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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: April 23 - 24, 2008

LOCATION: Radisson Hotel
500 Leisure Lane
Sacramento, CA 95815

BOARD MEMBERS PRESENT:
William Powers, Public Member, President
Ruth M. Conroy, PharmD, Vice President
D. Timothy Dazé, Esq., Public Member, Treasurer
Kenneth H. Schell, PharmD
Stanley Goldenberg, RPh
Robert Swart, PharmD
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Graul, RPh
Stanley C. Weisser, RPh
Shirley Wheat, Public Member
James Burgard, Public Member

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

Call to Order

The board meeting was called to order at 9:00a.m. by President Powers.

General Announcements

President Powers introduced Anne Sodergren as the board's new Assistant Executive Officer and welcomed her return to the Board of Pharmacy.

President Powers recognized Spencer Walker as former counsel for the Department of Consumer Affairs and his new role as special counsel for the department Director Carrie Lopez.

President Powers recognized Rich Mazzoni, former board member and board president.

I. Approval of the Full Board Meeting Minutes of January 23 and 24, 2008:

President Powers referred to the draft board minutes of January 23 and 24, 2008 provided in the meeting materials.

MOTION: Approve the board meeting minutes of January 23-24, 2008

M/S: BURGARD/WEISSER

SUPPORT: 11 OPPOSE: 0

II. Approval of the Full Board Meeting Minutes of March 25, 2008:

President Powers referred to the draft board minutes of March 25, 2008 provided in the meeting materials.

MOTION: Approve the board meeting minutes of March 25, 2008

M/S: SCHELL/WEISSER

SUPPORT: 11 OPPOSE: 0

Opening Remarks of the State and Consumer Services Agency Secretary Rosario Marin

President Powers introduced Rosario Marin, Secretary of State for the Consumer Services Agency. President Powers summarized Ms. Marin's background and responsibilities as agency secretary.

Ms. Marin recognized and thanked the board for their service to California consumers and the pharmaceutical industry and reminded them of the significance of their impact on the public and California consumers.

Mr. Powers provided Ms. Marin with an honorary board member pin.

III. Enforcement Committee Workgroup on E-Pedigree:

Stan Goldenberg provided introductory remarks including that he recently attended a conference on global intellectual property centers provided by a local chamber of commerce. He explained that one of the guest speakers at the conference was Billy Townsend, the president and CEO of PhRMA.

Mr. Goldenberg stated that at this conference Mr. Townsend thanked the board for extending the e-pedigree implementation. Mr. Townsend gave his personal story on how his life was saved by drugs and his commitment to do right by the patients and consumers of the United States. He also addressed the current counterfeiting problem, with a focus on the pharmaceutical industry.

Mr. Goldenberg referenced a specific website that Mr. Townsend shared in the presentation where every counterfeit drug can be purchased, including drug logo "stamps." He shared additional interesting points provided by the presentation relating to the cost and conviction of counterfeiters. Mr. Goldenberg reported that he requested Mr. Townsend to come to a future board meeting and make a similar presentation.

A. Presentations To The Board On Electronic Pedigree Implementation

Dr. Paul Rudolf and Mr. Jim Dahl, officials of the Food and Drug Administration:

Dr. Rudolf and Mr. Dahl provided a presentation on the impact of counterfeiting and the challenges the FDA encounters in investigating and prosecuting counterfeiting cases.

Dr. Rudolf provided a regulatory and statutory overview of how the FDA operates with respect to counterfeiting.

Dr. Rudolf gave a brief background on the Prescription Drug Marketing Act (PDMA), and emphasized that the statute requires minimal information from non-authorized distributors and is difficult to enforce. He noted that pedigree regulations of the PDMA are not implemented at this time and is currently in litigation.

Mr. Dahl gave background on the Office of Criminal Investigations (OCI) and its role related to violations of the Food & Drug and Cosmetic Act. He emphasized the limited resources for counterfeit drug investigations. He discussed the focused efforts on diversion. Mr. Dahl noted the weak penalties for counterfeiting activity, as well the challenge in getting federal prosecutors interested in cases unless other violations are involved. Mr. Dahl explained the time consuming process involved in reconstructing the drug pedigree in order to track down the original producer of the counterfeit drug, including the difficulty in obtaining the necessary subpoenas throughout the chain of custody investigation because the FDA does not have administrative subpoena power. Mr. Dahl presented a diagram from *Dangerous Doses* by Katherine Eban, which was a flowchart of a drug tampering scheme which detailed the flow of the drug from the producer to the victim. He provided an example pertaining to a Lipitor recall and described the process of the counterfeiters to get their product to the drug supply, including the ability to duplicate Pfizer's branding. Mr. Dahl sreviewed an additional example involving the counterfeiting of Viagra, and shared the difficulty and delays experienced in getting subpoenas for the wholesaler source due to limited resources.

Dr. Rudolf noted new federal legislation has been introduced. He also noted the focus on counterfeiting in the supply chain and additional risks of counterfeit drugs reaching consumers who purchase medicine through the internet. Dr. Rudolf indicated that state laws have been passed which provide stronger pedigree requirements. He pointed out that states

have stepped in and enacted tougher pedigree and wholesale licensing requirements, as well stronger penalties. He concluded the presentation with an emphasis on the need for stronger pedigree legislation, and said that state laws are invaluable tools for supporting counterfeit drug investigations.

Questions to the presenter:

Ken Schell asked if the federal government is considering increasing the penalties and sentencing guidelines to counterfeiters to deter people from attempting such activities.

Mr. Dahl responded that a recent request by FDA to increase penalties was denied. He believes increased penalties will come once there is "political will" to get congress to move on it, but doesn't believe it will be in the near future. He indicated that he does not see big constituencies out there opposing it.

President Powers asked how they account for the fact that FDA is not being given the tools for dealing with problems of counterfeiting and diversion. Mr. Dahl responded that it is an issue of politics and tradeoffs, and that the FDA views itself as a public health organization first and enforcement entity second. He shared that OCI has proposed numerous changes to the criminal portion of the Food, Drug and Cosmetic Act over the years, which have been denied.

Mr. Goldenberg referenced the pedigree challenge, and the focus on trying to create an environment of safety before it becomes "body count legislation". He asked at what point a Sentinel event would trigger a response in Washington. Mr. Dahl responded that he couldn't predict what will happen politically. He stated that globally they are reaching products, as well as components of products, from all over the world, yet they can't effectively regulate and investigate. He also stated that, unless corrected this puts consumers at risk, and that the goal is to build the best standards in the world.

Mr. Goldenberg asked if he believes that these events will refocus government to give FDA the tools they need. Mr. Dahl responded that he does. He noted that many parts of the government have a stake in this. Mr. Dahl gave an example of recent legislation which has put various regulatory investigators in China, however there are no OCI agents outside of the US borders.

Mr. Goldenberg referenced the recent conference he attended, and the discussion of a potential plan by Al-Quaida to counterfeit the drug Sipra with a "white powder" and bring it into the US. He noted the topic of the presentation, "Using America to Fight America". Mr. Goldenberg discussed the need to bring this type of information to the attention of the lawmakers without scaring the public.

