, Hospital, Wholesaler, etc:				
Premises Address:	Number and Street	City	Zip Code	Telephone Number:

Indicate what part of the total investment will be in cash, and from what source(s) it will be or has been derived. Please attach documentation. \$ _____ Source: _____ _____ _____
List all other sources of funding for the pharmacy and how it will be paid. Provide the name, address, telephone number and amount. Use additional sheets if necessary. \$ _____ Source: _____ _____ _____

If the pharmacy is franchised, list the name of franchisor:

Who will be the **primary** wholesaler for dangerous drugs and/or dangerous devices? Please attach a photocopy of the **approved** application filed with the wholesaler.

Name of primary Wholesaler				Telephone number	
Address of Wholesaler	Number & Street	City	State	Zip Code	

Who will be the **secondary** wholesaler for dangerous drugs and/or dangerous devices? Please attach a photocopy of the **approved** application filed with the wholesaler.

Name of secondary Wholesaler				Telephone number	
Address of Wholesaler	Number & Street	City	State	Zip Code	

Business Bank Name & Address (list all accounts for the pharmacy)	Telephone Number	Account Number	Balance of Account

Please submit a copy of most recent bank statement for each bank account listed above.

List all individuals authorized to sign on business bank account.

Signature	Name (please print)	Title

Name of bookkeeper/accountant for applicant premises:				Telephone Number ()	
Address of bookkeeper/accountant:	Number and Street	City	State	Zip Code	

Estimated annual gross sales \$ _____	Estimated annual purchases \$ _____
--	--

APPLICANT(S) AUTHORIZATION FOR DISCLOSURE OF FINANCIAL RECORDS

For a period of nine months, from this date, for the purpose of authorizing the Board of Pharmacy to conduct an investigation on my/our qualifications pursuant to section 4207 of the Business and Professions Code, I/we hereby authorize the Board of Pharmacy, or any of its authorized personnel to examine and secure copies of financial records consisting of signature cards, checking and savings accounts, notes and loan documents, deposit and withdrawal records, and escrow documents of my/our financial institution(s) or any financial records established in connection with this business.

I/we also authorize the Board of Pharmacy, or any of its authorized personnel, to examine and secure copies of any business records or documents established in connection with this business, including, but not limited to, those on file with my/our bookkeeper/accountant or with the escrow holder. I/we agree to furnish current financial information on the annual renewal if requested by the Board of Pharmacy. Applicant understands that falsification of the information on this form may constitute grounds for denial or revocation of the license.

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in the foregoing application, including all supplementary statements.

If corporation owned, one corporate officer must sign; if partnership owned, all partners must sign.

Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date

Date	Place	Attest (Notary Public)
------	-------	------------------------



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INDIVIDUAL PERSONAL AFFIDAVIT

Please print or type All blanks must be completed; if not applicable enter N/A

Full name:		Last	First	Middle		
Previous name(s) – include maiden name, also known as (AKA's), "aliases":			Attach a photograph taken within 60 days of the filing of this affidavit NO POLAROID			
Residence address:		Number and Street			City	State
Date of birth (month/day/year)		Place of birth (city, state, country)				
Driver's license no & state issued in		*Social Security number				
Home telephone:		Current work telephone:				
Name of applicant premises:		Number and Street	City	State		
Zip Code						
Address of applicant premises:						
Premises telephone:						
I am (Check all that apply) <input type="checkbox"/> Sole owner <input type="checkbox"/> Officer <input type="checkbox"/> General partner <input type="checkbox"/> Financier/lender Other - Specify: _____ <input type="checkbox"/> Partner <input type="checkbox"/> Director <input type="checkbox"/> Stockholder _____% <input type="checkbox"/> Member (LLC only)						
Spouse's name (Include alias or maiden)		Last	First	Middle		
Spouse's social security number		Spouse's Date of Birth		Will your spouse work in any capacity under the permit?		
				Yes <input type="checkbox"/> No <input type="checkbox"/>		

Do you have, or have you had, any direct or indirect beneficial interest in any other premises licensed by any board of pharmacy? Include sites licensed in states other than California.

Yes No

If yes, list current direct or indirect beneficial interests (use an additional sheet if necessary).

Name	Address	Permit Number
Name	Address	Permit Number
Name	Address	Permit Number

If yes, list past direct or indirect beneficial interests during the last five years (use additional sheet if necessary):

Name	Address	Permit Number
Name	Address	Permit Number

Have you -- as an owner, shareholder, officer, member, director or partner -- been involved with a pharmacy, drug wholesaler, medical device retailer, hypodermic permit or out-of-state distributor whose license has been disciplined or an offer in compromise accepted or rejected by a state board of pharmacy or federal regulatory agency? Have you as an individual held a pharmacist license, pharmacy technician registration or exemption certificate that has been disciplined or an offer in compromise accepted or rejected by a state board of pharmacy or federal regulatory agency? Also describe if any of the above actions have occurred with your spouse or palimony partner, or an associate with whom you have shared any ownership interest. Describe the event, regulatory agency involved and date for each incident. (If yes, explain. Use additional sheets if necessary)

Yes No

Have you as an individual ever been issued any professional or vocational license such as a medical doctor, attorney, dentist, contractor, etc. that has been disciplined by a state regulatory board? (If yes, explain.)

Yes No

Current and past employment for at least the past five years. (Use additional sheets if necessary).

From (mo/yr)	To (mo/yr)	Type of Work	Firm name and city

Please read carefully and sign below.

I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license. I hereby authorize the Board of Pharmacy, or any of its authorized personnel, to examine and secure copies of financial records consisting of signature cards, checking and savings accounts, note and loan documents, deposit and withdrawal records, and escrow documents of my financial institution(s) or any financial records established in connection with this business. This authorization to examine records at any financial institution may be at any time. I also authorize the Board of Pharmacy, or any of its authorized personnel, to examine and secure copies of any business records or documents established in connection with this business including, but not limited to those on file with my bookkeeper.

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in the foregoing individual personal affidavit, including all supplementary statements and I personally completed this personal affidavit.

Applicant Signature _____ Title _____ Date _____

Place _____ Attest (Notary Public) _____

Disclosure of your social security number is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C)) authorize collection of your social security number. Your social security number will be used exclusively for tax enforcement purposes of compliance with any judgement or order for family support in accordance with section 11350.6 of the Welfare and Institutions Code, or for verification of examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security number, your application for initial or renewal license will not be processed AND you will be reported to the Franchise Tax Board, which may assess a \$100 penalty against you."



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 ARNOLD SCHWARZENEGGER, GOVERNOR

Individual Financial Affidavit

Please print or type All blanks must be completed; if not applicable, enter N/A

Full Name:	Last	First	Middle	Telephone number
				()
Residence Address	Number and Street	City	State	Zip Code
Premises Address	Number and Street	City	State	Zip Code
				Telephone number
				()

You must indicate one or more of the following:

- I am making a contribution: total amount \$ _____ cash amount \$ _____
- I am contributing labor/expertise only valued at: \$ _____
- I am receiving a loan: total amount \$ _____ (please attach copy of loan agreement)
- I am making a loan: total amount \$ _____ (please attach copy of loan agreement)
- I am not making a contribution in any form.

