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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: July 23 - 24, 2008

LOCATION: Radisson Hotel
4545 MacArthur Blvd.
Newport Beach, CA 92660

BOARD MEMBERS PRESENT:

Ken Schell, PharmD, President
D. Timothy Dazé, Esq., Public Member, Vice President
Stanley Goldenberg, RPh
Henry Hough, Public Member
Robert Graul, RPh
Stanley C. Weisser, RPh
Shirley Wheat, Public Member
James Burgard, Public Member
Andrea Zinder, Public Member
William Powers, Public Member

STAFF PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Senior Staff Counsel
Tina Thomas, Staff Analyst

The board meeting was called to order at 9:05 a.m.

President Schell recognized John Jones, past member and board president.

President Schell recognized Rich Mazzoni past board member and president.

President Schell recognized Clarence Hiura, past board member.

President Schell introduced two new inspectors of the Board of Pharmacy staff, Ben Rustia and Anna Yamada.

President Schell recognized all of the students that have taken time to attend the board meeting. He added that the board appreciates their attendance and looks forward to their future participation.

President Schell recognized Lynn Rolston from the California Pharmacists Association (CPhA).

President Schell recognized Bob LeWinter, whom will be presenting today on behalf of the California Department of Public Health.

Virginia Herold provided additional announcements.

Ms. Herold indicated that the Department of Consumer Affairs is completing their annual report and will need a picture of each board member. She asked the board members to contact Tina Thomas prior to the end of the meeting in order to take their picture.

Ms. Herold shared examples of Prescription Drug Bingo, which were created by board staff for a team-building event at the staff meeting last month. She was very impressed by the creativity and professionalism.

Ms. Herold advised the board members of a clothing line with the Board of Pharmacy logo, now available for purchase. She passed around a catalog. She explained that the board staff receive a portion of each purchase as a fundraiser for teambuilding events.

Ms. Herold indicated that the July issue of *The Script* is available outside of the meeting room. The newsletter was mailed to all pharmacies and wholesalers. She noted that it is also included on the website so that individual pharmacists can download the newsletter as well.

President Schell recognized Sam Shimomura, the Associate Dean from Western University School of Pharmacy.

I. Approval of the Full Board Minutes of April 23 and 24, 2008

President Schell referred to the draft board meeting minutes of April 23 and 24, 2008 provided in the board packet.

MOTION: Approve the board meeting minutes of April 23 – 24, 2008.

M/S: BURGARD/POWERS

SUPPORT: 9 OPPOSE: 0

II. Approval of the Full Board Minutes of June 24, 2008

President Schell referred to the draft board meeting minutes of June 24, 2008 provided in the board packet.

MOTION: Approve the board meeting minutes of June 24, 2008.

M/S: WEISSER/HOUGH

SUPPORT: 9 OPPOSE: 0

III. Enforcement Committee

A. Discussion and Action on the Federal Drug Enforcement Administration's (DEA) Proposed Rule to Allow E-prescribing of Controlled Substances

Mr. Dazé indicated that at the June 24, 2008 Board Meeting, the primary topic was e-pedigree enforcement matters. He noted that there has been no independent Enforcement Committee meeting since the June Board Meeting.

Mr. Dazé indicated that in late June 2008, the DEA announced proposed regulations to allow the e-prescribing of prescriptions for controlled substances. He stated that the proposed rule would allow pharmacies to receive and dispense controlled drugs pursuant to electronically transmitted prescriptions. Mr. Dazé noted that comments are being solicited by the DEA, and are due September 25, 2008.

Mr. Dazé indicated that the proposed rule from the Federal Register and a press release from the DEA regarding this proposal are contained within the board packet provided.

Mr. Dazé stated that for a number of years, the board has awaited the DEA's approval of electronic transmission of controlled substances prescriptions. The board has actively sought such a policy shift in the belief that such transmissions will benefit patient care.

Board discussion:

Stan Weisser noted that the Federal Register refers to a lot of different communication devices which can be used to transmit prescriptions. He gave the Blackberry as an example. Mr. Weisser stated his concern over network security issues with handheld devices and the ease of passing information in an unauthorized and illegitimate manner. He stated that he is also concerned over the cost. He explained that he is under the understanding that there could be a cost to the pharmacies for the prescriptions generated.

Deputy Attorney General Joshua Room asked if it would be helpful to the board if he provided a brief summary of the requirements of the DEA rule.

President Schell responded that, prior to such a briefing, he would suggest a motion to prepare comments for the DEA.

Ms. Herold provided background on the need for e-prescribing. She gave history on the law and provisions made for data transmission in 1994. Since then California has been able to e-prescribe. The DEA prevented full implementation because they would not allow e-prescribing for controlled substances. Ms. Herold explained that the new law that is being proposed provides for the opportunity to include controlled substances in e-prescribing. She addressed the questions raised by Mr. Weisser and said that they seem to apply to all prescriptions, not just controlled substances. Ms. Herold stated that that is more global than the topic being addressed today. She added that, for a number of years, the board has been a strong proponent of e-prescribing including controlled substances. Ms. Herold responded to Mr. Weisser's concern over security, and stated that the pharmacy will be responsible for the verification of the prescription by a legitimate prescriber, just as they are currently responsible with a paper prescription.

Stan Goldenberg stated that he supports any activity to lead the profession to an electronic media prescribing network. He stated that he thinks patient safety would be tremendously improved and

would allow for better efficiency by way of more interaction between professionals and their colleagues and patients. He added that he understands the security and cost challenges, but that the overall movement for e-prescribing is well overdue. Mr. Goldenberg stated that the board should continue its path of assisting and providing recommendations to the DEA in order to move this as fast as possible into reality.

Mr. Dazé shared with the board that he had read an article recently which stated that Medicare is requiring e-prescribing by 2012. He pointed out that regardless of what the board does, e-prescribing of controlled substances will happen. Mr. Dazé stated that the board should do whatever they can to put thoughts together for the DEA for the protection of the consumer.

Mr. Goldenberg added that maybe stakeholders can help the board by giving their thoughts to the DEA.

Mr. Weisser stated that he agrees conceptually with the discussion. He pointed out the advancement in technology today, providing the Blackberry as an example, and reinstated his concern over the liability for receiving pharmacists in verifying the orders. Mr. Weisser's concern is over how easy it is for "hackers" to gain access, and added that it seems that technology has brought as many problems as benefits.

Bob Graul provided information on a pilot conducted in Rhode Island by Surescripts, an organization that handles Internet transmissions. He stated that it was very successful and suggested contacting them for feedback on the pilot. He also stated that the board needs to reach out to the Medical Board. Mr. Graul noted that some physicians and medical offices aren't as advanced in technology as the pharmacies and input from them would be useful. He stated that he agrees that it is one of the most important things they can do for consumer protection.

Bill Powers stated that he would like to accept the offer from counsel for background on the proposed rule.

Mr. Room restated that it might be helpful for the board to understand what the register notice does and doesn't do. Mr. Room pointed out that, although the register is very detailed about some items, it is not detailed about what the network security requirements would be. Mr. Room added that he thinks the assumption would be that it would be covered under normal HIPPA protections. Mr. Room proceeded to explain some of the register requirements. He noted that, as Mr. Dazé stated earlier, Medicare will be requiring e-prescribing. Therefore, some of this is being placed in parallel with Medicare Part D requirements, and that exemptions are already in place for federal health care providers who are already complying with the Medicare Part D timeline. Mr. Room detailed the three requirements for non-Medicare prescriptions. The first requirement is that the prescriber must be "in-person identity proofing", which means that the prescriber must go to an appropriate federal agency and complete the identity proofing process The second requirement would be to obtain and utilize "two-level authentication" during e-prescribing. Those two levels of authentication are a logon id (i.e. password) and a hard key used to authenticate into the system. The third requirement is a digital certification which needs to be done by the service provider, rather than the prescriber. As the third requirement involves the service provider, this will allow for at least one intermediary to complete their own identity proofing prior to receipt by the pharmacy, thus removing complete responsibility on the pharmacists and pharmacies.

Mr. Room questioned the board as to whether they would like to conduct discussion on the specifics of the requirements as he has just detailed. He indicated that the letter could be a more general statement of support or a more detailed response to the particulars of the requirements.

Mr. Goldenberg suggested that a timeline be provided in the content of the letter. He noted the group of interns and students attending today's board meeting, and pointed out that they will be coming into the profession to serve the public and should be able to perform at the level that they are trained. He stressed that the idea of implementing a timeline and the importance of adhering to that timeline.

Mr. Room added that the required economic analysis determined that there would be a significant economic impact, which may likely drag out the timeline for implementation. Mr. Room stated that he could conduct research on how that will affect the board's input on a timeline.

Mr. Goldenberg stated that he would also like to have the letter created as an independent entity, not sponsored by any stakeholders of industry, so that it is not used to influence how medicine is practiced, but rather to benefit both the profession and the consumer.

Andrea Zinder asked for clarification that the motion of support is to allow e-prescribing of controlled substances, rather than to mandate. She asked for clarification that the e-prescribing would still be optional on the part of the prescriber even if a timeline is added.

Mr. Goldenberg confirmed that it would and clarified that the board is only providing comments to prepare a plan.

Mr. Powers stated that he feels the board should suggest that e-prescribing be more required than not. He stated that historically the medical profession does not want to participate for various reasons and that may not want to have these requirements imposed on them.

Public comment:

Kenn Horowitz stated his concern that physicians would turn over their handheld devices which contains their security codes to someone else in their office to conduct e-prescribing on their behalf. He stated the he feels a penalty should be required if that occurs.

MOTION: To prepare comment for the federal Drug Enforcement Administration in support of the proposed rule to allow e-prescribing of controlled substances.

M/S – WEISSER/GRAUL

SUPPORT: 9 Oppose: 0

Ms. Zinder asked if the comments should go back to the Enforcement Committee prior to submitting to the DEA.

Ms. Herold stated that the comments are due by September 25, 2008. She stated that an Enforcement Committee meeting has been rescheduled to the week of September 15th. She said that they can wait until that meeting, but typically the president would review the comments.

Steve Gray (Kaiser Permanente) stated that they are predicting the comment period to be extended. He suggested that the Board ask for an extension and stressed the significant ramifications of this law. He also suggested that the board should have a contingency plan for the enforcement committee in the event that there is an extension past the current deadline.

B. Discussion and Action Regarding Efforts to Implement E-Prescribing

Mr. Dazé stated that a number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing for all medicine. He indicated that a principal reason is that statistics indicate that medication errors cost the health care system $77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing.

Mr. Dazé stated that by in the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. He advised that, since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions.

Mr. Dazé said that an important piece needed to permit full scale adoption of e-prescribing is the ability to prescribe controlled substances via this manner. Federal requirements prohibit the use of e-prescribing; however, with the DEA reconsidering its position on e-prescribing of controlled substances, wider adoption and use of e-prescribing can be expected.

Whereas controlled substances account for 10-15 percent of prescription drugs dispensed, the inability for these drugs to be e-prescribed has been considered a deterrent to wide adoption of e-prescribing.

Mr. Dazé stated that some of the major California laws that support e-prescribing, as well as various background articles about e-prescribing, are provided within the board packet.

Mr. Dazé explained that e-prescribing includes both facsimile transmission of prescriptions (where a prescription document is created and then electronically forwarded to a pharmacy via a fax) or data generation of a prescription (in which case a prescription has not been handwritten but instead electronically created on a hand-held device or computer and sent electronically to a pharmacy).

Mr. Dazé said that while California law supports e-prescribing, many prescribers do not use this technology. Over the prior few years, repeated efforts to encourage and facilitate e-prescribing have not resulted in wider adoption. This includes efforts by the Schwarzenegger Administration to require e-prescribing by 2012 in its health care reform proposals earlier this year. Mr. Dazé indicated that excerpts of those provisions (which were not enacted) were provided within the board packet.

Mr. Dazé stated that one element of these proposals is often to enable e-prescribing to include integration of a patient's health history and prescription benefit coverage at the time of prescribing. This would prevent errors and benefit coverage lapses for a particular drug that could be known to a prescriber at the time a prescription order is created. He indicated that essentially at the time a medicine is prescribed, the electronic device would check a patient's medical record for allergies, contraindications, etc., and whether a particular drug is covered by the patient's health benefit.

Mr. Dazé said that one problem with e-prescribing is that some systems include too many drug choices in diverse dosage combinations that may be unfamiliar to prescribers. In these cases, wrong medicine may be mistakenly prescribed because a wrong choice is mistakenly selected. He noted that several articles describing this problem are contained within the board packet provided.

Mr. Dazé indicated that one solution to this problem is for limited formularies to be pre-programmed into a device for particular specialties or groups of prescribers. Many practices are doing this currently to prevent having too many drug options appear on the screen. Nevertheless, pharmacist

review of the prescription order is still a needed and is an important "double check" to protect the health of patients.

Board discussion:

Mr. Powers confirmed there were no recommendations from the committee meeting.

Mr. Powers asked if the administration has any legislative proposal.

Ms. Herold responded that there is none that she is aware of, but that the provisions in the Assembly Speaker Health Care bill originated with the administration.

C. Discussion and Action Regarding the Board's Heparin Recall Inspections 2008

Mr. Dazé stated that by early June, the board had completed its inspections of 533 hospital pharmacies in California and identified 94 hospitals where recalled drugs were still in patient care areas. He stated that enforcement activities are now underway, and will include citations and fines to the pharmacies, pharmacists–in-charge and consultant pharmacists for failure to secure the hospitals' drug supplies by allowing recalled drugs to remain in the pharmacies, dispensing machines and in patient care areas. Mr. Dazé noted that several pharmacies who were found with recalled heparin will not be sanctioned because they received recalled drugs from wholesalers after the recall took place, although the wholesalers who shipped these recalled drugs will receive sanctions.

Mr. Dazé indicated that additional investigatory elements with these inspections and subsequent investigations, including activities with the Department of Public Health, would be released in the future.

Mr. Dazé said that another long-range outcome would be a joint report with the California Department of Public Health on what deficiencies have been identified in the recall system. The regulatory oversight of recalls is prevue to the FDA. He stated that recommendations would be made to improve the recall system, which clearly is not effective in removing recalled drugs. Mr. Dazé noted that California is again at the forefront of this problem, in part, because we are the only state to have specifically looked for recalled drugs in facilities after the recall took place. Alarmingly, recalled drugs have been found far too frequently in California facilities – and the existing recall system is broken and needs repair.

Mr. Dazé indicated that one recommendation will be to require all pharmacies to become sign up for notification from the board's *Subscriber Alert* system so that electronic notices to the pharmacies about important recall information is widely and immediately released to all pharmacies.

Additionally, informational/educational articles will be developed for the board's newsletter about what actions pharmacies and pharmacists are expected to undertake for recalls. Questions will be added to the board's pharmacist licensure examination to ensure future pharmacists seek and maintain this knowledge as well.

Mr. Dazé added that the use of serialization of products throughout the supply chain, as will be required under California's e-pedigree law, would have allowed a far more complete recall of heparin and Digitek (and all future recalls) because the pharmacies would know specifically which recalled containers it had received from a wholesaler or manufacturer, and by checking the decommissioning data, would have known exactly what containers to look for. Wholesalers would have known what recalled product they received, and where the recalled items had been shipped.

Board discussion:

Mr. Weisser asked what the board would have to do to require pharmacists to join the Subscriber Alert program.

Ms. Herold responded that they could encourage pharmacies to subscribe now. She noted that there are over 5000 entities on the Subscriber Alert at this time. She stated that in order to mandate it, it would require legislation. This proposal could be a discussion item at the October board meeting.

Mr. Powers asked if this should be referred back to the Legislation and Regulation Committee.

President Schell agreed that would be appropriate. He added that they should get input from key public entities and pharmacies before mandating any type of regulation or legislation on subscribing.

Mr. Goldenberg asked Ms. Rolston (CPhA) what her input has been and what feedback she has received from colleagues at CPhA about being required to subscribe.

Ms. Rolston responded that the feedback she has received was in support. She stated that one of the current issues CPhA has discussed is that, in the event of disaster, there is no way of reaching the pharmaceutical industry as a whole because there is no entity that has an e-mail list for everyone. Nelson added that even though CPhA, the Board of Pharmacy, and other such agencies put out information through wholesalers, etc., they are not "reaching the universe". She said that she doesn't think it requires a lot of time or effort to subscribe and finds it difficult to believe anyone would object. She referred to the San Diego fires, and noted the challenges in communication during those natural disasters. She stressed that driving this piece of communication through the network was crucial.

Mr. Dazé asked if there is a cost to subscribe.

Ms. Herold responded that there is not, other than an internet connection charge which most pharmacists already pay for. She stated that there does not seem to be concern over subscribing, but rather widespread support. She noted the need for subscribers to keep their e-mail address current so that the board can continue to reach them when it is crucial to do so. Ms. Herold reiterated that they cannot rely on the current communication systems in place at this time. She noted that there will be a report done jointly with the Department of Public Health (DPH), which will hopefully be available for release by the October Board Meeting. She added that it is a joint effort with the FDA, DPH and the Board of Pharmacy.

Mr. Dazé asked if the board placed an alert out on the recall.

Ms. Herold responded that the board put multiple alerts out. She stated that as they continued to find pharmacies with the recalled drugs in their facilities, they continued to alert the practitioners on the subscriber list. Public speaking engagements also occurred, where the recall was announced. She added that "all facility letters" were also sent out, yet 23% of the facilities still had recalled drugs on their shelves.

Mr. Dazé provided his viewpoint as an attorney. He stated that if he had a client who had received a recalled drug, and the pharmacist who dispensed the drug had received such an alert, he would see that as severe negligence on the part of the pharmacy.

Mr. Goldenberg stated that he hopes the board doesn't limit this to pharmacies only. He noted that the board has over 100,000 licensees that they oversee, with only 5,000 that subscribe. He

suggested that the requirement should be to all licensees and possibly even other boards for physicians, dentists, and veterinarians, for example.

Mr. Graul commented that the current state of communication for more rural pharmacies is less than ideal. He added that the Subscriber Alerts are extremely useful. He stated that in the past his pharmacy would often find out about recalls initially by a patient bringing in a newspaper article. Mr. Graul strongly supported a requirement for pharmacies to subscribe and would not be opposed to requiring other boards and their licensees.

Mr. Goldenberg added that he would like interns to be required to subscribe as well.

D. Update on the Implementation of Drug Take Back Programs

Mr. Dazé explained that last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) authorized the California Integrated Waste Management Board to develop regulations for model drug take back programs for prescription drugs. These regulations are to be developed by December 2008.

Mr. Dazé further explained that Senate Bill 966 was a response to repeated efforts by communities and patients to find appropriate and "green" ways to dispose of unwanted drugs. He stated that these include receptacles at outreach events or at waste disposal sites, pharmacies and other locations (e.g., city halls). A particular problem is what to do with unwanted controlled drugs, where the pharmacy is prohibited by federal requirements from accepting these drugs back from patients, where the loss of the DEA permit is one sanction for such violations.

Mr. Dazé stated that the reality is that there is no good solution currently, to advise patients about what to do with unwanted or outdated prescription and OTC medicines they have in their possession. While pharmacies do have options to return unwanted drugs they have not dispensed to reverse distributors, pharmacies are not authorized to take back prescription medicine from patients for disposal.

Nevertheless, some pharmacies in California and in other states are part of a growing consumer movement seeking a green way to ensure that disposal of unwanted drugs is done ecologically.

Mr. Dazé advised that for the last few months, there have been meetings with various state agencies involved in establishing parameters for pilot programs for implementation of SB 966. He noted that these include the Board of Integrated Waste Management, the state and regional water resources agencies, the Department of Public Health, Toxics, and the Board of Pharmacy.

Mr. Dazé noted that last week, the board's executive officer spoke at a conference in San Diego to interested parties, principally representing waste disposal, about how to dispose of sharps and unwanted pharmaceuticals. He stated that it is clear that regulators have no law that adequately addresses how patients should dispose of unwanted pharmaceuticals and sharps, and that community waste management representatives see these items as "waste" without any value to diverters. However, other agencies (e.g., DEA, Board of Pharmacy) recognize the value caches of returned drugs offer to diverters and those seeking unregulated access to pharmaceuticals.

Mr. Dazé indicated that the pharmaceutical supply chain is carefully regulated with respect to the movement of pharmaceuticals from manufacturers to wholesalers to pharmacies to patients, but once items are dispensed to patients, existing law does not specify how patients are to get rid of unwanted prescription items. He stated that, on the waste management side, once collection of pharmaceuticals occurs into an aggregation (such as a collection center), this aggregation is

considered medical waste and toxic, and must be handled as such by specific regulated entities. For patients with unused medicine, especially controlled drugs, there are few solutions.

Mr. Dazé advised that state regulators will convene meetings in the next few weeks to discuss what directions each of the agencies may take based on their respective jurisdictions.

