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

DATE:	June 2, 2009
LOCATION:	UCSF Laurel Heights Conference Center 3333 California Street San Francisco, CA 94118
BOARD MEMBERS PRESENT:	Kenneth Schell, Pharmacist Member, President Randy Kajioka, Pharmacist Member
STAFF PRESENT:	Virgina Herold, Executive Officer Anne Sodegren, Assistant Executive Officer Caroline Kline, Legislation and Regulation Coordinator Tessa Fraga, Administrative Analyst
CONSULTANTS PRESENT:	Val Sheehan, Meeting Facilitator Carmen Fraser, Senior Associate

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

1. Welcome, Meeting Overview, Introductions

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

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

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

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

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

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

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

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

2. Revisiting Drug Recall Practices

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

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

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

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

- Under the section on procedures, a participant commented that the list did not have a requirement for timelines for the hospitals. The participant added that wholesalers also needed a deadline expectation beyond which they will no longer ship recalled drugs. Ms. Herold responded that timelines will be considered with further editions of the recommendations.

- Another participant commented on designating specific people who are accountable in procedural and diagnostic areas where medications are also sequestered. These people need to share responsibility for complete evaluation of all possible drug storage areas and communication to their respective departments. Even though there may be specific authorized drug storage areas in the hospital, the reality is that drugs are often found outside these areas.

- Ms. Herold continued by reviewing the remaining sections under ACTIONS and asked participants for any additional comments that would benefit recall in hospitals. A participant asked if there was regulatory or legal

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

- The participant added that without that regulatory or legal authority, it is left to the authority of the Pharmacy Director to ensure that others are accountable, and that hasn't worked well historically. Ms. Herold responded that these meetings were hoping to address that very issue. She added that a single model may not meet everyone's needs and perhaps various models need to be examined.

- Another participant noted that the FDA currently requires wholesalers to sequester recalled product upon receipt of a notice from the manufacturer, which typically comes through the mail. Because of the time gap between electronic notices to hospitals and mail notices to wholesalers, wholesalers continue to distribute recalled product up to a week following electronic notification of recall. She added that the State needs to narrow that period of time so that the wholesaler is held to a similar standard as the hospital. Electronic notification should be required for wholesalers. This may not be done nationally, but it could certainly be done in California.

- A participant representing wholesalers remarked that once they receive a recall notice from the manufacturer via email or regular mail, they notify their distribution centers to sequester the recalled product. Typically, within an hour of receiving a manufacturer's recall notice the wholesaler notifies its distribution centers via email and the recalled product is sequestered. She acknowledged that there can be a delay because manufacturers still send recall notices through the mail. She added that manufacturers have email addresses for wholesalers are able to contact wholesalers via email. Ms. Herold pointed out that having a situation where the end user is aware of a recall and a wholesaler has to wait to get an official notice before acting upon the recall notice, highlights a very serious gap in the system.

- A participant suggested having sites check inventory with the understanding that the wholesaler may not have received the recall notice yet. This can be done for a period of time following the issuance of a recall notice. Ms. Herold acknowledged that continuing to check inventory, for a week or two after a recall notice has been issued, was a good addition to the list of suggested best practices.

- A participant commented that the list of suggested actions relied on the fact that the notification system is in tact and that you get timely notification. She added that the list of suggestions did not include anything targeting notification. She said that she had a pilot program with her wholesaler where the wholesaler electronically notified them directly about recalls. She acknowledged that she gets more notification from her wholesaler than from the FDA. She felt that wholesalers were doing a good job of notifying them about recalls.

- Ms. Herold responded by saying that the Board of Pharmacy did not believe that any hospital or wholesaler deliberately shipped or dispensed recalled drug product. However, the reality was that recalled drug product was made available to patients. She added that the Board of Pharmacy is considering using subscriber alerts to connect all pharmacies to the Board of Pharmacy. She acknowledged that the Board of Pharmacy may not get information as quickly as hospitals and encouraged participants to forward suggestions about how the Board can share information about recalls most effectively and efficiently. She added that once a hospital is notified about a recall, even if the manufacturer has not given explicit directions about what to do with the recalled drug product, that hospital is expected to sequester and quarantine the recalled drug product until it receives instructions about what to do with the drug.

- A participant commented that manufacturers often send recall notices just to their purchasers and don't share the information more broadly. In many communities, hospitals share drugs because of shortages or

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

- Another participant shared her positive experience using RASMAS, a web-based subscription service that provides comprehensive notification, distribution, and management of product alerts and recalls for all healthcare and consumer products used in healthcare facilities. She added that RASMAS constantly searches multiple websites for recall information. Her hospital had several coordinators who receive electronic notification through RASMAS.