SOURCE OF FUNDS USED TO FINANCE BUSINESS

INSTRUCTIONS: Fully explain the source of your financial contributions (e.g. stock/bonds, real estate). If cash funds are from savings, indicate where the money was or is kept. If the source is from the sale of property, indicate what was sold, the address (if real estate), the name and address of the buyer, and the net proceeds from the sale. If a loan is involved, show the date, amount, terms, security, name and address of the lender. Describe any other sources of funds such as inheritances or gifts. Documentation may be requested.

SAVINGS (Please use additional sheets if necessary)

	ITEM 1	ITEM 2
Financial Institution(s)		
Address		
Amount		
Account Number		
Source of savings		

CHECKING (Please use additional sheets if necessary)

	ITEM 1	ITEM 2
Financial Institution(s)		
Address		
Amount		
Account Number		
Source of checking		

LOANS & CREDIT APPLICATIONS FOR THIS BUSINESS

(Please use additional sheets if necessary)

ITEM 1

ITEM 2

Date(s)		
Amount(s)		
Term(s)		
Item(s) secured		
Security(s)		
Lender(s)		

SALE OF PROPERTY TO FINANCE THIS BUSINESS

(Please use additional sheets if necessary)

ITEM 1

ITEM 2

Type		
Location(s)		
Date sold		
Buyer		
Net proceeds		
Other source(s)		

Will funding be provided in any amount from an individual, partnership or corporation whose professional or vocational license has been revoked, denied or in any other manner disciplined by a regulatory board in California or any other state?

Yes No

If yes, please explain fully below (attach additional sheets if necessary). Attach copies of all disciplinary orders.

Please read and sign below in the presence of a Notary Public.

For a period of nine months from this date and pursuant to section 4207 of the Business and Professions Code, I hereby authorize the Board of Pharmacy, or any of its authorized personnel, to examine and secure copies of financial records consisting of signature cards, checking and savings accounts, note and loan documents, deposit and withdrawal records, and escrow documents of my financial institution(s) or any financial records established in connection with this business. This authorization to examine records at any financial institution may occur at any time. I also authorize the Board of Pharmacy, or any of its authorized personnel, to examine and secure copies of any business records or documents established in connection with this business including, but not limited to, those on file with my bookkeeper.

I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license.

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in the foregoing Individual Financial Affidavit, including all supplementary statements and I personally completed this financial affidavit.

Applicant's signature

Title

Date

Place

Attest (Notary Public)

Information on the VIPPS survey and the Vet VIPPs program

NABP Position Paper Calls for Action Against Proliferation of Rogue Internet Drug Outlets

Editor's Note: The following passage is excerpted from the "State of the Internet: NABP Position Paper on the Continued Proliferation of Rogue Internet Drug Outlets." The complete position paper is posted under News/Press on the NABP Web site, www.nabp.net.

In March 2003, NABP identified a crisis, wherein the need for affordable medications was "driving patients outside of the [United States] regulatory system into unidentified and unregulated areas." The NABP "Position Paper on the Importation of Foreign Prescription Drugs" further states, "[p]urchasing medications from unknown and illegal sources via the Internet and other means is compromising the US medication distribution system and making US citizens vulnerable to bioterrorism attacks." In the six years since NABP called attention to this situation, little has changed.

Valid Prescription Needed

The laws are fairly clear on this issue: To obtain prescription medication, a patient needs a valid prescription drug order. Professional consensus on what constitutes a valid prescription drug order is also clear: A prescription must be written by an authorized medical practitioner who has a pre-existing relationship with the patient that has included an in-person physical examination. So then why, out of 1,351 Internet drug outlets assessed by NABP as of January 2009, do 1,183 (88%) of them continue, unhindered, to offer pre-

scription drugs without a valid prescription?

To see why this "wild west" of an electronic marketplace is a problem, one need only follow the trail of dead and injured patients:

- Ryan Haight died on February 21, 2001, at the age of 18 from an overdose of Vicodin® he had purchased over the Internet without a doctor's examination. He is, of course, the namesake of the Ryan Haight Online Pharmacy Consumer Protection Act, which, as of fall 2008, prohibits the dispensing of controlled substance medications over the Internet without a valid prescription that

has included a face-to-face physical examination by the prescribing practitioner.

- Justin Pearson, 24, of St Cloud, MN, died on December 25, 2006, from an overdose of prescription drugs he had ordered from a rogue Internet pharmacy. He reportedly became addicted to Vicodin after injuring his back during a four-wheeling accident. When his doctor stopped prescribing the drug, he obtained it online without a prescription. In his memory, Minnesota adopted "Justin's Bill" in early 2008, according to which, a prescription is not considered valid unless documented proof of a face-to-face, patient-physician evaluation is provided.
- A deadly overdose from drugs purchased over the Internet without a prescription or a physical examination by a practitioner is spotlighted in a news story appearing May 22, 2008, on CNN.com/health, "Widow: My husband died from online drugs" (www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html).
- In July 2007 came news of a Canadian woman's death from drugs that turned out to be coun-

terfeit purchased over the Internet. These drugs were later determined to be contaminated with extremely high quantities of metal. The pharmacy claimed to be in Canada.

- In February 2007, Food and Drug Administration (FDA) reported that several patients who thought they were purchasing a variety of different medications, including Ambien®, Xanax®, Lexapro®, and Ativan®, over the Internet, instead received the schizophrenia drug, haloperidol, sending some patients to the emergency room. FDA said the agency had received reports of several patients seeking emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms, and muscle stiffness after taking the pills. The patients reportedly ordered the drugs through a variety of commercial Web sites.
- NABP also has received several reports from patients who became ill after taking medications received from Internet drug outlets, received the wrong medications, or were defrauded by Internet drug outlets that charged their credit cards but never sent the ordered medications.

Seek and Ye Shall Find

Despite obvious problems with the rampant

availability of prescription medications, Internet search engines continue to post advertisements and search results linking to rogue sites. Several major search engines filter the drug outlets they allow to advertise on their Web sites through a verification program (not recognized by NABP). An alarming number of Internet drug outlets advertising on search engines flagrantly offer prescription medicine, including controlled substances, without a valid prescription.

Many of these sites violate the recently adopted Ryan Haight Online Pharmacy Consumer Protection Act, which prohibits the dispensing of controlled substance medications over the Internet without a valid prescription that has included a face-to-face physical examination. The question often asked is why are these sites allowed to continue their advertising and presence on search engines. The answer may be advertising dollars.

Internet Filters Have Holes

One of the problems with some Internet drug outlet screening services is the size of the holes in their filters. While federal law prohibits the importation of prescription medications from foreign sources, some screening services openly approve them, regardless of the fact that many of these sites may be rogue

operations masquerading as legitimate pharmacies. Many sites purporting to be Canadian pharmacies, for instance, sell medications that are not approved under Canadian regulations, and many have no discernable ties to Canada whatsoever.

Additionally, many of the sites currently posing as Canadian pharmacies advertise adulterated concoctions of brand-name drugs. For instance, legitimate Viagra® is sold only as a 25 mg, 50 mg, and 100 mg tablet. So called Viagra Soft Tabs or quick-dissolving Viagra are not legitimate branded products and do not go through the same tests for safety and efficacy as the legitimate product, and are not approved for sale in the United States.