Meanwhile, new problems are emerging. Mr. Dazé advised that this week, the board's staff was confronted with two new but related issues involving unwanted dispensed medicine and devices: (1) are pharmacies required to take back sharps containers and (2) how to dispose and track overages in potent controlled substances that are typically found in containers of medicine (e.g., a 10 ml container actually has a manufacturer overage of 1 ml, which turns out to be left after 10 mls have been removed to administer to a patient).

Mr. Dazé said that vendors have seized a market opportunity and are selling mail-box type containers that are being used to collect medicine and sharps from patients. He noted that these containers have been installed in city halls, senior centers and in some pharmacies. The board is unaware under what authority these containers are being placed in these facilities, and who is responsible for thefts from the units. Mr. Dazé indicated, however, that the mailbox containers are aggregate collectors of drugs, and their contents are considered hazardous waste, which must be handled according to specific requirements by specialized staff.

Mr. Dazé stated that the DEA's current position is that controlled drugs cannot be returned to pharmacies or to these take-back containers, and will remove the DEA permit of entities that take back controlled substances. However, the DEA may be changing its position on this policy, and moving to a solution. Mr. Dazé concluded by indicating that there is no place a patient can return an unwanted controlled substance, unless the police department will take it.

Mr. Dazé noted that a survey developed by the California Integrated Waste Management Board is contained within the board packet provided.

Board discussion:

Mr. Powers asked if it is the role of the board to offer solutions.

Ms. Herold responded that there is no solution, and that is part of problem. She stated that there are two groups involved who represent different interests – one group being those on the regulation side (including the Board of Pharmacy) and the other being those who deal with waste collection. She pointed out that from the viewpoint of the waste collection entities, the more segregated the waste becomes, the more expensive it becomes for them. Ms. Herold added that their whole system is set up in that trash has no value, only expense. They also see it as a risk for those collecting these waste units. Ms. Herold advised that, since the preparation of the summary provided by Mr. Dazé, she has learned that there is a bill that is being modified. She also advised that there is a law that goes into effect September 8th, 2008 that prohibits sharps containers from being disposed of in landfills. There are no previsions to take back sharps containers, however. She noted that there are over a billion needles being generated in California. Ms Herold stated that she drafted language to give to Senator Simitian, the author of the bill, to allow pharmacies to have the option to take back sharps containers so that the pharmacists are not placed in a position of being held liable for violating the law if they take back sharps for disposal. She noted that there will be costs to the pharmacies, which will be expensive. One option being considered to lower cost is to have common carriers pick up the materials instead of licensed waste-haulers. She pointed out there would be a big difference if that were to occur, as the board does not have the same authority over common carriers as they would with a waste-hauler.

Mr. Room asked if the issue of removing the materials needs to be determined by December.

Ms. Herold responded that they are rewriting the hazardous waste act and will probably make it to the governor.

Mr. Room stated that Integrated Waste Management board has to come up with regulations by December. He asked what they are doing in regards to that.

Ms. Herold responded that the survey provided in the board packet is what they are using to collect the information. She stated that the Integrated Waste Management board plans to learn the components of the model program, and evolve the components into regulations. She indicated that the two tracks are going on simultaneously, and added that there are a series of meetings scheduled with the DEA, Board of Pharmacy, the Department of Public Health, California Retailers Association as well as a few entities on the regulating side of the issue. Ms. Herold emphasized the high cost involved in the take back programs and the issue of requiring the pharmacies to take on the cost burden of the program since they are the ones who sell the drugs initially. She added that the best option they can hope for is to allow the pharmacies the ability to charge their patients for the disposal service, as there is a cost to society in allowing the drugs to go back into the waste dumps or down the drain. Ms. Herold welcomed any input and solutions to assist in solving the pharmacy waste program issue.

Mr. Powers asked what the pharmaceutical firms do with drugs they end up with.

Ms. Herold responded that they incinerate them. She added that it is very expensive because specially licensed personnel handle them.

President Schell stated that he has a lot of concerns over the potential requirements, as there are other industries with similar hazardous products whom are not required to take back their hazardous products. He gave the examples of manufacturers providing oil, gasoline and paint. He pointed out how there have been other solutions to those products in terms of waste disposal and does not see pharmaceutical waste as any different in that regard. President Schell agreed that the drug waste is an environmental toxin, but does not know if it is pertinent for pharmacists to take drugs back without the ability to divert the costs for pharmacies. He also agreed that there needs to be a way for consumers to dispose of their drug waste in a safe fashion, but does not feel that the requirements which the bill would impose is going to allow for that.

Ms. Herold stated that she thinks the current law is tough on pharmacies in requiring them to take back anything they sell. She indicated that some efforts have been made to require manufacturers to pay for some method of disposal. She gave an example of the DEA's intention to require a self-addressed mailer to be provided by manufacturers whenever a controlled drug is shipped.

Mr. Graul asked if the common carriers would be aware of what they will be carrying. He added that he wasn't sure they would agreeable to carrying potentially hazardous products.

Ms. Herold responded that her understanding is that they are. She added that other solutions have been presented as well, such as cutting back supply from 30 days to three days.

Mr. Goldenberg gave an example from a recent conference he attended, and stated that a speaker was talking about security issues. He shared that the criminals have become more sophisticated in their theft attempts. He explained that, because the don't want to go to the difficulty of finding the drugs disbursed among the stores, they often will simply go the next step and hijack 18-wheelers transporting the drugs instead. Once they have the knowledge of boxes full of drugs being shipped on carrier trucks, they will target them as well. Mr. Goldenberg added that this danger needs to be

brought to the attention of the common carriers and drivers, and believes that they will fight such a mandate to avoid the dangers it brings. He suggested that they bring the information provided to the committee to ensure that they are fully aware and informed of the consequences before it is moved forward.

Mr. Room asked Ms. Herold if it would be helpful to have something in writing from the board that lays out the categories of concerns identified by the board and audience. He added that doing so might help to provide clear support from the board in terms of the safety and health issues to counterbalance the waste management issues that are cost driven.

Ms. Herold responded that she thinks the committee is listening "one speaker at a time", and that they are dealing with a whole group of people who do not see waste as anything other than waste, which has no value. She acknowledged that the board sees things from our own focus in return. She stated that the board needs to get involved to assist the consumer who is "stuck in the middle" and find ways for them to dispose of their unused drugs responsibly. Ms. Herold added that, in order to do that, consumers may need to pay more to dispose of the drugs. Ms. Herold stated that the committee is listening to the Board of Pharmacy and their input, and added that she recently spoke to the group in San Diego by providing a presentation on the drug abuse issue in California.

President Schell asked if it would it be helpful if the board provided a written document detailing the main concerns raised by the board and distribute it to those involved in the activity of this issue.

Ms. Herold responded that it certainly wouldn't hurt.

Clarence Hiura asked if anyone has contacted the mortuaries in terms of the option of incineration.

Ms. Herold responded that it might be a good suggestion.

Mr. Goldenberg referred back to the 1980 time period, when there was a large concern over infectious waste and how it was disposed. He explained that, at that time, the Department of Health Services approved the ability to incinerate such waste in mortuaries. Ultimately, it was shown that the incineration was not adequate because the temperature for cremation is not the same as the required temperature for destruction.

Sam Shimomura (Western University) shared the issue of terminal cancer patients who receive large amounts of prescriptions at home. He stated that in many cases, when a patient passes, their family members' have the drugs accessible in their home and are subsequently taking the drugs as suicide attempts. Dr. Shimomura asked if the pharmacy should take the drugs back and who has ownership of the drugs.

Ms. Herold responded that, according to DEA regulations, if the pharmacy takes back the drugs, their DEA permit is at risk. She added that the only option is to refer the family to the local police department, which is the only entity that the DEA will recognize as a legitimate option for disposal right now.

Steve Gray (Kaiser Permanente) stated that it is important to speak to this as two separate issues - sharps as one, and take back drugs as another. Dr. Gray advised that there is a new law going into effect on September 1, 2008, that states consumers cannot dispose of sharps in anything other than sharps containers, and that the sharps containers cannot be placed in standard waste containers of any kind. He stated that there is a concern over counties who are considering passing local ordinances to require pharmacies to take back sharps containers. Dr. Gray gave San Luis Obispo County as an example. He pointed out the issue of a conflict of laws within counties, cities and the state. Dr. Gray stated that there are several problems caused by the unwanted drugs. He added his

opinion that water contamination is the least of the problems, whereas misuse of unwanted drugs by other people is the bigger issue. He gave examples of senior centers where they are sharing unwanted drugs amongst each other. He also gave the example of hospice patients where family members own the drugs when the patient passes, and are less likely to know what to do with them. Dr. Gray also provided an example of a hospice staff member of Kaiser who was charged for taking back drugs from family members. Dr. Gray discussed the cost of disposal. He stated that there are only three places in the United States where one can legally dispose of unwanted drugs, and none of them are in California. He added that the disposal by incineration must be at a temperature of 2500 degrees Centigrade because it is a chemical, rather than physical, incineration. Dr. Gray shared that the three legal disposal locations are in Texas, North Carolina and Utah, with three different types of disposal methods. He added that the high cost of disposal options by weight has motivated entities to discard the containers in order to lower cost, which then causes safety issues with loose drugs and handling issues. Dr. Gray stated that the board should address the issue of local entities attempting to mandate ordinances on the matter of disposal, as well as support and provide input on regulations of the model program of SB 966. He added that the supporters of SB 966 believe strongly that the programs should be voluntary.

Cookie Quandt (Long's Drugs) agreed with Dr. Gray's comments and emphasized the needs for the sharps and take-back program to be divided into two separate items. She stated that, as a retailer, they are very concerned over the local ordinances being placed in some counties as Dr. Gray had mentioned prior. She added that there is a lack of sufficient information being provided to consumers regarding the new requirements of the sharps and take back program which will go into effect on September 1, 2008. As retailers, the local ordinances would require them to provide disposal units to for the public for sharps. Dr. Quandt stated that the cost is very high, with pick-up service from a certified waste-hauler at $700-$900 each. She indicated that Long's is actively participating in the take-back program. She restated that the solutions can not include a requirement of the pharmacies to incur all of the cost. Dr. Quandt pointed out the requirement within SB 966 that there be no cost to consumers, and feels that this should be revisited.

Mr. Room asked if the mandatory sharps take back is tied to what is sold from that location only.

Dr. Quandt responded that it does not specify. She pointed out those patients who receive their syringes in the mail and expect to receive those to be returned within their pharmacies as well. It has been suggested that the pharmacies "tag" their sharps in some way to indicate where they were purchased, which is infeasible. Dr. Quandt pointed out that it would be virtually impossible to take back only the ones sold by them.

Mr. Powers asked if there is any information on how other countries are handling the situation.

Ms. Herold responded that she has no knowledge of that.

Mr. Goldenberg stated that he is only hearing reasons of why this can't be done. He stated that Ms. Herold needs to be provided with information on how it can be done. He asked if anyone has talked to the reverse distributors that we license to receive their input.

Ms. Herold responded that the two companies that are the largest reverse distributors are very involved in the meetings.

Mr. Goldenberg raised the issue of educating the public. He referred to the large amount of direct to consumer advertising occurring currently, which includes the disclaimers at the end of those ads. Mr. Goldenberg suggested a cooperative effort to pass on the information to consumers about the disposal of drugs in a similar manner. He added that it would need to be on a national basis and

would provide awareness to the consumer while possibly bringing more affected parties to the table on the issue.

Dr. Quandt addressed Mr. Goldenberg's comments. She commended Marin County's sharps take back program in place, pointing out that they have all of their pharmacies participating in the program, as well as educating and providing awareness to the public. She added that the county pays for that cost, as well as arranging and providing reception bins and pickup service. Dr. Quandt indicated that other counties cannot afford to do the same, however, and need to be able to place the cost elsewhere.

Mr. Powers stated that he called Sacramento County to find out what to do with medications no longer needed. He stated that they told him to put the drugs in plastic bottle, wrap it with duct tape and place it with the weekly trash.

MOTION: To draft a written document from the board which provides input and concerns relating to the health and safety of the public on the current proposed solutions to the drug take back program.

M/S: GRAUL/BURGARD

SUPPORT: 9 OPPOSE: 0

E. Update of the Committee's Strategic Plan for 2008/09

Mr. Dazé indicated that the plan is contained within the board packet provided.

MOTION: Approved the update of the Committee's Strategic Plan for 2008/09.

MOTION: WEISSER/BURGARD

FAVOR: 9 OPPOSE: 0

F. Citation and Fine Program

Ms. Herold provided a presentation on the Board of Pharmacy's citation and fine program, which included statistics over the last few years relating to medication error cases. She noted that the figures will have some variances due to open cases which are at different stages at the year end.

Ms. Herold provided data from 2005 - 2006 on cases involving drug errors. The statistics indicated that the leading reason for cite and fines in that year was due to the wrong drug being dispensed to the patient. Statistics were also presented which showed the majority of fines were issued at $250.

In 2006 - 2007, the statistics indicated that majority of errors were due to wrong strength, followed closely by wrong drug. The majority of these cases resulted in no fines, but there was an overall increase in the fine amount from last year to $500 – $750 for those cases which did result in fines.

In 2007- 2008, statistics indicated that the top reasons for medication errors was due to the wrong drug being dispensed, and the amount of these types of errors was significantly higher than the other violation cites – wrong drug strength and wrong instructions. The majority of medication error

cases resulted in no fine, but there was also an increase from last year in the average fine amount to $500-750 for those cases which did result in fines.

Ms. Herold reviewed lists of the most common drugs involved in errors for the last four years and provided a comparison of the similarity in names which has resulted in many of the prescription errors. Ms. Herold stated that board staff will include a list of some of the similarly named drugs in the next *Script* newsletter along with an article on medication errors. She indicated that this has been done in the past on a routine basis. Ms. Herold noted that the next article should run in the January 2009 issue.

Ms. Herold provided specific examples of cases where the fines were $500 and above. She noted that the issue of "ml" versus "teaspoon" directions is a large issue with patients, as they do not understand the difference. Ms. Herold also noted that the fines were raised in cases where there was a failure to provide a consultation. She added that the cite and fine amounts should remain within the current range for a while.

G. Enforcement Statistics 2007- 2008

Mr. Dazé indicated that the 2007-2008 Enforcement Statistics are contained within the board packet provided.

Public Comment:

Lynn Rolston (CPhA) stated that CPhA would like to applaud the board for their ability to reduce medication errors. She advised that there is a lot more interest from the industry since the increase of cite and fines. She added that many of CPhA's members and board members are interested in finding ways to have proactive communication on current trends and issues amongst the industry prior to being issued a cite and fine. Ms. Rolston suggested a task force to help collect statistics and share them with the industry in an effort to stay on top of current problems. She requested this be added as an agenda item for the next Enforcement Committee meeting.

President Schell agreed with Ms. Rolston's suggestion, and stated that the board will consider moving this item of discussion into the Enforcement Committee as an activity.

Mr. Graul stated that education to the industry on the cite and fine process is critical. He provided an example of a customary question within the industry relating to whether there is specific protocol for fine amounts.

Dr. Gray (Kaiser Permanente) stated that the California Pharmacy Foundation is doing a lot of work to prevent prescription errors. He stated that he is unaware of any guidelines being provided to board staff which would include specific criteria on determining when to cite and fine and the appropriate amount. He said that it is important for board members to have an idea of that criteria as well. He said that when he talks to board members, they are not aware of what the board staff uses to determine the cite and fine portion of disciplinary action. Dr. Gray also raised the issue previously addressed on whether or not pharmacist(s)-in-charge (PIC) are to be disciplined for all errors within their pharmacy, and encouraged the board to revisit the issue again. He also commented on the lack of information available to pharmacists due to closed office conference appeal hearings, as he sees those sessions as an educational opportunity for the industry to hear details and learn from them.

Mr. Room provided the difference to board members between how citations and fines were done prior and today. He indicated that pharmacy law does list factors and guidelines which are in place when determining citation and fine amounts. He noted that citation and fines are not part of the licensee's disciplinary action. He also said that board members used to be more involved in issuing citations, but due to legal reasons, the change of authority was delegated to the Executive Officer and his or her staff. He noted the delicate balance between giving authority and relying on accumulative experience of the Executive Officer and board staff and their ability to differentiate on a case-by-case basis.

Kristy Schieldge addressed the comment previously stated regarding guidance provided to staff, or lack thereof. She quoted California Code of Regulations § 1775.2 from Pharmacy Law and stated that there is enough guidance for the Executive Officer and staff within the regulatory framework for the issuance of citations and fines.

Mr. Graul offered clarification that he was not critical of what the board is doing, and that he was merely indicating that there should be an educational process for the licensees of the cite and fine process as it is currently conducted.

Ms. Herold stated that the board does have a cite and fine continuing education program which board members and supervising inspectors provide to associations. She stated that it is a similar format to what was presented today. Ms. Herold explained that the all of the details of someone's discipline can be viewed, and referred to the board's Web site where the information can be retrieved. She encouraged employers of pharmacists and technicians to get into the habit of viewing the Web site prior to making hiring decisions.

Ms. Herold indicated that an important part of the overall process is the appeal process. She explained that if someone disagrees with the issuance of the cite and fine, they have the opportunity to meet with the appropriate enforcement staff and provide an argument. She noted that she and/or a supervising inspector sit in on those appeal meetings. Ms. Herold stated that they may decrease or remove the citation, depending on the circumstances and information provided. On the other hand, the decision remains the same in many cases. She indicated that, if someone is unhappy with the decision of the office conference appeal, the licensee can go to the Attorney General's office to schedule a hearing. In the event of a hearing, the board will have the opportunity to provide input on any decision that was made.

Mr. Room provided clarification that the initial opportunity to meet with board staff is an informal office conference, and not an appeal. The actual appeal hearings initiated in the Attorney General's office are public, so members of the public can attend. He added that it is not easy to determine when to attend if someone wants to view a specific hearing. He suggested the option to peruse the Office of Administrative Hearings Web site and view all the hearings listed for the Board of Pharmacy.

Ms. Schieldge asked if there is an explanation on the website of circumstances when a fine might be reduced.

Ms. Herold responded that there is not, and that the information is provided in correspondence with the licensee. She reiterated that the office conference is an opportunity for the staff to gain additional information not previously available which will be included in consideration of the decision. She noted that there are very few cases which end up going as far as the official appeal process in the Attorney General's office.

Mr. Goldenberg asked if it would it be possible to put a couple of cases on the Subscriber Alert on some type of routine basis in order to allow the industry the opportunity to become educated.

President Schell added that this relates back to Ms. Rolston's suggestion of a communication tool, which may need to include more than one communication option. He suggested this discussion be incorporated into the plan to address within the Enforcement Commitee for the following year.

H. Fourth Quarterly Report on Enforcement Committee Goals for 2007-2008

Mr. Dazé indicated that the 2007-2008 Enforcement Committee Goals are contained within the board packet provided.

Ms. Herold indicated that President Schell had requested a three-year comparison of enforcement statistics. Those statistics were compiled after the packet was mailed, and were distributed to the board at this time in the meeting. They will also be brought to the next Enforcement Committee meeting for discussion. She added that the annual statistics included in the board packet were not updated. Those updates were provided during the meeting as well.

Board discussion:

Mr. Powers noted that Fred Mayer was unable to attend today, but that he is the beneficiary of comments that Fred has been sending out. He stated that one of the issues often raised in regards to prescription errors is the amount of workload on the pharmacists. He added that when he sees statistics of pharmacies filling 200 to 300 prescriptions a day, he understands the concern and how that might affect accuracy.

Ms. Herold responded that whenever a prescription error case is investigated, the inspector assigned to the case will look at how many prescriptions were filled that day, the amount of staffing, etc. She stated that that is information that is collected and included in the decision process. Ms. Herold indicated that when the volume is unusually high, it sometimes results in cite and fines being issued to the pharmacy and PIC, as well the pharmacist who made the error.

IV. Licensing Committee Report and Action

A. Report of the meeting of June 23, 2008

1. Recommendation for Board Recognition of Schools of Pharmacy that Have Received Precandidate Status from the Accreditation Council for Pharmacy Education (ACPE) for Purposes of Issuing Intern Licenses

Mr. Weisser stated that two Schools of Pharmacy have submitted requests to the board seeking board recognition for purposes of approving intern applications. He indicated that current regulation, Title 16 CCR 1719, states that a "recognized school of pharmacy" means a school accredited, or granted Candidate status by ACPE.

Mr. Weisser advised that Sullivan University College of Pharmacy was granted precandidate status by the ACPE in January 2008. He noted that Sullivan University is in the middle of their 2008 - 2009 review period for advancement to Candidate accreditation status. He indicated that there is a letter from Sullivan to the Board of Pharmacy provided within the board packet.

MOTION: Recognition by the board for Sullivan University to allow students to obtain intern cards.

M/S: WEISSER/BURGARD

FAVOR: 9 OPPOSE: 0

Mr. Weisser stated that the California Northstate College of Pharmacy (CNCP) was recently granted Pre Candidate status by the ACPE this month to admit their first class of students in fall of 2008. The board staff received confirmation that CNCP has since received pre-candidate status.

