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

Licensing Committee Report

Members:
Stan Weisser, RPh, Chairperson
Randy Kajioka, PharmD
Ramón Castellblanch, Public Member

LICENSING COMMITTEE REPORT AND ACTION

The Licensing Committee had not met since June 18, 2009, in Sacramento.

A. Subcommittee to Evaluate Drug Distribution within Hospitals

1. FOR INFORMATION and DISCUSSION: Meeting Summary of the Meeting Held September 17, 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. Board staff worked closely with the California Department of Public Health, the California Society of Health-System Pharmacists to identify problems and 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.

September 17, 2009 Meeting

The most recent meeting was held on September 17, 2009 in Sacramento. During this meeting presentations were given by Marjorie DePuy, Director, Industry Relations, HealthCare Distribution Management Association, Larry Hunley, Distribution Center Manager, McKesson Supply Solutions, Amy Gutierrez, PharmD, Director of Pharmacy Affairs, Los Angeles County Health Services and Elizabeth (Betty) Gregg, Manager, Recalls and Licensure, Cardinal Health. Each of the presenters provided information on the recall process from their perspective.

Also during the meeting, attendees discussed the draft best practices document and provided feedback. A summary of the main best practices in a recall process include:

1. Pre-position the facility to receive early notice of recalls from multiple sources.
2. Identify if the facility has the product.
3. If so, quickly remove the product from all patient care areas.
4. Identify, assess, notify and treat patients who may have received the product.
5. Identify alternative products to maintain therapy.
6. Return the quarantined product.
7. Evaluate the process.

Attendees heard a presentation by Deputy Attorney General Joshua Room highlighting possible legislative and regulatory changes to improve drug distribution within a hospital. At the conclusion, attendees provided comments of the presentation and offered additional changes to be considered.

A copy of the minutes from this meeting are included in **Attachment 1.**

2. FOR DISCUSSION: <u>Draft Recall Procedures for Hospitals</u>

Attachment 2

Attachment 2 contains a copy of the draft recall best practices for board member consideration. A finalized document will be presented during the next scheduled Licensing Committee Meeting, December 3, 2009 at LAX. At the conclusion of this process, the best practices will be published on the board's Web site.

3. FOR DISCUSSION: <u>Survey Results: Drug Distribution Within a Hospital</u>

Attachment 3

During the June 2009 Subcommittee Meeting, a survey was distributed to elicit responses to several questions surrounding the control of drugs within a hospital. The results of this survey are provided in **Attachment 3**.

4. FOR DISCUSSION: <u>Possible Future Activities of this Subcommittee</u>

All subcommittee meetings held were very outcome oriented and proved to be a valuable forum to take on such an important issue and ensure it was fully vetted. Staff recommend that this separate subcommittee be dissolved and the matter referred back to the Licensing Committee for final approval.

B. Licensing Issues

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

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."

Over the course of the last year, the Licensing Committee has heard presentations and discussed disaster response. Most recently, the committee and attendees heard a presentation from Dr. Dana Grau, the Department of Public Health Emergency Response Unit, who oversaw California's HINI 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.

During the board meeting, Dr. Grau will provide the board with an update on CDPH's response to the H1N1 emergency. In addition, Dr. Grau will outline public health's needs from pharmacies and pharmacists to respond to the emergency. Dr. Grau will also update the board on the needs of infants and young children that require a compounded version of Tamiflu and Relenza

2. FOR ACTION: Proposed Delegation to the Board President to Act Pursuant to California Business and Professions Code Section 4062 to Waive Statutory Requirements to Benefit Public Safety in response to a Declared Emergency or Disaster.

Attachment 4

<u>Background</u>

During the October 2006 Board Meeting, the board voted to adopt a policy statement for pharmacies when providing emergency response. A copy of this policy statement was published in the January 2007 issue of *The Script* and is provided in **Attachment 4**.

Business and Professions Code section 4062 provides the board with broad waiver authority and was recently amended in SB 819 (Chapter 308, Statutes of 2009) to allow for the use of a mobile pharmacy in the event of a declared emergency as specified.

> 4062 (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.
(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:
(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.
(2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).
(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.
(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
(5) The mobile pharmacy is located within the declared emergency area or affected areas.
(6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

Procedurally the board should consider delegating to the Board President the authority to implement the provisions authorized in (b) - - waiving statutory requirements to benefit public safety in response to a declared emergency or disaster.

3. 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 an Executive Order signed by the Governor, we were 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 resume this process and provide an update to the committee during its December 2009 meeting.

4. FOR INFORMATION: Reporting and Accounting of Intern Hours for California Pharmacy School Students

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.

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 determine 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. Additionally, the distinction upon whether these hours have been earned in a pharmacy under the supervision of a pharmacist cannot be discerned. Some states have specific requirements for their respective jurisdictions that are not consistent with our requirements. For example, board staff was recently advised that New York will no longer verify intern hours.

Over the last few years, the Licensing Committee Meetings has considered proposals to amend the intern hour requirements. The committee has also discussed a major change to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. These new requirements added hours to the educational requirements students need as part of their intern training and are required as a condition for a school to maintain its accreditation status with the ACPE.

Given the changes surrounding the intern hours requirements as well as the disparity in how the board accepts hours from various jurisdictions, board staff recommend that the intern hours requirements remain unchanged, but that the method by which staff confirm this information be contingent upon one of the following:

- a candidates PharmD graduation from an ACPE accredited school of pharmacy <u>OR</u>
- licensure status in another state for one year <u>OR</u>
- 500 hours of experience for foreign educated pharmacist that satisfies all other requirements for licensure.

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

In late June, the governor issued an Executive Order was issued by the governor imposing a third furlough day on each month on state employees. This order also closes state offices three Fridays each month through June 2010.

Board and executive staff continue to evaluating our most mission critical functions for the board's licensing unit staff. Unfortunately, even with changes, processing times are extending well beyond the board's strategic objectives detailed in the strategic plan and will continue to grow. The current processing times for pharmacy technician applications is about 90 days and is about 60 – 75 days for all other application types. While this is not where we want to be organizationally, it is reality for the near future.

To allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff twice previously authorized a temporary stop in responding to applicants calling on the status of a pending application. This temporary stop allows staff to focus on reducing the backlog of new applications as well as complete a file inventory.

We are again responding to status inquiries. However, workload studies show that on average, most board staff spends about 1.5 days each week responding to status inquiries. Currently applicants can request the status of an application either over the phone or via e-mail.

Executive management recently advised staff that pharmacy technician applicant can now only submit a status request via e-mail. This method of request allows the board to research and respond to such inquiries more a more efficient manner. (Currently the board receives over 600 telephone status inquiries from pharmacy technician applicants on a monthly basis.)

In an effort to provide applicants with general information, all licensing staff update their voice-mail message to include the date range of applications currently being processed the boards' receptionists are advising callers as well. Executive staff and managers continue to be available to address immediate or urgent applicant concerns.

6. FOR INFORMATION: Competency Committee Report

Attachment 5

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

Included in **Attachment 5** 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 78.3 and 97.8 for the NAPLEX.

b. Job Analysis for the CPJE to be undertaken at the end of 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. To complete this analysis, the committee recently developed a job analysis with the board's contracted psychometric firm. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

We anticipate releasing this survey to a random sample of pharmacists before the end of year. Pharmacists that complete the survey will be awarded three hours of continuing education.

C. INFORMATION: First Quarterly Report on Licensing Committee Goals for 2009-10

Attachment 6

Attachment 6 contains a copy of the board's licensing statistics and the first 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:	September 17, 2009
LOCATION:	Department of Consumer Affairs 1625 N. Market St. First Floor Hearing Room Sacramento, CA 95834
BOARD MEMBERS PRESENT:	Kenneth Schell, Pharmacist Member, President Randy Kajioka, Pharmacist Member
STAFF PRESENT:	Virginia Herold, Executive Officer Joshua Room, Deputy Attorney General Kristy Schieldje, Senior Staff Council Robert Ratcliff, PharmD, Supervising Inspector Tessa Fraga, Administrative Analyst
CONSULTANTS PRESENT:	Val Sheehan, Meeting Facilitator Carmen Fraser, Senior Consultant

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The meeting was called to order at 9:15 a.m.

1. Welcome, Agenda Overview, Introductions

Val Sheehan, Meeting Facilitator, introduced herself and Senior Consultant, Carmen Fraser and welcomed the group to the subcommittee meeting, the third in a series of meetings. Ms. Sheehan then introduced Board of Pharmacy staff and board members who were in attendance.

Board President Ken Schell gave opening remarks and noted that the goal of these was to improve patient care by receiving the best input from pharmacists and others concerned with drug distribution in hospitals. These meetings provide an opportunity review and discuss pharmacy law with an eye towards making updates or changes as necessary. He reiterated the need to have an open and frank discussion and "get issues out on the table" so that they can be addressed in the best way possible to protect and enhance the health and safety of the public.

Ms. Sheehan then asked all meeting participants to introduce themselves.

Ms. Sheehan reviewed the proceedings and outcomes of the previous two subcommittee meetings held on March 2, 2009 and June 2, 2009. Ms. Sheehan also reviewed findings from a drug management survey completed by fourteen meeting participants at the June 2nd meeting. Ms. Sheehan acknowledged that while the sample size was small, the preliminary results still offer useful information.