Mr. Dahl responded that, after 9/11, his primary focus was communication between OCI and intelligence agencies, and that those concerns are very real. He noted that the terrorist threat to the drug supply is at least as great a threat as to the food supply. He also pointed out the concern of the internet as a source of drug supply. He feels that education is part of what is needed, as well as more investigative resources.

Ron Bone (McKesson Corporation) referenced the regular drug supply chain (ADR) from the presentation. He noted that the PDMA requirement of ADR status be in writing which has strengthened the ADR relationships. Mr. Bone noted that the wholesaler community has committed to buying directly from manufacturers, and not through the grey market. Mr. Dahl agreed there are less counterfeits in the legitimate supply chain now because of the recent activity Mr. Bone noted. He emphasized that the industry has instituted some best practices which have been helpful, and agreed that wholesalers have made significant changes to secure the drugs in the supply chain. However, the regulatory point of view is that as long as diversion is still going on, tools are necessary to enable FDA to find the diverted drugs and locate counterfeiting.

Bob Celeste – GS1

Bob Celeste provided updates on efforts taken for development and adoption of global standards.

Mr. Celeste reviewed the goals of GS1 in providing global standards that meet all of the supply chain partners' needs. He provided a visual example of the confusion which occurs when standards are misused, numerous types of bar codes currently used, and their goal of eliminating such confusion. Mr. Celeste explained the process involved in standards development and the global standards management process, including the benefits to the results of such standards. He reviewed GS1's objectives, progress and timelines on the global standards to date, including AIDC application standards, global traceability, global data synchronization and product classification. Mr. Celeste discussed standards adoption, including the specific phases identified throughout the process of adoption. He noted the specific systems validation process included prior to the final adoption phase, which is extensive. He also noted that GS1 is focused on the traceability and adoption phases. Mr. Celeste gave an overview on the assessment of two standards - pedigree messaging and EPCIS. He also gave a summarized update of GS1's progress to date.

Questions to the presenter:

Stan Weisser referenced GS1's linear timeline and asked if Mr. Celeste feels that their product will be ready for the manufacturers, allowing them time for implementation. Mr. Celeste responded that he didn't have data on whether anyone in the supply chain will be completely ready. He indicated that the pedigree messaging standard is functional and is widely used already. He stated that many supply chain partners want to use EPCIS for other purposes besides pedigree, and plan to combine those efforts. He restated that he couldn't comment on readiness.

Joshua Room asked what GS1 sees as their role with regard to standards setting docketing events from FDA. He asked if they would be presenting comments.

Mr. Celeste responded by providing a summary of the 2 dockets. He stated that they are responding to FDA and creating response documents to those dockets. He said that GS1 is trying to get their document out so that others can review it and use it for their documents as well. Mr. Celeste indicated that, in terms of identifiers, they will talk about how identifiers are used globally and give examples of how it works with current identifiers.

Mr. Room asked if GS1 has had discussions with FDA in regards to an ongoing role in the standardization process. Mr. Celeste stated that although they have not had direct discussions with FDA, but hope that their standard will "fit the bill" and that the FDA will support it.
Mr. Room noted that the board would be discussing its own response to the FDA's docket. He stated that one question in the docket is whether the standardized numerical identifier would include the NDC as an embedded code. Mr. Room asked Mr. Celeste to discuss the pros and cons in including the NDC number in the serialized number.

Mr. Celeste explained that GS1 has reserved a series of numbers that could embed the NDC number within the G10. Manufacturers can use the GS1 bar code standards, and they would embed their NDC code into the G10, which creates a legitimate global number that manufacturers can use around the world.

Mr. Room asked what the industry's current consensus is.

Mr. Celeste explained that many systems are based on NDC and will emphasize to the manufacturers their ability to accommodate their codes within GS1's system.

Dr. Schell asked for clarification on the "promotions" portion of the timeline presented. Mr. Celeste stated that hospitals have not been engaged so far in gathering input and marketing to the supply chain. He stated that the "promotions" portion is about educating those end users.

Dr. Schell asked how their system is significantly different from other tracking systems in other industries.

Mr. Celeste stated that they have worked with other consumer products industries (i.e., the protein industry) to gain knowledge on the process of identifiers. He noted that the some of those processes do not lend themselves well to automation.

Dr. Schell restated that it appears a similar system is already in affect, and questioned why we would be recreating the same.

Mr. Celeste indicated that the repackaging process is a unique issue with pharmaceuticals.

Brad Godshall - Federal Bureau of Investigations:

Mr. Godshall began by summarizing the issues with regards to on-line internet based pharmacies and counterfeit drugs. He also stressed the impact of counterfeiting to the health and well being of the public, as well as the increased costs to the companies for research, development and marketing of legal drugs.

Mr. Godshall explained that he has been on a special task force for the last 6 years, which includes participants from the FBI, Dept. of Homeland Security, Customs and Immigration Enforcement, the Food and Drug Administration, Office of Criminal Investigations, the US

Postal Inspection Service, and the IRS (Criminal Investigations Division). The task force was created to take on the wave of counterfeit drugs coming into the United States.

Mr. Godshall provided a history on the underground market of counterfeit bodybuilding products. He noted the impressive level of sophistication and creativity involved in the duplication of the packaging and security hologram. He also pointed out that the wife of one of the counterfeiting subjects was a licensed pharmacy technician. Mr. Godshall mentioned the specific drugs that have been targeted the most for counterfeiting. He also discussed a large counterfeit scheme of Viagra via an on-line pharmacy operation. He explained how the leader of this scheme secured services of a pharmaceutical manufacturer in Tijuana prior to his arrest, and was set to begin production of his own counterfeit version of the drug on the day he was arrested. He noted that fraudulent documentation was used to import raw materials into the US from China. Mr. Godshall gave another example of a local group involved in a Viagra counterfeit ring. He stated that raw materials from Asia are finding their way into the US where they are then obtained by counterfeit rings in the US and being sold on the internet. Mr. Godshall summarized by stating that he strongly believes that any additional security measures, through the support of manufacturers as well as more strict legislation, will elevate the risk associated in engaging in counterfeit activity and dissuade individuals from acting. He also spoke in favor of the e-pedigree system specifically and welcomes such evidence of documentation that would assist in apprehending a perpetrator.

Mr. Goldenberg referenced a recent program on National Geographic. He noted the significance of counterfeiting as an organized crime, as well as how global the crime has become. Mr. Goldenberg shared his concern that the atmosphere of delay appears to be a window of opportunity for counterfeiters. Mr. Goldenberg explained that the program discussed the global market and the ability to move the product under the veiled secrecy of the internet.

Mr. Godshall agreed with Mr. Goldenberg's comments, and highlighted the ease with which counterfeiters make a profit without shouldering the costs incurred by the legitimate manufacturers and suppliers, such as marketing, clinical trials and research and development. He also said that he would be surprised if most worldwide terrorist organizations are not aware of or involved in this type of crime at this point.

Mr. Room noted that he has a copy of the National Geographic program referenced and can make it available to anyone interested.