Dave Carroll (CNCP) stated that he was pleased to see the board recognizing the CNCP and would be happy to answer any questions.

Mr. Goldenberg asked where the college is located.

Mr. Carroll responded that the college is in Rancho Cordova.

Mr. Weisser noted that at the time of the initial written request for recognition, they had not yet moved into the facility. He asked if they have now moved in.

Mr. Carroll responded that they moved into the facility on February 1, 2008. He also noted that they were granted Pre-Candidate status by the ACPE at their meeting on June 22, 2008.

Anne Sodergren clarified that the Licensing Committee did not take a position at its last meeting because they had not been advised on whether Pre-Candidate status was granted. She noted that they have since received confirmation of Pre-Candidate status.

Board discussion:

Jim Burgard indicated that he was a member of the committee involved in the review. He confirmed the intention of the committee to move forward with the motion to approve recognition once information was received indicating ACPE approval of Pre-Candidate status. He stated his support of the motion.

MOTION: To approve the request for board recognition of California Northstate College of Pharmacy.

M/S: POWERS/ZINDER

FAVOR: 9 OPPOSE: 0

2. Recommendation to Update the Strategic Plan for the Licensing Committee Goals for 2008 - 2009

Mr. Weisser indicated that there were no changes discussed at the committee meeting, and no recommendation to changes of the goals for 2008-2009.

3. Discussion of Licensure of Ambulatory Surgical Clinics by the Department of Public Health Under Health and Safety Code Section 1204 That Are Owned by Physicians

Mr. Weisser indicated that the California Ambulatory Surgery Association (CASA) is requesting guidance from the board to rectify the regulatory consequences from *Capen v. Shewry (2007) Cal. App 4th 378* (Capen Decision) as it relates to the board's ability to issue a clinic permit to ambulatory surgical clinics.

Mr. Weisser stated that currently, the board can only issue a clinic license to an entity also licensed by the Department of Public Health (DPH). He referred to the Capen Decision, which determined that DPH does not have jurisdiction over surgical clinics owned in part, or wholly by a physician. Mr. Weisser indicated that the purview, according to the decision of the clinic, is with the Medical Board. He reiterated that currently, without a DPH license, we are unable to issue a pharmacy clinic license which allows clinics to purchase drugs from wholesalers as well as to comingle drugs. Mr. Weisser explained that currently, each prescriber must maintain a separate drug supply or the drug supply must be wholly owned by the professional director or some single prescriber.

Mr. Weisser stated that until a legislative fix is provided, the board cannot issue a clinic license unless the entity is also licensed by DPH. He noted that the board will continue to renew existing clinic licenses that are no longer licensed by DPH.

Mr. Weisser explained that AB 1574 (Plescia) contains provisions which would allow the board to issue a clinic license to entities licensed by DPH, as well as to those accredited as specified or Medicare certified. He indicated that the Legislation and Regulation Committee is recommending a support position on this bill.

Public comment:

Bryce Docherty (CASA) reiterated that state licensure for a surgical clinic by DPH has provided a variety of downstream issues, including no longer being able to obtain permits issued by the Board of Pharmacy for commingling of drugs. Mr. Docherty added that he will be in the next day's meeting and is prepared to discuss AB 1574 in further detail where it is appropriate in the agenda. He added his commendation to the board and staff in the work they have done with the industry, consumers and legislature in attempting to provide solution to this issue. CASA appreciates the board's help going forward to maintain the licenses to those who currently have it and hope that AB 1574 will be signed by the governor so that new licenses can be issued to ambulatory clinics and those who are accredited and/or Medicare certified.

Board discussion:

Mr. Dazé asked how the board is able to renew a license if the board can't issue them.

Mr. Room explained that the condition is precedent to issuance. He added that it is not a renewal qualification, but rather an issuance qualification.

4. Discussion Regarding Formation of an Industry Task Force to Evaluate Pharmacy Technician Qualifications

Mr. Weisser explained that the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. He noted, however, that the bill was pulled.

Mr. Weisser stated that discussion at both the committee meeting and a stakeholder meeting, which was held on June 25th, 2008, revealed that there is disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements and whether continuing education (CE) is appropriate for pharmacy technicians. Mr. Weisser indicated that he was in attendance of the meeting via conference all, and that Ms. Sodergren was in attendance as well in order to provide information to report back to the board.

Board discussion:

President Schell asked if any "next steps" were determined at the conclusion of the stakeholder meeting.

Mr. Weisser responded that they would continue to meet, but that exact dates had not been determined.

Mr. Docherty (CSHP) explained that, as the sponsor of AB 1947, they realized there were some questions and concerns with the intent of the specifics of the bill. Therefore, the purpose of the first stakeholder meeting was to review and discuss any concerns needing to be addressed as well as allow the author of the bill to reinforce his commitment to providing standardized and ongoing education and training for pharmacy technicians. He stated that feedback from that meeting will be presented to their board, and the committee will reconvene in an additional stakeholder meeting in August. He stated that it is the intent of CSHP to move ahead on this issue in the 2009 legislative session.

Mr. Weisser asked to be informed of the next meeting date, as he plans to attend.

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

Mr. Weisser provided a brief explanation of current law, which is the requirement of 1500 intern hours under the supervision of a pharmacist before eligibility to take the pharmacist exam for licensure. He provided a breakdown of the requirement, which is 900 hours in a pharmacy and 600 hours under the supervision of a pharmacist (if substantially related to the practice of pharmacy), but not specifically within a pharmacy. Mr. Weisser added that students also typically earned about 600 discretionary hours, which is experiential training.

Mr. Weisser indicated that the committee discussed whether to allow current intern hours to be obtained outside a typical pharmacy setting. He stated that the committee decided to table any action to alter any requirements.

Public Comments:

Landon Dean indicated that he wrote the initial letter to the board requesting the amendment. He explained that the proposal was not to add hours, but rather to increase the 600 hours to 1000 hours. He added that their request has since changed. They would now like to request a revision to the definition of "in a pharmacy" to include any type of setting which includes direct supervision of a pharmacist. Mr. Dean shared his personal experience in earning his hours in ambulatory care, unaware that the hours earned would not qualify towards his internship. He provided his argument that interns may not obtain any outpatient experience while earning their 900 hours for licensure as they are able to obtain all of those hours inside a pharmacy. He added that each pharmacy has different policies which will require retraining when a student transfers to another entity to earn hours. He stated that pharmacists should therefore factor in hours for re-training at each new facility. Mr. Dean also addressed the fact that, during the 4th year of internship, the rotation requirement

includes several weeks in an outpatient pharmacy setting. He feels that, considering the caliber of students, that the current requirement is sufficient time to learn the mechanics of dispensing. He also added that he believes the extra training required of students will reduce the amount of prescription errors and improve public safety. Mr. Dean also added that he had heard of a rule to include ambulatory clinics to be licensed as a pharmacy, but that the rule did not pass. He indicated that if that rule had passed, he would not be in his current predicament in regards to his intern hours being potentially void for purposes of licensure.

Board discussion:

Mr. Goldenberg asked if the board would be able to get statistics on how many licensed pharmacists are dispensing pharmacists. He added that he was provided information by one institution indicating that, over the last 5-year period, only 30% of their pharmacy school graduates go into the area of dispensing. He noted that there may be more comfort by the board in considering other venues if there was evidence of more graduates going into non-dispensing careers.

Ms. Herold responded that the board does not have access to that information. She added that once every five years, the board does a job analysis to validate the pharmacist exam, which includes up to 4000 surveys. She indicated that one question on that survey includes an assessment of what type of duties the licensee performs and their frequency. She explained that there is an issue with that data, however, as it would only include those who were willing to respond, and may not be a valid representative sample for these purposes of actual practices. Ms. Herold did note that NACDS does conduct such surveys for manpower issues.

Mr. Goldenberg suggested whether the colleges in California can assist with collecting such data in the future in order to reevaluate how intern hours are earned.

President Schell commented on the importance of attempting to distinguish a "non-dispensing" entity, when very often pharmacists complete all aspects of the dispensing process with exception of actually handing the drug to the patient. He gave his personal experience within an ambulatory clinic and how other activities were related. He agreed that it could be very useful information in relation to demographics and knows that there are colleges who collect that data, but that we should first discuss further the parameters of what we are asking for.

Public comment:

Dr. Gray (Kaiser Permanente) stated that there is confusion among the schools and the students. He gave examples of specific wording within the requirements of earning intern hours, which included the requirements of the Accreditation Council for Pharmacy Education (ACPE), and suggested written clarification for the schools on this topic. He added that every pharmacist needs to know basic dispensing and compounding, but that it isn't necessarily happening with regard to graduates entering the field.

Mr. Graul agreed with Dr. Gray's comments and recommended that the board defer the items of discussion back to the Licensing Committee for a more detailed look at the issues.

Mr. Weisser stated that he will refer the item back to staff.

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

Mr. Weisser stated that recently board staff was forwarded a request from a pharmacy applicant requesting that the board issue a pharmacy permit prior to the opening of the pharmacy to allow sufficient time for the owner to also obtain a DEA license and Medi-Cal provided number. He explained that currently, Board staff work with pharmacy applicants who are also concurrently seeking licensure with the DEA as well as applying for a Medi-Cal provider number. Each agency initiates application processing without a board license number.

Mr. Weisser stated that board staff routinely works with other agencies and is available to assist applicants who experience delays in the process.

Mr. Weisser stated that the committee feels the best way to address the issue at this time is to have board staff update the Frequently Asked Questions portion of the Web site and incorporate the information.

7. Status Report to the Committee on Continuing Education Audits

Mr. Weisser explained that the current requirement is 30 hours of approved continuing education during the two years preceding the application for renewal. He added that when a licensee submits their renewal application, they sign the document which certifies that the information provided is correct.

Mr. Weisser explained that, effective in 2006, this section was amended to state that the board would not renew a license if proof of continuing education is not provided and instead requires the board to issue an inactive pharmacist license. He stated that the board's primary goal is to obtain compliance with the continuing education requirement, and that currently random audits are performed to verify legitimacy of information provided on renewal forms.

Mr. Weisser noted that over the last year, these audits have revealed approximately 12% of the pharmacists that were audited provided false information on their renewal. He stated that, as a result, the board completed an investigation substantiating the violation and a citation and fine was issued.

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

Mr. Weisser explained that, during the public comment portion of the April 2008 board meeting, the board heard comments from Jennifer Delaney regarding the board's Quality Assurance (QA) review of the CPJE.

Mr. Weisser explained that the board contracts with a psychometric firm who provides the board with expert guidance on the appropriate administration and scoring of the CPJE, including quality assurance assessments. He added that the contractor determines the criteria that needs to be met in evaluating the examination's performance before candidate scores are reported.

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

Mr. Weisser noted that the board is sympathetic to the anxiety and stress of the students. He added that the board however, needs to ensure that, with public protection as the core, the exam is a valid assessment of whether or not each pharmacist applicant is minimally competent.

9. Competency Committee Report

Mr. Weisser stated that both Competency Committee workgroups will be meeting in August 2008 at an annual meeting to discuss examination development. He noted that each Competency Committee workgroup will also meet once in the fall.

Mr. Weisser stated that the current competency committee chairperson has diligently and graciously served in this capacity since 2005. He advised that at the August 2008 meeting a new chairperson will assume these duties. Mr. Weisser stated that the board greatly appreciates the time and commitment during a person's tenure as Competency Committee Chairperson.

President Schell explained that the board typically maintains the identity of the committee members as confidential. Once they have completed their tenure, however, they can be publicly recognized. President Schell recognized Francis Wong for her duties and efforts as chair of the committee. Ms. Herold presented Ms. Wong with a framed certificate and a Board of Pharmacy pin.

Ms. Wong thanked the board for the opportunity to serve on the Competency Committee. She stated that the committee works very hard, and hopes that their efforts have helped to ensure that qualified pharmacists are working in the field.

Mr. Weisser added that he has given the report on behalf of Susan Ravnan, and he is sure that she would want to give her acknowledgement and thanks as well.

Mr. Weisser noted that the next CPJE statistical report will be provided at the next board meeting in October.

10. Review and Discussion of "Standards and Guidelines for Healthcare Surge During Emergencies"

Mr. Weisser explained that earlier this year, the board received a copy of the "Standards and Guidelines for Healthcare Surge During Emergencies" manual prepared by the California Department of Public Health (CDPH). He stated that these documents are being released by CDPH to help healthcare providers, payers, local government and local communities better plan to sustain a functioning healthcare delivery system during a catastrophic emergency.

Mr. Weisser indicated that the manual included four volumes and is designed to provide guidance, operational tools and training curriculum for healthcare facilities, insurers, licensed healthcare professionals, local health departments, local communities and other interested parties.

Mr. Weisser stated that the board continues to actively engage in disaster planning and response. He added that, most recently, the board took a support position on AB 2756 (Duvall) relating to the furnishing of dangerous drugs by a pharmacist during an emergency.

Mr. Weisser advised that the committee discussed prior challenges in getting prescriptions filled for patients during an emergency, such as the fires last October in Southern California. In addition, the committee discussed the challenges for residents in remote areas as well as the possible need for specifics and parameters for appropriate pharmacists' response in the case of a disaster.

Mr. Weisser said that the committee requests that the board continue to remind pharmacists on an ongoing bases of the guidelines established by the board and to use professional judgment in emergency situations.

Public Comment:

Dr. Gray (Kaiser Permanente) discussed an impression of misunderstanding of pharmacy law in regards to emergency refills. He indicated the Licensing Committee's understanding that those sections allow pharmacist to use professional judgment to refill a prescription to a patient even if that original fill was not dispensed at that same pharmacy. There is concern that some pharmacists may feel that they cannot refill a prescription unless prescribed by them, even in a proclaimed disaster. Dr. Gray encouraged clarification to the industry on this issue. He gave the example of the recent wildfires throughout California and pointed out how some patients may have been displaced to other parts of the state and need prescriptions refilled at other pharmacies.

Mr. Room confirmed that the statute does not require a pharmacy to be same pharmacy which provided the original prescription fill.

President Schell raised the question of how to disseminate the information.

Ms. Herold responded that the board can provide the information in the Question & Answer section of the next *Script* newsletter or it can be done in the purview of their emergency response. She noted that she is checking with the Emergency Pharmaceutical Deployment of the Department of Public Health to find out whether there were any inquiries during the wildfires in terms of anyone being unable to gain access to their medication. She explained that the board has been carefully monitoring whether the issue of accessing prescription refills has been an issue during the natural disaster, and they have not received any information as such. Ms. Herold added that she has also been in contact with the Office of Emergency Services, and stated that they had not heard of any related issues either. She concluded by saying that an outreach effort by way of the *Script* in the Question and Answer section would be the most beneficial.

Hank Hough requested that the information provided in the newsletter would include the suggestion of an ID card containing important medical information which can be kept within a person's wallet or purse.

B. Meeting Summary of the Licensing Committee Meeting of June 23, 2008

Mr. Weisser indicated that the summary of the meeting is contained within the board packet provided.

C. Licensing Statistics 2007- 2008

Mr. Weisser advised that the 3-year Comparison Licensing Statistics were being handed out, and that the 2007 - 2008 Licensing Statistics are contained within the board packet provided.

D. Fourth Quarterly Report on Committee Goals for 2007- 2008

Mr. Weisser indicated that the Committee Goals are contained within the board packet provided.

Recognition of Pharmacists Licensed with the Board for 50 Years

President Schell advised that the recognition of pharmacists in service for 50 years was a program initiated by Mr. Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition, as will be done today for several pharmacists.

Fred Startz graduated from USC in 1958. He has 6 stores in the Los Angeles area, and has "stood on his feet for 50 years". Mr. Startz stated that it was an honor to be at the meeting. He was excited to be here and thanked everyone. Mr. Startz was honored with a pin by Mr. Dazé.

Gregory G. Roumpos graduated from the University of Utah. He decided to move to California in 1958 and become a licensed pharmacist in the state on July 27, 1958. He has been a practicing pharmacist for all 50 years and at the present time is working for Victory Drug and Surgical Supply in Bellflower, California. Mr. Roumpos thanked the state of California for the great honor. Mr. Roumpos was honored with a pin.

Lee Eugene Ward graduated from Ohio State School of Pharmacy in July 1958. He bought his store in 1960 and sold it in 1990. Mr. Ward stated that he has really enjoyed being a pharmacist for 50 years. He indicated that he has a small pharmacy, which is still going strong, filling about 300-400 scripts a day. He added that he has received a lot of honors, including receiving the key to the city, being awarded citizen of the year, and being grand marshal in a parade. Mr. Ward was honored with pin by Mr. Goldenberg.

W. Alvin Thunquest was licensed in 1958 and has been a pharmacist at Loma Linda University Medical Center for the entire 50 years. He indicated that he was a staff pharmacist from 1958 through 1964, and was promoted to pharmacy director from 1964 to 1990. Since 1990, Mr. Thunquest has been working as a staff pharmacist at Loma Linda.

Mr. Thunquest said that he would like to thank the board for the opportunity to be here. Mr. Thunquest explained that 55 years ago Loma Linda offered him a scholarship due to the shortage of pharmacists back then. He stated that although there may still be a shortage, it seems that the issue is being addressed with the new schools of pharmacy coming in. Mr. Thunquest was honored with a pin by Shirley Wheat.

Richard Franklin was licensed in 1950 and has been a pharmacist and owner at Mid Wilshire Pharmacy, Century City Medical Center, Malibu Pharmacy, Westchester Pharmacy, and others. Mr. Franklin's father was a past board president. Mr. Franklin thanked the board for the recognition. He explained that he passed the board in 1950 in June, but didn't get his license until July because he wasn't 21 years old yet. He stated that his father was president of the board in the mid-1940's when there were only seven members of the board and life was much simpler. He commended the board for the excellent job they do. Mr. Franklin was honored with a pin by Ms. Zinder.

President Schell provided a special presentation to past board member, Clarence Hiura. President Schell explained that, of all the people who have mentored him while on the board, Clarence was "number one". He explained that Dr. Hiura has given a tremendous part of his life to improve health safety, the efficiency of the board, and to act as a model for all to emulate. President Schell addressed the pharmacy school students attending the meeting and stated that if they ever needed a role model, Dr. Hiura is the one to look to and learn from.

Dr. Hiura encouraged pharmacists to get involved because the board members have learned so much within their positions and duties. He thanked the board. He explained that he has served 4 four-year terms since 1979, haven been appointed by various governors. He stated that he continues on with his career, but could not have done so if it wasn't for the support of his family.

Dr. Hiura was honored with a 50-year-pin by Mr. Powers, a cake and golf balls autographed by each board member in honor of his favorite sport.

Mr. Goldenberg invited the family to join the celebration.

V. Communication and Public Education Committee

Shirley Wheat advised that there was no meeting this quarter, and there was no new information to report. She noted that the next Committee Meeting will be this afternoon following the board meeting. She invited the public to attend.

Ms. Wheat indicated that there are three speakers presenting today regarding medication error. She also noted that there are attachments within the board packet which provide information on the board's requirements for Quality Assurance review in analyzing prescription errors and why they occur.

Ms. Herold indicated that she brought Health Notes booklets to share with the board members. The booklets were developed by the board in 2002 and mailed to all pharmacies upon completion. Ms. Herold explained that the booklets provide the requirements relating to medication errors, which includes quality assessment requirements. She noted that they are also available on the board website.

A. Presentation by Michael Cohen, RPh, MS, ScD on Medication Errors in the Pharmacy Setting

Ms. Herold introduced Michael Cohen from the Institute for Safe Medication Practices (ISMP), provided information on his extensive background and thanked him for presenting.

Mr. Cohen thanked the board for the opportunity to attend and gave his congratulations to the 50-year pharmacists honored previously.

Mr. Cohen provided history on his career as well as ISMP's existence, particularly their growth within publication of journals and newsletters, as well as the expansion of a national reporting organization, on the topic of drug error. Mr. Cohen noted that they work closely with the FDA - Division of Medication Error Prevention. He explained that ISMP also spends a lot of time in assisting others within the industry on problem resolution, which includes providing recommendations for drug naming, labeling and design to industry.

Mr. Cohen stated that he feels California has done more to address the issue of drug error than other states. He complimented the board on the *Script* newsletter and its content, as he was very impressed. Mr. Cohen noted the Heparin recall issue, as well as other incidents that have recently occurred across the country, and stated that the healthcare industry as a whole doesn't seem to be learning from the serious and fatal incidents that have occurred.

Mr. Cohen explained that ISMP runs the Medication Error Reporting Program jointly with United States Pharmacopeia (USP). He added that in Pennsylvania, the state has a mandatory error reporting program, which includes reporting of all types of medical error. The program requires the submittal of reports, which are often very large due to the breadth of institutions required to participate. He stated that there are over 800,000 reports since June of 2004, which provides great data in a large-scale aspect. On the other hand, the voluntary program which ISMP runs is more helpful in communicating more detail of the incidents involved. Thus, both types of reporting are important.