One of the questions on the survey addressed the issue of contracted service providers bringing outside drugs into the hospital setting. One participant commented that patients and researchers can legally bring in their own drugs. FDA-approved drugs, drugs for premarket analysis, anesthesia services, organ procurement, and ambulance services represent other channels for drugs to get into hospitals. Ms. Sheehan noted that seven survey respondents indicated they had a policy banning outside contractors from bringing drugs into the hospital. However, in a related survey question about whether professional or other staff can bring in drugs for administration to patients, thirteen out of fourteen responded "no." Another participant thought the question had perhaps been misunderstood because national regulatory standards state that the pharmacist needs to be responsible for all drugs. Participants discussed the discrepancy between pharmacists being accountable or responsible for all drugs in a hospital without having the authority to control whether or not drugs were being brought into the hospital. There was agreement that a broader set of responses to the survey was needed to get a better understanding of actual practices in hospitals.

Ms. Sheehan presented results of the evaluations of the first two subcommittee meetings noting that participants rated the meetings very favorably. 93% rated the March 2, 2009 meeting as excellent or good, and 82% rated the June 2, 2009 meeting as excellent or good. Meeting participants stated they gained and benefited from:

- good and valuable information;
- opportunity to dialogue with regulators; and
- peer learning and brainstorming.

Ms. Sheehan reviewed today's meeting agenda and reminded participants of the meeting ground rules - open dialogue, collaboration, solution-oriented - as well as meeting courtesies. She noted the meeting was being recorded and that meeting minutes will be posted on the Board's website. She asked if there were any questions and reiterated the opportunities for public comment throughout the meeting.

2. Discussion and Group Presentation of Drug Recall Best Practices for Wholesalers and Manufacturers

Ms. Fraser noted that an important purpose of this series of subcommittee meetings was to provide information on drug recall practices from different perspectives. She mentioned that at the first meeting, regulatory agencies (FDA, CDPH and BOP) outlined their role in the recall process. At the second meeting, directors of four hospital pharmacies discussed policies, procedures and systems related to drug distribution and management in their facilities. At today's meeting, another key player in the recall process, drug wholesalers, as well as a major health service provider discussed how they manage recalls.

Presentations were given by:

- Marjorie DePuy, Director, Industry Relations, HealthCare Distribution Management Association
- Larry Hunley, Distribution Center Manager, McKesson Supply Solutions
- Amy Gutierrez, PharmD, Director of Pharmacy Affairs, Los Angeles County Health Services
- Elizabeth (Betty) Gregg, Manager, Recalls and Licensure, Cardinal Health

Marjorie DePuy – HDMA

HDMA represents thirty-two primary full-service healthcare distributors who deliver healthcare products to 145,000 healthcare settings in the country. One hundred seventy-seven manufacturer members are also represented. HDMA's strategic objectives are to:

- Protect patient safety;
- Create and exchange industry knowledge and best practices; and
- Advocate for standards, public policies and business processes that produce safe, innovative healthcare solutions.

Ms. DePuy outlined drug recalls from a distribution perspective saying that 1) the manufacturer initiates recall/market withdrawal, 2) HDMA members have recall/withdrawal procedures in place, and 3) distributors facilitate communications/product return as instructed. All parties have the shared goal of swift identification and quarantine of recalled product and operate under FDA guidance and oversight. She noted that most distributors and hospitals deal with hundreds of recalls each year.

Ms. DePuy highlighted HDMA's *Product Recall & Withdrawal Notification Guidelines,* developed by a Returns Task Force composed of 25 – 30 manufacturers, distributors and returns processors. This document includes:

- General recall regulations, responsibilities and guidelines
- Instructions for drug recall notice form
- Three sample drug recall notice forms: Wholesale, Retail, Consumer

Ms. DePuy outlined recalls from a company perspective saying that individual companies determine the most effective practices. Companies focus on continual assessment and improvement to secure the supply chain.

Audience members had questions about recall timelines and Ms. DePuy responded that HDMA doesn't set specific timelines for its members. A participant stated that recall timeline standards among all stakeholders would be helpful. The participant also asked whether it was within HDMA's purview to set timeline standards for its members. Ms. DePuy responded that from the Association's standpoint, it didn't make recall-related timeline recommendations to its members, but suggested that the group come back to the question following Mr. Hunley's presentation.

Larry Hunley – McKesson

Mr. Hunley covered the following agenda items during his presentation:

- Pharmaceutical Recall Profile
- Process Overview
- Inventory controls
- Communication
- Product Quarantine Developments.

Mr. Hunley stated that McKesson is involved in a significant number of recall events each year. He presented information on the number of recall/withdrawals in 2007, 2008 and 2009 broken down by the level of notification to wholesaler, retailer/hospital or consumer. The same product can have multiple events whether through added lots or a change in the notification level. He noted that recalls are increasing and in particular to the consumer/patient level of notification. The manufacturer's recall provider, a third party such as Stericycle or Genco, manages most recalls.

Mr. Hunley described MeKesson's overall recall process. If they receive advance notification, MeKesson immediately quarantines product and lots even if some recall items are pending. Audience members had questions about timing of recall notification. Mr. Hunley stated that the manufacturer determines who issues the recall notification (manufacturer or distributor) however, McKesson notifies its retail customers by both paper and electronic mail in any case. In response to a question whether McKesson makes a distinction about timing of notification to customers depending on its receipt of paper or electronic alerts from manufacturer, Mr. Hunley stated that McKesson is required to notify customers upon receipt of the first recall notice from a manufacturer, whether it is a mail or email notice. A comment was made that during the heparin recall some hospitals received notification from the manufacturer before the wholesaler. Mr. Hunley acknowledged that situation and stated that he wasn't sure whether McKesson was getting notified sooner than the large customers of the manufacturers.

Audience members had several questions about lot numbers and the accuracy of the recall process. Mr. Hunley stated that when a recalled product lot number has been entered into McKesson's SAP system, it cannot be picked and is quarantined in another part of the warehouse. If a recalled product is returned, it is not saleable and is blocked from going back into circulation. For returns, whether recall-related or not, the item is either scanned or

the lot numbers are entered manually if there are no bar codes. If a recall is issued and recalled product is en route, McKesson immediately notifies all customers who would receive it. However this process is not lot-specific.

When ordering drugs, customers go through a portal on McKesson's website, and recall notifications can be seen there. However it is possible for customers to not see the notification if they do not remain on that specific page.

Participants wanted clarification about McKesson's process for blocking a recalled product. Mr. Hunley outlined that if there is a recall notice at 8am, no order placed after that would have recalled product. It's possible that orders received within the previous 12 hours would have recalled product on the trucks that have already left the warehouse. If so, McKesson immediately notifies customers by telephone that a recalled product has been shipped. A participant commented that FDA has specific regulations about the handling of recalls, and 21 CFR Section 7 has information about timeframes.

Mr. Hunley stated that about a year ago his office introduced a system to better handle recalls. A designated staff person works with the inventory department to quarantine the product and identify lot numbers. Before each order is picked, a manager runs a query from the SAP system showing all recalled items and lot numbers. It is not possible for a recalled item to be included in an order's pick slot. Every order is verified and signed off by a manager. Mr. Hunley stated that McKesson monitors the recall process in its distribution center, and it is error-free.

One participant commented that it would be highly useful if recalled product could be identified by lot number, time and quantity so that customers can better track and reconcile their drug supplies. Mr. Hunley agreed that an e-pedigree system of tracking and tracing by lot number would be ideal.

Amy Gutierrez, Los Angeles County Health Services

Dr. Gutierrez gave an overview of Los Angeles County Health Services, but also highlighted a pilot project with their wholesaler, Cardinal Health, focused on more effective drug recall practices. Los Angeles County Department of Health Services is the second largest public health system in the country. It employs 22 licensed pharmacists, fills its own prescriptions and spends $160 million in pharmaceutical products each year. The LA County System features multidisciplinary collaboration among specialty medical expert panels as well as pharmacy and medication safety committees to develop best practices. Dr. Gutierrez chairs the Pharmacy and Therapeutics (P & T) Subcommittee.

Dr. Gutierrez stated the LA County System's previous recall notification process included reporting to LA County Board of Supervisors and receiving a paper recall notice from the wholesaler (Cardinal). They were not satisfied with the existing system and felt that the paper process was unreliable. It was challenging to get notifications to facilities, some notifications were getting lost and recalls weren't being acted upon in a timely manner.

The LA County System issued a new policy in August 2008. The first component of the new policy was to work with Cardinal to devise a better system through a *Wholesaler Collaboration Pilot Project.* They arranged with Cardinal for all pharmacists in the LA County System to receive advance recall notice by email. In the email notice, the wholesaler lists which accounts purchased the recalled product, when the order was placed as well as the type of notification by class. Dr. Gutierrez noted that after the inception of this program, they received more notices from Cardinal than from the MedWatch system through FDA.

The second component of the new policy was a centralized reporting process within the LA County System about actions taken as a result of the recall. Facilities throughout the LA County System use a form to notify the central committee about action taken within seven days of a recall. If it is a Class I recall, they require immediate notification from the facilities. The System's core P & T Committee reviews these forms monthly and decides whether further action needs to be taken.

Dr. Gutierrez stated that many notices from Cardinal were coming as "unclassified retail level." Ms. Gregg commented that the FDA often releases recall notices that have not yet been classified, therefore Cardinal release the notices as unclassified. However at its distribution center, Cardinal treats them as Class II. LA County is now getting notices from Cardinal for recalled products even if they haven't purchased the products.

Ms. Herold expressed concern about the lack of a centralized recall notification system and the inconsistency and unreliability of recall notices. Ms. Gregg stated that Cardinal, as a wholesaler, is never certain it is getting all recall notices from the manufacturer. Manufacturers track by lot number; therefore if a wholesaler didn't purchase that particular lot, they would not receive the recall notice. In addition, the number of FDA MedWatch notices is far fewer than the notices from manufacturers. MedWatch notices often lack the information that is needed for a wholesaler to initiate a recall; Cardinal often calls manufacturers for clarification. Subscription sites have proven to not be very helpful in this process.