- A participant suggested that since wholesalers are saying that they cannot act until they receive official notice from a manufacturer, wholesalers may want to consider putting an asterisk or other denotation on a shipment invoice indicating that a shipment may contain recalled drug product. This way a hospital that receives the shipment has some way of knowing that a shipment may contain recalled drugs and can act accordingly.

- Another participant countered that she didn't understand why wholesalers who are licensed in the State of California are held to different standards than hospitals. She added that if the hospital can get access to the information through RASMAS and other services, why can't the wholesaler get that same information? The result would mean that all entities would be on the same timeframe and the level of due diligence would be equal.

- A participant cautioned everyone about the reliability of products like RASMAS. For a wholesaler to create a drug shortage based on information that may not be reliable could be devastating. They key would be to have an early and reliable recall notice system in place.

- Ms. Herold asked participants for clarification regarding recalled lot numbers. A participant confirmed that any recall notice sent has to have a lot number. However, invoices do not have to go out with lot numbers, which means hospitals often don't know what lot numbers are in their facilities. Another improvement would require wholesalers to provide lot numbers on every invoice.

- Ms. Herold pointed out that an electronic tracking system or e-pedigree would address some of these issues. The coding would contain information which would allow hospitals to know exactly what lot numbers they have in their possession. In addition, Ms. Herold pointed to the suggested use of bar codes and radio-frequency identification (RFID) on the list of best practices document as other potential tracking mechanisms. Ms. Herold stressed that while the systems are not in place right now to implement e-pedigree or RFID, the Board of Pharmacy is working towards finding effective solutions in the future.

- Ms. Herold closed by thanking participants for their comments on the document. She informed the group that the Board will continue to collect feedback and comments at this meeting and will collect more feedback once the document is posted on the Board's website. For the next meeting, a more finalized version of the suggested best practices will be distributed, hopefully in advance of the meeting. Ms. Herold also addressed the issue of having more disciplines, Boards and organizations represented at future meetings (e.g., nursing, California Hospital Association, etc.). She stressed the importance of gaining clarity and consensus as pharmacists before opening up the discussion more broadly to other professional groups.

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

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

- The goal of the presentation was not to make each Pharmacist-in-Charge (PIC) fit into every requirement that applies to the pharmacy or to the PIC. The goal of the presentation and of the subcommittee in general was to communicate what's expected of a PIC and empower PICs with information to help them be more proactive about their roles as leaders within their organizations.

- Each Pharmacy Director has pharmacy departments that look very different in terms of size and complexity, but each director has similar tools at his/her disposal. These tools include:
    - Knowledge, Training & Experience
        - Staff – knowledge
        - Training & experience
        - Policies & Procedures
        - Associations guidance
        - Board of Pharmacy
            - Pharmacy Law
            - Self Assessment
        - CA Dept. of Public Health
            - Title XXII
        - Joint Commission

- The Hospital Pharmacy Self-Assessment tool is extremely helpful in knowing what is expected by the Board of Pharmacy. PICs are encouraged to share the assessment tool with staff as a public document.

- From the Board's perspective, PICs have a similar "authority, responsibility and accountability" as nurses have for the nursing service within a facility per 22 CCR § 7021 (c).

- A participant commented that a PIC's area of responsibility is much broader. PICs are responsible for all medication management throughout a hospital.

- The purpose of reviewing a PIC's areas of responsibility per various regulations and statutes is to ensure that PICs have the appropriate authority within their organizations to influence policies and procedures and effect the necessary changes that have to be made to ensure that the hospital is in compliance with relevant laws. It is also to ensure that when they are held accountable, they've had the power and authority up until that point to make the necessary changes. In addition, subverting this authority by a non-pharmacist owner can constitute a misdemeanor.

- A participant commented that even though all of this is in the law, administrators prioritize risks. It is not often seen as a risk when a pharmacist is not reporting to the right person.

- Another participant pointed out that influence is the key element to make change happen. If there are no consequences for the administrator for not ensuring the proper level of authority for a PIC, then things are not likely to change.

- Mr. Room reiterated that one of the purposes of the subcommittee is to determine what can be done to address whether or not PICs have authority to do their jobs effectively. From the Board of Pharmacy's perspective, there are enough statutes and regulations to bolster a PIC's authority. Mr. Room added that if that's not the case, the Board would like to hear from participants about what needs to change.