According to an FDA statement before the Nevada State Board of Pharmacy in 2006, "evidence shows there are weaknesses in the oversight of the drug distribution system by foreign governments for drugs that are imported into the U.S. We have found that although 'Canadian pharmacies' purport to dispense drugs that are FDA approved, generally the drugs, in fact, are not. Rather, the dispensed drugs are of unknown quality and country of origin."

Following the death of the Canadian woman who ingested counterfeit drugs she bought online, Canadian Pharmacists Association Executive Director Jeff

nabp newsletter

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Poston was quoted in a news release as saying, “[m]any internet pharmacies claim to be Canadian but in fact can be based anywhere in the world. A Canadian flag is no guarantee – nor can the origin and safety of drugs bought online be guaranteed.”

Whols Data Is Anybody’s Guess

Also contributing to the problem is the fact that domain name registration information is frequently falsified and never verified by the domain name registrars that sell the Web site names. This registration information, accessible online by means of a “WhoIs” search, can be listed either as public or, for a fee, private, but there is ample evidence that a significant number of public domain records are falsified, rendering this means of accountability less than trustworthy.

The US Government Accountability Office (GAO) undertook a study to determine just how accurate

domain name records are. Citing the results of this study in its 2005 report to the US House of Representatives’ Subcommittee on Courts, the Internet, and Intellectual Property, GAO estimates that 2.31 million domain names (5.14%) were registered with data that appeared obviously and intentionally false in one or more of the required contact information fields.

More recently, in a June 24, 2008 statement before the US House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security, Christine N. Jones, general counsel and corporate secretary of the Go Daddy Group, Inc, corroborated this finding. The Go Daddy Group consists of eight Internet Corporation for Assigned Names and Numbers (ICANN)-accredited registrars, including GoDaddy.com, and manages some 30 million domain names. Jones says, “bad actors typically do not want to pay extra to hide their WHOIS data when they are probably going to provide false WHOIS data, anyway. Most online phar-

macies do not have privacy protection on them. More often than not, the registrant simply provides false, but typically valid looking, WHOIS data, upon registration.”

Bob Parsons, CEO and founder of GoDaddy.com writes in a March 23, 2005 blog post, “often times the information within the [WhoIs] database is inaccurate. Inaccurate information happens mostly because some registrants who want to achieve anonymity – for a myriad of reasons, some of which are despicable – provide false information to begin with. . . . There’s often no way to track down a registrant who provided false information when registering their domain name.”

Credit Where None is Due

The majority of Internet drug outlets advise patients to pay by credit card. Some major credit card companies actively screen and refuse to conduct business with Internet drug outlets selling controlled substances. Many sites selling controlled substances ille-

gally, however, still post the logos of major credit card companies, presumably to give themselves a veneer of credibility.

Credit card companies do not, however, screen for illegal transactions involving the sale of non-controlled substances without a prescription, or the sale of foreign or non-FDA-approved drugs to patients in the US. Through various sources, NABP has confirmed that a major credit card can be used in the purchase of prescription medications online without a prescription. NABP also has confirmed that a major credit card can be used in the purchase of controlled substances through an online auction site.

Community Pharmacies Solicited

Several boards of pharmacy, including those in Iowa, Ohio, and Kansas, have reported that community pharmacies in their jurisdictions have been bombarded by faxed solicitations from Internet drug outlets to fill prescription drug orders for its operations, frequently

NABP Position Paper

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written by physicians who have never examined or even met the patients.

The Iowa Board of Pharmacy reported in its November 2007 newsletter that the Board had received numerous complaints about faxes transmitted from an Internet company to private and business fax machines, including those of pharmacies and medical clinics, throughout Iowa. The company offers a variety of prescription drugs to consumers without a valid prescription.

The Ohio State Board of Pharmacy warned pharmacists in its February 2007 and February 2008 newsletters about scams involving Internet drug outlets soliciting pharmacies to fill prescription drug orders without a prescription after answering questions on the Web site. The Board reported that pharmacists were

being bombarded with offers from these Internet sites. The offers seem to primarily target independent pharmacies, "probably knowing that many of them are suffering financially due to the initial problems with Medicare Part D, Medicaid reimbursement cuts, insurance cuts, etc," the Board states.

In its December 2007 newsletter, the Kansas State Board of Pharmacy also reported that the Board has received numerous complaints from physicians and pharmacists in Kansas concerning faxes that are being transmitted from an Internet company to business fax machines, including those of medical clinics and pharmacies, in Kansas. The source of these faxes appears to be the same company referenced by the Iowa and Ohio boards.

State Laws . . . or Not

State laws specifically prohibit the dispensing of prescription medications

without a valid prescription that has included a face-to-face physical examination, as Drug

"Further, the lack of resources for enforcement must be addressed prior to a complete compromise of the US drug distribution system, and subsequent patient injury or death."

Enforcement Administration and the Ryan Haight Act now do for controlled substances. In the state, although regulatory language is broad, it is instead addressed and defined through the compilation and interweaving of federal or state laws and regulations and recognized standards of practice.

"Illegal activities should not be allowed to continue due to inefficient regula-

tory systems and rules that were developed at a time when huge problems such as the one we are currently experiencing could not have been foreseen," NABP stated in its 2003 position statement. "Further, the lack of resources for enforcement must be addressed prior to a complete compromise of the US drug distribution system, and subsequent patient injury or death." Six years later, as consumer use of Internet drug outlets has grown exponentially and shifted to purchasing controlled substances, this imperative is more urgent than ever. "As regulatory authorities in the US and other countries grapple with this important issue, educating the American public on the danger and illegality of purchasing prescription medications abroad is a necessary component of any solution to the problem" – as much now, as it was then. ®

NABP Reports Rogue Internet Drug Outlets

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achieved VIPPS accreditation and one site has been accredited through the Vet-VIPPS program.

Also stated in the February 2009 report to regulators, NABP is seeking collaborative efforts from state boards of pharmacy and other organizations to help combat the rising number of rogue Internet drug

outlets. Since the Internet Drug Outlet Identification program launched in May 2008, several state boards of pharmacy have expressed interest in displaying a link on their Board Web site to the Internet Pharmacies section of the NABP Web site to help educate the public about the dangers of buying drugs online.

In addition, NABP has sent letters to three Internet search engines, Google, Yahoo!, and MSN, recommending that they replace

their current third-party verification service with one that adheres to pharmacy laws and practice standards. Also, in collaboration with LegitScript, LLC, NABP will soon be sending a report to Congress, calling attention to search engine advertising programs that promote illegally operating Internet drug outlets.

Paypal and the National Center on Addiction and Substance Abuse at Columbia University

have also demonstrated their willingness to share research relevant to the Internet Drug Outlet Identification program.

For a full listing of Recommended and Not Recommended sites, along with the Internet Drug Outlet Identification program criteria and related patient information, visit the Internet Pharmacies section of the NABP Web site at www.nabp.net. ®

European Union Seizes 34 Million Fake Drugs in Two Months with Medi-Fake; NABP's Not Recommended List Increases

While NABP continues to list Internet drug outlets on the NABP Web site that do and do not meet state and federal laws and NABP patient safety and pharmacy practice standards, increased efforts and awareness to protect patients from illegitimate drugs have surfaced across international borders.