A participant commented that while the discussion has focused primarily on hospital based drug distribution, she was concerned about the issue from a broader public health perspective. She asked how independent pharmacies are receiving information about recalls and whether procedures exist to ensure that their patients are not buying recalled drugs? Ms. Gregg responded that such pharmacies would receive retail- and/or consumer-level notifications.

A participant asked whether Cardinal has an internal Cardinal-led recall process if it notices something wrong with a product. Ms. Gregg responded that the product would first be quarantined, and calls would be made to the manufacturer. In such a case, Cardinal would not notify its customers before the manufacturer issued a recall.

Participants expressed concern about the disparity between the number of FDA-issued recalls and the number of wholesaler-issued recalls. Dr. Gutierrez added that the LA County System does not rely on FDA for recall notices because they are often inconsistent, inaccurate or delayed in classification. She noted that food-related FDA recalls are much more numerous than drug-related recalls. From a provider perspective, Dr. Gutierrez stated that knowing about a recall can be more challenging than knowing what to do about it.

Dr. Gutierrez reported that the LA County System was able to evaluate the effectiveness of its new policy because of a March 31, 2009 consumer-level recall of Digoxin. By the end of that day, Cardinal provided a list of all impacted LA County facilities whose pharmacy, medical and nursing directors were affected. By the next morning, all the Digoxin in the LA County System had been sequestered. By the next day, through NDC numbers from a central database, all patients who took Digoxin were identified. By the fourth day a bilingual (English/Spanish) patient notification letter was mailed to all affected patients. To supplement the letter, phone calls were made to patients, and patient charts were updated with this information. Overall, the new notification system was a success.

A participant asked whether patients in one-time use or limited use settings in procedural areas are identified or have received recalled items, even though they may no longer have access to the drug. Given the patient has a right to know, how far retrospectively is LA County required to notify? Dr. Gutierrez responded that there are no lot numbers for inpatient or outpatient services, so it is a challenge.

Betty Gregg – Cardinal Health

Ms. Gregg gave a brief overview of Cardinal Health's current recall process, its trial project with LA County and UCSF, and future recall processes. Prior to working with Cardinal, Ms. Gregg was a hospital pharmacist for many years and therefore understood the concerns participants were expressing.

Current process: Cardinal receives multiple recall notices, but many arrive without enough information to adequately process the recall. To process recalls, Cardinal needs lot numbers. Without lot numbers there is a risk of pulling all of the product, not just the recalled portion, which could add to market shortages. Within half an hour of receiving a recall notice, Cardinal's corporate office is able to notify its distribution centers. Distribution

centers are required to quarantine the product by the end of day. Cardinal creates a daily recall list, and distribution centers are required to check so that recalled product does not get into live inventory. Cardinal's customers will receive a notification within the first twenty-four hours.

Trial Project with LA County and UCSF: After the heparin recall, Cardinal was asked to pilot test a better notification system. This involved sending an email alert to customers in addition to the speedy-gram printed notice. Customers were responsible for providing and updating the email contact list for Cardinal to use. Ms. Gregg noted that LA County and UCSF are now getting notification sometimes twelve to twenty-four hours in advance of customers who are not involved in the trial project.

Ms. Gregg reiterated the three levels of recall notices, and noted that, unlike the Digoxin example described by Dr. Gutierrez, a wholesaler-level recall would not affect customers. An example of a recall that would only go to the wholesaler level would be a minor packaging issue or something that has minimal effect on patient safety. One participant commented that a wholesaler recall could affect market availability depending on their share of the market. Customers may need to know about wholesaler recalls because they have to plan for shortages. In addition, manufacturer's field corrections can have the same impact on market availability.

Ms. Gregg noted that the FDA has been doing more effectiveness checks lately and in particular the last six weeks.

Future recall process: Cardinal would like to develop an electronic notification system for recalls. Two aspects of importance are: 1) whether such a system meets FDA requirements and 2) the degree of customer ownership of the process in terms of participation. Cardinal is now in a fact-finding stage to see how the proposed system would work from corporate, distribution centers' and customers' standpoints. Cardinal expects the new recall notification system to be activated in the summer of 2010.

One participant asked why the number of recalls has been escalating over the last few years. Ms. Gregg noted the lack of good manufacturing standards and practices as well as assay findings of sub- or super-potency or contamination. Another participant commented that the manufacturing of drugs outside the country could be a contributing factor. Within five years, it is estimated that 85% of pharmaceuticals will be manufactured off shore. Other participants noted that a lack of FDA enforcement could be part of the problem. Ms. Herold noted that in October 2008 a Federal FDA study was released which concluded the recall system works and that there is no intention to modify existing procedures. This was the opposite of what California concluded. Ms. Sheehan noted that California has the opportunity to play a leadership role in closing the gaps in the system.

A comment was made that manufacturers should be part of this meeting process; manufacturers need to be sensitive to how their recalls affect the health care system. Another participant commented that other players such as physician-owned and operated entities also need to understand the system. The medical and dental communities need to be brought into this process as well.

3. Discussion and Possible Action to Develop Drug Recall Best Practices for Hospital Pharmacies

Virginia Herold, Board Executive Officer, thanked wholesalers for their input and the efforts they have made to correct deficiencies in the recall process. She then presented a draft best practices document and requested feedback from meeting participants. While hospitals would not be mandated to follow these best practices, Ms. Herold emphasized that hospitals should consider following them. This document was developed based on input received during the first two meetings as well as suggestions submitted to the Board directly. The underlined text generally represents the additions to the document since it was first presented at the June 2, 2009 meeting. Meeting participants had several questions and comments (summarized below). Ms. Herold stated that the revised document would be circulated again, finalized and brought back to the Board in October. Dr. Schell and Ms. Sheehan thanked Ms. Herold for her work in assembling the various comments and creating this document.

Ms. Herold summarized the main best practices in a recall process and elaborated on them by reviewing the document:

1. Pre-position the facility to receive early notice of recalls from multiple sources.
2. Identify if the facility has the product.
3. If so, quickly remove the product from all patient care areas.
4. Identify, assess, notify and treat patients who may have received the product.
5. Identify alternative products to maintain therapy.
6. Return the quarantined product.
7. Evaluate the process.

One participant wanted some type of measurable objective (for example: "a successful recall is defined as...") so that hospitals can know whether they are successful. She thought a hospital could follow all best practices and still be perceived as doing a successful recall. Ms. Herold stated that the specifics regarding timelines have to be decided upon at a facility level otherwise it could be perceived as too much regulation. Kristy Schieldje, Board Counsel, added that such language could be interpreted as prescriptive and perceived as regulatory and would require a full APA process and noticing.

A participant asked whether the document addressed hospitals only or other providers. Ms. Herold stated that the subcommittee's immediate task was to address hospital-based issues of concern. While it's clear there are other issues of concern, the purpose of this document at this meeting at this time is to find a collective consensus for best practices. She added that other pharmacy law-related issues and concerns could be brought forward at the Board's October meeting.

A participant commented that the word "product" should be defined as "drugs and devices." There is a concern that some devices are "just appearing" in the hospital without the pharmacy director's knowledge. FDA classifies drugs differently from devices. Participants reached consensus that "pre-filled drug-containing devices" would be good language. 42 CFR §482 addresses whether devices used to deliver medications are recalled products. Ms. Herold clarified that the federal definition of devices will be used.

A participant commented that the term "hospital" needs to be defined. Some pharmacists do not have authority over outpatient facilities (such as an outpatient dialysis unit) owned by a hospital but not under the hospital license. Dr. Schell acknowledged this as an area of conflict because such facilities may be using the license to purchase drugs but are not under control of the hospital pharmacist. Loriann DeMartini, Chief Pharmaceutical Consultant, California Department of Public Health (CDPH), Center for Healthcare Quality (licensing and certification), clarified that CDPH, under its state or federal authority, only looks at services that are on the hospital license. The CDPH license is issued annually and is clear about physical location. The hospital must specify services provided at different locations, and this is used to establish boundaries of oversight. One participant commented that actual practice and the license do not always match. Dr. DeMartini suggested that such facilities work directly with the CDPH District Manager and stated she would be willing to help facilities to clarify their licenses. Dr. Ratcliff referred to Title 22 which states the PIC is responsible for purchase of all drugs in the institution. Whether or not another department purchases the drugs, in its inspection and enforcement efforts, the Board of Pharmacy will hold the PIC responsible. Ms. Herold clarified that the consolidated license will define the community to whom the Best practices document applies.

A comment was made that if the hospital pharmacy takes the lead in setting recall policies then hopefully those are followed by materials management departments for devices. There are many non-pharmacy hospitals in the state, and they also need best practices procedures. This best practices document could serve as a model for a system-wide improvement in recalls. Ms. Herold agreed.

A comment was made about the challenge of knowing about the drugs in ancillary storage areas and that this is more of an administrative leadership issue. All hospitals already have a policy that the PIC predetermines what the storage locations are; compliance is much more of an issue.

A participant asked whether this document is an optimal best practice or a minimum standard. Ms. Herold responded that if it becomes a minimum standard, this would be the result of a statute or regulatory change. The Board has not indicated it would undertake a legislative process and instead formed this subcommittee to address best practices. She added that pharmacists are accountable now whether or not there is a Best practices document. The intent is to have a collective sharing to avert another crisis; whether FDA or CDPH does this too is at their discretion. Mr. Room added that the document would not have the force of law. While it is an optimal compliance mechanism, neither is it a defense or safe harbor if recalled product is found. It could be evidence of good faith, but it's not a legal document.