- The Board of Pharmacy has at its disposal the ability to create regulations to support effective pharmaceutical care in California, but only has the power to hold the PIC accountable. From the Board's perspective, a citation is a public record of the problem and a proposed remedy.

- Another participant commented that through regulation, nursing is required to sit at the C-Suite level which gets them to the table earlier regarding allocation of resources. Getting the resources and tools to

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

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

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

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

The presenters were:

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

The main points from the presentations are as follows:

<u>Elaine Levy, Sharp Healthcare</u>

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

- They used several tools to improve work flow, including many borrowed from Japanese business settings including the Heijunka and the Kan Ban.

- Since opening, they are still working out many issues such as recycling and reporting from two systems that had to be combined. They continually measure as part of the Lean Six Sigma framework and look at expense per unit of service (UOS) as a way to measure success.

- They are currently mostly still manual, but are considering using Intellifill, an automated robot that produces syringes. They are also considering Intelliflow to manage the IV room workflow. Some advantages include recording and storing data for regulatory compliance and standardizing practices.

Tom Dotts, Pomona Valley Medical Center

- Pomona Valley is one of the few remaining stand-alone hospitals in California. They have 456 beds and have the third largest number of deliveries in state. Last year, they had over 8000 deliveries. They have a 65-bed ICU and a very busy emergency department.

- Dr. Dotts commented on the previous discussion regarding pharmacy director leadership. Dr. Dotts expressed that the issue had more to do with the pharmacists themselves rather than the administrators. Mr. Dotts added that he thought pharmacists may be hesitant to take on the challenges of the position and that he had not come across an administrator who wouldn't be more than happy to have a PIC take on more authority and accountability.

- Dr. Dotts sits on the medical executive committee, which he acknowledged may not be the norm. At his hospital, pharmacy is highly integrated with every aspect of nursing and they work well with the medical staff in general. Outside consultants validated that the hospital was near benchmark in terms of drug utilization. Staffing analyses also revealed that they were very productive in the area of pharmacist and tech staffing.

- They have a centralized model and they use automated drug dispensing cabinets. In excess of 90% of the administered medications come out of cabinets. Dr. Dotts added that the key aspect for medication distribution is to be proactive and not let things go on auto pilot. He added that it was important to have someone on top of issues every day.

- They conduct continuous quality improvement (CQI) procsses on a quarterly basis and the information collected often can help PICs continue to raise the bar.

- They are planning to institute bedside bar coding.

James McNulty, Kaweah Delta Health Care District

- They are a 500 bed licensed facility in Central California. A current expansion will push them to 630 beds. They are spread out over multiple cities and multiple campuses.

- Most of their drug distribution challenges are related to having 630 beds on three campuses. Most of those beds are in the main hospital; the challenges are distributing drugs to the other two campuses.

- Some of their services include a dialysis center, oncology, skilled nursing facilities, home infusion and hospice. They also have an acute care hospital for adult, peds. and NICU.

- They have five pharmacies including two outpatient pharmacies, an employee pharmacy and infusion pharmacy. In addition, there are inpatient and operations. When other pharmacies close, all orders are sent to the main hospital.

- The main hospital pharmacy is open 24 hours a day. More than 98% of their drugs are in Pyxis machines. They are scheduled for bedside patient/drug bar code verification in February 2010 and computerized provider order entry in November 2010.

- Their main challenge came down to implementing new technology or bar code strategies within current laws or lack of current laws. Some additional challenges to bar coding included:

    - Bar coding of product for all campus areas.
        - Because they prefer to package at one campus and transfer to other campuses, they are considered a manufacturer and are held to different standards. One suggestion is to work with CDPH to get a manufacturing license.
    - Use of Pharmacy Order Management System (POMS) from remote location.
        - Because they work with pharmacists in remote locations, the expectation is to notify the Board of Pharmacy and the Drug Enforcement agency when operating under this scenario.
    - Replenishment of Automated Dispensing Cabinets (off campus)
        - One of their biggest challenges is filling of Pyxis units for off-campus areas when pharmacy areas are closed. Sending bulk product can mean that a pharmacy becomes a wholesaler.
    - Pharmacist oversight of drug areas
        - Oversight continues to be a challenge, particularly regarding drug recall management and management of IV solutions at off campus locations.