Mr. Cohen indicated that approximately 20% of incidents reported to the Pennsylvania Patient Safety Reporting System (PPSRP) are related to medication use. He noted that they have support staff, analysts, nurses, pharmacists, a medical director and additional staff within ISMP, some of

which are analysts for both the PPSRP and ISMP programs. He added that they are "MedWatch Partners" and work frequently with the FDA.

Mr. Cohen listed some of the organizations that ISMP works with through the program. He also listed the publications where ISMP's articles are placed, the number of subscribers to each publication and the frequency of how often the newsletters are run. Mr. Cohen stated that they also provide Medication Safety Alerts, and gave an example of an alert where a large drug error was occurring in the industry which needed immediate widespread attention. He discussed the issue of the alarming amount of repetitive errors being made on a continuous basis.

Mr. Cohen explained that they are conducting research which includes three phases. The first phase involved developing a list of drugs and/or categories that are most likely to injure a patient. He advised that the list was completed and will be published in the early part of next year. Phase Two involved working with front-line practitioners as a focus group and looked at the failures in the system for four of the major categories of drugs on their "high alert" list. He explained that they used the focus group to conduct a "Socio-Technical Probablistic Risk Assessment", which gives them "real world" scenarios of what really happens and how often it can happen. In Phase Three, they looked at the prevention methods that were measured. He indicated that they were able to identify that most incidents could have been avoided with a simple scripted consultation with the patient at the point of sale.

Mr. Cohen stated their current intention within the research project is for the board to focus on a specific small group of drugs and provide surveys to determine if appropriate consultations are occurring when those specific drugs are dispensed. Mr. Cohen gave an example of a pharmacy who has established a system where documentation is required to be printed out of their register before they can complete the purchase transaction.

Mr. Cohen discussed prior drug errors which received substantial media attention. He also discussed the recent Heparin issue. He noted that the Board of Pharmacy in North Carolina is considering a mandate of counseling for higher level drugs.

Mr. Cohen provided examples of system failures within the Heparin cases, which included failure to learn from previous incidents, look-alike drugs, drug storage conditions, non-existent or failed check systems, not embracing available technology, and others.

Mr. Cohen gave another example of U-500 insulin being confused with U-100, providing a visual of the two bottles of insulin to demonstrate how similar the bottles are. He noted that many pharmacists don't even know there is a U-100 option. He also explained how physicians are using their hand-held devices to submit a prescription, which causes an error in choosing the wrong drug because the full name is not visible on their screen. He noted that they were able to work with the vendors of drug information, whom agreed to change the order of the information as listed on the software to avoid this particular type of error in the future. Mr. Cohen also indicated the issue with errors relating to incorrect measuring devices being used.

Mr. Cohen provided data from USP which detailed the leading products involved in harmful medication errors. The program is known as Med Mark, and is used for hospital and community pharmacy incidents. He noted that many of drugs from the high alert list are on the list presented from the USP data. Mr. Cohen stated that by focusing on those drugs, he feels the industry can greatly reduce the amount of patient harm.

Mr. Cohen listed the facilitators of reducing errors, including education and training, e-prescribing, bar code scanning, etc. He also listed the various barriers to medication error reduction, which

included lack of patient education as well as lack of adequate reimbursement for patient education, etc.

Mr. Cohen reiterated the plan to survey patients on proper consultation. He shared the results of a survey which indicated that the highest priority to customers in relation to their pharmacy experience is speed, which is discouraging as it is so important to educate the patient on their medications.

Mr. Cohen shared a recent incident involving a teenager who was prescribed Oxycodone concentrate in error, which resulted in patient coma.

Mr. Cohen discussed the critical need for sharing and learning within the healthcare industry, and gave examples of how that can be conducted. Mr. Cohen provided key concepts in safeguarding high alert medications, such as use of constraints that limit access or use, forcing functions, redundancy and improved access to information. He ranked the order of error reduction strategies as well.

Mr. Cohen explained the Medication Safety Self-Assessment which is available to community pharmacies and hospitals. He stated, however, that some state boards have been using the self-assessment incorrectly in having the form completed by a pharmacist who has made errors as part of their discipline. This approach does not allow for full assessment of the pharmacy, which is highly crucial to evaluate for correction as well. Mr. Cohen noted that the self-assessment can be found on ISMP's website.

Mr. Cohen also noted the importance of the role of oversight agencies. He gave the example of deaths from potassium chloride overdose between 1995 and 2007, and explained how there have been no similar incidents since then due to the efforts of the oversight agencies.

Mr. Cohen explained ISMP's Action Agenda publication. He indicated that it is a review of the major issues addressed over the previous several months, and pharmacies can utilize the information to implement an action plan within their pharmacy relating to the issues or topics which they feel need to be addressed. The Action Agenda has been presented and offered to chain stores who are interested in the program.

Mr. Cohen encouraged the board's involvement by utilizing a volunteer expert panel. The panel would include the Board of Pharmacy and other professional organization and government entities, who would review the recommendations resulting from the expert analysis of an outside agency to be implemented into community hospitals and pharmacies. The panel would establish annual pharmacy patient safety goals as well as quality improvement requirements. Mr. Cohen indicated that it could also include a training program for inspectors so they can be educated on what to look for during their pharmacy visits.

Mr. Cohen stated that ISMP is preparing to launch a consumer-oriented medication website, which includes on-line newsletters, helpful tips, etc. He also noted that ISMP has a consumer reporting program so that consumers can contact them and advise them of any adverse drug events they have experienced. He stated that the information would be forwarded to the FDA, as well as shared with the public and industry.

Questions to the presenter:

Ms. Rolston referred to the documents Mr. Cohen detailed, which can be used to self-assess, and asked what drives the pharmacists to take the steps and complete the self-assessment.

Mr. Cohen responded that in some cases there is an incentive put in place by state boards to provide an increase in reimbursement on Medicare prescriptions. He also noted one large pharmacy chain who simply required it from all of their chain store pharmacies. Mr. Cohen said that, for the most part, it has been "pushes" from APHA, NACDS, other pharmacy organizations, as well as ISMP. He noted that it is on the website at this point, and that there is no charge to utilize the self-assessment. He also added that revisions will be made in the future to improve the program as well. Mr. Cohen gave a brief description of the assessment tool and the scoring and comparison aspects.

Mr. Goldenberg clarified that there was enough value in the self-assessment tool to make a state board willing to provide financial incentive. He asked if there is data to show that the program was successful.

Mr. Cohen responded that there is. He explained that in 1999, when the Institute of Medicine released their first report on medical error, President Clinton announced the project - "To Err is Human". He stated that there were ultimately 2300 acute care pharmacies who participated. Following, there was funding for a second project of the same nature, which was completed in 2004. The results were a 23.4% increase in scoring overall between 2000 and 2004, which is dramatic.

A member of the public asked if there is data available that shows the impact of manpower issues on how it has impacted prescription errors over the past few years.

Mr. Cohen responded that they do not have specific data as such on pharmacists, but there is quite a bit of research that has been done in the nursing industry, including in California. He said that there are individual chain pharmacies that have collected the data, but is unsure whether they would share the information.

President Schell stated his concern over the significant focus on pharmacists and pharmacy systems in placing responsibility and managing the problem. Additionally, he stressed the need to look at the number of errors in context, and to consider how much the system can afford to pay in order to drop the amount to zero harmful errors.

Mr. Cohen responded that they only have knowledge of a fraction of the actual incidents which occur.

Mr. Graul referred to Mr. Cohen's point in the presentation of patient counseling not being compensated. He provided his opinion that quality counseling will require payment, and asked if ISMP has seen any movement toward compensation for the service, especially in the high-alert med list area where scripted counseling is being provided.

Mr. Cohen responded that they have not, and as it is a fairly new concept to develop the small amount of drug categories which would have the requirement. He said that he is not aware of any third party payer doing that right now, but agreed that it is time to start considering it.

Ms. Rolston referred to E-prescribing, which the industry is moving rapidly towards, and asked what impact Mr. Cohen thinks that will have.

Mr. Cohen responded that that he thinks it will be tremendously positive, however there is a downside. He pointed out that there is a certain amount of drug errors that occur as a result of e-prescribing due to lack of regulatory requirements within the design of the software, ambiguous orders, confusion, conflicting directions, wrong dosage form chosen, etc. Mr. Cohen stated that there is a government-funded study in effect that is looking at the adverse effects of e-prescribing. He concluded by saying that overall, e-prescribing will have a very positive impact, however the inefficiencies need to be designed out of the system first.

B. Presentation by John P. Keats, MD, on the California Patient Safety Action Coalition (CAPSAC) and Its Efforts Toward "Fair and Just Culture" for Medication Errors in Health Care Facilities

Ms. Herold introduced Dr. John Keats.

Dr. Keats thanked the board for the opportunity to present on the topics of California Patient Safety Action Coalition (CAPSAC) and Just Culture.

He provided his background to the board.

Dr. Keats explained that CAPSAC is a coalition of leading institutions and group organization. He indicated that CAPSAC had their first statewide meeting on July 11th, 2008, which President Schell and Ms. Herold attended.

Dr. Keats stated that the goal of CAPSAC is to improve patient safety throughout California by the prevention of medical errors. He noted that the program is modeled by programs and coalitions in other states, and listed participants involved in the coalition.

Dr. Keats reviewed the purpose of the CAPSAC Charter. He added that they are not advocating any type of confidential reporting system or holding practitioners blameless for their actions, but rather they are attempting to promote Just Culture - striking a balance between recognizing human error and attempting to minimize that, as well as holding people accountable for the choices that are made.

Dr. Keats referred to the Institute of Medicine's project – "To Err is Human" (2000) report and the fact that "...more people die from medical error each year than suicides, highway accidents, breast cancer or AIDS". He noted that there is fairly little evidence of progress over the last few years since the project in 2000, and that the industry has not learned as much as would be hoped.

Dr. Keats also addressed public concern by referencing two polls conducted in 1997 and 2002. The results showed a large percentage of people who had been affected in some way by medication error, as well as a high concern by the public over medication related issues and being prescribed the wrong drug. Dr. Keats referenced a report from the Institute of Medicine in 2006, which indicated at least 1.4 million preventable adverse drug errors which occur per year, which relates to one medication error per patient per day.

Dr. Keats raised the question of why the industry hasn't been able to do better. He stated that one theory is that it is because we punish people for making mistakes. Society still believes that human error is completely avoidable, which simply isn't true. He noted that research showed the highest reason for errors is due to stress, with a rate of 250 per 1000 mistakes. Dr. Keats also listed the factors that increase the risk of error, which includes unfamiliarity with the task, shortage of time and poor communication. Dr. Keats identified a second theory, where systems are completely to blame, rather than people. He pointed out that neither theory should be accepted, and that a combination of the two is what is needed.

Dr. Keats discussed the need for culture change, and provided a definition of organizational structure. He indicated that current cultures include "shame and blame" with no follow-through on prevention to avoid the error in the future, with judgment focused on the severity of the outcome rather than on the action taken that caused the error. He identified another culture known as "bend and mend", where errors result in repeated attempts at system repair and ignores the role of the individual and their behavioral choices.

Dr. Keats referred to the "normalization of deviance" and used the Challenger Launch decision as an example. He explained its definition as the risk that is continuously redefined in the context of accidents that do not occur, and how standards degrade over time. Dr. Keats provided a clinical example of dispensing the wrong medication within a hospital to an infant because the nurse assumed the medication was correct based on its location. He stressed the point of the example, which is how the error is addressed by the staff member by either correcting the problem, or correcting the problem and reporting it to supervisors. The goal is to promote systems where people will report errors and not avoid it because of being held liable.

Dr. Keats provided the definition of Just Culture, as stated from the Agency for Healthcare Research and Quality and recognized the founder of Just Culture, David Marx, BS, JD. Dr. Keats reviewed the features and goals of a Just Culture.

Dr. Keats discussed how to prevent error in a Just Culture, which includes training, performance shaping factors, and developing systems of recovery.

Dr. Keats stated that Just Culture recognizes the three classes of human fallibility which include inadvertent error, at-risk behavior and reckless behavior. Just Culture also responds to those three classes by way of consoling, coaching and punishing the behavior, respectively. Dr. Keats reviewed a model of a Medical Error Algorithm to assist in review of errors and response of action steps.

Dr. Keats discussed the reasons for implementing a Just Culture, which includes the need to build trust, promote a reporting culture and foster "mindfulness". He explained the stages of error reporting as Just Culture is being established and trust developed. Dr. Keats touched on the definition of "mindfulness" and how crucial that is within the organization to ensure the success of Just Culture and reduction of medication error.

Dr. Keats reviewed CAPSAC's action steps in promoting the adoption of Just Culture throughout California. Those steps include the creation of a Just Culture document (completed), conducting a Safety Attitudes survey, education in safety concepts, use of an unsafe acts algorithm, and supporting "good citizenship".

Dr. Keats addressed the role of regulatory agency involvement with regard to Just Culture as not only providing sanction and discipline when needed, but also as a role of support. He emphasized that regulatory agency support of Just Culture will in turn support something that has a proven pathway to cultural change and error reduction in institutions.

Questions to presenter:

Mr. Weisser asked if there has been any survey to indicate a decline in errors due to new nurse/patient ratios.

Dr. Keats responded that he is unaware of any studies having been conducted related to the new staffing ratios.

Mr. Hough referenced procedures that are used in the operation and maintenance of nuclear weapons, and suggested that the step-by-step, two-person process might be utilized in our industry as well.

Dr. Keats responded that there are some analogies within nuclear weapons as well as aircraft operations that would be useful to model. He stated that medicine has ignored some of the lessons

which can be learned from those industries. He noted that David Marx began his career in the aviation industry and brought his experiences with him in his research.

Mr. Powers referenced the statistics within the presentation, indicating that 25% of medication errors are preventable. He asked why the percentage is so low.

Dr. Keats responded that the data was from the Institute of Medicine, and he believes they were referring to what percentage could be corrected by changing the systems of care currently in place. He feels that they may not have included the large amount of errors that occur due to behavioral choices and not following procedures currently in place.

Ms. Herold asked where Dr. Keats sees CAPSAC going in subsequent years, as well as the plan to integrate involvement in the community.

Dr. Keats responded that CAPSAC's plan is to promote Just Culture, and to look for other projects that will promote patient safety such as the world health organization safe surgery checklist. He added that CAPSAC may not be the body to invent the program, but can be a body for disseminating practices widely and more quickly than has been done in the past.

Mr. Goldenberg referenced venues of error prevention. He asked if Dr. Keats has found any information concerning the outpatient arena and medication error. He asked if there are more patients on critical drugs in the outpatient arena versus the inpatient arena.

Dr. Keats responded that there was a study conducted a few years ago which focused on outpatient prescriptions. The results of the study indicated an error rate in those settings as being just as high.

C. Presentation from Loriann deMartini, Pharm D, Department of Public Health, Regarding California's Requirements for Reporting Adverse/Never Events in California Hospitals

Ms. Herold introduced Mr. LeWinter from the California Department of Public Health (CDPH), who was presenting on behalf of Dr. deMartini.

Mr. LeWinter introduced two of his colleagues attending the meeting, Joan Jones and Paul Crea.

Mr. LeWinter provided his background, and noted that the last couple of years have been the most exciting part of his career.

Mr. LeWinter discussed SB 1301 (Adverse Events) and provided some history. He explained that it defines 28 "adverse events" which should never occur in hospital settings, and specifies that those events are to be reported by the hospital to CDPH if they should occur. Mr. LeWinter explained that the 28 "adverse events" are placed into seven categories, which he listed and provided definitions for.

Mr. LeWinter provided a definition of a serious disability in the context of adverse events. He also provided an explanation of the requirements of reporting an adverse event, including the mandated timeline. Mr. LeWinter reviewed the financial penalties charged to a hospital in the event that an adverse event is not reported as required.

Mr. LeWinter reviewed the statistics provided on adverse events, which detailed the specific causes of all 1225 cases between July 2007 and June 2008.

Mr. LeWinter described a case of patient who had a stroke and clot-busting drugs were administered. He explained that the patient died because the physician and nurse referred to the wrong side of a dosage chart of the prescription needed, giving 54% of the suggested drug quantity. He explained that the plan of correction was to call the pharmacist on call to verify the dosage, regardless of whether that pharmacist is on-site or not. They failed to call the pharmacist, however.

Mr. LeWinter advised that new regulations will be in place, requiring adverse events to be publicly reported. The reported events will be made available on the CDPH website by 2015. He also indicated some of the steps being taken by CDPH in regards to clarification of redefinition of language within the regulations. Mr. LeWinter concluded with some of the goals of CDPH in relation to adverse event reporting.

Questions to the presenter:

Mr. Goldenberg asked what the range or guidelines are of fines with relation to severe hospital incidents.

Mr. LeWinter indicated that currently the maximum fine has been $25,000. He stated, however, that when the regulations are promulgated, the maximum fine will be $100,000. He noted that when a hospital is fined $25,000, the event is also is publicized in the local newspaper.

Mr. Goldenberg mentioned a star-rating of nursing care facilities that will eventually evolve, as well as current ratings of hotels, restaurants, etc. He noted that the public seems to be "the last to know" right now in terms of hospital settings, and hopes that there will be a change in that arena.

President Schell referenced the issue brought up prior on fines from pharmacy inspections. He asked if CDPH has any methodology on determining fines.

Mr. LeWinter responded by explaining that a fine is assessed only in the case that "immediate jeopardy" is determined in the incident. He added that there is no fine with other cited deficiencies.

Joan Jones (CDPH) responded in that it depends on the type of facility. CDPH has the capability of fining hospitals for "immediate jeopardy". She explained that the hospital can dispute the charge within 10 days, however no hospital has ever filed a dispute because there is always clear supporting evidence. She indicated that in a nursing home, for example, fines can go up to $100,000 but is based on the type of deficiencies found. Ms. Jones stated that there is a rating of citations, where a letter grade is applied. She emphasized that the rating system for nursing homes is very structured, and that hospitals are now starting to be viewed in the same way. She added that, in the past when investigated, there were no civil monies penalties. Now that they have $25,000 "incentives" to issue, there has been quite a change.

Mr. LeWinter indicated that in the event of an "immediate jeopardy", CDPH can report the incident to the Centers for Medicare and Medicaid Services (CMS) and recommend they perform a validation survey, which then becomes a federal survey. If it is a survey for CMS, it will have major impact on their Medicare/Medicaid funding.

D. <u>Discussion and Recommendations for Future Action</u>

Ms. Herold referenced the interest in the specific medication errors that were fined during the earlier presentation by the board. She suggested an opportunity to share best practices by taking a medication error incident that has gone fully through system, and releasing the details of the incident as well as what the institution was cited and fined for.

Mr. Goldenberg agreed. He asked if tandem agencies could be involved as well, since the event can be can be looked at by several different agencies and provide more impact.

Ms. Herold responded that she believes the information could be routed through ISMP and FDA and then referred back to the drug companies in order to document what is happening and provide awareness that it is being monitored.

President Schell suggested placing the item on the agenda for the next Communication and Public Education Committee meeting in order to flush out the details and determine if a plan of action is feasible.

Ms. Herold noted that the board has been working closely with CDPH on the Heparin recall, and that both entities are still fully engaged in the investigation.

E. Discussion Regarding the Next Meetings of the SB 472 Medication Label Subcommittee

Ms. Wheat briefed the board that the sub-committee held a forum in April with little attendance by the public. As an additional effort to gain more input from the public, the board and staff have initiated a survey.

Ms. Herold explained the initial plan to hold a series of public meetings in order to allow the public an opportunity to provide input on what they would like to see on prescription labels. She reiterated that the turnout was low and that the process was inefficient. She indicated that the board rolled out consumer surveys which will be discussed in the Communication and Public Education meeting immediately following this meeting. Ms. Herold stated that the next SB 472 subcommittee is scheduled to hold their next meeting at the Professionals Achieving Consumer Trust Summit on November 20th, 2008. The intention is to utilize the Summit meeting to join with other prescribing boards in order to collectively hold a public forum and gain a wider audience of feedback.

Ms. Wheat has asked whether waiting until November is too long.

Ms. Herold opened up a discussion of the board to determine whether action should be taking prior to the Summit.

Ms. Wheat suggested that the board utilize the website for feedback.

Ms. Herold responded that it is already being utilized, and that the survey is provided in two different locations - "What's New" and "Information for Consumers". She noted that the staff will pursue adding some type of "tag line" to gain attention as people view the website home page.

Supervising Inspector Janice Dang asked if the surveys are being distributed at the health fairs where the Board of Pharmacy is attending as vendors.

Ms. Sodergren responded that they are already doing that. The initial attempt is to interview people during interaction at the booth, but there is also the option to mail back the surveys.