Over a two-month period, European Union (EU) custom officials seized approximately 34 million counterfeit drugs – originating mostly from India, Pakistan, and China – through operation Medi-Fake. Medi-Fake, which began in mid-October 2008, is the first coordinated action undertaken by custom controls through the 27 EU member states in an effort to protect citizens and legitimate business from new and increasing security and safety threats.

Since its launch, Medi-Fake seized 2.2 million fake pills at the Brussels airport, consisting of 1.6 million painkillers and 600,000 anti-malaria treatments, the largest seizure of illegal medications ever recorded in Europe. Also, Le Havre customs in France prevented 400,000 counterfeit medicine pills and 11 million pseudoephedrine pills from entering the drug distribution system.

These results of Medi-Fake's seizures demonstrate that counterfeit medications continue to threaten public safety, both in and through surrounding international borders. And these counterfeit products are often sold via the Internet.

As part of its mission to educate patients about the potential dangers of purchasing medication online,

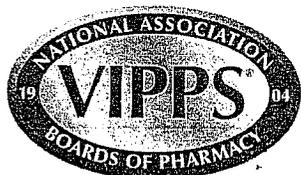
NABP continues to identify and list Not Recommended Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards on the NABP Web site.

As of April 10, 2009: 2,084 sites were reported as Not Recommended. Of these:

- 1,983 sites do not require a valid prescription
- 1,088 sites offer foreign or non-FDA-approved drugs
- 768 sites are located outside the United States and selling drugs illegally to patients in the US

Sixteen sites are listed as Recommended Internet pharmacies. These sites are accredited through the NABP Verified Internet Pharmacy Practice Sites™ program (VIPPS®). Celebrating its 10th anniversary this year, the VIPPS program enables consumers to confidently access important information regarding the licensure and practices of legitimate Internet pharmacies in the nation.

A full listing of Recommended and Not Recommended sites, along with program criteria and related patient information, is available in the Internet Pharmacies section of the NABP Web site at www.nabp.net. ☉



VIPPS Celebrates 10 Years as a Trusted Source for Patient Safety

The NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) program celebrates its 10th anniversary this year. See the March 2009 *NABP Newsletter* article "VIPPS: 10 Years of Guiding Consumers to Legitimate Internet Pharmacies," for more details.

NABP Reports Rogue Internet Drug Outlets to Regulators

In its ongoing effort to educate patients and protect the public health from illegitimate Internet drug outlets selling prescription medications online, NABP continues to review, identify, and list Internet drug outlets on the NABP Web site that do and do not meet state and federal laws as well as NABP patient safety and pharmacy practice standards.

As part of this initiative, NABP submits a bimonthly report on its findings to various state and federal regulatory bodies. In its February 2009 "Internet Drug Outlet Identification Program Progress Report for State and Federal Regulatory

Bodies," NABP reports the need to curb the illegal sale of prescription medications over the Internet, and stresses the importance of educating consumers on the potential risks of purchasing medications over the Internet and empowering them to make informed choices.

As of April 24, 2009, NABP has reviewed and verified its findings on 2,385 Internet drug outlets selling prescription medications. Of these 2,385 sites, 2,217 appear to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards and are listed on the NABP

Web site as Not Recommended. Of these:

- 2,115 sites do not require a valid prescription
- 1,198 offer foreign or non-FDA-approved drugs
- 866 sites are located outside the United States and selling drugs illegally to patients in the United States.

In addition to listing Not Recommended sites on the NABP Web site, NABP continues to list Recommended sites, those accredited through the Verified Internet Pharmacy Practice Sites™ (VIPPS®) and Vet-VIPPS™ programs. Currently, 16 sites have

NABP Reports Rogue Internet Drug Outlets

(continued from page 103)

achieved VIPPS accreditation and one site has been accredited through the Vet-VIPPS program.

Also stated in the February 2009 report to regulators, NABP is seeking collaborative efforts from state boards of pharmacy and other organizations to help combat the rising number of rogue Internet drug

outlets. Since the Internet Drug Outlet Identification program launched in May 2008, several state boards of pharmacy have expressed interest in displaying a link on their Board Web site to the Internet Pharmacies section of the NABP Web site to help educate the public about the dangers of buying drugs online.

In addition, NABP has sent letters to three Internet search engines, Google, Yahoo!, and MSN, recommending that they replace

their current third-party verification service with one that adheres to pharmacy laws and practice standards. Also, in collaboration with LegitScript, LLC, NABP will soon be sending a report to Congress, calling attention to search engine advertising programs that promote illegally operating Internet drug outlets.

Paypal and the National Center on Addiction and Substance Abuse at Columbia University

have also demonstrated their willingness to share research relevant to the Internet Drug Outlet Identification program.

For a full listing of Recommended and Not Recommended sites, along with the Internet Drug Outlet Identification program criteria and related patient information, visit the Internet Pharmacies section of the NABP Web site at www.nabp.net. ©



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nabp

National Association of Boards of Pharmacy

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Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
 FROM: Nancy Tay, Accreditation Director
 DATE: January 8, 2009
 RE: NABP to Launch Vet-VIPPS Program

On January 10, NABP will launch its Veterinary-Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS™) program. This new program provides a vehicle for evaluating and accrediting legitimately operating online veterinary pharmacies in an effort to protect companion animals as well as non-food producing animals.

The new Vet-VIPPS program will assist the state boards in their efforts to maintain control over the Internet-based distribution of prescription drugs and ensure a valid veterinarian-patient/client relationship exists. Based on the Association's original VIPPS® criteria, the newly designed Vet-VIPPS will also incorporate new criteria specific to veterinary pharmacies.

Pursuant to discussions with several state boards of pharmacy, NABP learned that boards were receiving complaints against Internet pharmacies dispensing prescription drugs without a veterinarian-patient/client relationship. In addition, the program supports the Virginia Board of Pharmacy's requirement for nonresident Internet pharmacies to be accredited through NABP or a similar program approved by the Board.

In order to receive Vet-VIPPS accreditation, Internet pharmacy practice sites that dispense prescription veterinary drugs for use in non-food producing animals, must be licensed in good standing with their respective state boards of pharmacy and adhere to the Vet-VIPPS criteria and program requirements. Pharmacies that dispense prescriptions for food-producing animals are not eligible to apply for accreditation.

More information about the Vet-VIPPS program will be available on January 10 in the Accreditation Programs section of the NABP Web site at www.nabp.net. Feel free to contact me via e-mail at ntay@nabp.net with any questions or comments.