Comments pertaining to Item 2. Know Drug Storage Areas in Hospital:

- A comment was made about clarifying the use and interpretation of the terms "quarantine" and "sequester." For a product to adequately be quarantined it must meet three FDA parameters of separation, barrier, and notice by labeling. Ms. Herold stated the intent was quarantine and that the product needs to be labeled as well as set aside.

- There was consensus to strike the 3rd bulleted statement.

- A participant disagreed with the 4th bulleted statement (first sentence) referring to not allowing drugs not purchased through the pharmacy. Participants agreed the 2nd underlined sentence is more acceptable.

- Under the 7th bulleted statement, rather than specify "72 hours", use language such as "immediately" or "as timely as is reasonably feasible." Because recall timeframes depend on the class of recall, insert language defining these terms as well as examples of expected timeframes.

Comments pertaining to Item 3. Additional Steps:

- Under the 1st bulleted statement, add "or quarantined if they are shipped into the facility."

- Under the 4th bulleted statement, change "an individual" to "a process."

Comments pertaining to Item 5. Activities With Drug Wholesalers to Improve Recalls:

- Add the statement: "establish electronic communication with all wholesalers." A suggestion was made to set up a pharmacy group email box so notifications don't get detained in the email boxes of vacationing employees or those who are quitting. There should be one email account for the hospital so that the PIC receives recall information from all wholesalers regardless of who from the hospital ordered or purchased the drug or device. A participant commented that the same principle should apply to wholesalers; wholesalers should demand of their suppliers/manufacturers that they receive all recalls so that they can be aware of potential shortages.

Comments pertaining to Item 6. Technology-based Solutions:

- A comment was made that there is not enough information to know whether subscription services are effective.

- A wholesaler/distributor participant stated that based on recall notices sent by customers and manufacturers, they are compiling their own email notification services for pharmacy customers. They work with small regional suppliers too, but the notification is being sent to everyone.

Comments pertaining to Improvements for the System:

Item 1: Notification System for Recalls Needs Improvement: Ms. Herold stated that issues related to FDA's delay in classifying a recall would be handled separately in a letter to the FDA. A participant asked about unclassified recalls and where to obtain additional information to make a decision about what action to take. Another participant responded that drug manufacturers are cooperative to the extent they can be, but they don't always have the information; his facility involves medical staff in making a decision. Ms. Herold added that it is important to include the participation of the pharmacist.

Item 2: Establish Tracking of Drugs Throughout the Hospital: Ms. Herold stated this is self-explanatory.

Item 3: Method of Obtaining Recall Information: Ms. Herold acknowledged this could be revised based on today's discussion.

Item 4: Administrative Policies: Ms. Herold stated that this is related to knowing the hospital's CEO and making sure the PIC has the authority to carry out their mandated responsibilities.

Item 5: Geographic Concerns: Ms. Herold stated this item can be blended into Item 2.

Comments pertaining to Example of a Recall Plan and Components of a Recall Plan:

Ms. Herold asked the group for feedback on the Examples of a Recall Plan. Some participants thought it seemed duplicative, while others thought it was a good idea to include as a prototype. Ms. Herold suggested organizing the Best practices document into three sections addressing the 1) Pre-planning stage, 2) Event stage, and 3) Post-event stage. Mr. Room suggested that the Pre-planning section of the front document include a simple statement about the need to establish a recall plan and reference the attached sample plan following that statement. It was noted that Pre-planning included policies and procedures as well as training.

4. Discussion and Development of Suggestions for Possible Legislative and Regulatory Changes to Improve Drug Distribution in Hospitals

Ms. Herold stated that every fall the Board develops a legislative agenda to maintain current relevance with regard to pharmacy issues. Typically the board introduces a couple of bills each year. She invited meeting participants to offer suggestions for legislative changes. This discussion is summarized below. Ms. Herold stated that pharmacists may submit other ideas to her directly or come to the Board's October meeting.

Ms. Herold began the discussion and indicated she would recommend to the Board a change pertaining to satellites. Pharmacies would be required to attach a list of the satellites and their locations to their self-assessment checklist. Ms. Herold noted that unless an item is given enough importance by being included in a statute, it's easy to lose control. She asked the group whether there is a need for a clear legal definition of satellites given the complexities of the various hospital organisms throughout the state. A participant responded that yes, there is a need to define what a satellite or auxiliary pharmacy is.

Joshua Room, Deputy Attorney General, presented a document entitled *Possible Regulatory/Statutory Amendments to Address Real or Perceived Hospital Pharmacy Deficiencies in Authority/Responsibility to Address Drug Recalls and/or Other Matters of Distribution, Control and Recordkeeping*. This document explored the idea that language designating and describing a director of pharmacy services in Title 22 (Code of California Regulations) should mirror that for directors of nursing. Mr. Room noted that the first seven pages of the document are the most pertinent to pharmacists.

- Mr. Room noted that Title 22 is not within the section of the regulations that the Board of Pharmacy has any authority to promulgate, but it is the place to most easily make the change needed to elevate pharmacy directors to a status equivalent to that of nursing directors. This means that CDPH would need to be involved, however they have less autonomy for rulemaking than the Board tends to have. If the Board of Pharmacy pursued this independently, it would have to be done through Title 16 or through statute.

- In reference to the earlier discussion about the Best practices document and pharmacy directors' authority, Mr. Room asked whether such a change would be helpful to pharmacists. He noted that the thrust of such a change would be to require a hospital administrator to designate in writing a Director of Pharmaceutical Services and to provide that person with the authority and resources necessary to effectuate the regulatory requirements. Ms. Herold reminded audience members that this document is very preliminary and that the Board had not yet seen this document.

- One participant asked whether there could be a certification that would spell this out for the Administrator in an effort to make sure they agree with such a change in a Pharmacy Director's status. Ms. Herold asked whether there is an entity that certifies or accredits senior managers/administrators. A participant responded that there is not. Mr. Room noted that no statements exist regarding the qualifications of pharmacists that would be equivalent to the required qualifications for nursing directors.

- One participant commented that giving the pharmacy director authority doesn't necessarily mean resources will be made available. Another participant commented that from a small, rural hospital perspective, decisions about pharmacy resources need to be backed up by legislation.

- There was consensus from group that any support for the PIC's authority, particularly if legislated, would be helpful. One participant dissented saying that minimum requirements would be burdensome to fulfill administrative pharmacy positions, especially in small rural hospitals. Mr. Room responded that the requirements would be written so that they are not burdensome. It was noted that whether the PIC became the Director of Pharmaceutical Services had not been defined. A participant noted there are minimum staffing ratios for nursing and that something similar may be needed for pharmacists. Ms. Herold stated the Board would not be addressing this topic at this time.

- Under Section 70269, the phrase "a list of drugs" instead of the word "inventory" would be more accurate.

Audience members suggested the following additional legislative ideas:

- A participant stated that at a patient care level, the hospital needs to be able to make the decision to keep and perhaps decide to use a quarantined drug with patient consent if there is no alternative product available. Mr. Room responded there is no way to legislate this, but acknowledged there may be a way for the participant to write a proposal.

- A participant expressed concern that pharmacists are being pulled away from clinical duties to conduct floor inspections. Ms. Herold responded that this issue needs to be addressed with CDPH otherwise the Board would be usurping the authority of Title 22.

- A participant commented that for patient safety purposes, proper patient identification is important when picking up prescriptions. JCAHO requires identification for inpatient settings, but this element is missing for outpatient settings. Ms. Herold responded that the Board views this as a medication error and cites and fines the pharmacist. She noted the Board could consider adding more stringent guidelines such as asking for a recipient's birth date. One participant noted that in outpatient settings a complicating factor is that a person other than the patient often picks up the prescription. Mr. Room suggested that pharmacies establish their own procedures rather than seeking to regulate this issue.

5. Identification of Future Discussion Items of the Subcommittee to Evaluate Drug Distribution within Hospitals

Ms. Herold stated that the Subcommittee to Evaluate Drug Distribution within Hospitals has been an excellent forum for discussion and vehicle to address gaps in the recall system. However, Ms. Herold stated that the purpose and structure of the subcommittee may need to change over time depending what the Board deems necessary and optimal. She proposed that this subcommittee become part of the existing Licensing Committee that meets quarterly.

A participant noted that the Best Practices guidelines were not finished. Ms. Herold stated these would probably go to the Board at its October meeting or to the Licensing Committee meeting in December.

One participant asked about the status of compounding regulations inside hospitals versus outside hospitals. Ms. Herold acknowledged this was a topic the subcommittee could pursue. She stated there is currently a proposal under review by the Board and if approved, the regulation will go into effect nine months later.

A participant asked whether there is a committee to look at hospital practice. Ms. Herold responded that there is not, however it could be folded into the Licensing Committee. She encouraged participants to let the Board know what is specifically impeding hospitals' ability to provide quality care considering that the Board's concern is public safety.

Dr. Schell stated he was glad that an ad hoc committee was formed to deal with this topic and added that having a separate subcommittee as opposed to raising these issues in a standing committee, was successful. He invited participants to bring other issues to his attention especially if they are under the purview of the Board.

A participant asked about the process for adopting the possible regulatory or statutory changes related to pharmacy director authority described by Mr. Room. Ms. Herold responded that there are three possible outcomes: 1) the Board could write a letter to CDPH requesting they consider a rulemaking to modify Title 22 or the professional association could submit a similar request to CDPH, 2) the Board could initiate its own statutory modification, or 3) the Board could take no action.