Ms. Herold added that the board is receiving those surveys at the office. She also noted that the survey has been translated in Spanish.

President Schell suggested a meeting be held prior to November 20th, to allow the subcommittee and interested parties to discuss the survey and forum results so far and strategize how they would

like the Summit meeting to be formatted. He suggested that a date be determined during discussion in the Communication and Public Education meeting following.

Public Comment:

Mr. Horowitz suggested that the board may want to supply the surveys to licensees who would provide them to patients, in order to collect more surveys from consumers.

Dr. Gray (Kaiser Permanente) stated that the leading researcher on the issue spoke at a recent seminar for American Society of Health-System Pharmacists, and made a report where they have now come up with a model of a label and have received funding to test that label. He urged the board to contact the researcher in order to be aware of when the test results are completed and available. He noted that he had spoken to the researcher, and that he had no information from California as to their next steps. He suggested that gaining input from the scientific studies being conducted may be helpful in relation to the board's surveys.

Ms. Herold responded that part of the commitment and direction of the board is to collect information from the public as SB 472 mandates. She questioned the label design being used in the test.

Dr. Gray stated that the test is being approached scientifically and that the label design is significantly different from California's layout. He indicated that he has the report and will provide it to the board. He noted that since that report was written, funding has been provided for actual testing.

Ms. Wheat stated that SB 472 is on the Communication and Public Education Committee agenda, so it will be discussed further within that meeting.

VI. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Dr. Earl Mindell indicated that he has been collecting pharmacy artifacts for over 50 years. He felt that it was important not to ignore the past of our profession. He noted that some of the Deans of pharmacy schools have reviewed the collection. He also stated that he has conducted classes and provided video footage of his collection. Dr. Mindell stated that he was amazed that pharmacy education did not include any history of pharmacy within the curriculum. He invited the Board of Pharmacy to visit and see the collection as well as Long's and other chain stores. He noted that the museum is in Beverly Hills, and stated that it is an open invitation. Dr. Mindell indicated that he will pursue the possibility of providing a video at the next board meeting. He concluded by reiterating that he felt the history of pharmacy should not be ignored, and that it should be kept somewhere in the curriculum at the schools of pharmacy.

Ms. Herold noted that the meeting in November is in Los Angeles, so it may be feasible to visit at that time.

The meeting was recessed at 4:17 p.m.

The meeting reconvened at 8:43 a.m. (on July 24th, 2008)

VII. Closed Session

The board went into closed session pursuant to Government Code section 11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination.

General Announcements

President Schell recognized Dorethea Johnson (Department of Consumer Affairs, Legal Department) and Anna Yamada (Inspector, Board of Pharmacy).

President Schell stated that the board has an opportunity to attend the accreditation by the American Association of Colleges of Pharmacy (AACP) for the new three new schools of pharmacy opening in Southern California in 2009. The openings will be in January, March and April. He noted, however, that there are schedule conflicts with board and committee meetings in those months. President Schell suggested a change for the meeting dates from Wednesday/Thursday to Thursday/Friday meetings in order to accommodate the visit. Ms. Herold noted that one representative of the board attends the accreditation. President Schell stated that the definite dates would be determined at a later date. President Schell will be contacting the board members to see who would be interesting in representing.

VIII. Legislation and Regulation Committee Report and Action

Report of the Meeting of July 10, 2008

Part 1: Regulation Report and Action (Note: CCR as used below means California Code of Regulations)

A. Board Approved Regulations – Awaiting Notice (for information only)

1. Repeal of Title 16, CCR Sections 1716.1 and 1716.2 and Amendment to Sections 1751-1751.8 and Adoption of Sections 1735-1735.8 – Pharmacies that Compound

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. Mr. Graul indicated that the proposal would establish guidelines to provide uniformity in compounding for California consumers.

At the January 2008 board meeting, the board conducted a regulation hearing to hear testimony about the regulation proposal that establishes requirements for pharmacies that compound medications. As a result of this regulation hearing, the board voted to complete a 15-day notice with revised language to address some of the written comments received and oral testimony provided.

Given the significant amount of comments submitted and testimony provided, staff recommended that the board approve withdrawing this prior rulemaking to allow time to further refine the draft language.

The board packet contains the proposed language the board approved at the April 2008 Board Meeting for a new 45-day comment period. (This language reflects changes as a result of written comments received and public testimony provided.) Staff planned to notice the revised rulemaking in advance of the July 2008 Board Meeting, however because of conflicting priorities within the department, we were unable to submit by the deadline to allow for action by the board in July. Mr. Graul advised that staff will notice the rulemaking for action by the board at the October 2008 Board Meeting.

2. Title 16 CCR section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Mr. Graul stated that the self-assessment form would aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Mr. Graul stated that the draft language and form were included within the board packet provided. He added that staff anticipates initiating the 45-day comment period in advance of the October board meeting to allow for action by the board at that meeting.

3. Title 16 CCR section 1780 – Update the United States Pharmacopeia (USP) Standards Reference Material

The topic of discussion is in relation to temperature and humidity.

CCR 1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

Mr. Graul explained that at the April 2007 Legislation and Regulation Committee Meeting, the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather sought input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material.

At the July 2008 Legislation and Regulation Committee Meeting, staff requested guidance from the board on pursuing this regulation change, as no additional information was submitted. The committee was advised that comments are forthcoming detailing the possible consequences of incorporating the 2005 version of the USP Standards Reference Materials. Mr. Graul indicated that they are still awaiting written comment and that, upon receipt, the committee will review the concerns and make a recommendation to the board as warranted.

Public comment:

Dr. Gray noted that at the last board meeting, it was requested that he bring information to today's meeting regarding the USP Standards in relation to temperature and humidity. He presented Volume 1, which is one of four volumes of the latest edition of the USP manual. Dr. Gray discussed requirements and cost in obtaining those reference books. He also reviewed the history of the USP manual and previous editions. He indicated that the standards are now divided up within the volumes, making it difficult to locate sections for needed information. Dr. Gray explained that the prior standard on upper storage limit for temperature was 86 degrees Fahrenheit, but it is now listed as a "controlled room temperature", which is a standard of 77 degrees Fahrenheit. He pointed out that the standard has

become much more sophisticated and will cause some concern by various parties, as many drug warehouses are not air-conditioned and rely on high ceilings and roof trap doors to lower temperatures as needed. The concern, then, is that the new standard may cause many manufacturers to have to invest in air-conditioning systems. Dr. Gray stated that the board should be prepared to receive negative feedback from industry as this standard goes into formal regulation adoption because of the new temperature standard, and suggested the board consider determining their own standard rather than using that provided by USP. He also referred to the humidity standard, which is discussed in the USP manual. He noted that it will be difficult for him to provide written references because of the layout of the information within the book, as well as copyright issues.

Board discussion:

Mr. Weisser asked if the only alternative is to devise our own standards, as that would be a tremendous task.

Ms. Herold responded that we are not equipped to devise our own. She suggested looking at what other states are doing in terms of addressing the temperature and humidity levels, before attempting to resolve on our own. She added that she is unsure whether the board is able to make changes when the standards being set scientifically by USP are otherwise.

Mr. Graul added that they would need to go to industry to gain their input due to the impact it may cause.

Ms. Herold agreed. She indicated that it may be necessary to address the issue with the pharmacies as well.

Dr. Gray added that it will affect all types of storages for various categories of industry. He suggested contacting the FDA and military to find out how they address the issue.

Ms. Herold stated that the board cannot afford to ignore what USP is stating because they are the entity who conducts through scientific testing to determine these standards. She thanked Dr. Gray for providing the information, and commented that the board is in a difficult situation. She concluded that the board staff will need to collect more information on the issue and bring it back to the board with more options.

President Schell concurred with Mr. Graul and indicated that the wholesalers should be contacted as well to determine how they address the issue of temperature control since they must have guidelines to follow as well. He agreed that the board does not have the scientific knowledge to make a decision outside of USP standards, but stated that it would be best to find a solution which will be appropriate

Mr. Burgard stated that climate control standards are nothing new. He suggested that the pertinent data should be collected in order to understand the mechanics of heating and air-conditioning. Mr. Burgard indicated that he doesn't feel the entire industry should need to add air-conditioning systems simply based on what was shared by Dr. Gray. Instead, it is providing a warning to ensure that warehouses are not allowing temperature increases beyond 86 degrees on a consistent basis.

4.Title 16 CCR section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for

pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

Mr. Graul indicated that the proposed regulation would specify the criteria the board uses to evaluate these agencies. He noted that a copy of the language is contained within the board packet provided.

5.Title 16 CCR sections 1721 and 1723.1 – Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §§1721 and 1723. Mr. Graul stated that the proposal would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Mr. Graul advised that a copy of the language is contained with the board packet provided.

A. Board Adopted Regulations

1. Proposed amendment to Title 16 CCR Section 1760 – Disciplinary Guidelines

Mr. Graul stated that at the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. He explained that during discussion at the board meeting, counsel recommended that the board strengthen the response to comments submitted during the written comment period. Staff is awaiting further explanation from counsel for inclusion in the rulemaking. Mr. Graul explained that, upon receipt of this information, staff will move forward to compile the rulemaking file to submit for administrative review.

B. Proposed Regulation Language for Committee Consideration

1. Amend 16 CCR 1773 – Disciplinary Conditions of Probation of a Pharmacist and Adopt Title 16 CCR 1773.5 - Ethics Course for Pharmacists

Mr. Graul stated that at the October 2007 Board Meeting, the board voted to pursue a regulation proposal to develop an ethics course for pharmacists, modeled after the program used by the Medical Board of California.

Mr. Graul stated that the regulation proposal needs to put the parameters of the program into regulation, as it will be requiring pharmacists to comply as part of their terms and conditions of probation. He noted that the amendment to Section 1773 adds in the completion of the ethics course as a possible requirement for discipline, and the addition to Section 1773.5 details what that course would be comprised of.

Mr. Graul stated that draft language was developed and considered by the Legislation and Regulation Committee held on July 10, 2008 and is contained within the board packet provided.

MOTION: To direct staff to take all necessary steps to initiate the rulemaking process, including filing with attached proposed text with the Office of Administrative Law.

M/S: WEISSER/BURGARD

SUPPORT: 9 OPPOSE: 0

2. Amend Title 16 CCR section 1715 - Self Assessment Forms

At the July 10, 2008 Legislation and Regulation Committee Meeting, the committee was advised that board staff would begin work to update the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the new form.

The self-assessment form is completed every odd-numbered year. Staff needs to begin revisions on this form to allow time to complete the rulemaking. The revised form needs to be ready for 2009.

To update this form, the board needs to vote to pursue the regulation change, which can be done as a section 100 change. The final proposal will change the revision date of the form and the self-assessment form will be updated.

Mr. Graul indicated that counsel has advised that when text for the self-assessment form is developed, it will be brought back to the board for review.

Ms. Herold explained that the self-assessment form needs to be in place by July of every odd year. She stated that, in the past, they have not been able to meet that deadline. She indicated that the board should be aware of the new laws in effect by the October board meeting and can move forward with developing a draft self-assessment form for review.

Public Comment

No public comment provided.

Part 2. Legislative Report:

A. Discussion and Action on Pending Legislation

1. Board Sponsored Legislation for 2008

a. SB 1779 (Omnibus Provisions Previously Approved by the Board)

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership

This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative-in-Charge - Amend Sections 4022.5, 4305, 4329, 4330 and Add section 4036.5.
The Board of Pharmacy is proposing changes to several sections of the Business and Professions Code to clarify the reporting requirements to document a change in the Pharmacist-In-Charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There are also similar changes for the Designated Representative-in-Charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would also define the term "pharmacist-in-charge" currently referenced throughout pharmacy law as well as place into statute the approval process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC.

Amend Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section clarifies that a designated representative must sign for and receive delivery of drugs by a wholesaler. This is important for accountability of drug purchases and receipt in wholesale operations.

Amend Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section corrects a drafting error that occurred in Senate Bill 1307 (Chapter 857, statutes of 2004). The term "exemptee-in-charge" was incorrectly updated to "representative-in-charge" and requires correction to the appropriate term "designated representative in charge."

Amend Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section clarifies specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section addresses the need to authorize the board to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation. This authority already exists when a pharmacist fails to certify completion of continuing education as part of the renewal application.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispenses schedule III and schedule IV controlled substances must report weekly to CURES, similar to the requirements for pharmacies and prescribers who dispense controlled drugs as specified.

Mr. Graul indicated that all of the above provisions are contained within the board packet and will not be reviewed, with exception of Section 4161 which requires action.

Amend Section 4161 – Nonresident Wholesaler: When License Required: Application
Mr. Graul explained that this section clarifies that any person that sells, brokers or distributes dangerous drugs or devices within California must be licensed.

Because of timing within the legislative cycle, this provision was recently included in the omnibus bill at the request of staff. It was reviewed and approved by the Legislation and Regulation Committee for board approval.

Mr. Graul indicated that a copy of the proposed language as presented to Senate Business and Professions is contained within the board packet provided. He stated that the committee recommendation was to approve amendment to section 4161 – Nonresident Wholesaler for inclusion in SB 1779.

MOTION: To approve the amendment to section 4161- Nonresident Wholesaler for inclusion in SB 1779.

SUPPORT: 9 OPPOSE: 0

b. SB 1307 (Ridley-Thomas) Electronic Pedigree Requirements

The bill contains additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it specifies that the serialization number must be contained in the electronic pedigree, delays the implementation date and staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for interference requirements by regulation.

Mr. Graul stated that amendments are still being proposed, and the committee will keep the board updated as it progress.

The board has a support position. No action is required.

2. Legislation Impacting the Board's Jurisdiction or the Practice of Pharmacy

a. Active Bills

AB 501 (Swanson and Hancock) Pharmaceutical Devices

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide upon request of a consumer, a postage prepaid mail-back sharps container for safe disposal of the used device or a sharps container for storage and transport to a sharps consolidation location.

Board Position: Support

AB 865 (Davis) State Agencies: Live Customer Service Agents

This bill would require specified state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or automated telephone answering equipment which then must include an option to reach a live customer service agent.

Board Position: Neutral

AB 1394 (Krekorian) Counterfeit: Trademarks

This bill would remove the requirement that the sale of counterfeit mark be intentional and also make it a misdemeanor or a felony for a business entity to willfully manufacture, sell or knowingly possess for sale any counterfeit registered trademark.

Board Position: Support

AB 1436 (Hernandez) Nurse Practitioners

This bill would revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing. Expand the scope of practice to allow a nurse practitioner to perform comprehensive health care services as specified and is authorized to admit and discharge patients from health facilities, change a treatment regimen and initiate an emergency procedure in collaboration with healing arts practitioners.

Board Position: None

Mr. Graul stated that the board currently has positions on all of the above bills as noted and that all of the bills are contained within the board packet.

AB 1574 (Plescia) Surgical clinics: licensure

This bill would expand the board's licensing authority to issue a clinic permit to surgical clinics to such clinics that are Medicare certified or accredited by an recognized agency and require the board to perform periodic inspections and establish a self-assessment requirement.

The committee has a recommendation of support.

Board discussion:

Dr. Gray stated that he has read referenced materials within the bill. He indicated that the language now adds that the board will license any entity under Health and Safety § 1248 that is a clinic that is accredited under those subject sections. Dr. Gray suggested that the board review the language once more to determine if they want to issue permits to any clinic that has met accreditation requirements of that section of the statute rather than just surgical clinics. Dr. Gray stated that there may be an assumption that these clinics are owned only by physicians. He explained that the board would be issuing licenses to buy and store drugs to different types of entities where some may be owned and operated by non-healthcare companies.

Mr. Docherty responded that the intent of the language was to have it apply to entities that are licensed as a surgical clinic pursuant to Health and Safety code §1204, but also accredited as an outpatient setting pursuant to 1248 and that are also Medicare certified. He clarified that they are not referring to any accredited entities, but rather to those entities accredited as an outpatient setting pursuant to 1248. He added that 1248 defines those types of entities that would be accredited for purposes of meeting obligations of using certain levels of general anesthesia.

Ms. Sodergren asked if the accreditation process includes standards of care, responsibilities of operations, etc.

Mr. Docherty responded that the accreditation standards pursuant to Health and Safety code §1248 states that the Medical Board of California must approve any entities authorized to be accreditation agencies. He added that there are only four entities approved to provide accreditation in outpatient settings. Mr. Docherty listed the four entities approved as such.

President Schell asked if the four entities indicated would allow a non-licensed healthcare professional to manage a facility.

Mr. Docherty responded that, in order to be defined under current law as a surgical clinic, they must meet the definition of what a surgical clinic is. He indicated that a clinic can be exempt from being licensed as a surgical clinic if they meet 16 different exemptions. One of those exemptions would be a wholly-physician owned and operated surgical clinic. Those types of clinics are accredited and would be eligible for pharmacy permits by the board.

Mr. Powers asked if this addresses the issue raised by Dr. Gray and whether it supports his statement of other clinics besides surgical clinics being included.

Mr. Docherty responded that it would only apply to those entities that are defined as an outpatient setting pursuant to Health and Safety code §1248, which are entities themselves who use certain levels of general anesthesia. He confirmed that it can be any entity that uses a certain level of anesthesia.

Ms. Herold referred back to Dr. Gray's discussion of issuing permits to entities owned by non-licensed healthcare professionals. She stated that the board already issues licenses to such entities.

President Schell confirmed that there would be a substantial increase in the breadth of entities, which causes a concern over resource issues within the board if they are going to be responsible for a substantial amount of additional facilities to regulate.

Mr. Docherty agreed that it may expand the number of entities the board would license, but does not believe it would be a substantial increase. He stated that CASA believes they could be managed within existing resources, and that the permit fees incurred would be sufficient to compensate for additional workload.

Ms. Herold responded that the board will collect an increase in fees in this bill based upon the licensing of additional facilities. She stated that the board built their fiscal to be resource neutral, in that the additional revenue generated will offset the additional staffing needs. She noted that, because these clinics would not be licensed by any other agency, they will need to be inspected every year as a condition of renewal. Therefore, they have budgeted for staffing of an additional inspector and clerical staff person to cover for that. She noted that additional information has been provided more recently which indicates that the number of entities requiring licensure has increased from 200 to 400. Additionally staffing was budgeted with the understanding of 200 clinics planned. If the increase of entities goes to 400, more staffing will be needed.

Mr. Weisser asked if the bill would include oral and cosmetic surgeons who utilize general anesthesia.

Docherty confirmed that there may be dental and cosmetic practices who are wholly-owned physician clinics and are exempt from licensure who may seek a clinic permit from the board.

MOTION: To establish a position of support on AB 1574.

SUPPORT: 9 OPPOSE: 0

<u>AB 1587 (De La Torre) Personal Information: Pharmacy</u>

This bill would exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

Board Position: None

Mr. Graul indicated that the bill is not moving.

AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

This bill would specify that for purposes of furnishing dangerous drugs and devices during an emergency, a pharmacist is not required to await a declaration of emergency as long the declaration is reasonably anticipated due to the severity of the emergency or natural disaster.

Board Position: Support

Mr. Graul stated that no action is required.

SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review

The board was provided updated draft amendments at the beginning of the meeting.

This bill replaces the process whereby a sunsetted board becomes a bureau in the Department of Consumer Affairs (DCA) with reconstitution of the board's members, and specifies other reporting requirements. In addition, it subjects all Executive Officer's to approval of the Director of the Department of Consumer Affairs, as well as to Senate Confirmation, requires the standardization of board meeting minutes for all boards within the DCA and requires reporting of all ex parte communications by board members.

Board Position: None

Mr. Graul requested board staff to provide an overview of this proposal.

Ms. Sodergren highlighted portions of SB 963 and compared some of the requirements with current board operations. She explained that the reporting requirements are different and not as comprehensive as what the board currently provides annually and through the existing sunset process. Additionally, the bill includes a pro bono incentive, revised staffing requirements based on number of licensees, a reconstitution process in lieu of sunsetting a board, reporting requirements of ex parte communication, DCA approval over the final decision of the board's recommended Executive Officer, as well as standardized minutes and time frame.

Ms. Sodergren provided a more detailed explanation from the bill of the proposed change from board sunsetting to reconstitution and indicated that the drafted amendments to that proposed change are significant.

Ms. Schieldge questioned the language within the bill relating to board minutes and the ten day requirement. Ms. Sodergren clarified that the proposed amendments indicate the minutes would need to be posted on the website within 10 days of approval, rather than within 10 days of the meeting.

Ms. Schieldge provided an explanation of Ex Parte communication and the referenced the Bagley-Keene Open Meeting Act. She explained that currently, separate individuals of the board (which

creates less than a quorum) in discussion ("secret meeting") are not prohibited. She indicated that proposed amendments would indicate that such discussions, when related to board topics and with the intent of influencing the board member would need to be reported at the following board meeting by the individual initiating the conversation. Ms. Schieldge also stated that board members are not prohibited from discussion with a member of the public. However if that board member subsequently discussed the public member's issue with a quorum of the board, that would be prohibited.