Attachment

cc: NABP Executive Committee
 Carmen A. Catizone, Executive Director/Secretary

Passing rates for the CPJE and NAPLEX

**California State Board of Pharmacy
CPJE Statistics 10/1/08 – 4/22/09**

The charts below display data for all candidates who took the CPJE examination between 10/1/08 – 4/22/09, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

Overall Pass Rates

CPJE

	Frequency	Percent
Valid F	179	24.8
P	543	75.2
Total	722	100.0

NAPLEX

	Frequency	Percent
Valid F	21	3.1
P	661	96.9
Total	682	100.0

Location of School

CPJE

			CPJE		CPJE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	26	125	151	4	145	149
		% within PF	17.2	82.8		2.7	97.3	
	Other US	Count	89	291	380	10	341	351
		% within PF	23.4	76.6		2.8	97.2	
	Foreign	Count	64	127	191	7	175	182
		% within PF	33.5	66.5		3.8	96.2	
Total		Count	179	543	722	21	661	682
		% within PF	24.8	72.2		3.1	96.9	

Gender

			CJPE pass fail status		CJPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	109	336	445	12	413	425
		% within PF	24.5	75.5		2.8	97.2	
	M	Count	70	207	277	9	248	257
		% within PF	25.3	74.7		3.5	96.5	
Total		Count	179	543	722	21	661	682
		% within PF	24.8	75.2		3.1	96.9	

Degree

			CJPE pass fail status		CJPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy	Count	71	143	214	9	197	206
		% within PF	33.2	66.8		4.4	95.6	
	Pharm D.	Count	108	400	508	12	464	476
		% within PF	21.3	78.7		2.5	97.5	
Total		Count	179	543	722	21	661	682
		% within PF	24.8	75.2		3.1	96.9	

California Schools

			CJPE pass fail status		CJPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	2	20	22	0	21	21
		% within PF	9.1	90.9		0	100	
	UOP	Count	11	53	64	1	63	64
		% within PF	17.2	82.8		1.6	98.4	
	USC	Count	4	11	15	0	15	15
		% within PF	26.7	73.3		0	100	
	Western	Count	2	16	18	1	17	18
		% within PF	11.1	88.9		5.6	94.4	
	Loma Linda	Count	6	20	26	2	23	25
		% within PF	23.1	76.9		8	92	
	UCSD	Count	1	5	6	0	6	6
		% within PF	16.7	83.3		0	100	
Total		Count	26	125	151	4	145	149
		% within PF	17.2	82.8		2.7	97.3	

US Schools of Pharmacy

	CJPE pass fail status		Total
	F	P	
Samford	1	2	3
U of AZ	0	1	1
UCSF	2	20	22
U of Pacific	11	53	64
USC	4	11	15
U of CO	0	5	5
U of Conn	0	3	3
Howard DC	1	2	3
FL A&M	0	4	4
U of FL	4	4	8
Mercer	1	2	3
U of GA	0	1	1
Idaho SU	1	2	3
U of IL Chi	0	8	8
Butler U	0	2	2
Purdue	2	4	6
Drake	2	2	4
U of IA	0	1	1
U of KS	1	5	6
U of KY	1	1	2
NE LA U	1	3	4
Xavier	2	6	8
U of MD	2	4	6
MA Col Pharm	6	30	36
NE-MA	3	4	7
Ferris	2	6	8
U of MI	0	8	8
Wayne SU	1	1	2
U of MN	1	3	4
U of MS	0	3	3
St. Louis Col of PH	0	2	2
UMKC	0	1	1
U of MT	0	1	1
Creighton	2	3	5
U of NE	1	2	3
Rutgers	0	4	4
U of NM	3	4	7
Western	2	16	18

	CJPE pass fail status		Total
	F	P	
Midwestern U Chicago	1	7	8
A&M Schwartz	5	10	15
St. Johns	2	4	6
SUNY-Buff	1	7	8
Union U	1	2	3
UNC	0	2	2
ND SU	1	1	2
OH Nrthm U	2	1	3
OH State U	0	7	7
U of OK	0	1	1
OR State U	0	2	2
Duquesne	2	2	4
Phl C of Pharm	4	9	13
Temple	4	12	16
U of RI	1	2	3
Med U of SC	0	1	1
U of SC	0	2	2
U of Hous	1	4	5
U of TX	0	5	5
U of UT	0	1	1
Med C of VA	1	5	6
U of WA	1	7	8
WA State U	0	2	2
U of WI-Mad	1	0	1
U of WY	1	1	2
Nova Southeastern	1	7	8
Wilkes University	0	2	2
Texas Tech	0	1	1
Bernard J Dunn	1	3	4
Midwestern AZ	3	11	14
Nevada College of Pharm	6	25	31
Loma Linda U	6	20	26
UCSD	1	5	6
MA School of Pharm - Worcester	7	6	13
Palm Beach Atlantic University	0	1	1
Lake Erie Col	2	3	5
U of Appalachia	2	0	2

	CJPE pass fail status		Total
	F	P	
Hampton U (VA)	0	1	1
Other/FG	64	127	191
Total	179	543	722

Country

	CJPE pass fail status		Total
	F	P	
Australia/Ashmore/Coral Sea Is/Cartier Is	0	1	1
Canada	0	2	2
Switzerland	1	0	1
Chile	0	1	1
Egypt	9	12	21
United Kingdom	1	1	2
GE	0	1	1
India	12	28	40
Iran	3	6	9
Jamaica	0	1	1
Jordan	1	1	2
Korea (N&S)	0	2	2
S. Korea	1	4	5
Niger	0	1	1
Nigeria/New Guinea	1	2	3
Philippines	13	18	31
Pakistan	1	1	2
Romania	1	1	2
Singapore	0	1	1
USSR	0	1	1
Syria	1	2	3
Taiwan	0	2	2
Ukranian	1	0	1
UK	0	1	1
USA	131	445	576
Yugoslavia	1	3	4
South Africa	1	5	6
Total	179	543	722

10-year comparison of passing rate by exam type

**OVERALL PASS RATES
10-Year Comparison by Exam Type**

CPJE

	3/04-3/05		4/05-9/05		10/05-3/06		4/06-9/06		10/06-3/07		4/07-8/07		09/07-03/08		04/08-09/08		10/08-4/09	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pass	1683	81.5	861	77.5	494	80.3	796	80.2	420	69.9	845	85.5	553	73.0	979	81.6	543	75.2
Total	2065	100.0	1111	100.0	615	100.0	992	100.0	601	100.0	988	100.0	758	100.0	1200	100.0	722	100.0

NAPLEX

	3/04-3/05		4/05-9/05		10/05-3/06		4/06-9/06		10/06-3/07		4/07-8/07		09/07-03/08		04/08-09/08		10/08-4/09	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pass	1738	96.2	1018	95.9	499	91.1	905	94.5	477	90.7	918	95.7	688	94.5	1112	97.6	661	96.9
Total	1807	100.0	1061	100.0	548	100.0	958	100.0	526	100.0	959	100.0	728	100.0	1139	100.0	682	100.0

Pharmacist Licensure Examination

	January 1999		June 1999		January 2000		June 2000		January 2001		June 2001		January 2002		June 2002		January 2003		June 2003	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pass	209	41.1	539	56.7	234	43.6	606	56.9	272	45.3	691	59.8	269	50.2	616	53.3	385	57.0	726	56.5
Total	508	100.0	950	100.0	537	100.0	1065	100.0	601	100.0	1155	100.0	536	100.0	1156	100.0	675	100.0	1284	100.0

Meeting Summary of the Licensing Committee Meeting



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

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

DATE: 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. Emergency and Disaster Response Planning: Presentation on the H1N1
Emergency Response Activities in California by the California Department of
Public Health (CDPH)**

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 H1N1 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 H1N1 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 medications. 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. Ravnar 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 "depotting." 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. Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiencies

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*

Total Current Licensees 41,068 44,713 50,510 54,219 57,002**

* As of June 11, 2009

** As of May 3, 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 Standardized 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.

4. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy 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. Discussion of the Reporting and Accounting of Intern Hours for California 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. Private/Public Partnerships to Add Health Care Practitioners to California's Work Force

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. Impact of State Furloughs on Processing Timelines and Work Flow of the 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. Pharmacies Refilling Orders for Other Pharmacies with Prescription Drugs Owned by Neither Pharmacy

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. Accreditation of Internet Pharmacies by the National Association of Boards of Pharmacy

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

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

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.

Attachment 12

Strategic Plan Update for the Licensing Committee for 2009/10

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

<p>Objective 2.1</p> <p>Measure:</p>	<p>Issue licenses within three working days of a completed application by June 30, 2011.</p> <p>Percentage of licenses issued within three work days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Review 100 percent of all applications within seven work days of receipt. 2. Process 100 percent of all deficiency documents within five work days of receipt. 3. Make a licensing decision within three work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. <ul style="list-style-type: none"> • Pharmacists • Intern pharmacists • Pharmacy technicians • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Designated Representatives (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors • Sterile Compounding 3. Process changes in pharmacist-in-charge and designated representative-in-charge. 5. Withdrawn licenses to applicants not meeting board requirements. 6. Deny applications to those who do not meet California standards. 7. Respond to e-mail status requests and inquiries to designated e-mail addresses. 8. Respond to telephone status request and inquiries.
<p>Objective 2.2</p> <p>Measure:</p>	<p>Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.</p> <p>Percentage of cashiered application and renewal fees within two working days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Cashier application fees. 2. Cashier renewal fees. 3. Cashier citations with fines. 4. Cashier probation and cost recovery fees. 5. Cashier fingerprint fees. 6. Cashier all other fees.

<p>Objective 2.3</p> <p>Measure:</p>	<p>Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.</p> <p>Percentage of licensing records changes within five working days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Make address and name changes. 2. Process discontinuance of businesses forms and related components. 3. Process off-site storage applications. 4. Transfer intern hours to other states
<p>Objective 2.4</p> <p>Measure:</p>	<p>Implement at least 25 changes to improve licensing decisions by June 30, 2011.</p> <p>Number of implemented changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. 2. Evaluate the drug distribution system of clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. 7. Review requirements for qualifications of pharmacy technicians with stakeholders 8. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. 9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards. 10. Implement new test administration requirements for the CPJE. 11. Participate in ACPE reviews of California Schools of Pharmacy. 12. Initiate Review of Veterinary Food Animal Drug Retailer Designated Representative 13. Convene Committee to evaluate drug distribution within hospitals. 14. <u>Improve reporting of and accounting for intern hours.</u> 15. <u>Participate in initiatives to increase the number of pharmacists in California to meet demand.</u> 16. <u>Assess the operations of specialty pharmacy services.</u> 17. <u>Encourage use of technology where it benefits the public.</u> 18. <u>Secure the implementation of e-prescribing in California by the earliest possible date.</u> 19. <u>Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.</u>

Attachment 13

1. FY 08/09 Licensing statistics
2. Fourth quarter's status of Licensing Committee Goals.

Board of Pharmacy Licensing Statistics - Fiscal Year 2008/09

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	225	119	118	143	94	100	111	93	89	211	311	662	2276
Pharmacist (Initial licensing applications)	184	290	33	332	90	90	68	110	67	67	49	11	1391
Intern pharmacist	70	502	130	526	49	68	122	100	92	125	100	99	1983
Pharmacy technician	850	573	775	657	555	625	734	719	731	799	843	1117	8978
Pharmacy	44	28	33	265	289	26	27	25	27	35	27	47	873
Sterile Compounding	7	5	3	2	7	3	1	6	5	3	8	8	58
Clinics	6	12	9	7	9	2	2	1	18	6	10	7	89
Hospitals	4	0	1	3	0	0	0	2	0	0	0	2	12
Nonresident Pharmacy	6	8	9	14	5	7	5	8	6	5	5	7	85
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	1	1
Hypodermic Needle and Syringes	1	3	4	6	0	1	2	2	4	3	0	3	29
Nonresident Wholesalers	12	5	4	9	11	9	8	10	4	10	10	14	106
Wholesalers	16	8	2	7	1	4	4	4	5	6	7	5	69
Veterinary Food-Animal Drug Retailer	0	0	1	1	0	0	0	0	0	0	0	1	3
Designated Representatives	34	37	44	62	25	25	42	33	22	48	32	53	457
Issued													
Pharmacist	193	291	42	316	93	95	74	99	68	71	52	15	1409
Intern pharmacist	85	282	285	489	111	51	72	108	68	106	58	105	1820
Pharmacy technician	481	926	681	552	550	593	474	399	704	500	607	629	7096
Pharmacy	26	23	59	34	461	39	25	17	18	22	39	33	796
Sterile Compounding	7	2	8	15	3	9	4	2	4	2	4	4	64
Clinics	1	5	22	6	2	1	9	4	0	3	4	10	67
Hospitals	3	6	2	3	3	2	0	1	0	5	2	2	29
Nonresident Pharmacy	1	8	7	15	7	5	5	5	10	7	6	4	80
Licensed Correctional Facility	2	0	0	0	0	0	0	0	0	0	0	0	2
Hypodermic Needle and Syringes	3	0	1	1	0	6	2	1	0	0	0	0	14
Nonresident Wholesalers	3	3	7	5	7	6	7	9	9	7	5	16	84
Wholesalers	4	5	5	3	0	6	2	1	2	3	3	7	41
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	2	2	0	0	0	0	4
Designated Representatives	43	10	44	37	28	61	32	27	34	47	39	40	442

*u/a = unavailable

Board of Pharmacy Licensing Statistics - Fiscal Year 2008/09

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	u/a	1324	1228	851	820	748	814	662	655	130	907	311	311
Intern pharmacist	u/a	309	304	323	286	210	263	u/a	292	285	309	291	291
Pharmacy technician	u/a	1154	1233	1375	1221	1021	1364	u/a	1544	1459	1574	2094	2094
Pharmacy	u/a	86	59	233	67	62	61	60	57	59	54	65	65
Sterile Compounding	u/a	39	42	27	24	19	17	20	17	18	22	25	25
Clinics	u/a	62	77	71	72	83	72	36	36	31	38	27	27
Hospitals	u/a	15	14	12	12	12	14	18	15	21	13	18	18
Nonresident Pharmacy	u/a	68	66	64	59	66	45	45	41	39	41	40	40
Licensed Correctional Facility	u/a	0	0	0	0	0	0	0	0	0	0	1	1
Hypodermic Needle and Syringes	u/a	11	12	16	16	14	13	17	17	17	19	19	19
Nonresident Wholesalers	u/a	109	110	111	114	117	113	114	111	97	100	90	90
Wholesalers	u/a	46	39	39	44	39	38	41	44	42	47	45	45
Veterinary Food-Animal Drug Retailer	u/a	5	5	5	6	7	4	1	1	1	1	1	1
Designated Representatives	u/a	166	158	181	177	137	126	179	170	96	110	104	104
Change of Pharmacist-in-Charge													
Received	110	149	153	215	118	157	101	129	125	66	100	152	1575
Processed	112	126	246	227	89	129	114	85	167	113	98	161	1667
Pending	157	180	87	75	104	132	119	163	121	74	76	67	67
Change of Exemptee-in-Charge													
Received	12	21	9	12	7	8	4	4	0	0	23	15	115
Processed	0	0	0	0	5	7	3	8	0	0	0	0	23
Pending	12	33	42	54	56	57	58	54	54	54	77	92	92
Change of Permits													
Received	94	46	95	142	64	58	82	53	89	90	74	415	1302
Processed	116	6	16	236	15	59	118	147	26	6	117	298	1160
Pending	209	249	328	234	283	282	262	152	215	299	256	373	373
Discontinuance of Business													
Received	21	21	25	10	34	33	44	30	20	0	43	57	338
Processed	0	13	0	0	40	41	19	48	0	0	70	39	270
Pending	34	42	77	87	81	73	98	80	100	100	73	91	91