Continuation of questions to presenter (Bob Celeste - GS1):

Bob Graul referenced the issue of numerous types of bar codes in the system at this point. He asked what the chances are of getting the bar code standards to one type of standard for the community pharmacy level.

Mr. Celeste replied that he doesn't think one standard is feasible. They are trying not to force people to use one particular standard. He pointed out that the packaging might be larger than the product if using serialized bar codes, for example. Mr. Celeste stated that GS1 is looking at what it takes for a small pharmacy to use standardized bar codes and how it applies to them.

Mr. Graul commented that a sightless system would be beneficial to pharmacies.

Mr. Celeste replied that GS1 would like input such as Mr. Graul's from the pharmacies. He also noted that the additional time being given on implementation due to the e-pedigree extension is allowing GS1 an opportunity to take a second look at the exception processes, for example. He commented that they don't want to create opportunities for counterfeiters to thwart the system.

Mr. Goldenberg referenced cell phones being used in the retail industry to view products (price, etc.). He asked if they have knowledge as to whether readers are readily available in cell phones at an affordable cost.

Mr. Celeste confirmed that a bar-code or RFID reader could be purchased which can interface with a cell phone or Bluetooth. He also noted that PDA's are being used bedside by St. Clare's Hospital in Pittsburg, PA to read patients' wristbands and match them with the drug to ensure accuracy and dosage, etc.

Mr. Goldenberg asked if cell phones are priced reasonably in Japan.

Mr. Celeste gave an example of a bottle of wine being scanned with a cell phone and subsequently ordered and delivered within minutes from that scan.

B. Discussion And Action Regarding Implementation Of Electronic Pedigree Requirements For Prescription Medicine In California

Ms. Herold stated that as of March 25, 2008 the board has extended the e-pedigree implementation date to January 1, 2011. She also stated that the exemption provision for injectable drugs administered in a prescriber's office was also extended to January 1, 2011. In the interim, the board is sponsoring a bill enhancing some of the pedigree requirements, allowing for staggered implementation, as well as provisions for regulations on inference and grandfathering. She also noted that in the coming months the board would be addressing the issues of repackaging and kits and will meet with members of the industry who would like to address these topics. No action is necessary by the board at this time.

C. Discussion And Action Regarding Submission Of Comments Regarding Federal Standards For Technologies For Prescription Drugs – Docket No. FDA-2008-N-0120, OC 200841
and
D. Discussion And Action Regarding Submission Of Comments Regarding Federal Standards For Technologies For Prescription Drug Identification, Validation, Track And Trace Or Authentication, Request For Information – Docket No. FDA-2008-N-0121, OC 200842

Mr. Room stated that the FDA has, in general, supported California's law. He recommended the board seize the opportunity to make its viewpoints known on various issues as well as to share input on behalf of the supply chain via written comments to the FDA.

Mr. Goldenberg noted a large pharmacy which was having problems tracking their large quantity of orders. He stated that they have attached RFID tags to every order and solved the problem. He gave this example to point out that the entire system will assist suppliers in more ways than just track and trace. Mr. Goldenberg opened the discussion up for comments from board members.

Dr. Swart stated that he endorses the RFID, and stated the advantages across the supply chain.

Mr. Goldenberg stated that there are some additional comments that can be attached regarding error prevention and shrinkage where RFID would assist with significantly.

Mr. Burgard is concerned about the technology aspect of the system and stated that the board should elaborate on security. He noted that there are computer designers involved and there should be a security system in place for enforcement of those individuals as well. Mr. Burgard suggested security in the program design where the numbering system can be changed.

President Powers asked Mr. Room if he is prepared to draft a letter on behalf of the board in response to the FDA dockets. Mr. Room confirmed that he would.

Mr. Room reviewed the specific topics of the 2 dockets, with suggested points to be addressed within the letter of response. He focused on the first docket, including the topic of embedding NDC Codes.

Dr. Schell stated that he would rather not be too specific in their response, since this is not their area of expertise. He feels that it would be better to take a step back and endorse what has already been said.

Hank Hough shared concern over organization of the process, as it is becoming a complex issue. He pointed out that it is not just technological, but also administrative. He stated that there should be an administrative lead that has the authority and knowledge to tie all of this together.

Mr. Room stated the need to ensure an understanding by the board of the limited scope and purpose to which they can respond. Mr. Room responded to Mr. Hough's comments and said that thus far, no one has been set up as an implementation "czar" on the federal level. One would expect the FDA to be that czar, but as of yet there is no specific statutory mandate for the FDA to take the lead role in a national pedigree implementation. Mr. Room clarified that the dockets solicit comments for law that will be outside the PDMA.

Mr. Goldenberg clarified that the board's comments to FDA would be to provide more specific requirements as we move further along, and to simply focus on getting information to them and answering their questions for now.

Mr. Room stated that FDA, California and GS1 are trying to lead this movement, which is why conversations with those entities have been more focused. Mr. Room stressed that the standards utilized by California may lay the groundwork for suppliers to be able to comply with other similar laws in other states.

Mr. Goldenberg confirmed the board's understanding of their scope and requested understanding of where to go from here in responding to the FDA.

Mr. Goldenberg asked Kristy Schieldge to assist in developing the language in written response to the FDA docket.

Ms. Herold indicated that there is a core group at the staff level that is dealing with the implementation issues and working with industry. She noted that it was understood that there will be a point when a formal standardized serial number would be needed, and that we are now at that point. Ms. Herold indicated that no other numeric standardized schemes have been suggested other than GS1's system, and that it is important to recognize that, for the system to work, there must be a standard. The FDA is now in a place to develop that standard, and now is the time for the board to give input on that standard. Mr. Herold stated that she agrees with the privacy advocates in considering not having the NDC number as part of the serialized number.

Mr. Room responded to Mr. Weisser question regarding the process, and suggested that the staff could delegate the board president to represent the board in writing.

Dr. Wiesser stated that the board appears to be moving forward. He encouraged the board to go continue in this direction.

> MOTION: To give authority to the board president to approve written comments provided to the FDA in response to dockets No. FDA-2008-N-0120, OC 200841 and FDA-2008-N-0121, OC200842
>
> M/S: BURGARD/WEISSER
>
> VOTE: 11 OPPOSE: 0

Tim Dazé asked if they could "turn off the switch" at the pharmacy level.

Mr. Room discussed the decommission issue, and stated that the technology allows for that. He also stated that some enforcement agencies don't want that to happen however, as it can affect their ability to track drugs.

Ms. Herold noted that there are a lot of bottles which will be tagged at the pharmacy level and will be dispensed to a patient directly into a non-tagged vial.

A discussion of unit of use ensued, including the issue of change of ownership where it is not a pedigree transaction.

A discussion ensued regarding a serialized number versus an NDC number being used in the RFID tag.

Mr. Room clarified that the board should choose this time to give input on the decision of placing the serialized identifier in the embedded NDC for the purposes of response to the FDA.

Mr. Weisser and Mr. Graul both gave their input that the NDC number is a valuable piece of information, and should be included. Dr Graul stated that the issue of security in relation to unit of use could be addressed in the future.

Susan Ravnan stated that she feels the NDC needs to be included, but is unsure whether ts should be in the identifier or in the pedigree in some other form.