Ms. Herold clarified that they are making a decision on an addendum which would prohibit a board member from having any conversations with a licensee if there are disciplinary matters being discussed within the board on that individual. In such a case, the board member would be required to advise the administrative law judge and attorney general to advise that they were contacted.

Mr. Graul stated his concern with some of the proposed addendums. Specifically, he referred to the ex parte issue, the Executive Officer confirmation, the meeting minutes requirements, and the reconstitution of the board with all board members having same term.

Public Comment:

Mr. Docherty (CSHP) stated that they currently have a watch position on bill. He indicated that a letter was sent to the author's office with concerns in line with those noted by Mr. Graul. He stated that their concern over maintaining the autonomous nature of the board and what downstream effects that would have. He said that they also have concerns as the bill is currently written with regard to the Executive Officer position. He advised that the bill was a late "gut and amend" in late July and work is still in progress. Mr. Docherty added that they are prepared to move to an oppose position if amendments will go in the direction as they are to date.

Ms. Rolston (CPHA) stated their agreement with Mr. Docherty's comments and position.

Board discussion:

Mr. Graul suggested a neutral or watch position at this time and submit a letter in support of those draft amendments that address the board's issues, as well as concerns regarding the issues that are not addressed in the draft amendments.

Mr. Weisser reviewed the ex parte section of the draft amendments briefly and had further issues with the requirements.

Mr. Goldenberg stated that he sees the amendments as politicizing the board. He stated that the board's focus on consumer protection and enhancement of the profession would be compromised by the bill. He added that the board members' leadership would be compromised. Mr. Goldenberg indicated that he would take the strongest opposition possible on the bill.

Ms. Wheat asked how the board would be affected if they stay in a neutral or watch position. She added that she doesn't want to take position until they have a final draft of the bill.

Mr. Hough stated that it seems it would raise havoc of the continuity of the board.

Ms. Zinder confirmed that the board would be making their motion based solely on the current version of the bill, not including the drafts amendments provided at the meeting today.

Mr. Weisser asked if the board will have an opportunity later to raise any opposition or concern to the author of the final draft.

Ms. Herold explained that the session ends at the end of August. The board will not have an opportunity to take a position on the bill unless the board empowers the President to take a position on their behalf. She provided clarification on the board's options in regards to taking a position on the bill.

Mr. Graul asked for clarification in the event the board chooses to take a position of opposed, unless amended. He stated that the board would need to provide amendments in that case. He suggested that, due to the short deadline, the President and board staff would need to represent the board in drafting proposed amendments He added that the board would need to identify the areas of concern and then rely on the President and staff to draft the amendments.

Mr. Powers stated that he is not in full opposition of the ex parte communication amendment. He felt that it may be a legitimate position in law to take.

President Schell explained his viewpoint and understanding of the ex parte amendment in that it would include all communication. He noted that the intention of the author on this issue may have been towards lobbyists. His concern, however, is that it would include any conversation with students, general public members, etc. which would create a significant impact on board meeting time in publicizing those conversations. He pointed out that if board members simply don't have those conversations, then the industry, students and general public may be disenfranchised and lose a sense of trust with the board.

Mr. Powers responded that he has never been contacted by a student in his eight years on the board.

President Schell responded that he has had the opposite experience.

Ms. Zinder asked what constitutes ex parte communication and asked about the choice to contact a member of industry in order to gain knowledge or understanding on a topic of any type.

Ms. Schieldge quoted the portion of the law on this item relating to someone who is intending to influence the decision of a board member. She noted that it does create vagueness in the matter. Board members would most likely choose to simply not have any conversations at all to avoid any conversations of that nature from occurring.

Ms. Herold stated that the amendments relating to ex parte communication are modeled after the current requirements of the Public Utilities Commission.

Ms. Wheat asked for clarification that ex parte communication is not just relating to conversations with lobbyists or students.

Ms. Herold responded that it includes conversations with anyone.

Mr. Goldenberg stated that part of the value of all members of the board is to be able to accept communication from all of the constituents. He gave the example of past issues with exams and numerous conversations with the industry, students, etc. which helped him to be more informed when bringing topics to the board. He stated that the amendment would reduce the board's ability to share information. He added that the board has been very careful to ensure multiple member conversations do not occur. Mr. Goldenberg stated that there must be some type of wording in the amendment to ensure that board members can continue to have appropriate conversations with consumers, industry members, etc.

Public Comment:

Dr. Gray stated his concern over the reluctance of various divisions of government to talk to each other. He stated that, in his opinion, this amendment would make the situation worse. He indicated that conversations with other departments outside of the Department of Consumer Affairs would also need to be reported. Dr. Gray pointed out the example of the reluctance of board members to answer questions of students or general public following a speaking event. He also noted that there is no clarity of what details would need to be provided. He suggested that an opposed unless amended position may not be strong enough.

MOTION: To establish a position on SB 963 of oppose unless amended.

M/S: ZINDER/POWERS

SUPPORT: 9 OPPOSE: 0

Mr. Graul suggested that the board define amendments for staff, who in turn would then draft amendments with the president.

Ms. Schieldge suggested the board discuss the general areas of concern and delegate the president to review the final draft before submission.

Ms. Herold agreed with the suggestion but requested further discussion on the issue of ex parte communication to clarify what the board would want to see in the amendment. She gave examples of communication with industry during research on E-pedigree, as well as communication with school of pharmacy students following a presentation by a board member.

Ms. Zinder stated it is important for board members to be able to speak freely to members of industry in order to gain knowledge of various topics discussed at board meetings in order to be able to make informed decisions.

Ms. Wheat stated that appointing board members should reflect a level of trust that they are able to make decisions without being influenced by lobbyists, industry members and public members they have conversations with.

Mr. Dazé agreed with Ms. Wheat's comments and stated that the ability to have communication should be either freely allowed without reporting requirements or not at all. He explained that there will be tremendous confusion in determining what needs to be reported.

MOTION: To direct staff to draft amendments to SB 963 regarding the ex parte communications, the appointment and confirmation of the Executive Officer, the reporting requirements, the minutes and format, and the reconstitution of board. Those amendments, once drafted, would then be approved by the President on behalf of the board.

M/S: GRAUL/DAZÉ

SUPPORT: 8 OPPOSE: 0 (Mr. Burgard not present to vote)

Board staff will use the draft amendments to craft proposed amendments on the behalf of the board.

Mr. Graul indicated that all of the inactive bills are contained within the board packet provided.

SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

Create an Electronic Pedigree Taskforce to provide the board with updates regarding industry readiness on the implementation of the pedigree requirements as well as submit an annual report to the board and specified legislative committees.

Board Position: None

SB 1441 (Ridley-Thomas) Healing Arts Practitioners: Substance Abuse

Create the Substance Abuse Coordination Committee with the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board would be required to use in dealing with substance-abusing licensees.

Board Position: None

b. Inactive Bills

AB 1947 (Emmerson) Pharmacy Technicians

This bill would increase the minimum requirements for licensure as a pharmacy technician to include both certification by the Pharmacy Technician Certification Board as well as either completion of a technician training program or a specified associate's degree. In addition, would require pharmacy technicians to complete 20 hours of continuing education each renewal cycle.

Board Position: None

AB 2516 (Mendoza) Prescriptions: electronic transmission

This bill would require a prescriber to ensure that any prescription issued shall be electronically transmitted to the patient's pharmacist of choice, except as specified.

Board Position: None

AB 2643 (Cook) Drugs and Devices

This bill would replace references to the United State Pharmacopoeia in relevant sections of the Business and Professions Code, Health and Safety Code, Insurance Code, Penal Code, Public Resources Code and Welfare and Institutions Code.

Board Position: None

SB 1096 (Calderon) Medical Information

This bill would allow a pharmacy under specified conditions, to mail specified written communications to a patient, without the patient's authorization.

Board Position: Oppose

SB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution.

This bill would prohibit a pharmacist from filling a prescription for an antiepileptic drug that is prescribed by its trade, brand or generic name by substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

Board Position: None

SB 1594 (Steinberg) Bleeding Disorders Clotting Products

This bill imposes requirements on providers of blood clotting products for home use that are used to treat hemophilia and other bleeding disorders.

Board Position: None

AB 2122 (Plescia) Surgical clinics: licensure

This bill would define the operational, staffing and procedural standards for surgical clinics and would require the board to perform periodic inspections at least once every three years.

Board Position: None

c. Other Legislation Impacting Pharmacy or the Board's Jurisdiction

SB 1702 (Machado) Medi-Cal: Fraud

This bill would require the Department of Health Care Services (DHCS) to review and, if necessary, conduct a field audit of, a Medi-Cal provider who serves in excess of a threshold percentage of out-of-county beneficiaries. Directs DHCS to determine the threshold in conjunction with the Attorney General and exempts specified providers from mandatory review.

The California Retailers Association (CRA) requested that the board add SB 1702 to their watch list. CRA is concerned that in its current form, this legislation could result in additional Medi-Cal audits because it is using county lines as the triggering event for such audits. CRA proposes that a "service area" should be used instead.

Mr. Graul stated that SB 1702 is dead.

Public Comment

No public comment provided.

Part 3: Legislation and Regulation Committee

A. Meeting Summary of the Legislation and Regulation Committee Meeting of July 10, 2008

Mr. Graul indicated that the minutes of the meeting are contained within the board packet provided.

B. Request from the California Pharmacy Foundation (CPF) for Clarification of Business and Professions Code Section 4076

Mr. Graul explained that at the July 2008 Legislation and Regulation Committee Meeting, the committee received a request from Steve Gray, representing the California Pharmacy Foundation. He stated that the Foundation is requesting that the board sponsor legislation that will clarify a pharmacists' authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to the patient. One of the Foundation's primary focuses is on the reduction of medication errors and they believe that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient outcomes.

Mr. Graul noted that the written request from Dr. Steve Gray requesting that the board sponsor a legislative change as well as draft language for board consideration is contained within the board packet.

Mr. Graul stated that as this a request from CPF to sponsor a bill, action needs to be taken by the board. He recommended to defer to staff and the legislative calendar in terms of a feasible timeframe to address this issue.

Public comment:

Dr. Gray (on behalf of CPF) stated that they have had extensive discussion on the topic of medication safety. He referred to SCR 49 as well as the report on SB 472 and the current survey in progress on patient labeling. He indicated that there was a significant amount of requests from the public relating to wanting more communication to patients in a reliable form about what the purpose of the medication is. CPF feels that the best way to provide that communication is on the prescription label. Dr. Gray also stated that there is substantial confusion about pharmacist's ability to make label additions in order to identify the purpose of the drug specifically for the patient. He also gave background on the concerns for the patient in not having more specific information on the prescription label. Dr. Gray noted that there have been concerns by the pharmacists on violating patient privacy. He stated that the draft includes language to "opt out" to address that. He restated that the issue at hand does not have to do with a patient knowing what their prescriptions are for when they first receive them, but rather when they take them home and combine them on the shelf with all of the other prescriptions that they already have. Many have problems remembering which drug is for which medical issue. Dr. Gray stated that he urges the board to move forward with legislation on this issue. He added that it is the start of a two-year legislative session and he does not anticipate that the amendment will move through easily, but that it will make significant improvement on patient and drug safety once it is passed.

Ms. Rolston (CPHA) urged the legislation go forward. She stated that it is a very serious public safety issue. She added that industry has made multiple attempts in the past to address this, but that it is time to try again. Ms. Rolston suggested identifying co-sponsors to the bill in conjunction with the board. She stated that there should be enough ways to make their position more palatable and get opposition to move back, even if it allows for an "opt in".

Mr. Powers asked Ms. Rolston where the opposition has come from in the past when attempting to pass the legislation.

Ms. Rolston responded that it has come from physicians, with legitimate concerns from their standpoint. She stated that there will be a definite need to discuss the plans with them in advance, which would assist in gaining their support.

President Schell asked if it would be an issue for a professional organization to carry the bill.

Ms. Rolston stated that it would then appear to be self-serving. She stated that consumer support is of particular importance.

Ms. Herold referred to the SCR 49 committee, which was a large group of people. She asked if everyone on the committee did in fact agree that it was an appropriate option.

Ms. Rolston responded that she believed so, but was not sure.

Ms. Herold stated that the committee would thus be another core of widespread support base. Those industry representatives within the committee would bring forth a much stronger co-sponsorship position rather than the board sponsoring the legislation independently. She noted that the board will already "have their hands full" with the immunization bill.

Ms. Rolston agreed that the broader coalition that can be created, the better. She concluded that the legislation would be a significant breakthrough in consumer protection.

Dr. Gray responded to the issue of prior opposition on the previous legislation from the medical community. He stated that it was because it required the prescriber to put a diagnosis in electronically before they could prescribe a drug, which is not always known at the time of prescribing the medicine. In response to the question of association sponsorship, he felt that it would not send the same message, and may show as self-serving. He added that if the board is the sponsor, it becomes a statement of intent or expectation of the industry.

Mr. Graul recommended referring the item back to the next Legislation and Regulation Committee meeting.

President Schell agreed.

C. <u>Update of the Committee's Strategic Plan for 2008- 2009</u>

Mr. Graul indicated that the Strategic Plan for 2008-2009 is contained with the board packet provided. There were no recommended changes.

D. <u>Fourth Quarterly Report on Committee Goals for 2007 – 2008</u>

Mr. Graul indicated that the goals for 2007-2008 is contained within the board packet provided.

Public Comment

Heidi Barsuglia (California Retailers Association) advised the board that AB 2756 will be moved from inactive on August 4th, 2008 and will be presented to the Senate floor. There are no amendments to the bill.

IX. Organizational Development Committee Report and Action

A. Report of the Meeting of July 14, 2008

1. Recommendation to Update the Strategic Plan for the Organizational Development Committee Goals for 2008/09

President Schell stated that many of the boards are experiencing retirement of their senior staff. He indicated that it is important to conduct succession planning to ensure smooth operations and support of the organizations mission during those transitions. President Schell noted that a copy of the Board of Pharmacy's strategic plans is included within the board packet. He stated that the committee's recommendation is to include a section to perform such succession planning.

MOTION: To add to the strategic plan an action item of performing succession planning to ensure continuity for board operations during staff retirements.

SUPPORT: 9 OPPOSE: 0 (Mr. Powers not present for vote)

2. Approval of the Board of Pharmacy's Strategic Plan for 2008/09

President Schell explained that at the committee meetings held before today's board meeting, the committees reviewed their current strategic plan objectives for updates. He indicated that these proposed changes have been brought to this board meeting, where the board has discussed modifications needed to update its strategic plan for 2008-2009.

President Schell stated that the board needs to take a final vote to amend its strategic plan as modified during this board meeting. He noted that the board packet contains the committee's current plan, and stated that amendments made to the plan during this meeting will be added. The plan will then be added to the board's website and distributed to staff and board members.

Ms. Herold reviewed a few technical changes needed on the plan, which included an update of the title page with the current officers, an updated picture to be that of the current president, and a change in the budget within the licensing statistics.

MOTION: To approve the board's strategic plan of 2008-2009 as proposed to be amended.

SUPPORT: 9 OPPOSE: 0 (Mr. Graul not present for vote)

3. Proposed Board Meeting Dates for 2009

President Schell indicated that the board meeting dates for 2009 are contained within the board packet provided. He noted the prior discussion on the possibility of modifying some of the dates proposed for the first part of the year. He also indicated that the committee meeting dates will be established.

4. Budget Update/Report – For information

a. 2007 – 2008 Budget

President Schell stated that the final budget figures would be available in August. He indicated that the projected revenues and expenditures provided within the packet are estimates, and that the revenues included a fee increase effective as of January 1, 2008.

- *Revenue Projected: $6,776,000 (includes fee increase 1/1/08)*
- *Expenditures Projected: $9,383,000*

b. 2008 – 2009 Budget

President Schell stated that the new fiscal year started July 1, 2008 without a state budget being in place. He indicated that currently, legislative versions of the budget contain a $1 million loan from the board's fund to the state's general fund. This loan will be repaid in the future, in advance of any need for the board to increase fees because of a deficit in the board's fund.

President Schell said that the Governor's budget for 2008-2009 proposes a 10 percent cut for all general fund agencies. He noted, however, that as a special fund agency, the board is not included in these reductions.

The current proposed figures for 2008-2009 are:

- *Revenue Projected: $7,556,000*
- *Expenditures Projected: $9,733,000*

c. Fund Condition Report

President Schell indicated that the details are contained within the board packet provided. He noted that the revenue does not include cost recovery or cite and fine revenue that is collected by the board during the year.

d. Reimbursement to Board Members

The quarterly report on reimbursement to board members was provided in the board packet.

e. Fee Audit Initiated

President Schell explained that the board will need to seek a statutory increase in fees to take effect about July 2010. He stated that staff will continue to monitor the fund condition and provide a report to the board at each meeting. He noted, however, that the board will need to sponsor legislation to increase fees next year.

President Schell stated that as part of the background for any fee increase, the board has initiated an audit of its fees to ensure the fees are set at the appropriate levels with respect to the expenses of providing services. This process, which will involve a cost allocation of all duties performed by board staff, is scheduled to be completed by the end of 2008.

f. I-Licensing Progress

President Schell explained that the I-Licensing project will offer online application and renewal of

licenses. He indicated that a feasibility study report was approved by the Department of Finance several years ago, and the board is in the first tier of new agencies that may be able to offer this service in the future. Nevertheless, the board is still a long way from implementing this system for its licensees.

President Schell stated that the board continues to move forward as a department in order to obtain I-licensing. He noted, however, that the Licensing Manager will be leaving the board staff soon due to a transfer, but is confident that the Assistant Executive Officer and Executive Officer will keep the project moving forward.

Ms. Herold commented that I-Licensing has been a priority of the board over the past several years, however there has been a lack of expeditious movement thus far.

5. Recognition Program of Pharmacists Who Have Been Licensed for 50 Years

President Schell noted the presentation of six pharmacists in the board meeting the day prior. He indicated that since July 2005, the board has acknowledged 750 pharmacists with 50 or more years of licensure as pharmacists in California. He also noted that 58 pharmacists reached this milestone between April and July 2008. Each was sent a certificate and invited to a future board meeting for public recognition.

Mr. Graul asked if the pharmacists need to apply for the 50-year recognition or if the board staff tracks the information.

Ms. Herold responded that the board staff tracks them.

Mr. Goldenberg raised the issue of prior discussions on 10% reductions in salaries "across the board". He asked about the 10% Medi-Cal cut to pharmacies and their ability to selectively fill prescriptions of Medi-Cal patients.

Ms. Schieldge and President Schell responded that the board would not be able to discuss at this time. They suggested a request that it be placed on the agenda for the next board meeting.

5. Personnel Update

Ms. Herold indicated the forthcoming retirement of Enforcement Unit Manager, Karen Cates, in October. She also noted the transfer of the Licensing Unit Manager, Christine Soto, to another department in mid-August. She stated that they do not have anyone in mind at this time, but they are aggressively recruiting for both positions and have requested to be allowed to use an "open list". By doing so, the board is able to hire candidates outside of the departments as well as promotional candidates, providing the board with a larger pool. Ms. Herold advised that there is one vacancy in the office but have someone interviewed with plans to hire. She noted that all inspector positions are filled. She also indicated that they have hired someone for the public inquiry desk, and that Enforcement Analyst Debbie Funes has been promoted.

Ms. Herold noted that the board had their staff meeting in June. She stated that the meeting included the drug identification bingo game which was presented at the board meeting yesterday, as well as viewing the National Geographic video, "Illicit Trade".

Ms. Herold stated that the inspector staff has focused on standardized training and enforcement priorities. She indicated that they spent two days in June working on standardizing their training, answering questions and talking about uncertainties of the law.

6. Future Joint Board Meeting In November 2008 with Other Departmental Boards and Bureaus

President Schell stated that, during the week of November 17, 2008, the Department of Consumer Affairs will host a Professionals Achieving Consumer Trust Summit for all boards, bureaus and the public to showcase the department's regulatory agencies and consumer protection functions. He noted that the week-long meeting will take place at the Westin near LAX, and that on November 20th, the board will hold a public meeting. President Schell stated that the board has intended to schedule a public discussion of SB 472 (standardized prescription container labels), and perhaps an e-prescribing meeting with the Medical Board, Dental Board and other healing arts boards as well.

President Schell also noted that on November 19, the department will hold a series of workshops for board members. He indicated that the board packet contains a preliminary list of training sessions that will be offered.

E. Fourth Quarterly Report on the Committee's Goals for 2007- 2008

The fourth quarterly report is contained within the board packet provided.

Public Comment

No public comment was provided.

X. Petition for Reinstatement

An administrative law judge was present to conduct a hearing to consider petition for reinstatement submitted from:

- Perry Joe Humphrey

XI. Petition For Reinstatement

An administrative law judge was present to conduct a hearing to consider petition for reinstatement submitted from:

- John Cole

XII. Closed Session

The board went into closed session pursuant to Government Code section 11126(c)(3) to deliberate on the requests for reinstatements.