*u/a = unavailable

Board of Pharmacy Licensing Statistics - Fiscal Year 2008/09

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	1081	4018	1264	1493	1044	1336	1256	1723	1399	999	369		15982
Pharmacy technician	2011	5133	2055	2365	1656	2222	1837	2390	2201	1600	800		24270
Pharmacy	625	640	337	554	387	272	486	1180	752	372	578		6183
Sterile Compounding	18	54	26	29	10	32	21	13	18	12	8		241
Clinics	65	179	87	71	48	51	97	94	79	72	31		874
Nonresident Pharmacy	26	39	16	19	14	17	21	17	25	21	6		221
Licensed Correctional Facility	u/a	u/a	u/a	u/a	u/a	u/a	0	0	0	0	0		0
Hypodermic Needle and Syringes	18	35	20	43	17	30	20	15	21	0	15		234
Nonresident Wholesalers	21	68	32	45	28	33	31	28	51	44	15		396
Wholesalers	26	98	31	31	29	40	40	25	37	31	11		399
Veterinary Food-Animal Drug Retailer	2	3	2	1	2	2	1	1	1	1	4		20
Designated Representative	114	449	92	113	94	192	178	214	278	114	30		1868

*u/a = unavailable

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within three work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
		Apps. Received:				Average Days to Process:			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	462	337	293	1184	20	9	15	7
	Pharmacist (initial licensing)	507	512	245	127	4	2	3	8
	Pharmacy Intern	702	643	314	324	11	10	14	15
	Pharmacy Technician	2198	1837	2184	2759	26	29	38	48
	Pharmacies	110	583	79	110	19	15	30	30
	Non-Resident Pharmacy	23	26	19	17	24	20	30	30
	Wholesaler	26	12	13	18	20	17	30	30
	Veterinary Drug Retailers	1	1	0	1	14	0	0	15
	Designated Representative	115	112	97	53	30	17	15	30
	Out-of-state distributors	21	29	22	34	25	17	30	30
	Clinics	27	18	21	23	32	30	30	30
	Hypodermic Needle & Syringe Distributors	8	7	8	6	14	5	15	30
	Sterile Compounding	15	12	12	19	14	14	15	30
	Change of Permit	235	264	291	579	U/A	U/A	156	90
Pharmacist in Charge	246	445	355	318	26	26	28	30	
Designated Representative in Charge	5	12	8	38	34	38	29	30	
Discontinuance of Business	13	81	94	100	21	86	46	30	

2. Process 100 percent of all deficiency documents within five work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	7	7	7	7
Pharmacist (initial licensing)	7	7	7	7
Pharmacy Intern	8	8	8	8
Pharmacy Technician	8	10	10	10
Pharmacies	15	14	21	10
Non-Resident Pharmacy	20	17	17	10
Wholesaler	14	14	14	10
Veterinary Drug Retailers	14	0	0	0
Designated Representative	10	14	7	10
Out-of-state distributors	14	14	14	10
Clinics	15	14	15	10
Hypodermic Needle & Syringe	14	14	7	10

3. Make a licensing decision within three work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1	1	1	1
Pharmacist (initial licensing)	1	1	1	1
Pharmacy Intern	1	1	1	1
Pharmacy Technician	5	5	5	5
Pharmacies	10	5	3	5
Non-Resident Pharmacy	5	5	5	6
Wholesaler	5	3	5	5
Veterinary Drug Retailers	3	0	0	0
Designated Representative	2	2	2	2
Out-of-state distributors	5	3	5	5
Clinics	5	5	2	5
Hypodermic Needle & Syringe	3	2	2	2

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	526	504	241	138
Pharmacy Intern	652	651	248	269
Pharmacy Technician	2,008	1,695	1,577	1736
Pharmacies	121	542	61	103
Non-Resident Pharmacy	16	27	20	17
Wholesaler	14	9	5	13
Veterinary Drug Retailers	0	0	4	0
Designated Representative	97	126	93	126
Out-of-state distributors	13	18	25	28
Clinics	28	9	13	17
Hypodermic Needle & Syringe	4	7	3	0
Sterile Compounding	17	27	10	10

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	0	70	9
Pharmacies	0	1	1	0
Non-Resident Pharmacy	0	1	7	0
Clinics	0	0	44	0
Sterile Compounding	0	0	0	0
Designated Representative	0	5	0	0
Hypodermic Needle & Syringe	0	0	1	0
Out-of-state distributors	0	5	6	0
Wholesaler	0	1	2	0
Veterinary Drug Retailers	0	0	2	0

6. Deny applications to those who do not meet California standards.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	8	11	26	6
Pharmacies	0	0	0	0
Non-Resident Pharmacy	0	0	0	2
Clinics	0	0	0	0
Sterile Compounding	0	0	0	0
Designated Representative	1	0	0	0
Hypodermic Needle & Syringe	0	0	0	0
Out-of-state distributors	0	0	1	0
Wholesaler	0	0	0	0

7. Responding to e-mail status requests and inquiries to designated e-mail addresses.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	1,055*	901	1,012	973****
Pharmacy Technicians	747*	876**	1,176	920****
Site licenses (pharmacy, clinics)	625	695	840	941
Site licenses (wholesalers, nonresident pharmacies)	516	1056	667	639
Pharmacist in Charge	***	91	***	550
Renewals	238	210	427	427

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	94*	101**	109	58****
Pharmacy Technicians	69*	67	140	176****
Site licenses (pharmacy, clinics)	76	103	141	182
Site licenses (wholesalers, nonresident pharmacies)	126	155	243	212
Pharmacist in Charge	***	12	***	25
Renewals	12	U/A	38	49

* E-mail and voicemail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 8/8/08-9/8/08 to allow board staff time to focus on processing applications and issuing licenses. E-mail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 10/2/08 to 10/20/08 to allow board staff time to focus on processing applications and issuing licenses.