MOTION: To end discussion on the issue of the identifier number.

M/S: SCHELL/DAZÉ

SUPPORT: 11 OPPOSE: 0

Mr. Weisser asked if there is intent to include the NDC issue in the letter drafted to FDA. Mr. Goldenberg responded that that appears to be the intent as indicated from the board members.

Other Enforcement Matters

E. Discussion Regarding The Senate Committee On Business, Professions And Economic Development's Review Of The Physician And Health Practitioners Substance Abuse Programs, Including The Board Of Pharmacy's Pharmacist Recovery Program

Mr. Goldenberg stated that the Medical Board is being challenged with regard to their substance abuse program.

Ms. Herold stated that the issue is in regards to the Medical Board's diversion program. She stated that the results of five critical audits all listed program failures and failures to protect the public. She stated that the Medical Board voted to repeal their diversion program effective July 1, 2008, and that part of the repeal included review of the diversion programs of the other healing arts boards. She noted that there was a hearing last month where information was provided about our board's program to the Senate Business and Professions committee. Currently staff is waiting to here back on any actions they will be taking on the rehabilitation programs of the healing arts boards. Ms. Herold reviewed the board's Pharmacist Recovery Program, the process involved by a subject placed in the program, and the significance of being able to monitor pharmacists in the program in conjunction with disciplinary action taken. She indicated that there has been no indication as of yet on what direction the Senate Business and Professions committee will be taking.

Steve Gray (Kaiser Permanente) stated that he believes a bill was introduced to create an oversight body for all licensing boards with diversion programs. Mr. Gray suggested the board research such legislation.

F. Discussion: Medication Errors

Mr. Goldenberg stated that the board might wish to discuss positive actions it desires to initiate in the future, in light of all the recent reports of medication errors, especially with focus on pediatrics.

Dr. Schell stated that he feels it is largely an educational issue. He feel that there needs to be enhanced training regarding the dosing of pediatric patients, and that there are a lot of opportunities to provide pharmacists with the knowledge and expertise to manage pediatric patients. Dr. Schell noted that the issue of medication errors is often due to the wrong dose rather than the wrong drug, and that it is more often an under dose rather than an overdose. Dr. Schell suggested a subcommittee to address the specifics of this issue.

Mr. Goldenberg noted that there would be a presentation on this issue at the July meeting. He questioned whether the board should be taking action on the issue now or wait until the July meeting.

Ms. Herold asked for the board's input. She stated that some of the findings in Sentinel report could be placed in the board's newsletter in July. Ms. Herold suggested an article in the next Script be included, highlighting licensees and special considerations when dealing with pediatric patients.

Mr. Room asked if we are still developing fact sheets with the UCSF Center for Consumer Self Care. Ms. Herold responded that the board is expanding the program to allow interns to develop fact sheets.

Mr. Goldenberg added that in many cases the pharmacist is not aware of the age of the patient they are dispensing the drug for.

Dr. Ravnan stated that she would like to see an education piece added to disciplinary actions placed on pharmacists when needed.

Mr. Graul asked if there was a bill in the past that had created a Med-Error panel.

Dr. Gray (Kaiser Permanente) stated that the Med-Error panel was created with a bill sponsored by the California Pharmacists Association, known as SCR49. The Pharmacy Foundation of California is now entirely focused its mission toward the eradication of medication errors. He stated that they are currently looking for sponsors, partners, etc. for programs to research and educate all members in the healthcare community who might be involved in preventing medication errors (including patients). Dr. Gray stated that the panel's report was completed and is on the Pharmacy Foundation website. He wanted to bring this to the board's attention and indicate that it is seeking grants, expertise and professional personnel who will be committed to helping in this project, as it is a major issue in California.

Ms. Herold noted that the board is involved because she has been asked to join in on the discussions. This will be an ongoing agenda item.

Dr. Gray also added that the CEO of the foundation would be happy to appear at a meeting and provide an update as requested.

Dr. Schell noted that the one of the outcomes of SCR 49 is the reason why we have the labeling subcommittee on SB 472. He stated that part of the reason the subcommittee was created to focus on a restructure of the label was due to concern over errors possibly resulting from the label itself.

Dr. Ravnan stated that she was a member of that panel, representing CSHP.

Mr. Graul commented on a presentation he recently gave on behalf of the board. He referenced a slide within the presentation, which listed citations issued by the board. He noted that there was a significantly larger amount of citations issued for failure of utilizing the QA program where medication error was involved. Mr. Graul suggested the board focus more on this topic.

H. Third Quarterly Report on Enforcement Committee Goals for 2007/08

The board meeting packet contained the third quarterly update of the committee's strategic plan.

I. Recognition of pharmacists licensed with the board for 50 years

Mr. Graul honored 50-year pharmacist, Charles Hoagland. Mr. Hoagland was presented with a 50-year lapel pin by the board.

Mr. Hoagland stated that he works full time at the Napa State Hospital, has worked his entire 50 years in California and has no plans to retire. He commented on the fact that continuing to work is a pretty good endorsement of pharmacy as a career. He thanked everyone and appreciated the recognition.

Dr. Swart honored 50-year pharmacist, Walter Breshears. Mr. Breshears was presented with a 50-year-pin by the board.

Mr. Walters pointed out that when pharmacists are owners such as himself, put in 12-14 hours a day and still enjoy it, "it's got to be great".

Recognition of Pharmacist Sylester Flowers

President Powers welcomed Sylester Flowers, and provided details of the extensive background Mr. Flowers has in the community, including the development of his own non-profit organization to assist individuals and HIV/AIDS patients who cannot afford medication. Additionally, Mr. Flowers was presented with the California Pharmacy Hall of Fame award earlier this year by the California Pharmacists Association. Mr. Flowers was presented with a board pin by Dr. Schell.

Mr. Flowers stated that there is no greater honor than to be recognized and celebrated by your peers. He said that if you didn't have HIV, weren't a heroin addict, or of a minority with English as 2nd language, you probably wouldn't know him. Mr. Flowers gave background on his company and stated that they currently have, under the rims of their holding corporation, an international division. They opened an office in Vietnam, and is creating mobile wireless

information technology for that country. They have an AIDS drug assistance program in Washington, Colorado, and Texas. They also do consulting in North Carolina, Montana and Puerto Rico. Mr. Flowers commented that he is semi retired as of the 6th of January, but he is "on the 'semi' side of that", because he still has work to do. He indicated that his son is running the day-to-day operations of the business, and that they have become a "big little" company with over 150 employees. Mr. Flowers said he was delighted to be honored at the board meeting; he values what the board is doing. He referenced his website and company for those interested.

Part 1. Regulation report and action

A. Regulation Hearing – Proposal to Amend Title 16 CCR § 1760 – Disciplinary Guidelines

President Powers read the following information to begin the regulation hearing:

"This hearing is to consider the proposed amendments to Title 16, California Code of Regulations § 1760 – Disciplinary Guidelines.