A participant commented that these discussions have been very helpful. He expressed a concern that a more formal subcommittee with more boundaries could hamper the openness of discussion and the spirit of partnership. He encouraged the Board to continue with this type of a dialogue. There was consensus among meeting participants that the spirit of open discussion be maintained.

Ms. Herold mentioned participants were welcome to submit additional ideas for the subcommittee to consider. Dr. Schell indicated that this opportunity would always be available regardless of the specific committee form or structure.

6. Additional Public Comment

Ms. Fraser asked if there was further public comment. Ms. Gregg expressed appreciation for the open communication and educational nature of this subcommittee.

7. Closing, Evaluation, Adjournment

The meeting was adjourned at 3:00 pm.

Attachment 2

Draft Recall Procedures for Hospitals

Best Practices for Recalls in Hospitals

September 2009 Draft

Developed by participants at the meetings of the California State Board of Pharmacy's Subcommittee to Evaluate Drug Distribution in Hospitals

Note: This draft will become a best practices guidance document (not law, statute or regulation) for recalls in hospitals. Interested parties are encouraged to review the information below and provide comments and augmentations will lead to development of an optimal list of actions to take to remove recalled drugs from all patient care areas in hospitals. These comments can be returned to: Executive Officer Virginia Herold at virginia_herold@dca.ca.gov

The best practices for hospitals to follow in response to recalls can be summarized as:

1. Pre-position the facility to receive early notice of recalls from multiple sources,
2. Identify if the facility has the product,
3. If so, quickly remove the product from all patient care areas,
4. Identify, assess, notify and treat patients who may have received the product,
5. Identify alternative products to maintain therapy,
6. Return the quarantined product,
7. Evaluate the process.

Best Practice Actions for Recalls:

A product recall includes any notice from a drug manufacturer, wholesaler and/or FDA to return a drug product or medical device due to suspected contamination or defect.

There are seven parameters that should be included in preparation and activated in response to any recall. These are:

- Training of staff
- Notification receipt of the recall
- Evaluation of the recall and determination of the action plan
- Communication of the recall
- Removal of the recalled drug
- Documentation of the recall action
- Followup and monitoring.

Pre-Recall Planning

Procedural:

The pharmacy department has direct authority and ultimate responsibility for implementation of the facility's recall policy and procedures.

The pharmacy department is to develop and implement written policies and procedures for the effective and efficient removal of recalled products from all patient care (inpatient and outpatient) areas and storage areas. However, policy and procedure development must be multidisciplinary in approach. At a minimum, representatives from nursing, medicine, pharmacy services and administration should be involved. The focus should encompass all patient care areas, including outpatient services.

1. Components of 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. The procedures shall identify the specific roles and responsibilities of all personnel involved in the recall process in sufficient detail to ensure maximum compliance.
   - Ensure knowledge of drug recall procedures by developing facility-wide systems and providing periodic training at least annually.
   - Ensure personnel designated to receive, interpret and disseminate information on recalls are competent to perform such duties. Competency shall include, but is not limited to:
     - Knowledge of federal and state regulations governing drug product or medical device recalls.
     - Establishment of a centralized method to receive, interpret and disseminate information about recalls, especially Class 1 recalls.
     - Ability to discern the actual or potential clinical significance of the recall on patient care.
     - Ability to readily identify all storage and/or use areas for any recalled product.
     - Communication of all pertinent recall information to all impacted areas, including appropriate staff in a timely manner.
   - Establish timelines for completion of each task.
   - Ensure the recall process is capable of activation at any time.
   - Limit and identify the number of people pulling the product during a recall for better accountability and control. Specify who is responsible for checking which areas.
   - Establish a dedicated and trained recall team that knows all the policies, procedures and pertinent regulations.
   - ~~Identify individuals pulling products in each location.~~
   - Require individual departments to verify in writing or via a signature that they looked for the recalled product.
   - Identify avenues for notification for communication throughout the organization (email, fax inter-campus, interoffice mail, hospital newsletter – some of these methods are too slow but can serve as reminders).
   - Post flyers about recalls; for example, post flyers saying "bad heparin" with the lot numbers. This information will be 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.)~~

- Recall notices are received by designated facility staff. All facility action is fully documented. Recall notices are centrally located and readily retrievable.
- Recalled drugs identified as recalled and stored in the pharmacy must be clearly labeled as "recalled" and sequestered in a quarantine area to prevent inadvertent redistribution

2. Know drug storage areas in hospitals:
   - Identify all locations where drugs are kept throughout the hospital: storage outside these areas shall be prohibited, with the exception of bedside storage.
   - 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. There should be no allowance for drugs to be brought in for patient use without the express knowledge and approval of the pharmacy department.
   - 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 redundant system approach for the identification, sequestering and removal of recalled products.
   - Establish a method to ensure all drug storage areas are checked, and then perform an audit. For example, if recall notices are faxed to all pharmacies and responses confirming that all recalled drugs have been removed are expected within 72 hours. After the faxes are received, consider double checking via audit of the drug storage locations.
   - Ensure that recalled drugs and devices are secured by the pharmacy in an area clearly designated as a quarantine area until disposed of as directed in the recall notice.
   - Medical devices should be inventoried and controlled in a manner that facilities their rapid location by the manufacturer, model product or serial number.

3. Additional steps:
   - Monitor subsequent product shipments to ensure recalled products are not shipped into the facility.
   - Establish a system by which patients who may have been affected by the recalled product and identified, notified and assessed for any adverse outcome.
   - Establish a system to monitor implementation on a regular basis to provide insight into opportunities for process improvement.
   - Designate an individual to identify a suitable replacement product that can be used in place of the recalled product.

4. Quality Assurance and Process Improvement:
   Implement monthly reporting of recall activities. Such reports should include:
   - The number of recalls received by the organization.
   - The number of recalls requiring action by the organization.
   - The amount of time from receipt of the recall notice until closure is attained.

- The number of patients affected or potentially affected, including any adverse outcomes.
- The location and quantity of recalled product returned.
- Identification of any problems encountered with the recall process.
- Share these reports with staff to review and identify opportunities for process improvement.

5. Activities with drug wholesalers to improve recalls:
   - Have a wholesaler representative dedicated to the hospital or hospital group. (Alternatively, designate one person as the hospital's liaison with the wholesaler.) This person can run reports and identify recalled drugs purchased by the hospital.
   - Require that all drug purchases be made under the control of the pharmacy.
   - Collaborate and communicate with the wholesaler on drug shipments and recalls, including shipments after a recall is announced.

6. Technology-based solutions:
   - Maintain all stock in automated dispensing cabinets (Pyxis, Omnicell) 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 being administered to patients. Outcome: better communication with patients.
   - Obtain an electronic receipt of recall notices from multiple sources.

IMPROVEMENTS FOR THE SYSTEM:

1. Notification System for Recalls Needs Improvement:
   - 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.
   - Recall notices should state whether the recall is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
   - Recall messages are not always clear. Improve and simplify messages regarding recalls. Create recall notices with more uniform language or have the notice come from one source.
   - 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 though 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.
   - Encourage the FDA to develop a standardized format for recalls, including listing the reason for the recall, so adherence is easier to achieve.

- Recalled products repackaged under another name or brand by a different distributor should be recalled by all names, and a separate recall notice should be listed for the distributor.

2. Establish 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.

3. Methods of Obtaining Recall Information:
   - Recall notices can arrive at hospitals via fax, certified letter, standard mail, emails from manufacturers, wholesalers, or notices with invoices for other drugs. Listserves of the FDA (http://www.fda.gov/Safety/MedWatch/default.htm or the California Board of Pharmacy and other entities can provide recall information.
   - Redundant notification systems should be established: facilities are encouraged to subscribe to more than one listserves available for product recalls. Sole reliance on recall notification via the US Postal Service is not acceptable.

4. Administrative Policies
   - ~~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 for their failure to follow the facility's recall procedures.
   - Increase accountability and collaboration among members of the health care team. There is a lack of consequences for other health care professions.

5. "Geographic" concerns:
   - 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.
   - The PIC should work with the hospital regulatory department to identify what is under the hospital license or clinic license.
   - The PIC should ensure that all recalled drugs are removed in both surveyable and on-surveyable patient care areas.
   - 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.

Examples of a recall plan and components of a recall plan

A designated "recall coordinator" within the pharmacy department will be responsible to coordinate any recall effort. This individual will alert the recall/alert team

1. Evaluation of the recall and determination of action plan
   - The pharmacy recall coordinator, with oversight of the PIC, will develop an action plan (with time frames) based on the classification of the recall or the significance of a voluntary manufacturer recall.
   - When a recall is issued, the recall coordinator will review the situation and activate a Recall/Alert Team within the pharmacy department.

2. Communication of the recall
   - For class 1 recalls, the pharmacy recall coordinator shall communicate immediately to the PIC, pharmacy department manager, and hospital administrator on call.
   - The recall coordinator shall notify pharmacy staff of recall notification by standardized communication methods.
   - The pharmacy recall coordinator shall notify designated directors/managers and clinics of recall notification by standardized communication methods. This will include the anesthesiologist for medications that are stored in the surgery or recovery areas.
   - The recall coordinator shall direct pharmacy staff to search their assigned drug storage areas.
   - Designated directors/managers of departments with drug storage areas will communicate recall information to their staffs by standardized communication methods.