** E-mail/Voicemail on hold 10/4/08 - 10/20/08

*** Included in sites (PHY, CLN)

**** E-mail/Voicemail on hold 5/8/09 - 6/7/09

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.																																																																															
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Tasks:	<table border="1" data-bbox="370 289 1495 762"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Revenue Received:</th> <th colspan="4">Average Days to Process:</th> </tr> <tr> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Applications</td> <td>471,599</td> <td>668,139</td> <td>360,965</td> <td>325,491*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> <tr> <td>Renewals</td> <td>2,297,253</td> <td>1,529,994</td> <td>1,962,244</td> <td>722,732*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> <tr> <td>Cite and Fine</td> <td>359,300</td> <td>247,225</td> <td>210,163</td> <td>211,837*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> <tr> <td>Probation/ Cost Recovery</td> <td>23,397</td> <td>47,193</td> <td>22,751</td> <td>26,016*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> <tr> <td>Request for Information/ License Verification</td> <td>3,390</td> <td>4,750</td> <td>3,520</td> <td>3,820*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> <tr> <td>Fingerprint Fee</td> <td>17,208</td> <td>17,529</td> <td>20,623</td> <td>20,660*</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> <td>2-3</td> </tr> </tbody> </table> <p data-bbox="370 804 1365 835">* Reflects April and May 2009 data available at the time of report development</p>										Revenue Received:				Average Days to Process:				Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Applications	471,599	668,139	360,965	325,491*	2-3	2-3	2-3	2-3	Renewals	2,297,253	1,529,994	1,962,244	722,732*	2-3	2-3	2-3	2-3	Cite and Fine	359,300	247,225	210,163	211,837*	2-3	2-3	2-3	2-3	Probation/ Cost Recovery	23,397	47,193	22,751	26,016*	2-3	2-3	2-3	2-3	Request for Information/ License Verification	3,390	4,750	3,520	3,820*	2-3	2-3	2-3	2-3	Fingerprint Fee	17,208	17,529	20,623	20,660*	2-3	2-3	2-3	2-3
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Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.																																																					
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Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 220 1485 283">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores. <li data-bbox="370 514 1412 546">2. Evaluate the drug distribution system of clinics and their appropriate licensure. <li data-bbox="370 556 1469 588">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure. <li data-bbox="370 808 1477 913">4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>Sept. 2006:</i> Committee hears presentation by DHS on emergency preparedness. <i>Oct. 2006:</i> Presentation by Orange County and L.A. emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies. <i>Jan. 2007:</i> Board publishes disaster response policy statement. <i>Feb. & March 2007:</i> Board attends seven-day DHS-hosted training session on SURGE emergency response as part of the state's disaster response. <i>April - June 2007:</i> Board continues to participate in SURGE planning activities and in a joint public/private partnership project envisioned by the Governor. <i>June 2007:</i> Board staff aids in contract evaluation to select a consultant to provide pre-emergency registration of health care providers. <i>Sept. 2007:</i> Board attends Rough & Ready Demonstration in Orange County. <i>Oct. 2007:</i> Board considers legislative proposal to license mobile pharmacies for deployment during declared disasters. Staff resume attendance at ESAR VHPs meeting of EMSA. Board activates disaster response policy to allow rapid response to patients affected by California wild fires. Use of subscriber alerts proves effective in conveying board messages to licensees in effected areas. <i>Dec. 2007:</i> Committee hears presentations on emergency preparedness by California Department of Public Health, L.A. County and Orange County emergency response offices. Focus continues on getting pharmacists prescreened and registered for disaster response. Discussion also includes lessons learned during California wild fires, ESAR-VHPS, renamed California medical volunteers, readied for widespread promotion by January 1, 2008 by EMSA.

	<p>Oct. 2008: <i>Licensing Committee reviews a revised request from San Diego County for an exemption of first responders and families. The Committee directs board staff send a letter to San Diego County expressing concerns and requesting attendance at a future committee meeting. Committee was advised ESAR-VHPS was renamed to Disaster Healthcare Volunteers of California.</i></p> <p>Jan. 2009: <i>Board hears presentation from San Diego County on proposal. Board staff offer an alternative solution, which is acceptable to San Diego County.</i></p> <p>5. Evaluate the need to issue a provisional license to pharmacy technician trainees.</p> <p>6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.</p> <p>Sept. 2006: <i>Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.</i></p> <p>Dec. 2006: <i>DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.</i></p> <p>March 2007: <i>DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.</i></p> <p>May 2007: <i>Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.</i></p> <p>Sept. 2007: <i>Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.</i></p> <p>Oct. 2007: <i>Board postpones work on this topic until CSHP and CPhA complete their review.</i></p> <p>March 2009: <i>Board executive staff meet with the executive director of the ExCPT exam.</i></p> <p>April 2009: <i>Board directs staff to secure a psychometric review of both the PTCB and ExCPT exams, in wake of AB 418 being stalled in the legislature.</i></p> <p>7. Review requirements for qualifications of pharmacy technicians with stakeholders</p> <p>4th Qtr. 07/08: <i>Future work on the training of technicians will occur as joint activities of the pharmacist associations. Legislation to require an exam and continuing education for pharmacy technicians is dropped (AB 1947) Board participates in CSHP sponsored stake holder meeting.</i></p> <p>2nd Qtr. 08/09: <i>Executive officer participates in a meeting with CPhA and CSHP to provide technical advice on proposed legislation to be introduced next year. Attend CSHP sponsored stakeholder meeting.</i></p> <p>3rd Qtr. 08/09: <i>Senate Bill 418 introduced to add new requirements for technicians.</i></p>
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8. **Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.**
July 2006: Board executive officer becomes executive sponsor of program.
Nov. 2006: Board completes system identification of parameters for each licensing program.
Dec. 2006-Jan. 2007: Preparatory work and pilots completed; board staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.
3rd Qtr 08/09: Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward.
9. **Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.**
3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).
Oct. 2007: Board considers basic internship competencies developed under the program and develops letter of support.
Oct. 2008: California Pharmacy Council meets to discuss Intern requirements.
10. **Implement new test administration requirements for the CPJE.**
March 2007: Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.
June 2007: Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.
Oct. 2007: Transition efforts to PSI continue.
2nd Qtr. 07/08: Transition efforts to PSI continue.
3rd Qtr. 07/08: New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.
3rd Qtr. 08/09: Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.
11. **Participate in ACPE reviews of California Schools of Pharmacy.**
Oct. 2007: Board participates in review of California Northstate College of Pharmacy.
Jan. 2008: Board participates in review of UCSF.
March 2008: Board participates in review of Touro.
12. **Initiate Review of Veterinary Food Animal Drug Retailer Designated Representative Training.**
Sept. 2007: Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.
Oct. 2007: Board evaluates options for training of designated representatives.
Sept. 2008: Licensing Committee hears testimony regarding program.
June 2009: Evaluation of designated representative training scheduled for September 2009.

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| | <p>13. Convene Committee to evaluate drug distribution within hospitals.
 <i>2nd Qtr. 08/09: Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.</i>
 <i>3rd Qtr. 08/09: Board establishes subcommittee to initiate review.</i>
 <i>March 2009: First meeting convened.</i>
 <i>June 2009: Second meeting convened in San Francisco.</i></p> <p>14. Improve reporting of and accounting for intern hours.
 <i>4th Qtr. 08/09: Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.</i></p> <p>15. Participate in initiatives to increase the number of pharmacists in California to meet demand.
 <i>4th Qtr. 08/09: Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.</i></p> <p>16. Assess the operations of specialty pharmacy services.
 <i>4th Qtr. 08/09: Board initiates review of refill pharmacies.</i></p> <p>17. Encourage use of technology where it benefits the public.
 <i>June 2009: Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.</i></p> <p>18. Secure the implementation of e-prescribing in California by the earliest possible date.
 <i>4th Qtr. 08/09: Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.</i></p> <p>19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.
 <i>4th Qtr. 08/09: Board assists the California Department of Public Health in responding to distribution of Tamiflu and Relenza. Pharmacy law requirements regarding labeling and dispensing not waived as standard and necessary pharamcists care could still be provided.</i></p> |
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