For the record, the date is April 23, 2008 and the time is 1:30p.m. At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record, which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the board pursuant to the requirements of the Administrative Procedure Act before the board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

A record of this hearing, as well as testimony received, will become a part of the rulemaking filer. A complete copy of the rulemaking file will be available for review at the board's main office in Sacramento.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations. Responses by the board to all recommendations or objections will be included in the Final Statement of Reasons that is filed with the Office of Administrative Law.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means,

you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin? (There were none)

I will now call on those persons wishing to testify regarding § 1760."

There were no persons wishing to testify.

President Powers closed the regulation hearing.

B. Discussion And Possible Action To Amend 16 CCR § 1760

No discussion was provided by the board regarding the written comments submitted by interested parties.

MOTION: As there are no proposed changes to the regulation, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulation before completing the rulemaking process, and adopt the proposed regulation of § 1760 as filed.

M/S: BURGARD/DAZÉ

SUPPORT: 11 OPPOSE: 0

Ms. Schieldge recommended board staff further respond to written comment received on the rule-making to be included in final statement of reasons.

IV. Communication and Public Education Committee Report and Action:

Dr. Schell noted that the committee has not had a formal meeting, but that they have been active.

A. Report of the SB 472 Medication Label Subcommittee Meeting Held April 12, 2008

Dr. Schell gave a brief background of SB 472 as well as listed those included in the subcommittee. He explained that the board worked closely with the author of the bill and created a timeline with regards to the process of implementing the bill. Dr. Schell provided the results of the public forum on April 12. He noted that Senator Corbett, the author of the bill, was present and made opening remarks. Dr. Schell also noted that there were approximately 40 individuals present, but only three were from the public. He stated that they are working on finding alternative venues to involve the public in the future forums. Dr. Schell thanked Kaiser Permanente and the California Retailers Association for providing the

diverse bottles and other containers used in dispensing drugs, which provided a visual sample of the types of labels necessary. He noted that auxiliary labels would be provided in future as well.

B. Update Report on "The Script"

Dr. Schell stated that the next issue, July 2008, will focus on applications of laws and regulations and will be mailed to pharmacies and wholesalers. He indicated that the California Pharmacy Foundation has been the financial supporter of the newsletter distribution, but that they will be unable to fund distribution throughout California for the future. He thanked them for the funding to date on behalf of the board. Dr. Schell also noted that the website seems to be the most useful tool for distribution, and that we may want to consider doing away with hard copies as a cost-savings.

Mr. Weisser suggested approaching the wholesalers to distribute the newsletters to the pharmacies in conjunction with their own deliveries.

Dr. Schell pointed out that so many are getting copies via the website, but agreed that Mr. Weisser's suggestion may be a good option for those pharmacists who do not have access to the internet.

C. New Notice to Consumers Poster Required by AB 2583 (Nation, Chapter 487, Statutes of 2006)

Dr. Schell gave background on the reason and purpose for the posters. He stated that designs were presented to the committee at the January board meeting. A design was selected, and the board will print the posters and mail them to all the California pharmacies in July. He noted that the budget is $80,000, which is twice the cost of the last poster order due to the necessary change of address.

D. Update On Public Outreach Activities

Dr. Schell noted that between the months of February and April, the board has participated in five presentations to professional associations, five presentations to major conferences, and staffed a booth at a public information fair.

Mr. Goldenberg stated that the outreach programs provided by the board are done very well. He encouraged the board to contact Ms. Herold, or to take some programs to the pharmacy schools near their residence, and present to graduating classes. He noted the benefits to such presentations, which includes providing updates to students on new laws, gaining exposure of the Board of Pharmacy, as well as increased knowledge of new laws for board members.

E. Third Quarterly Report on Committee Goals for 2007/08

The board meeting packet contained the third quarterly update of the committee's strategic plan.

V. Legislation and Regulation Committee Report and Action:

Part 1: Regulation Report and Action:

C. Board regulations update – noticed, pending adoption
"Requirements For Pharmacies That Compound" Repeal Of Title 16, CCR § 1716.1 And 1716.2 And Amendment To § 1751-1751.8 And Adoption Of § 1735-1735.8 (Awaiting 15-Day Notice)

Anne Sodergren reviewed the background of the proposal and indicated that the 15-day notice voted on at the January 2008 board meeting has not occurred. She stated that they are bringing it back to the board for consideration, and that board staff is recommending that the board withdraw the rulemaking with the Office of Administrative Law, getting further consensus on the language, and then moving forward with a new 45-day comment period. She noted that the suggested language is included in the board packet.

Ms. Herold added that the hearing was held in January, with a large number of comments and considerable discussion. The staff would prefer to "start over", and feel that the rulemaking will be smoother if we initiate the hearing again in July.

> MOTION: To take board staff's recommendation to modify the process of rulemaking to include the withdrawal of previous language, inserting the new language and going forward with the 45-day process.
>
> M/S: SCHELL/BURGARD
>
> VOTE: 11 OPPOSE: 0

D. Board Approved Regulations Update – Awaiting Notice:

1. Title 16 CCR § 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. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

2. Title 16 CCR § 1780 – Update on USP Standards Reference material

Section 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 are 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

Ms. Sodergren noted that the board approved the draft language. She noted that it was not included with the section 100 changes that were pursued last year, as there was public comment that indicated that there might be some unintended consequences by referencing that version of the USP. She added that we have not yet received any additional concerns, but that the regulation has not yet been noticed.

3. Title 16 CCR § 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. This proposed regulation would specify the criteria the board uses to evaluate these agencies. At the July 2007 Board Meeting, the board voted to move this proposal. Staff anticipates initiating the rulemaking process for final adoption by the July 2008 board meeting.

Ms. Schieldge noted the language of "e.g." within the language regarding a California healthcare payer. She stated that we don't typically use examples due to lack of clarity and stressed that it can cause vagueness with specific intent.

Ms. Herold asked if everybody governed by this would know who a "California healthcare payer" is. She questioned whether it is necessary to be any more specific beyond such a phrase.

Discussion ensued regarding the need for clarity on what entities are included on "healthcare payer".

Dr. Schell stated that it might be worth further investigation to determine if more specific language is needed.

4. Title 16 CCR § 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 1723.1 that 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.

Ms. Sodergren stated that the board has voted to approve the language on both proposals. The 45-day notice has not been initiated. She indicated that the intent of the proposed change is to strengthen those penalties for those who compromise or are caught cheating during the exam.

E. Board Approved – Regulation Language To Be Developed

Ethics course for pharmacists

Ms. Sodergren indicated that draft language will be presented at a future Enforcement Committee meeting for discussion.

Part 2 Legislative Report
A. Discussion and Action on Pending Legislation

1. Board Sponsored Legislation for 2008

a. 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, 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

Ms. Herold provided an update on the bill and reviewed amendments to the bill that have been made since the last meeting. She discussed inference, and listed staggered dates of implementation for pharmacists and manufacturers, as well as staggered dates of e-pedigree for injectables administered by the prescriber. Ms. Herold also noted the amendments for grandfathering and the reasons for such provisions

b. SB 1779 (Omnibus Provisions)

SB 1779 Omnibus Provisions previously approved by the board

§ 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.