3. Removing the recalled drug
   - The pharmacy department will reference its list of all approved medication storage areas throughout the facility.
   - Medications located outside of the pharmacy must be stored in designated storage areas approved by pharmacy.
   - All approved drug storage areas and potential drug storage areas, identified by staff, are inspected.
   - Recalled drugs that are found during the inspection process are immediately isolated from drug stock areas and returned to the pharmacy to prevent use.
   - All recalled drugs are quarantined within the pharmacy in a location that is distinctly removed from any medication routinely used for treatment, and clearly marked as quarantined.
   - The recall coordinator assigns pharmacy staff to inspect all areas within the pharmacy department to remove a recalled drug from stock.

- The pharmacy buyer or designee contacts the drug wholesaler to confirm that the wholesaler is aware of the recall and has taken steps to remove the recalled drug. (as an alternative, the facility and the wholesaler may develop a communication tool that identifies that the wholesaler has responded to the drug recall).
- Reports for all automated medication cabinets (e.g., Pyxis, Omnicell) are generated to determine the location of potentially recalled medication. However such reports should not replace a physical inspection of each storage area.

4. Documentation of the recall action
   - A readily accessible detailed report (Drug Recall Log) of the medication storage areas will be created and maintained within the pharmacy with specific drug recall information. The report will contain at the least, the date of the storage inspection, who inspected the area, and the results of the inspection.
   - The recall coordinator will monitor the recall periodically to confirm documentation and insure that the inspections are completed within the time frame prescribed by the action plan.

5. Follow-up and monitoring
   - The recall coordinator will notify executive leadership when the class 1 drug recall process is complete, and provide updates as necessary.
   - A summary report of any class 1 drug recalls will be submitted to an appropriate committee (e.g., the Pharmacy & Therapeutics Committee).
   - The pharmacy buyer or designee will confirm that the recalled product is not being shipped into the facility by the wholesaler or other sources for 30 days following the drug recall notice.
   - The recall coordinator shall ensure adherence to the manufacturer's or FDA's recall guidelines for destroying or returning the recalled product to the designated shipping point.
   - Patient medication profiles are reviewed BY WHOM? to determine if patients may have received the recalled drug.
   - If it is determined that it is likely that a patient received a recalled drug, the patient's primary physician is notified and provided with the specific recall information.
   - The recall coordinator will audit the recall report periodically to confirm documentation and insure that the inspections are completed within the time frame prescribed by the action plan.

NOTES:

1) All pharmaceutical products for an institution must be received through the pharmacy services department unless specific approval is given by the director of pharmacy.
2) Encourage the use of technology (RFID, e-Pedigree or bar codes) to facilitate quick identification and storage of recalled drugs.

FDA Classification

Product recalls may be classified as I, II or III relative to the degree of health hazard presented by the product being recalled. The FDA uses a Health Hazard Evaluation to determine the classification.

- Class I – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse consequences or death.
- Class II – A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

SHARP HEALTHCARE PHARMACEUTICAL PRODUCTS RECALL PROCESS

Pharmacy COORDINATOR Responsibilities

RASMAS^ sends alert electronically to Rx Coordinator

Rx Coordinators:
Primary: _____
Back-up: _____

Rx Coordinator reads alert and determine if product is purchased

^RASMAS: Risk And Safety Management Alert System

If YES, determine if it's an outpatient or inpatient product

If NO, close RASMAS alert and indicate rationale as appropriate

Post Class I & II Recall in the Pharmacy Department

Assign task to appropriate Rx responder and indicate any specific instructions when applicable

Inpatient Responders:
_____
_____
_____
_____

Outpatient Responders:
_____
_____
_____
_____

View responder actions to determine if further follow-up is needed. If CLASS I & II recall, verify with Rx management of all actions taken for complete documentation

Close RASMAS alert notification

*Quarantine Location:
(Inpatient) _____
(Outpatient) _____

***Class I Recall: the use of or exposure to a violative product will cause serious adverse health consequences or death. Class II Recall: the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**Documentation Note:
1. State what your actions were
2. If recall med found, indicate where you found it, how much was found, and where is it quarantined
3. Indicate the time/date your action was taken
4. If removal process was delegated, document who it was delegated to and when they communicated the task was completed.

Pharmaceutical Product Recall Process
Safe Medication Practice v.1o 12/08 dv

Pharmacy RESPONDER/PIC/PHARMACY MANAGEMENT Responsibilities

Primary Responder(s) are notified via email notification of RASMAS task by Rx Coordinator

Primary Responder(s) read alert and any specific instructions from Rx Coordinator

Primary Responder(s) determine where medication is stored (refer to checklist of locations)

SAMPLE AREAS:
- Pyxis
- Floorstock
- Crash Carts
- Unit dose bins
- IV bins
- Procedural Trays

(see Drug Location Reference Guide for storage outside pharmacy)

PYXIS Quarantine Instructions: Refer to specific instructions

Remove and quarantine* affected medication

For Outpatient Pharmacy, identify patients on recalled items by running fill report

If patients received recalled item(s), instruct to immediately return affected item(s) for safe disposal and prescribing physician notified if necessary

Primary Responder(s) complete response in RASMAS with action taken**

Notify Pharmacist-In-Charge (PIC)

Auto alert is sent to Rx Coordinator of task completion

Pharmacist-In-Charge
If alert is a CLASS I & II Recall***, notify Rx management, monitor inventory stock, determine if any patient received recalled products, contact prescriber if necessary and notify nursing managers of affected area via direct communication

PIC - Document all actions taken, fill out an eOVR if a variance occurred, and submit a written summary to Rx management

Rx management to send unit managers and leads Drug Recall Alert for Class I & II Recall via email to prompt inspection

Rx management to provide any follow-up or reporting to appropriate departments/ committees (e.g. P&T, SMP) as applicable

Nursing/Procedural units to inspect area using Nursing Tool: Medication Recall Checklist

Rx management to discuss event with pharmacy staff, nursing, and/or appropriate committees to explore improvement opportunities if necessary

Return recalled items and checklist to pharmacy within 48 hours of Drug Recall Alert receipt

Nursing Tool
Medication Recall Checklist

Use this tool when inspecting your area for Recalled Medications. Complete checklist and return to the Pharmacy Department within 48 hours of receipt of Medication Recall Alert

Area being inspected: _____ **Date:** ____/____/____

Inspected by: _____ **Contact Number:** X_____

Inspect the following locations	Actions taken/Comments
☐ Med Room Area ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____
☐ Nursing Station ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____
☐ Other area/room *(specify)* _____ ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____
☐ Med Kits, Crash Carts, Emergency Boxes etc.. *(Specify name and location kit/box found, N/A if no such item exists on the unit)* ☐ _____ ☐ _____ ☐ _____ ☐ _____	☐ N/A ☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____

1. Pyxis Medstation machines will be inspected by Pharmacy personnel.
2. Focus your inspection on areas OUTSIDE of Pyxis Medstation.
3. Once recalled medication(s) are located, sequester it in a safe place and contact Pharmacy Department at _____ for proper return.
4. Return this completed form to the Pharmacy Department within 48 hours of receipt of Medication Recall Alert via direct drop-off or fax. Pharmacy Fax: _____.
5. For questions, contact Pharmacy Department at _____
6. Thank you for making Sharp Healthcare a safer place.

Sharp Hospital Logo HERE

Medication Recall Alert

To: Managers, Charge & Leads

Situation: FDA has posted a ***(State the type of recall)*** on ***(State recalled medication here and reason for recall)***. Details of the FDA recall can be found at *(Link to FDA website or* http://www.fda.gov/medwatch/index.html). Below is a list of recalled medications:

- *List item(s) stated in the recall here –*
  - Includes: *List specifics here if applicable or more room needed*

Background: Sharp _____ Department of Pharmacy has been inspecting all drug storage areas for ***(drug/product name here)*** and removing them to ensure they are no longer available for patient use. ** provide any other applicable background information **

Assessment: Recalled products are not acceptable in any unit at Sharp _____ including emergency kits, crash carts, procedural trays, nursing stations, and automated dispensing cabinets (Pyxis®).

Recommendations: Inspect your area for the recalled item(s) listed above. Look in drawers, cabinets, med kits, trays, and any other place medications are stored. Notify Pharmacy at _____ and return any recalled items to Pharmacy within 48 hours of this recall notice. Report any adverse drug events (ADE) associated with the use of ***(drug/product name here)*** through Sharp intranet eQVR system. Only use products provided by Pharmacy as instructed during this recall process. A joint effort among nurses, doctors, pharmacists, and all healthcare staff is required to ensure no recalled products are available for patient use.

For additional information, please contact the Pharmacy Department at _____. Thank you for your attention and your cooperation in this matter.