- Dr. McNulty concluded by saying that he hoped that the subcommittee would take a hard look at current practices and determine whether current law was appropriate. As more technology is implemented, it is more important than ever to work collaboratively with the Board of Pharmacy, CDPH and other pharmacists to ensure safe and effective patient care.

<u>Terry Nishizaki, UC Davis Med Center</u>

- UC Davis Med Center in Sacramento has a central pharmacy and three satellites. They get their physician orders through computerized physician order entry (CPOE). Dr. Nishizaki commented that in all his years of practice, CPOE has been the greatest change to utilize their pharmacy and pharmacy staff much better.

- They are a 577 bed facility. They are a major teaching hospital; they have a Level 1 trauma center, burn center and children's hospital.

- They have decentralized drug distribution through automated dispensing machines (ADMs). They have over 100 Pyxis machines throughout the institution. Medications are accessible and secure and there's accountability.

- They refill the Pyxis machines centrally and deliver them daily to the automated dispensing machines. They dispense 250,000 doses per month out of Pyxis machines.

- They have been able to drop their error rate substantially through the use of bar coding.

- They have a centralized IV preparation area. First and miscellaneous doses are done from the satellite to catch up between batches. They do over 1,000 IVs per day.

- They are moving toward compliance with USP 797, Pharmaceutical Compounding: Sterile Preparations, the first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP). USP Chapter 797 describes the procedures and requirements for compounding sterile preparations

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

- The IV compounding requirements have definitely changed the way all the UC hospitals do business. The regulations need to reflect both manual and automated compliance strategies. In the future, they are looking at robots to do IV compounding to help with efficiency and worker safety. Bar coding has also brought a whole new level of patient safety.

- Some suggestion for the Board of Pharmacy include:

    - All of their sites are signed up for the Board of Pharmacy email alerts, but one suggestion would be to have a similar mechanism as JCAHO where you can send in a question via email and receive an answer within a couple of days.

    - Better communication around change in interpretation of existing regulations. For example, PICs were cited during the heparin recall. It would have been beneficial to get more advance warning about that change.

    - Better communication regarding licensure status and better advance warning about recalls.

    - More education around the new manual of disciplinary guidelines and how it will impact practice and incorporation of technology in regulations with timelines.

- The pharmacist is just one part of a very complex system that is ultimately trying to deliver effective patient care.

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

- One of the panelists suggested having more centralized control with the ability to radiate out. Another added that they needed flexibility to adapt because changes happen so fast.

- An audience member asked, in recent years have regulatory agencies helped or hindered your practice? Elaine Levy responded that conversations with the Board of Pharmacy in the conceptual stages of creating the centralized pharmacy were extremely helpful. She added that she received very valuable guidance about licensing.

- Another panelist added that even though the JCAHO process can be difficult, it has made it possible to make significant changes in the health care setting. The accreditation process has brought better understanding and more visibility to the fact that medication management is a very complex issue. In particular, there is better understanding from the C-Suite.

- A participant asked how one goes about changing laws when you have Title 22 on the books and you run the risk of contradicting what is outlined by the laws that the govern hospitals.

- Dr. DeMartini confirmed that there is no plan to revise Title 22. To clarify about the issue of conflict, Dr. DeMartini added that statutes specifically covering scope of work will usually trump Title 22. She added that whenever you have two regulatory bodies that have jurisdiction, the more stringent one will apply. At any point in time if you want to flex a regulation in Title 22, you can submit a program flex request to your district office for licensing and certification. A request is usually sent with the understanding that a proposed alternative will still meet the intent of the regulation.

- Ms. Herold responded by saying that the Board of Pharmacy does not have the authority to flex regulations in the way that the CDPH does. The Board of Pharmacy tends to go to the legislature more often. One of the potential outgrowths of the subcommittee meetings is to examine where statutory regulations are needed. For example, over the years the Board has done statutory modifications to allow the use of technology. She added that if you can make a compelling case that the patient's interests will be served by doing a particular modification, the Board has been known to carry that particular modification through the legislature. The Board is sponsoring six bills this year.

- Dr. Schell acknowledged the number of regulations that have been enacted in the last 20 years to improve the quality of products and services produced in hospital pharmacies and asked the panelists if they've seen any demonstrable improvement in the types of sterile products they produce or the ways the provide services.

- Dr. McNulty from Kaweah Delta responded by saying that they evaluated a product long before USP 797, clean room standards. They have seen no significant difference after being fully compliant with USP 797 and spending $1.2 million. The consensus was that the medical literature supported Dr. McNulty's observation.