Ms. Sodergren explained that public comment provided during the committee meeting related to the language not allowing for a mobile pharmacy during a structure remodel. She stated that the decision during the committee meeting was to review and refine the language to allow for a mobile pharmacy during remodel.

§ 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.

Mr. Dazé stated that a number of sections are being amended on this bill.

Amendments were made to the following General Omnibus Provisions

§ 4059.5 – Who May Order Dangerous Drugs And 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.

§ 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 § 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.

Section 4362 – Entry In to Pharmacist Recovery Program
This section specifies the administrative co-pay participants pay as part of their participation in the PRP. The board subsidizes the administrative cost, however requires the participant to also pay a portion of the administrative costs of the program. The current administrative co-pay, $75.00, is set by contract only. The board has not sought a change in this co-pay in over 10 years, and has continually absorbed the additional monthly administrative fee, currently about $230/month per participant.

This section allows the board the ability to waive the participant's co-pay for demonstrated financial hardship.

Health and Safety Code § 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.

No discussion from the board. No comments from the public.

Corrections to § Referencing Prior Business & Professions Code § 4052

Omnibus changes based on recodification of Business and Professions Code § 4052.

In 2006 Business and Professions Code § 4052 was recodified into four sections. The below B&PC and H&SC § reference 4052 and require update.

- § 733 – Dispensing Prescription Drugs and Devices
- § 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- § 4040 – Prescription; Content Requirements
- § 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- § 4060 – Controlled Substance – Prescription Required, Exceptions
- § 4076 – Prescription Container – Requirements for Labeling
- § 4111 – Restrictions on Prescriber Ownership
- § 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

No discussion from the board. No comments from the public.

MS. Herold suggested that the board to take formal position of support on SB 1779.

MOTION: Support SB 1779

M/S: SW/HH

SUPPORT: 11 OPPOSE: 0

c. Immunization by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – B&PC § 4052.8
Ms. Sodergren provided a summary of the bill and stated that they were unable to find a author and did not make it in as a legislative proposal. She suggested we revisit in 2009, and that if the Board desires, will develop a more defined coalition to move forward next year.

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

a. AB 501 (Swanson) 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 at no additional charge, a postage prepaid mail-back sharps container for safe disposal of the used device.

The board is in a current position to support. No further discussion.

b. AB 865 (Davis) State Agencies: Live Customer Service Agents
This billl would require all state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or an automated telephone answering equipment which then must include an option to reach a live customer service agent.

The board is in a current position of neutral. No further discussion.

c. AB 1394 (Krekorian) Counterfeit: Trademarks
This bill would strengthen the criminal penalties against counterfeit operations.

The board is in a current position to support. No further discussion.

d. 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.

The board has previously chosen to monitor the bill. No further discussion.

e. AB 1587 (De La Torre) Medical Information: Pharmacy-Patient Communications
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.

Mr. Dazé noted that the bill is not going forward, and the board was in an opposed position.

f. 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.

The bill has been withdrawn.

i. 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.

Mr. Dazé noted that the bill is not going forward, and the board did not have a position on the bill. No further discussion.

j. AB2643 (Cook) Drugs and Devices
This bill would replace references to the United States 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.

Mr. Dazé noted that the committee did not have a recommendation. Ms. Herold provided a summary of the bill, and noted that the bill has been dropped.

k. AB 2756 (Duvall) Pharmacists: Furnishing Drugs During an Emergency
This bill makes a nonsubstantive change to Business and Professions Code section 4062.

Mr. Dazé noted that the bill has been amended on April 21, 2008 to add natural disasters. The amended version is included in the supplemental packets provided to the board.

Public Comment:

Heidi Barsuglia (California Retailers Association)
Ms. Barsuglia noted that they are the sponsor of the bill, and that the committee did not have a recommendation prior because the amendment was not yet in print. Ms. Barsuglia would like the board to take a support position on the bill as it is adding natural disasters to that section of the language.

Ms. Herold referenced the amended bill and read the specific section with the changed language.

Ms. Barsuglia stated that there has been concern from pharmacists with regard to the actual declaration of an emergency, and gave the more recent Hurricane Katrina as an example of such an incident.

Mr. Room asked if a natural disaster is declared in the same way as an emergency. Ms Barsuglia responded that it is not.

Mr. Room clarified that a natural disaster would invoke 4062 without a Governor's declaration or otherwise.

Ms. Barsuglia responded that it would, with the pharmacists' discretion.

President Power asked Ms. Herold if this is consistent with the board's position on emergencies.

Ms. Herold responded that we activate our Emergency Response Plan in the event that a declaration of emergency occurs, either at a local or federal level. She added that the Department of Public Health has no objection to the language.

Mr. Room stated that he thinks it was the assumption of board members that it would be in the wake of a declared emergency. He clarified that this is a different situation that would not require a declaration in order for 4062 to be invoked. Ms. Barsuglia stated that CRA's intention would be to widen the scope merely to clarify that, in the event of a delay in the declaration of emergency that pharmacists be able to dispense medications during that emergency. CRA would be willing to work with the board on taking any amendments to clarify.

MOTION: Move to support SB 2756

M/S: POWERS/GRAUL

VOTE: 11 OPPOSE: 0

Mr. Weisser asked for clarification regarding the discretion of the pharmacist to determine whether to consider a storm as a natural disaster. He shared his concerns of a pharmacy being able to take action due to the vagueness of "natural disaster".

Ms. Herold noted the limited authority of the pharmacist without a prescription, as well as the obligation of the pharmacist to follow up and advise the prescriber.

Mr. Graul commented on support of the bill, and noted his own personal experience with regard to the effects of a delay of a governor's declaration during a natural disaster situation.

Mr. Goldenberg asked Bob Ratcliff (staff lead Supervising Inspector) whether this could become an enforcement problem. Mr. Ratcliff responded that he would like to see more specific language to address the issue of a natural disaster.

Mr. Room stated that the board could support the bill and still be involved in amendments.

Dr. Schell stated that he supports the bill, and gave his personal experience during a situation of a natural disaster.

Mr. Room suggested other options to amend the bill, besides adding natural disasters to the language.

Public Comment:

Steve Gray (Kaiser Permanente)
Dr. Gray urged support as written. He suggested to think beyond typical prescriptions, and to keep in mind that some of these drugs are a matter of life and death. He also noted that some pharmacists are rural and are the last to hear of a declared state of emergency. Dr. Gray pointed out that the Board of Pharmacy could always address issues of a disciplinary matter on an individual basis after the fact where authority is abused.

Ms. Herold asked if Kaiser Permanente is in support of the bill. Dr. Gray stated that they are in discussion on that.

Kathy Lynch (CPhA)
Ms. Lynch stated that CPhA is in support of the bill. CPhA urged support of the bill by the Board of Pharmacy. She gave an example of the Southern California fires and the difficulties associated with this issue at that time.

MOTION: Board staff assist the sponsors of the bill in resolving and amending the language.

M/S: POWERS/DAZÉ

SUPPORT: 11 OPPOSE: 0

l. SB 963 (Ridley – Thomas) Regulatory Boards: Operations
This bill would delete provisions subjecting boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection and instead make each of those boards subject to review by a standing policy committee of the Legislature upon request by a member of the Legislature or the chief of the Office of the Consumer Advocate. The committee was advised this proposal is intended to redefine the Sunset Review Process.