Attachment 3

Survey Results: Drug Distribution Within a Hospital

Review of Surveys - Providing Safe and Effective Patient Care: Oversight and Management of Drugs in Hospitals/ Health Systems

Subcommittee to Evaluate Drug Distribution in Hospitals Meeting
UCSF
June 2, 2009

# of surveys submitted: 15

ACQUISITION

1. When asked who orders drugs in your facility, the top responses were:
   - Pharmacy Technician – 13
   - Material Management – 6
   - PIC - 2
   - Pharmacy Director - 1
   - Other -
     - Pharmacist – 2
     - Buyer – 2
     - Technician - 1
     - Central SVC – 1
     - Procurement Pharmacist - 1
     - Procurement Technician – 1
     - Nuclear Medicine (radiopharmaceuticals) - 1

2. When asked which units of the hospital/health system order drugs directly for their use (How does the pharmacy maintain control?), the top responses were:
   - Pharmacy – 5
   - Radiology – 4
   - Material Management – 4
   - Clinics – 3
   - Nuclear Medicine – 2
   - Cental SVC – 1
   - Pharmacy Services – 1
   - Allergy Laboratory - 1
   - Anesthesia – 1
   - None – 1

3. When asked can contracted service providers bring in their own drugs, the top responses were:
   - No – 8
   - Yes – 6

4. When asked can professional or other staff bring in drugs for administration to patients, the top responses were:

- No – 13
- Yes – 1
- Sometimes – 1

5. When asked are there any other drug ordering or acquisition practices that you have found to be helpful, the top responses were:
   - No – 3
   - Yes,
     - Automated - 3
     - Pharmacy Buyer – 2
     - Prime Vendor – 1
     - Avoid or minimize shortage – 1
     - Scanning Technology - 1
     - Inventory Turns – 1
     - Prescription approved order books – 1
     - Dedicated Staff - 1
     - Single Wholesaler – 1
     - Centralize inventory - 1

6. When asked are there any other drug ordering or acquisition practices that you have found to be more problematic, the top responses were:
   - No – 3
   - Yes,
     - Manufacturer shortage and recalls
     - Buying drugs from specialty pharmacies outside of a wholesaler
     - Dialysis Contractor bringing in own drugs
     - Materials management controlling expirations dating, "stock rotation," for drug containing procedure kits
     - Borrowing from other hospitals
     - Buying from "gray vendors"
     - City and county restrictions in doing business with certain entities
     - Specialty pharmacy requirements

STORAGE/MANAGEMENT

1. When asked are drugs stored in your facility, the top responses were:
   - Main pharmacy – 12
   - Clinics - 10
   - Pyxis machine – 11
   - Crash carts/emergency kits – 11
   - Floor stock - 10
   - Additional pharmacies – 6
   - Satellite pharmacy - 5
   - Paramedic units - 2
   - Other: Medical Room, Clinical Labs, Material Management, Nuclear Medicine, Laboratory

2. When asked what services are being provided by the pharmacy staff for satellites and Pyxis machines, the top responses were:

- Stocking - 8
- Outdate check – 5
- Inventory – 3
- Discrepancy resolution – 2
- Unit inspection – 2
- Other provided responses: Maintenance, Unit based pharmacy, Medical Reco. Pharmacy, ICVRPh, Pocket analysis, Controlling access, Unit based pharmacy in the ER, Consultative and monitoring services

3. When asked are monthly inventories conducted of each identified location, the top responses were:

- Yes – 8
- No – 4

4. When asked who performs the stock check, the top responses were:

- Pharmacist – 4
- Pharmacist Technician – 4
- Inventory Control Clerk - 1

5. When asked who reconciles, the top responses were:

- Pharmacist – 5
- Pharmacist Technician – 5
- Pharmacy – 1
- Clinic – 1
- Medical Safety Pharmacist - 1

Attachment 4

Disaster Response Policy Statement

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.

[1]Expanded 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.

[2]See 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.

Attachment 5

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

California State Board of Pharmacy
CPJE Statistics 4/1/09 – 9/30/09

The charts below display data for all candidates who took the CPJE examination between 4/1/09 to 9/30/09, 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	264	21.7
	P	953	78.3
	Total	1217	100.0

NAPLEX

		Frequency	*Percent*
Valid	F	26	2.2
	P	1140	97.8
	Total	1166	100.0

Location of School

			CPJE pass fail status		*Total*
			F	*P*	
School	California	Count	78	627	705
		% within PF	11.1	88.9	
	Other US	Count	128	259	387
		% within PF	33.1	66.9	
	Foreign	Count	56	65	121
		% within PF	46.3	53.7	
	Unclassified	Count	2	2	4
		% within PF	50.0	50.0	
Total		Count	264	953	1217
		% within PF	21.7	78.3	

			NAPLEX pass fail status		Total
			F	P	
School	California	Count	7	695	702
		% within PF	1.0	99.0	
	Other US	Count	12	334	346
		% within PF	3.5	96.5	
	Foreign	Count	7	107	114
		% within PF	6.1	93.9	
	Unclassified	Count	0	4	4
		% within PF	0	100.0	
Total		Count	26	1140	1166
		% within PF	2.2	97.8	

Gender

			CPJE pass fail status		Total
			F	P	
gender	F	Count	163	673	836
		% within PF	19.5	80.5	
	M	Count	101	280	381
		% within PF	26.5	73.5	
Total		Count	264	953	1217
		% within PF	21.7	78.3	

			NAPLEX pass fail status		Total
			F	P	
gender	F	Count	18	786	804
		% within PF	2.2	97.8	
	M	Count	8	354	362
		% within PF	2.2	97.8	
Total		Count	26	1140	1166
		% within PF	2.2	97.8	

Degree

			CPJE pass fail status		Total
			F	P	
degree awarded	BS Pharmacy	Count	72	78	150
		% within PF	48.0	52.0	
	Pharm D.	Count	192	875	1067
		% within PF	18.0	82.0	
Total		Count	264	953	1217
		% within PF	21.7	78.3	

			NAPLEX pass fail status		Total
			F	P	
degree awarded	BS Pharmacy	Count	10	131	141
		% within PF	7.1	92.9	
	Pharm D.	Count	16	1009	1025
		% within PF	1.6	98.4	
Total		Count	26	1140	1166
		% within PF	2.2	97.8	

California Schools

			CPJE pass fail status		Total
			F	P	
School	UCSF	Count	7	95	102
		% within PF	6.9	93.1	
	UOP	Count	31	151	182
		% within PF	17.0	83.0	
	USC	Count	9	157	166
		% within PF	5.4	94.6	
	Western	Count	17	101	118
		% within PF	14.4	85.6	
	Loma Linda	Count	5	41	46
		% within PF	10.9	89.1	
	UCSD	Count	1	43	44
		% within PF	2.3	97.7	
	Touro U	Count	8	39	47
		% within PF	17.0	83.0	
Total		Count	78	627	705
		% within PF	11.1	88.9	

			NAPLEX pass fail status		Total
			F	P	
School	UCSF	Count	0	101	101
		% within School	0	100	
	UOP	Count	1	180	181
		% within School	0.6	99.4	
	USC	Count	0	165	165
		% within School	0	100	
	Western	Count	3	115	118
		% within School	2.5	97.5	
	Loma Linda	Count	2	44	46
		% within School	4.3	95.7	
	UCSD	Count	0	44	44
		% within School	0	100	
	Touro U	Count	1	46	47
		% within School	2.1	97.9	
Total		Count	7	695	702
		% within School	1.0	99.0	

US Schools of Pharmacy

	CPJE pass fail status		
	F	***P***	***Total***
Auburn	0	2	2
Samford	0	1	1
U of AZ	0	2	2
UCSF	7	95	102
U of Pacific	31	151	182
USC	9	157	166
U of CO	1	3	4
U of Conn	0	4	4
Howard DC	4	2	6
FL A&M	1	0	1
U of FL	3	10	13
Mercer	0	4	4
U of GA	1	1	2
Idaho SU	1	3	4
U of IL Chi	4	9	13
Butler U	1	1	2
Purdue	3	7	10
Drake	1	1	2
U of IA	0	6	6
U of KS	0	2	2
U of KY	0	2	2
NE LA U	3	0	3
Xavier	4	2	6
U of MD	1	6	7
MA Col Pharm	13	28	41
NE-MA	4	5	9
Ferris	1	4	5
U of MI	1	4	5
Wayne SU	1	3	4
U of MN	5	4	9
U of MS	0	2	2
St. Louis Col of PH	2	2	4
U of MT	0	2	2
Creighton	5	7	12
U of NE	2	1	3
Rutgers	3	2	5
U of NM	1	6	7
Western	17	101	118

	CPJE pass fail status		
	F	***P***	***Total***
Midwstern U Chicago	1	6	7
A&M Schwartz	5	2	7
St. Johns	2	1	3
SUNY-Buff	0	4	4
Union U	4	6	10
UNC	1	1	2
ND SU	0	2	2
OH Nrthrn U	1	1	2
OH State U	0	4	4
U of Cinn	2	2	4
U of Toledo	0	4	4
U of OK	3	2	5
OR State U	0	2	2
Duquesne	1	1	2
Phl C of Pharm	5	4	9
Temple	1	2	3
U of Pitt	0	1	1
U of RI	2	1	3
U of SC	1	1	2
U of TN	0	1	1
TX SO U	1	0	1
U of Hous	1	1	2
U of TX	1	0	1
Med C of VA	0	2	2
U of WA	2	6	8
WA State U	1	2	3
U of WI-Mad	1	1	2
U of WY	2	0	2
Campbell U	0	1	1
Nova Southeastern	3	11	14
Wilkes University	0	1	1
Texas Tech	0	2	2

	CPJE pass fail status		Total
	F	P	
Bernard J Dunn	1	3	4
Midwestern AZ	5	7	12
Nevada College of Pharm	6	24	30
Loma Linda U	5	41	46
UCSD	1	43	44
MA School of Pharm - Worcester	6	2	8
Palm Beach Atlantic University	1	2	3

	CPJE pass fail status		Total
	F	P	
Touro U	8	39	47
U of Appalachia	1	0	1
South U School of Pharm	1	1	2
Pac U of Or	0	6	6
Wingate U	0	1	1
Unclassified	2	2	4
Other/FG	56	65	121
	264	953	1217