The proposed decisions will be drafted by the judge and presented to the board for consideration via mail vote.

The meeting was adjourned at 1:37 p.m.

California State Board of Pharmacy Summary of Medication Errors

Virginia Herold
Executive Officer
July 23, 2008

PRESCRIPTION ERROR CASES

	FY 05/06		FY 06/07		FY 07/08	
Total Received	337		395		402	
Total Closed	397		344		600	
Total Substantiated Cases	276	70%	277	80%	563	94%
Total Unsubstantiated Cases	121	30%	69	20%	37	6%

CLOSED WITH CITATION & FINE

	FY 05/06	FY 06/07	FY 07/08
Pharmacists	82	101	128
PIC	20	37	98
Pharmacies	112	139	213

PRESCRIPTION ERRORS DATA

July 1, 2005 – June 1, 2006

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	38	37%
Wrong Strength	21	20%
Wrong Instructions	11	11%
Wrong Patient	17	16%
Wrong Medication Quantity	3	3%
Other Labeling Error	5	5%
Compounding/Preparation Error	3	3%
Refill Errors (frequency, timeliness)	3	3%
Delay in Therapy	3	3%
Total # Citations for errors (may have more than one category listed)	104	

PRESCRIPTION ERRORS DATA

July 1, 2005 – June 1, 2006

Citations

Fine Amount	Number	Percent of Total Citations
$0	17	18%
$125	21	22%
$250	46	48%
$500	7	7%
$750	1	1%
$1,000	3	3%
$2,500	1	1%
Total	96	

PRESCRIPTION ERRORS DATA

July 1, 2006 – June 10, 2007

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	65	22%
Wrong Strength	68	24%
Wrong Instructions	24	9%
Wrong Patient	31	11%
Wrong Medication Quantity	7	2%
Labeling Error	29	10%
Compounding/Preparation Error	15	6%
Refill Errors (frequency, timeliness)	16	6%
Other	29	10%
Total # Citations for errors (may have more than one category listed)	277	

PRESCRIPTION ERRORS DATA

July 1, 2006 – June 10, 2007

Citations

Fine Amount	Number	Percent of Total Citations
$0	123	44%
$100 - $125	11	4%
$250 - $400	76	27%
$500 - $750	50	18%
$1,000	7	3%
$1,500 - $2,000	5	2%
$2,500	5	2%
Total	277	

PRESCRIPTION ERRORS DATA

July 1, 2007 – June 30, 2008

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	174	39%
Wrong Strength	72	16%
Wrong Instructions	77	17%
Wrong Patient	46	11%
Wrong Medication Quantity	24	5%
Other Labeling Error	25	6%
Compounding/Preparation Error	11	2%
Refill Errors (frequency, timeliness)	1	<1%
Total # Citations for errors (may have more than one category listed)	445	

PRESCRIPTION ERRORS DATA

July 1, 2007 – June 30, 2008 Citations

Fine Amount	Number	Percent of Total Citations
$0	204	46%
$100 - $125	0	0%
$250 - $400	19	4%
$500 - $750	113	26%
$1,000 -$1,400	76	17%
$1,500 - $2,000	19	4%
$2,100 - $3.500	10	2%
$3,600 - $4,900	4	1%
$5000	0	0%
Total	445	

MEDICATION ERROR DATA

July 1, 2004 – June 2006

Common Look-alike / Sound-alike Errors	
Clomiphene	Clonazepam
Dynacin	Dynapen
Marinol	Moban
Metoprolol	Metoclopramide
Videx	Vicodin
Fluextine	Paroxetine
Lanoxin	Levoxyl
Prelone	Pediazole
Prilosec	Prozac

Loxapine	Lexapro
Lisinopril	Lovastatin
Lisinopril	Lipitor
Novolin N	Novolin 70/30
Norvasc	Navane
Proscar	Prinivil
Purinthal	Propylthiouracil
Darvocet	Fioricet
Alprazolam	Atenolol
Imipramine	Imitrex

MEDICATION ERROR DATA

July 1, 2004 – June 2006 Continued

Common Look-alike / Sound-alike Errors	
Clorpromazine	Chlorpropamide
Prednisone	Prednisolone
Topramax	Toprol
Mircette	Micronor
Nasocort	Nasolide
Coreg	Cozaar
Norvasc	Namenda
Zyprexa	Zyprexa Zydisc

Hydralzine	Hydrochlorthiazide
Clonidine	Clonazepam
Glipizide	Glyburide
Furosemide	Fluxetine
Lorazepam	Levoquin
Miralax	Maalox
Paxil	Prozac

MEDICATION ERROR DATA

July 1, 2006 – June 10, 2007

Common Look-alike / Sound-alike Errors	
Aciphex	Actos
Aciphex	Arimidex
Clomipramine	Clomid
Doxycycline	Doxepin
Hydralazine	Hydroxyzine
Levsin	Levlite
Lexapro	Lipitor
Lisinopril	Lovastatin
Lomotil	Lamictal

Migquin	Midodrine
Niaspan	Naprosyn
Ortho Cept	Ortho Cyclen
Pravachol	Protonix
Sudafed	Surgak
Toprol	Topamax
Uroxatral	Ursodiol

MEDICATION ERROR DATA

July 1, 2007 – July 1, 2008

Common Look-alike / Sound-alike Errors	
Abilify	Adderall XR
Augmentin	Amoxicillin
Darvocet N	Darvon N
Desipramine	Disopyamide
Felodipine	Feldene
Hydralazine	Hydroxyzine
Lipitor	Lisinopril
Lovastatin	Loratadine
Lumigan	Lotemax
Naproxen	Naproen
Metolazone	Metoclopramide
Rispersal	Requip
Parnate	Paxil
Pepcid	Prilosec
Pravachol	Prevacid
Simvastatin	Sertraline
Trazodone	Tramadol
Zyrtec	Zantac
Zyrtec	Zyprexa
Zetia	Zyrtec

PRESCRIPTION ERROR CASES

$500 Fine

- **Case 1:** An 8 month-old child was given a prescription for Novahistine DH (Phenylhist DH), a codeine-containing product. The Pharmacist incorrectly typed the directions on the prescription label as give 1 and ½ teaspoonfuls by mouth every 6 hours instead of the prescribed direction to give 1 and ½ cc (ml) by mouth every 6 hours. This resulted in the infant being dispensed seven times the prescribed dose. This infant's mother is a nurse and caught the error; the infant never received any of the medication.
- **Case 2:** A patient being treated for a craniotomy picked up her refill prescription of Hydrocodone/APAP 5mg/500mg (a medication for pain). She spelled out her name for the clerk/technician, who retrieved a prescription. The patient signed and paid for the medication and left the pharmacy. Later that evening the patient took her regular dosage (two pills) of medication, and became nauseated, lethargic, and started to vomit. She then discovered she had received another person's prescription, she received Lexapro 10mg (an antidepressant).

PRESCRIPTION ERROR CASES

$500 Fine

- **Case 3:** A patient picked up his prescription for Citalopram 40mg. After taking the medication for several days, (four doses total) suffered several incidents of dizziness. The patient noticed the pills looked different and returned to the pharmacy where the pharmacist informed him he had been taking Norvasc 5mg (a low blood pressure medication). The patient recovered without permanent harm.

PRESCRIPTION ERROR CASES

$1,000 Fine

- **Case 1:** An adult female refilled her Norvasc (5mg once daily) prescription (a drug to lower blood pressure). The pharmacist incorrectly dispensed Lipitor (a drug to lower cholesterol). Five days latter the patient suffered a stroke and was hospitalized. After 6 days in the hospital and six major procedures, she was released. One of her discharge medications was Lisinopril 10mg, which the pharmacist incorrectly filled with Lisinopril 20mg. The patient received the corrected medications and her condition stabilized.
- **Case 2:** An adult female refilled his prescription for Disopyramide 100mg. The pharmacist incorrectly filled with Desipramine 100mg. Within about 5 days the patient began to experience numerous symptoms, difficulty breathing; fainting spells; irregular or fast, pounding heartbeat; stomach pain; unusual weakness or tiredness; anxiety; constipation, or diarrhea; drowsiness or dizziness; and dry mouth all side effects of Desipramine. The patient contacted the pharmacy and the PIC stated the tablets were a generic replacement and the symptoms could not be related to the generic drug.

PRESCRIPTION ERROR CASES

$1,000 Fine

- **Case 3:** A 53-year-old female patient with diabetes was prescribed Avandia 4mg and Prevacid 30mg. The pharmacist incorrectly filled with Coumadin 4mg and Pravachol 40mg. The patient developed blurred vision and bruising and then went to urgent care. Her blood tests showed a markedly elevated clotting test (INR @ 6.3). She was seen by Ophthalmology and was diagnosed with a bleed (possibly a retinal bleed). She was treated and is better.

PRESCRIPTION ERROR CASES

$2,500 Fine

- **Case 1:** A mature adult female was prescribed Climara 0.045-0.015mg Pro Patch. The pharmacist incorrectly dispensed Estradiol 0.0375mg patch. The patient took the incorrect medication for 7 months. The patient suffered a uterine build-up requiring a D&C medical procedure as a result of taking this medication.
- **Case 2:** A 58-year-old female patient was prescribed Prednisone 2.5mg tablets as 1 tablet bid (5mg/day). The pharmacist incorrectly dispensed Prednisone 50mg tablets as 1/2 tablet bid (50mg/day). As a result of this error the patient required hospitalization. The patient recovered without permanent harm.

PRESCRIPTION ERROR CASES

$4,200 Fine

- **Case 1:** A 68-year-old female was receiving prescriptions from three doctors for enormous amounts of Soma and Tylenol with Codeine (both pain medications). In a nine-month period 4,696 doses were dispensed. The pharmacy dispensed all the prescriptions without contacting the prescribers. The patient died of cardiopulmonary arrest.

Medication error reporting...

Medication Errors:
ISMP Perspective

California Board of Pharmacy Meeting
July 23, 2008
Newport Beach, CA

Michael Cohen
Institute for Safe Medication Practices
200 Lakeside Drive
Horsham, PA 19044
mcohen@ismp.org

USP-ISMP Medication Errors Reporting Program

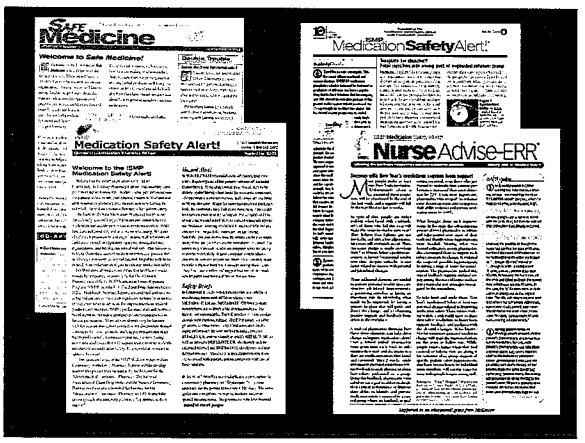
Operated by the
United States Pharmacopeia in Cooperation
with the
Institute for Safe Medication Practices
www.ismp.org

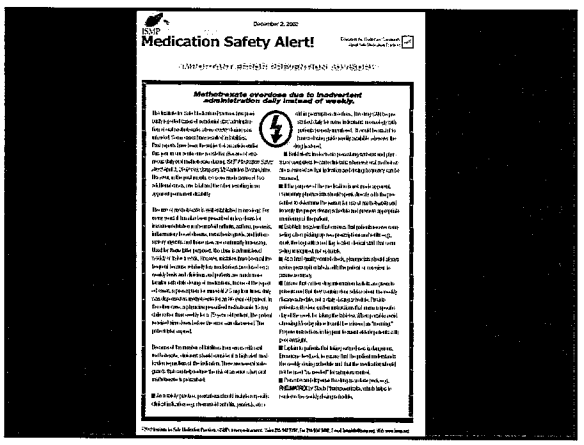
Pennsylvania Patient Safety Reporting Program

MEDWATCH PARTNER

Error Reporting Impacts These Organizations

- FDA
- USP expert committees, standards
- Medication and device manufacturers (for medical product changes)
- Other federal government agencies (military, Veterans Affairs), state health departments and state boards
- The Joint Commission
- Community pharmacy
- Healthcare organizations

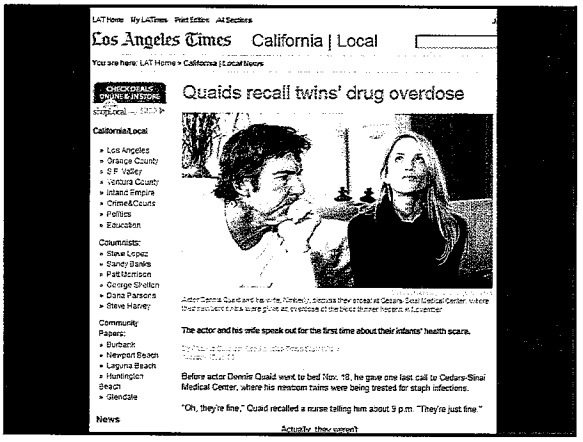




Erroneous methotrexate dosing
Erroneous lomustine (CCNU) dosing

- Alerts in electronic prescribing systems and pharmacy computers
- Pharmacist conduct a prospective drug utilization review before dispensing to determine indication for use, verify proper dosing, confirm the correct dosing schedule
- Outpatients receive counseling about weekly dosing on specific day of week
- Unit-of-use packs only

Medication error reporting...


Los Angeles Times California | Local

Quaids recall twins' drug overdose

The actor and his wife speak out for the first time about their infants' health scare.

Before actor Dennis Quaid went to bed Nov. 18, he gave one last call to Cedars-Sinai Medical Center, where his newborn twins were being treated for staph infections.

"Oh, they're fine," Quaid recalled a nurse telling him about 9 p.m. "They're just fine."

Deaths of 3 babies in Indiana spotlight medication mix-ups

Dow drops 44.55, ends week 78.71 lower

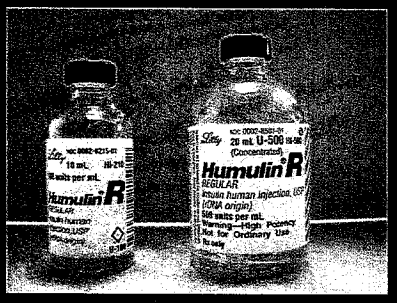
The Philadelphia Inquirer

3 Phila. infants die after mix-up at hospital pharmacy

Examples of system failures in heparin cases

- Failure to learn and react to experience of others
- Look-alike products and manufacturer role
- Drug storage conditions
- Non-existent or failed check systems
- Not embracing available technology
- Lighting conditions
- Availability of 10,000 unit vials
- Preparation of IV drugs on nursing unit

U-500 insulin product in US



Humulin R Concentrate U-500

- Errors seem to be related to the position of insulin product listings on computer screens.
  - "Humulin R Injection Solution 100 UNITS/ML"
  - "Humulin R Injection Solution 500 UNITS/ML."
- Depending on the screen size, the entire line, particularly the drug concentration, may not be visible.
- Since U-500 use is not common, prescribers may not look for information about concentration if they believe insulin is available only in a U-100 concentration.

Medication error reporting...

Leading Products in Harmful Medication Errors, CY 2005

Generic Name	n	%
Insulin*	386	11.3
Morphine*	164	4.8
Heparin*	120	3.5
Fentanyl*	98	2.9
Hydromorphone*	91	2.7
Warfarin*	88	2.6
Potassium Chloride*	69	2.0
Vancomycin	69	2.0
Enoxaparin*	60	1.8
Metoprolol Tartrate	42	1.2
Furosemide	41	1.2
Methylprednisolone	35	1.0
Meperidine*	33	1.0

MedMarx annual report 2007

Faciltators

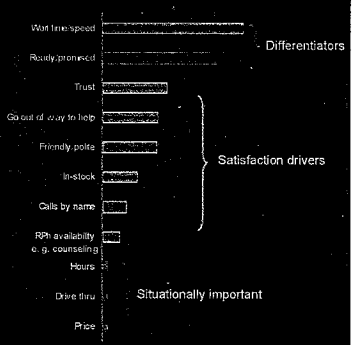
- Education and training
- E-prescribing
- Bar code scanning
- Image on screen
- Robotics
- Call centers
- Workflow systems

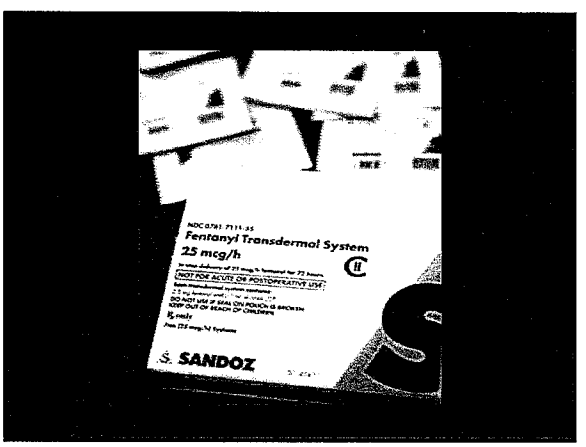
Barriers

- Lack of patient information
  - Laboratory
  - Diagnosis
  - Drug list incomplete
- Lack of adequate reimbursement for patient education, safety monitoring, work related to solving drug-related problems

What are the Drivers of Pharmacy Satisfaction Among Community Pharmacy Customers?

- Wait time, ready when promised are the most direct drivers of patient satisfaction
- Other drivers like trust and friendly are thought of as basic expectations that if NOT delivered can lead to lost customers
- Other factors such as pricing are situationally important
- Availability of pharmacist rates low



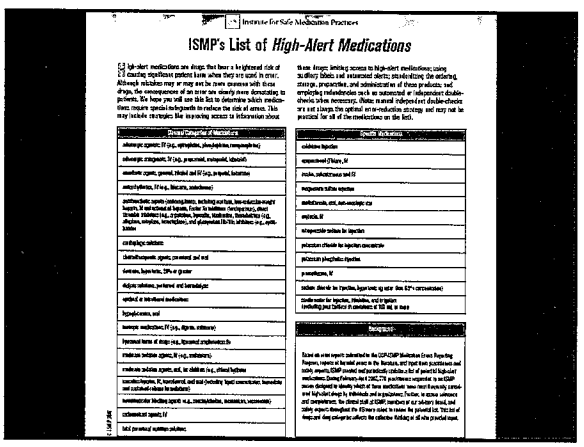


Medication error reporting...

Strategies to Prevent Adverse Drug Events

High Alert Medications

- Small number of medications that have a high risk of causing injury if misused
- Errors may or may not be more common with these than with other medications, but the consequences of errors may be devastating


Institute for Safe Medication Practices

ISMP's List of *High-Alert Medications*

Sharing and Learning

- Safety briefings - End of shift reports
- New protocols, New procedures, New or redesigned unit. service, clinic, New formulary medications
- Brief video or written presentations of actual errors within the institution and/or external errors
- Discussion of causes and recommendations for solutions
- Discussion of barriers to implementing safe practices

Key concepts in safeguarding high alert medications

- ***Use of constraints that limit access or use***
- ***Forcing functions***
- ***Redundancy (check systems, back-ups)***
- ***Reminders***
- ***Improved access to information***

Key concepts in safeguarding high alert medications

- ***Simplify - reduce steps and number of options***
- ***Externalize or centralize error prone processes***
- ***Differentiate items (appearance, location, touch, color, smell, etc)***
- ***Standardize (communication and dosing methods)***

Medication error reporting...

Rank Order of Error Reduction Strategies

Forcing functions and constraints

↓

Automation, computerization, bar code scanning

↓

Standardization and protocols

↓

Time out, checklists and double check systems

↓

Rules and policies

↓

Visual warnings (signs, auxiliary labels, etc)

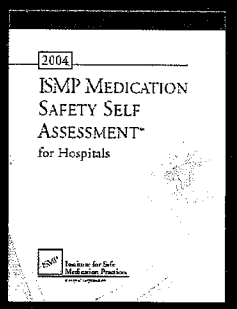
↓

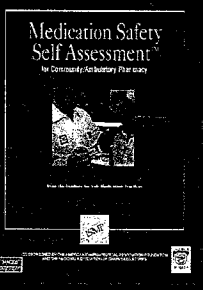
Education / Information

↓

Be more careful, be vigilant

Medication Safety Self Assessments



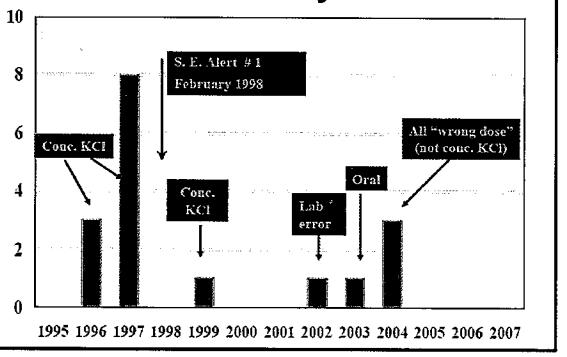


Role of oversight agencies

You can get much farther with a kind word and a gun than you can with a kind word alone.