The board did not take a position on the bill. No further discussion.

m. SB 1096 (Calderon) Medical Information: Pharmacy-Patient Communications
This bill would allow a pharmacy under specified conditions to mail specified written communications to a patient without the patient's authorization. This bill was recently amended to specify that the information provided to the patient must be in same language as the prescription label and that the information must instruct the patient when to contact a health care professional.

The board has a current position of opposed.

Dr. Ravnan stated that she felt that this is very beneficial information for the consumer to have. She stated that she would be in more support of the bill if it was an "opt-out," rather than "opt-in" program.

Ms. Herold explained that under existing law, patients can already "opt-in," and that the bill's intent is to have a mandatory "opt-out" program.

n. SB 1270 (Cedillo) Pharmacy: Dangerous Drug and Devices Pedigree
This bill was recently amended and now would create an Electronic Pedigree Taskforce, consisting of specified representatives from the pharmaceutical industry drug supply chain, to provide the board with updates regarding industry readiness of the implementation on the pedigree requirement and the challenges thereof. It also requires the task force to provide an annual report to the board and the Senate and Assembly policies committees with jurisdiction over the issue.

Mr. Dazé indicated that the amendment for this bill is in the supplemental packet provided to the board members.

Ms. Sodergren provided a brief explanation of the bill and the amendment. No further discussion.

o. 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 from substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

Mr. Dazé stated that the bill is not going forward. No further discussion.

p. 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.

The board currently does not have a position on this bill.

Public Comment:

Terry Cowger-Hill (Hemophilia Council of California)

Ms. Cowger-Hill indicated that they are the sponsors of the bill. Ms. Cowger-Hill gave a background on hemophilia and the Hemophiliac Council of California. She noted the additional issue of hemophiliacs being injected with HIV via transfusions. Ms. Cowger-Hill noted that the drugs needed by hemophiliacs is very expensive and that numerous companies have now gotten involved in manufacturing those drugs. The Hemophiliac Council of California feels that standards need to be put in place because of this. Ms. Cowger-Hill stated that they are very open to suggestions from the public, board and pharmacy community on the language and development of the bill. She noted that they do not expect a position today.

Ms. Herold asked why the Department of Healthcare Services is the agency developing the regulations on the bill, rather than the Department of Public Health. Ms. Cowger-Hill responded that they need to work with both departments to determine proper language. Ms. Herold explained the difference of both entities and their roles within the process.

Ms. Herold advised the board that, because these entities are already licensed pharmacies, the board would be obligated to enforce this regulation. A discussion ensued regarding the board's responsibility of enforcement on a bill that the board may not be involved in developing.

Mr. Room commented that the statute of the bill language uses the term "pedigree". Ms. Cowger-Hill responded that leg counsel was used to develop the language, and they are open to modifying the language.

Steve Gray (Kaiser Permanente)
Dr. Gray encouraged the board to look at page five of § 125286.4 and noted factors that the board is not typically involved in. He stated that the bill would involve more detailed requirements that the Board of Pharmacy should not be involved in enforcing. Dr. Gray suggested that the board work with the author and get some essential parts that will improve the ability to handle the care of hemophiliac patients, but not necessarily to this level of detail. Dr. Gray noted that it could have the effect of some pharmacies choosing not to do business in California anymore.

Ms. Herold stated that that same concern was addressed by the California Society of Health - System Pharmacists (CHSP), stating that because the requirements are so complex, some pharmacies in rural areas may opt to remove themselves from providing these services to hemophiliac patients. She shared a concern discussed in a prior meeting where hemophiliac drugs have been left outside of a building and not handled properly due to concern over complex legislation of the drugs.

Mr. Graul stated concern over the language of "pharmacies and other entities" and that the board may be regulating entities that are not licensed pharmacies.

Ms. Cowger-Hill responded that she would take the concern back to the client and respond back to the board.

Mr. Room and Ms. Schieldge requested that the board avoid having "bits of law" involved with enforcement, and that items that are going to regulate pharmacies be in the pharmacy law. Mr. Room suggested that, since this is expanding the jurisdiction into another code, we add into § 4011 that we also enforce these provisions as well as any other statutes. He stated that we need to be able to look at pharmacy law in some sort of cohesive way.

Dr. Schell shared his concern in expanding the board's role, especially if it will involve enforcement of entities other than pharmacies.

Mr. Room stressed that it is outside of the normal processes of the board to take action against others outside of licensees.

Mr. Goldenberg asked if Ms. Cowger-Hill knows the percentages of pharmacies versus non-pharmacies in this market. Ms. Cowger-Hill stated that she did not know, and actually thought they were only dealing with pharmacies on this subject. She noted that the patients are a very selective niche and the homecare pharmacies are normally who service them. She believes that the small group of pharmacies within the hemophiliac treatment centers are licensees, but will need to reply back to the board in the future to confirm.

Ms. Cowger-Hill noted that the standards of service for hemophiliac patients are "on the books" now in Pennsylvania and Minnesota.

President Powers recommended to the board staff that they continue discussions with appropriate parties and bring the results back to the board at a future board meeting.

Bryce Docherty (California Society of Healthsystem Pharmacists)
Mr. Docherty indicated that CSHP discussed the bill during a recent board meeting and took a "watch and refer" position. They referred it to group that specialize on these types of pharmacies and related drugs. Following a conference call, they are recommending a support if amended position to their board. Mr. Docherty stated that they feel strongly that there needs to be some sort of standardization in terms of the supply chain of these medications. He noted that this is a small niche. He stated some of CSHP's issues with regard to timeframe for drugs to be available, written consent and changes in dosage. He also stated that they have some technical amendments as well, but are optimistic that the

author will be open to them. Although there is no official support at this time, he feels that will occur shortly.

MOTION: Take watch position on this bill.

M/S: POWERS/SCHELL

SUPPORT: 11 OPPOSE: 0

g. AB 2122 (Plescia) Surgical Clinics: Operational Standards
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.

The board currently has no position. No further discussion.

Mr. Graul noted that the committee voted a change from none to support.

The committee recommendation is to support AB 2122.

SUPPORT: 11 OPPOSE: 0

h. AB2425 (Coto) Water Quality: Pharmaceuticals
This bill would require every pharmaceutical manufacturer that does business in California and whose pharmaceutical products have been detected in the drinking water supplies within California to file a report with the State Public Health Officer as specified.

The board currently has no position. No further discussion.

B. Other Legislation Impacting Pharmacy Or The Board's Jurisdiction

SB 1702
This bill requires 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) request 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.

Ms. Sodergren summarized the bill, including a discussion on using county lines as a determining factor regarding fraudulent activity. It was requested at the committee meeting that the board review this bill and to consider a change from county line to designated service areas.

AB 2661
This bill adds telephone communication to the definition of telemedicine, requires the practitioner practicing telemedicine by telephone to use an electronic medical record (EMR) and provides that a practitioner may be designated by the patient.