- Dr. Schell also asked the panelists if they have seen a decrease in medication errors.

- Dr. Nishizaki responded that CPOE and bar codes have been very effective in decreasing medication errors. Another participant commented that the use of smart pumps has also helped decrease medication error.

- Dr. Dotts shared his frustration with the scenario of roving nurses who commit drug theft in one hospital and end up working at new hospital the next day. He posed to the Board the question about how consumer protection can truly happen when the process to suspend nurses is so slow.

- Ms. Sodegren responded that there is a diversion process in place at the Board of Nursing. If a pharmacist submits a report to the Board of Pharamacy about a theft, the BOP takes it directly to the Board of Nursing. Ms. Sodegren's understanding is that if a nurse is in the diversion program, that nurse is restricted from practice for 90 days. Any board's enforcement process can take time because of due process. Ms. Herold added that an admission by a colleague that a professional is under the influence can help speed up the process. Another alternative is to involve the police, although the police may only arrest under petty theft or embezzlement. The key would be to make sure that the police are aware of the violations of the business and professions code, so that the penalties are stronger and the provider can be removed from practice.

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

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

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

- Another participant commented that this dialysis scenario was very significant during the heparin recall. They realized that the dialysis staff who bring in their own drugs did not have a consistent standardized notification process. To remedy the situation, their facility included dialysis staff in the notification process.

- A participant commented that organ procurement staff bring in their own medications and another participant added that samples are also a problem

- The Veteran's Administration Hospital in San Francisco has a "no outside source, no sample" policy. There is a disciplinary policy to support this policy. One difficult enforcement area is providers who carry medications in their pockets.

- With a patient's own insulin pump, there is no way to identify what's inside. Surgery kits pose similar challenges. Surgery kits are tricky because are they a drug or device? Are they considered under the regulations?

- A participant commented that physicians are not employees of hospitals and hospitals are at the mercy of doctors. Taking away a physician's privileges because he or she violated a no outside drugs policy may compromise the care provided by that hospital. This can be even more complicated in small communities with fewer doctors, where doctors practice at multiple hospitals or there are just too few doctors for the community.

- Anesthesiology and emergency room services are contracted out, so they have their own their policies that don't always match the hospital's policies. The group agreed that they have the option to spell out specifics in the contract.

- A participant pointed out that no administrator has his or her name on a license, so there isn't the same level of personal responsibility like nurses, lab directors, and pharmacists. A skilled nursing facility has a professional on the license; in general, licensed professionals have more to lose.

- Dr. DeMartini from CDPH confirmed that a nursing home has to have a licensed administrator and she added that an administrator's name does appear on a hospital license as well. She also clarified that if you have 100 beds or more, there's a hospital license that has to be used with a Pharmacist-in-Charge. A hospital with 99 or fewer beds still requires a pharmacist to run services, but there's a difference.

- A participant noted a trend with decentralized pharmacies (satellites) with centralized distribution. She added that rampant use of satellites throughout the hospital may not be the best use of resources especially in light of technology and pyxis storage units.

- A participant commented that the main problem with satellites was the belief that the same rules that apply to centralized pharmacies, apply to satellites. The main problem with satellites is that people grab their own drugs. There was a consensus that drugs need to be centralized and pharmacists need to be decentralized.

- Satellites initially were a way to have more control over the drugs and get pharmacy out of the basement, but now there is no need to have a satellite to justify having a pharmacist on the floor.

6. Additional Public Comment

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

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

7. Closing, Evaluation, Adjournment

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

The meeting was adjourned at 2:30pm

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

ACTIONS:

Procedural:

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

Know Drug Storage Areas in hospitals:

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

Wholesalers

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

Technology-Based:

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

IMPROVEMENTS

Notification System for Recalls Needs Improvement:

- Recall notices should state whether this is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
- Message is not always clear. Improve and simplify messages regarding recalls.
- To avoid confusion, create recall notices with more uniform language or have notice come from one source.
- Have a more effective notification system that originates in one place, listing what the issue is, what should be done, what steps should be taken, etc. Having one notice from one source with all the relevant information would minimize confusion.
- Establish a centralized method to interpret and disseminate information about recalls.
- Have a centralized system or body in a hospital that would distribute recall information 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

Tracking of Drugs Throughout the Hospital:

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

Staffing/Lines of Authority:

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

"Geographic"

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

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

Name (optional): _____

Facility (optional): _____

ACQUISITION

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

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

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

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

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

(over)

STORAGE/MANAGEMENT

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

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

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