Country

	CPJE pass fail status		
	F	***P***	***Total***
Argentina	0	1	1
Canada	2	2	4
Switzerland	1	0	1
Egypt	5	10	15
France	0	1	1
United Kingdom	0	2	2
Hungary	0	1	1
Israel/West Bank/Gaza Strip	0	2	2
India	17	13	30
Iran	0	4	4
Jordan	0	2	2
Korea (N&S)	1	0	1
S. Korea	1	0	1
Lebanon	2	2	4
Nigeria/New Guinea	1	2	3
Philippines	15	15	30
Pakistan	1	0	1
Poland	0	1	1
Sweden	1	0	1
Serbia	0	1	1
Suriname	1	0	1
Syria	2	1	3
Taiwan	0	1	1
Ukranian	1	0	1
USA	212	891	1103
Venezuela	0	1	1
South Africa	1	0	1
	264	953	1217

Attachment 6

1. Board licensing statistics
2. First 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)	185	287	132										604
Pharmacist (initial licensing applications)	280	134	161										575
Intern pharmacist	61	479	331										871
Pharmacy technician	962	887	1036										2885
Pharmacy	29	23	28										80
Sterile Compounding	6	2	1										9
Clinics	6	6	13										25
Hospitals	0	0	0										0
Nonresident Pharmacy	3	6	3										12
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	1	3	2										6
Nonresident Wholesalers	6	15	6										27
Wholesalers	5	7	6										18
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	34	57	36										127
Issued													
Pharmacist	243	308	139										690
Intern pharmacist	39	277	323										639
Pharmacy technician	751	788	764										2303
Pharmacy	35	24	36										95
Sterile Compounding	9	2	7										18
Clinics	5	4	11										20
Hospitals	6	1	5										12
Nonresident Pharmacy	10	3	1										14
Licensed Correctional Facility	1	0	0										1
Hypodermic Needle and Syringes	1	5	1										7
Nonresident Wholesalers	10	13	16										39
Wholesalers	8	7	15										30
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	45	26	40										111

*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	241	283	192										241
Intern pharmacist	278	496	488										278
Pharmacy technician	1894	1888	1837										1894
Pharmacy	58	54	49										58
Sterile Compounding	18	18	13										18
Clinics	30	28	24										30
Hospitals	19	16	12										19
Nonresident Pharmacy	34	32	33										34
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	19	10	11										19
Nonresident Wholesalers	92	79	72										92
Wholesalers	43	35	20										43
Veterinary Food-Animal Drug Retailer	1	1	1										1
Designated Representatives	132	88	128										132
Change of Pharmacist-in-Charge													
Received	189	159	130										478
Processed	151	91	75										317
Pending	38	106	161										
Change of Exemptee-in-Charge													
Received	37	22	19										78
Processed	6	7	0										13
Pending	31	46	65										
Change of Permits													
Received	347	103	74										524
Processed	37	1	311										349
Pending	310	412	175										
Discontinuance of Business													
Received	42	33	35										110
Processed	35	12	18										65
Pending	7	28	45										

*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	1213	2757											3970
Pharmacy technician	1632	3740											5372
Pharmacy	182	484											666
Sterile Compounding	21	49											70
Clinics	76	131											207
Nonresident Pharmacy	34	31											65
Licensed Correctional Facility	0	1											1
Hypodermic Needle and Syringes	10	23											33
Nonresident Wholesalers	32	54											86
Wholesalers	32	71											103
Veterinary Food-Animal Drug Retailer	2	4											6
Designated Representative	149	306											455

*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)	451				40			
Pharmacist (initial licensing)	728				2			
Pharmacy Intern	871				19			
Pharmacy Technician	2,885				69			
Pharmacies	80				25			
Non-Resident Pharmacy	12				38			
Wholesaler	18				30			
Veterinary Drug Retailers	0				0			
Designated Representative	127				30			
Out-of-state distributors	27				30			
Clinics	25				45			
Hypodermic Needle & Syringe Distributors	6				30			
Sterile Compounding	9				30			
Change of Permit	405				32			
Pharmacist in Charge	478				14			
Designated Representative in Charge	78				14			
Discontinuance of Business	110				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)	15			
Pharmacist (initial licensing)	7			
Pharmacy Intern	15			
Pharmacy Technician	15			
Pharmacies	15			
Non-Resident Pharmacy	7			
Wholesaler	7			
Veterinary Drug Retailers	0			
Designated Representative	7			
Out-of-state distributors	7			
Clinics	20			
Hypodermic Needle & Syringe	7			

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)	2			
Pharmacist (initial licensing)	2			
Pharmacy Intern	2			
Pharmacy Technician	5			
Pharmacies	2			
Non-Resident Pharmacy	3			
Wholesaler	2			
Veterinary Drug Retailers	0			
Designated Representative	1			
Out-of-state distributors	2			
Clinics	1			
Hypodermic Needle & Syringe	1			

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	690			
Pharmacy Intern	639			
Pharmacy Technician	2,303			
Pharmacies	108			
Non-Resident Pharmacy	14			
Wholesaler	30			
Veterinary Drug Retailers	0			
Designated Representative	111			
Out-of-state distributors	39			
Clinics	20			
Hypodermic Needle & Syringe	7			
Sterile Compounding	18			

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	95			
Pharmacies	0			
Non-Resident Pharmacy	1			
Clinics	0			
Sterile Compounding	0			
Designated Representative	19			
Hypodermic Needle & Syringe	4			
Out-of-state distributors	11			
Wholesaler	9			
Veterinary Drug Retailers	0			

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

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	32			
Pharmacies	0			
Non-Resident Pharmacy	0			
Clinics	0			
Sterile Compounding	0			
Designated Representative	1			
Hypodermic Needle & Syringe	0			
Out-of-state distributors	0			
Wholesaler	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	863*			
Pharmacy Technicians	1,214*			
Site licenses (pharmacy, clinics)	716*			
Site licenses (wholesalers, nonresident pharmacies)	701*			
Pharmacist in Charge	358			
Renewals	533			

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	100*			
Pharmacy Technicians	100*			
Site licenses (pharmacy, clinics)	200*			
Site licenses (wholesalers, nonresident pharmacies)	151*			
Pharmacist in Charge	143			
Renewals	112			

* E-mail and voicemail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 8/21/09-9/11/09 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.

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.
Measure:	Percentage of revenue cashiered application within 2 working days.

Tasks:

	Revenue Received:				Average Days to Process:			
	Qtr 1*	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Applications	$389,942				2			
Renewals	$1,343,163				2			
Cite and Fine	$244,450				4			
Probation/ Cost Recovery	$33,045				4			
Request for Information/ License Verification	$3,280				3			
Fingerprint Fee	$11,520				2			

* Refflects July and August 2009 data available at the time of report development

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.
Measure:	Percentage of licensing records changes within five working days.
Tasks:	

	Requests Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Address/Name Changes	739*				10			
Off-site Storage Applications (approved)	0				0			
Transfer of Intern Hours to Other States	200				15			

* Includes data from 7/1/09 - 8/7/09

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	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. *Jan. 2007:* *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.* *March 2007:* *Pennsylvania agrees to accept California NAPLEX scores.* *May 2007:* *At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.* 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. *June 2007:* *Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities.* *Oct. 2008:* *Board staff meet with Department of Corrections staff to develop regulatory structure for prisons.* *Dec. 2008:* *Met with receiver for correctional facilities to discuss regulatory structure.* 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. *Sept. 2006:* *Committee hears presentation by DHS on emergency preparedness.* *Oct. 2006:* *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.* *Jan. 2007:* *Board publishes disaster response policy statement.* *Feb. & March 2007:* *Board attends seven-day DHS-hosted training session on SURGE emergency response as part of the state's disaster response.* *April - June 2007:* *Board continues to participate in SURGE planning activities and in a joint public/private partnership project envisioned by the Governor.* *June 2007:* *Board staff aids in contract evaluation to select a consultant to provide pre-emergency registration of health care providers.* *Sept. 2007:* *Board attends Rough & Ready Demonstration in Orange County.* *Oct. 2007:* *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.* *Dec. 2007:* *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.*

	Oct. 2008: *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.* *Jan. 2009:* *Board hears presentation from San Diego County on proposal. Board staff offer an alternative solution, which is acceptable to San Diego County.* *June 2009:* *Licensing Committee hears presentation from DCPH regarding its response to H1N1 emergency.* 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. *Sept. 2006:* *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.* *Dec. 2006:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* *March 2007:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* *May 2007:* *Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.* *Sept. 2007:* *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.* *Oct. 2007:* *Board postpones work on this topic until CSHP and CPhA complete their review.* *March 2009:* *Board executive staff meet with the executive director of the ExCPT exam.* *April 2009:* *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.* 7. Review requirements for qualifications of pharmacy technicians with stakeholders *4th Qtr. 07/08:* *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.* *2nd Qtr. 08/09:* *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.* *3rd Qtr. 08/09:* *Senate Bill 418 introduced to add new requirements for technicians.*

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.*

1st Qtr. 09/10: *Competency Committee develops occupational analysis survey.*

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.*

3rd Qtr. 08/09: *Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.*

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.*

13. Convene Committee to evaluate drug distribution within hospitals.

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.*

3rd Qtr. 08/09: *Board establishes subcommittee to initiate review.*

March 2009: *First meeting convened.*

June 2009: *Second meeting convened in San Francisco.*

Sept. 2009: *Third meeting convened in Sacramento.*

14. Improve reporting of and accounting for intern hours.

4th Qtr. 08/09: *Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.*

15. Participate in initiatives to increase the number of pharmacists in California to meet demand.

4th Qtr. 08/09: *Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.*

16. Assess the operations of specialty pharmacy services.

4th Qtr. 08/09: *Board initiates review of refill pharmacies.*

17. Encourage use of technology where it benefits the public.

June 2009: *Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.*

18. Secure the implementation of e-prescribing in California by the earliest possible date.

4th Qtr. 08/09: *Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.*

19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.

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.*