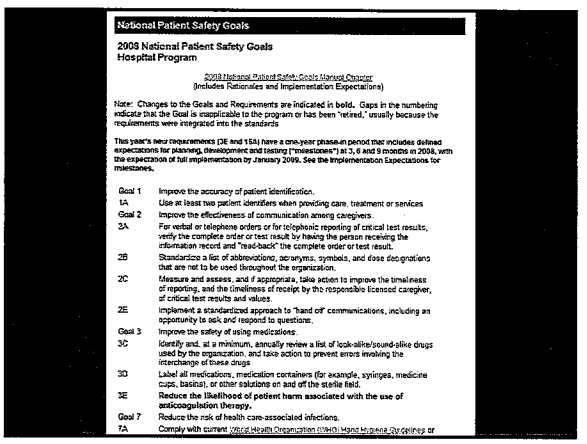
Al Capone

Potassium Chloride Deaths Reviewed by Year



The Sentinel Event Advisory Group

- Annually recommends core and program-specific NPSGs for adoption by the Board of Commissioners
- Reviews draft patient safety recommendations for potential publication in *Sentinel Event Alert*
- Provides advice on the acceptability of alternative practices implemented by accredited organizations in lieu of the specific NPSG Requirements
- Recommends topics for future consideration in *Sentinel Event Alert*



National Patient Safety Goals

2008 National Patient Safety Goals
Hospital Program

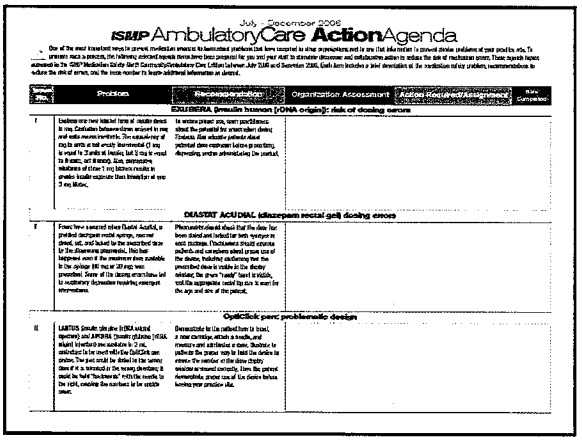
2008 National Patient Safety Goals Manual Chapter
(Includes Rationales and Implementation Expectations)

Note: Changes to the Goals and Requirements are indicated in **bold**. Gaps in the numbering indicate that the Goal is inapplicable to the program or has been "retired," usually because the requirements were integrated into the standards

This year's new requirements (3E and 15A) have a one-year phase-in period that includes defined expectations for planning, development and testing ("milestones") at 3, 6 and 9 months in 2008, with the expectation of full implementation by January 2009. See the Implementation Expectations for milestones.

Goal 1	Improve the accuracy of patient identification.
1A	Use at least two patient identifiers when providing care, treatment or services
Goal 2	Improve the effectiveness of communication among caregivers.
2A	For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and "read-back" the complete order or test result.
2B	Standardize a list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization.
2C	Measure and assess, and if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.
2E	Implement a standardized approach to "hand off" communications, including an opportunity to ask and respond to questions.
Goal 3	Improve the safety of using medications.
3C	Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used by the organization, and take action to prevent errors involving the interchange of these drugs
3D	Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field.
3E	**Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.**
Goal 7	Reduce the risk of health care-associated infections.
7A	Comply with current World Health Organization (WHO) Hand Hygiene Guidelines or

Medication error reporting...

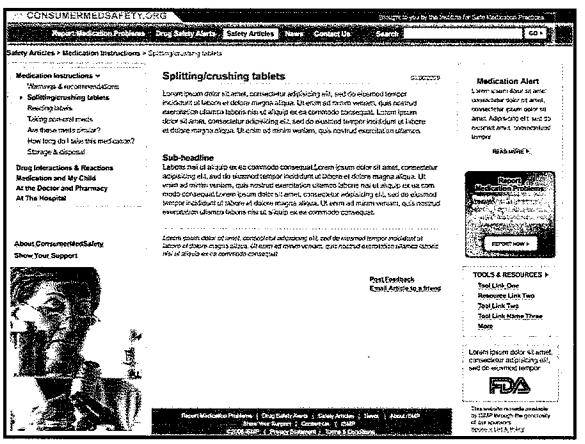

July - December 2006

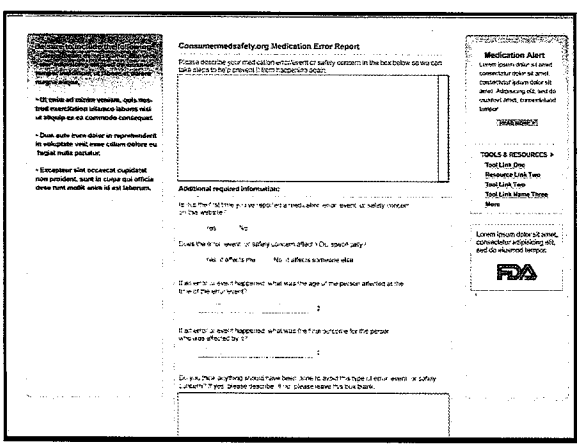
ISMP AmbulatoryCare ActionAgenda

Problem	Recommendation	Organization Assessment	Action Plan (and/or) Assignment	Date Completed
EXALGERIA (Dimaxilate Intranasal [CDHA origin]): risk of dosing errors				
DIASTAT ACUDIAL (diazepam rectal gel) dosing errors				
OptiClick: pen: problematic design				

Expert California Panel

- SCR 49 (confidential reporting program involving outside agency)
- Expert analysis by outside agency
- Formation of BOP volunteer expert panel
  - professional organizations, BOP, government, academic
- Review outside agency recommendations
- Establish annual Pharmacy Patient Safety Goals
- Trained board surveyors to provideoversite
- Include quality improvement requirements





CAPSAC and Just Culture

A Pathway to Improved Patient Safety in Healthcare in California

John P. Keats, MD
California HealthFirst Physicians
John.Keats@chw.edu

CAPSAC

- California Patient Safety Action Coalition
- Goal: Enhancing patient safety through -
  - Medical error prevention
  - Increased reporting of errors and near misses
- Models
  - Growing number of similar statewide coalitions
    - Massachusetts
    - Minnesota

Participants

- Hospitals
- Physicians
- Nurses
- Community clinics/safety-net providers
- Malpractice insurers
- Governmental agencies
- Regulatory bodies (?)

CAPSAC Charter

- The purpose of CAPSAC is to enhance patient safety and increase reporting of near misses and medical errors through promoting a fair and just culture across the continuum of healthcare in California. CAPSAC will strive to protect the public from medical errors by alerting healthcare providers to unsafe systems, and building a structure for accountability for human errors.

Medical Errors

- **Institute of Medicine: To Err is Human (2000)**
  - 44,000 – 98,000 deaths annually due to adverse medical events due to human error
  - Among top ten sources of hospital fatalities
  - "More people die from medical errors each year than from suicides, highway accidents, breast cancer, or AIDS"
- **Little evidence for progress**
- **Why not?**

Medication Error

- **Harvard Medical Practice Study**
  - Medication use was the most common category among non-operative types of errors (19.4%)

Leape et, al NEJM 1991

- **ADE Prevention Study**
  - 6.5 ADEs / 100 admissions
  - 28% preventable

Bates et al, JAMA 1995

The Public's Perception

- **1997 nationwide poll conducted by Lou Harris and Associates**
  - 42% of American reported either personally experiencing or having a family or friend experience a medical mistake
- **2002 ASHP National Survey found that 85% of Americans are concerned about one medication related issue**
  - 69% of respondents noted concern about being given the wrong medication

Preventing Medication Errors

- **2006 IOM report concludes at least 1.5 million preventable ADEs/year.**
- **About one medication errorper patient per day**
  - >25% of these medication errors are considered preventable (400,000 per year)
  - Patients who suffered a preventable ADE had an increase LOS of 4.6 days.

Barriers to Error Reduction

- Lucian Leape, M.D. – Professor of Harvard School of Public Health:
  - "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes"
- Belief that Human Error is avoidable
  - Human error is seen as a reflection of character
  - Medical errors can be fixed by eliminating "problem" individuals

Nominal Human Error Rates: Slips, Trips and Lapses

- **Commission – 3 per 1000**
- **Omission – 10 per 1000**
- **Omission (with reminders) – 3 per 1000**
- **Arithmetic – 30 per 1000**
- **Inspection or monitor – 100 per 1000**
- **Change of shift – 100 per 1000**
- **STRESS (time/high stakes) – 250 per 1000**

Factors Increasing Risk of Error

- **Monotony and boredom – X1.1**
- **Hostile environment – X1.2**
- **Disturbed sleep pattern – X1.6**
- **Poor instructions or procedures – X3**
- **Inexperience – X3**
- **Information overload – X6**
- **Poor communication – X10**
- **Shortage of time – X11**
- **Unfamiliarity with the task – X17**

Other Swing of the Pendulum

- Dr. Lucian Leape – "Error in Medicine" JAMA 1994:
  - "We must stop blaming people and start looking at our systems. We must look at how we do things that cause errors and keep us from discovering them.....before they cause further injury."
- Belief that all errors are system problems
  - Ignores individual's role in carrying out processes and following procedures
  - Ignores individual accountability

Culture Change

- Definition of organizational culture
  - Shared values and beliefs that interact with an organization's structure and control systems to produce behavioral norms
  - *"values and beliefs"* = what people think is important
  - *"structure and control systems"* = how things work
  - *"behavioral norms"* = the way we do things around here

Current Cultures

- "Shame and Blame"
  - Leads to under reporting of medical errors
  - Judgment focused on severity of outcomes
- OR
- "Bend and Mend"
  - Tolerates "Normalization of Deviance"
  - Errors result in repeated attempts at system repair

Normalization of Deviance

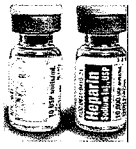
- **The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA**
  Diane Vaughn, U. of Chicago Press, 1996
- **Risk continuously redefined in the context of accidents that do not occur**
- **Standards degrade over time**
  - Slowly and incrementally
  - Especially prevalent when risks of harm are small
  - "Get away with it"
- **Prevention through active review of SOP**
  - Successful operations are viewed as potentially dangerous

Clinical Example

- A nurse is going to administer a medication to a baby in the neonatal ICU. The ICU has an automated dispensing system, which opens a drawer with four bins. As she has always done, the nurse reached into the second bin where the vial of medication is, confirms the blue cap on the vial, grabs the medication and takes it to deliver the medication. At no time in the process did the nurse actually confirm the medication label, instead relying on the medication's location in the dispensing system to confirm the correct medication.

Clinical Example

- In this case, pharmacy had dispensed the wrong dose in the dispensing system.



- Two alternative endings to this story

Just Culture

- Definition:

  "A just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, "routine rule violations"), but has zero tolerance for reckless behavior.....Frontline personnel feel comfortable disclosing errors – including their own – while maintaining professional accountability."

  Agency for Healthcare Research and Quality (AHRQ)

Just Culture

- David Marx BS, JD
  - Developed concept from aeronautical industry
  - Founder of the Just Culture Community
- Features
  - Errors are treated as information for learning
  - Accepted and safe when voicing concerns
  - Seek assistance easily
  - Accountable for increasing patient risks
  - Actions based on risks people choose to take, not outcomes

Goals of a Just Culture

- Educate caregivers about risk
- Hold caregivers responsible to follow best practices
- Create a safe haven around reporting
- Recognize what we can and can't control
  - Can't control:
    - Errors are going to occur
  - Can control:
    - Systems designed around caregivers
    - Our response to behavioral choices caregivers make

Can We Eliminate Human Error?

Error Prevention in a Just Culture

- **Training**
  - Competency
    - Acquisition of required knowledge
  - Skill
    - Ability to apply that knowledge to operations
- **Performance shaping factors**
  - Reducing stress
  - Improving procedural design
  - Improving the layout of controls
- **Perception of high risk**
  - Prevent normalization of deviance

Error Prevention in a Just Culture

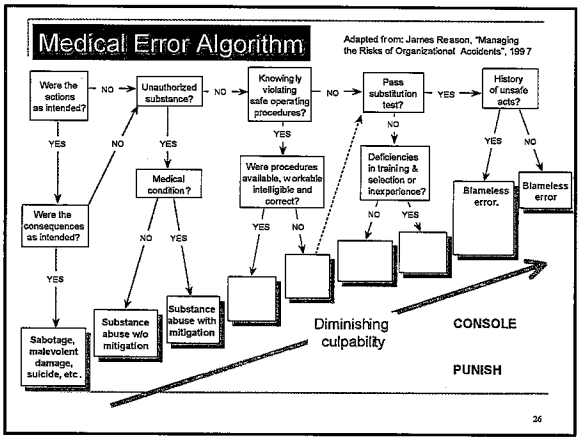
- **Barriers**
  - Decrease likelihood of inevitable human error
- **Recovery**
  - Detecting errors before adverse outcome
    - Feedback
    - Downstream tests
    - Checks
- **Redundancy**
  - Multiple pathways to successful outcome

Human Fallibility

- Three classes of human fallibility
  - Inadvertent error
    - Complete lack of intent
    - Example – Transcribing an incorrect medication dosage
  - At-risk behavior
    - Intentional taking of short cuts
    - Example – Skipping "two identifiers"
  - Reckless behavior
    - Choosing to put patients at risk
    - Example – Drinking on the job

Responses to Fallibility

- CONSOLE
  - Avoid "second victim" phenomenon
  - Look to redesign of processes and procedures to prevent recurrence
-
  - Training and education to improve awareness
  - Changing behavioral incentives
- PUNISH
  - Remedial or punitive action



Why a Just Culture?

- Builds Trust
  - Fair, enlightened, reasonable assessment of behaviors
- Promotes a Reporting Culture
  - Collects, analyzes and spreads knowledge gained from incidents and near misses
- Fosters "Mindfulness"
  - Supports creation of a High Reliability Organization
  - Systemic approach to error reduction with greater success

Reporting and a Just Culture

- Stages of error reporting as Just Culture becomes established:
  - 1. Reporting on equipment error/failure
  - 2. Reporting on others
  - 3. Reporting one's own inadvertent errors
  - 4. Reporting one's own at-risk behavior
- Aids to error reporting
  - Confidentiality
  - Ease of reporting
  - Feedback

Mindfulness in Organizations

- Defined by Weick & Sutcliff (2001)
  - Constant concern about the possibility of failure
  - Ability to concentrate on a specific task while maintaining a sense of the "big picture"
  - Ability to adapt when the unexpected occurs
  - Ability to alter and flatten hierarchy as suits the situation
  - Deference to expertise regardless of rank or status

Building a Just Culture

- Develop a Just Culture document
  - Requires participation and buy-in from all levels
- Conduct a Safety Attitudes survey
  - Staff safety attitudes questionnaire
- Educate in safety concepts
  - Communication, teamwork, human factors, etc.
- Use an unsafe acts algorithm
- Support "Good Citizenship"
  - What constitutes at-risk or reckless behavior
  - Duty to report any errors or unsafe behaviors

Regulatory Role in a Just Culture

- Legislative mandates and public accountability are recognized
- Regulation encourages individuals and institutions to take steps and adopt programs to reduce medical errors and adverse events
- "Just Culture" is a proven pathway to culture change and error reduction
- Ultimate goal is to make your enforcement function a very "boring" job!

Summary

A Just Culture is one that recognizes that:

- Medical errors can cause patient harm
- Some human errors are inevitable
- Some errors are due to behavioral choices
- Caregivers must be educated to make behavioral risks apparent, and to clarify what behavior is considered reckless
- If errors are evaluated fairly, reporting rates will go up, resulting in organizational learning
- Organizational learning leads to improvements in safety procedures and training
- This leads to a High Reliability Organization with significantly reduced rates of medical error and adverse patient events

Selected Bibliography

- Creating a Fair and Just Culture: One Institution's Path Toward Organizational Change: Connor et al. Joint Commission Journal of Quality and Patient Safety 33:10 October 2007
- Fair and Just Culture, Team Behavior and Leadership Engagement: The Tools to Achieve High Reliability: Frankel et al. Health Services Research 41:4 August 2006
- Managing the Risks of Organizational Accidents: Reason, 1997
- Managing the Unexpected: Assuring High Performance in an Age of Complexity: Weick and Sutcliff, 2001
- Patient Safety and the "Just Culture": A Primer for Health Care Executives: Marx, 2001
- Web sites: www.justculture.org; www.ahrq.gov; www.ihi.org; www.dana-farber.org;

Hospital Reporting of Adverse Events

Robert A. LeWinter, RPh
California Department of Public Health
Center for Healthcare Quality

Adverse Events - Senate Bill 1301

- Authored by Senator Alquist and signed into law September 26, 2006
- Effective July 1, 2007
- Defines 28 "Adverse Events" that should never occur in hospitals, and
- Specifies that those adverse events shall be reported by hospitals to CDPH.

28 "Adverse Events"

- Health & Safety Code §1279.1
- Seven categories:
  1. Surgical Events (1-5)
  2. Product / Device Events (6-8)
  3. Patient Protection Events (9-11)
  4. Care Management Events (12-18)
  5. Environmental Events (19-23)
  6. Criminal events (24-27)
  7. Other events (28)

Adverse Events

- **Surgical** – wrong site, patient, procedure, retention of a foreign object or death after induction of anesthesia
- **Product** – death or serious disability with contaminated drug, medical device or embolism
- **Protection** – infant discharged to wrong patient or patient suicide
- **Care Management** - death or serious disability with a medication error, hemolytic reaction, hypoglycemia or Stage 3 or 4 ulcer acquired after admission

Adverse Events

- **Environmental** – death or serious disability with use of restraints or bedrails, electric shock or death associated with a fall
- **Criminal** – care ordered by someone impersonating an MD, RN or RPh, sexual assault on a patient or death or significant injury of an individual from physical assault
- **Other** – An event or series of events that cause death or serious disability of a patient, personnel or visitor

Serious Disability Defined

- Health & Safety Code Section1279.1(d) defines "serious disability" as:

  A physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

Reporting of Adverse Events

- Adverse Events must be reported within 5-days of being detected, provided that the event is not an "ongoing urgent or emergent threat."
- "Ongoing urgent or emergent threats to the welfare, health, or safety of patients, personnel, or visitors" must be reported within 24 hours after being detected.

Failure to Report

- The Department may:
  - assess a hospital a civil penalty of $100 per day for each day that a facility does not report an adverse event timely.
- The Hospital may, within 10 days:
  - request a hearing to challenge the Department's determination regarding an alleged failure to report an adverse event.

July 1, 2007 – June 30, 2008

Adverse Event Category	No.
Abduction of patient of any age	0
Care by impersonating licensed provider	1
Death after induction of anesthesia	40
Death due to a fall	40
Death/disability due to labor/delivery/postdelivery	17
Death/disability due to spinal manipulative therapy	0
Death/disability directly related to hypoglycemia	0
Death/disability due to a burn	5
Death/disability due to disappearance	3
Death/disability due to electric shock	0
Death/disability due to intravascular air embolism	5
Death/disability due to use of restraints/bedrails	46
Death/injury from a physical assault	6
Failure to identify/treat hyperbilirubinemia	0
Hemolytic reaction	2

Adverse Event Category	No.
Infant discharged to wrong person	0
Medication error	34
Oxygen line used for wrong gas/toxic substance	2
Retention of a foreign object in a patient	172
Sexual assault on a patient	53
Stage 3 or 4 ulcer acquired after admission	607
Suicide/attempted suicide	18
Surgery performed on a wrong body part	28
Surgery performed on the wrong patient	3
Use of contaminated drug, device, or biologic	5
Use of device other than as intended	5
Wrong surgical procedure performed on a patient	13
Adverse event or series of adverse events	120
Grand Total	**1225**

Report Date: 7/7/2008
Data Source: ASPIS

Public Reporting of Adverse Events

- Adverse reporting information will become public (Note: currently, licensing information is accessible through a Public Records Act request.)
- By January 1, 2009, CDPH must make information about substantiated 1279.1 reported events and the outcome of inspections or investigations readily available to consumers. (HSC 1279.3)
- By January 1, 2015, information must be available on the CDPH website.

Next Steps

- Need to clarify some statute language through regulations, including terms such as:
  - low risk pregnancy
  - the wrong person (as in, "an infant discharged to the wrong person")
  - after surgery
  - on the grounds of the facility

Next Steps: Goals

- Analyze Adverse Event reporting:
  - Improve reporting,
  - How we receive reports
  - Investigation system
- Disseminate information about healthcare quality and patient safety
- Establish means to identify and promote improvements in healthcare quality