Mr. Dazé summarized the bill, and noted that the bill has been withdrawn.

C. Update on the Implementation of SB 966 (Simitian, Chapter 542, Statutes of 2007)

Ms. Herold provided a summary of the bill. She stated that there is a task force in place which includes five state agencies with jurisdiction in this area, and meetings are ongoing. The intent is to look at model programs, pick up components that comply with requirements of the Department of Public Health, the Toxics Program, Integrated Waste Management Board, the Department of Water Resources and the Board of Pharmacy. She noted that the bill requires that Waste Management Board have regulations in place by December, 2008. There have been committee and public stakeholder meetings where entities have provided comments. Ms. Herold stated that they are moving forward with developing the regulations, but that the actual charge is with the Waste Management Board.

Dr. Swart asked if there is something on record with regard to diversion. He stated that if there are no records of what is being brought in and taken out, he would be concerned about lack of responsibility and tracking sources.

Ms. Herold agreed with Dr. Swart's concern. She stated that the DEA is being asked to participate to ensure they are involved, and specific requirements are being requested from them. The concern is that patients do not understand what is a controlled substance, which will cause a "mix" in the programs.

D. Meeting Summary of the Meeting of April 11, 2008

Tim Dazé noted that the committee had a meeting on April 11, and referred the board to the minutes in the board packet

E. Third Quarterly Report on Committee Goals for 2007/08
Mr. Dazé noted that the committee goals as noted are attached in the board packet. There was no further discussion.

Public Comment:

Ron Bone (McKesson)
Mr. Bone asked if the board has an opinion on the Matheson legislation that has recently been released, as it parallels California Law. President Powers responded that they have only received a preliminary review of that legislation at this point.

VI. Licensing Committee Report and Action

A. Overview of Board of Pharmacy Licensing Programs - Christine Soto

Ms. Soto provided an overview of the Board of Pharmacy licensing programs.

Ms. Soto explained the primary goal as well as the roles and responsibilities of the Licensing Department. She reviewed the 12 licensing programs with a breakdown of which entities and individuals those programs support. Ms. Soto explained the minimum qualifications for licenses issued to individuals, and explained the roles and qualifications of each. She also defined the different entities within the supply chain licensed by the board as well as their respective roles.

Ms. Soto gave an overview and timeline of the licensing application process. She noted that additional review time might be needed based on the history of the applicant. Ms. Soto also referenced a flowchart which provides the details of the licensure exam process.

Ms. Soto explained when and how an applicant should contact the board office to check the status of a license, including visiting the website or e-mailing the appropriate contact.

Ms. Soto provided current license totals, including a breakdown of totals by type (business and individual). She also gave a total of new license applications received for the 3rd quarter of 2008.

Ms. Soto discussed the development of specialized teams within the staff, as well as their specific areas of responsibility. She reviewed the department's short-term goals with regard to customer service, including cross-training, process improvement, etc. Ms. Soto noted the department's new "YouTrack" program which will be in place in the near future, used to allow applicants to monitor their license application. She also discussed a long-term goal for improvement, which will involve on-line application processing.

Question to the presenter:

Dr. Schell asked if there is a breakdown of hospitals versus community pharmacies available.

Ms. Herold responded that there are approximately 6000 community pharmacies and 487 hospitals.

Mr. Graul asked what the applicants receive in return when they send an e-mail to check on the status of their license.

Ms. Soto responded that they receive an immediate acknowledgement e-mail, and that the staff then follows up with the status by replying via e-mail.

Mr. Weisser referenced the correctional institutions and asked where those entities are included within the categories of site licenses.

Ms. Herold believes they are included in the pharmacy total because they are viewed as pharmacies (not clinics). She noted that we have 35 prison facilities. Mr. Room added that the correctional facilities themselves are licensed as pharmacies.

Dr. Conroy made note that it is important to call OR e-mail, and not contact the board in both manners.

Ms. Soto noted the difficulty for the staff in processing applications when receiving e-mail and phone calls from applicants, including contact from additional individuals from the same business.

A member of the audience asked for a definition of a designated representative. Mr. Room provided the definition as an individual in charge of and responsible for dealing with the drugs at a wholesaler site. Ms. Herold expanded on the definition as someone who is designated in place of the pharmacist, as there is a requirement to have either a pharmacist or a certain amount of designated representative on site during business hours. Mr. Room added that you can have a pharmacist or designated representative, and a designated representative also has to meet certain qualifications.

Ms. Soto acknowledged the board's higher level of innovation and technology as well as their goal in streamlining service to the public.

Joan Coyne (Supervising Inspector) noted that Designated Representatives were previously referred to as "exemptees".

Janice Dang (Supervising Inspector) noted that some of the statistics provided by Ms. Soto in her presentation can be found on the Board of Pharmacy website.

Mr. Goldenberg asked about a new minimum age requirement to become a pharmacist. He asked how many licensed pharmacists are under the age of 21.

Ms. Soto responded that she does not have that information available today, but a query can be done based on date of birth.

Ms. Soto commended her staff and their creativity and well as the direction of the board.

B. Discussion: Public Health Preparedness, Mobilizing State by State, A CDC Report on the Public Health Emergency Preparedness Cooperative Agreement, February 2008

In February 2008, The CDC released a report on *Public Health Preparedness: Mobilizing State By State.* This report outlines the progress and challenges of emergency preparedness and describes how CDC and its partners are working to address these challenges.

Dr. Conroy noted that California has seven cities in the initiative while others had three.

There was no discussion from the board. There were no comments from the public.

C. Competency Committee Report

Dr. Conroy discussed the CPJE Exam result delay during the Quality Assurance assessment period, which started April 1, 2008. She indicated that the results would not be released until approximately 400 exams are completed, which is anticipated to be around the end of July. Dr. Conroy noted that this is a good time of the year to complete the QA because so many applicants sit for the exam at this time of year. She added that after a QA is complete, it takes approximately 14 days for the exam results.

Dr. Conroy indicated that the competency committee workgroups have met and are on schedule.

Dr. Conroy stated that the CPJE pass rate statistics are provided within the board packet with appropriate details.

D. Licensing Statistics

Dr. Conroy noted that the licensing statistics were covered in Ms. Soto's presentation.

E. Third Quarterly Report on Committee Goals for 2007/08

The board meeting packet contained the third quarterly update of the committee's strategic plan.

VII. Organizational Development Committee Report and Action

A. Budget Update/Report

a. Budget for 2007/08

Dr. Conroy reviewed the budget update report, as well as budget reserve amounts.

b. Fund Condition Report

Dr. Conroy noted that the fund condition report is provided and based on receipts provided to date.

Ms. Herold commented that we need to continue to watch our budget. She stated that there is a concern over the expenditures from this point on as our expenditures are now exceeding our income. She added that we may need to go to the legislature to increase fees, and this has not been done since 1986.

Mr. Dazé asked if it would be better to go to legislature earlier than later to get fees raised.

Ms. Herold responded that it would be would be best to address this during the Sunset Review, however there is not much interest in the legislature in doing future Sunset Reviews for boards who do not cause public health concerns. We are currently not one of those agencies.

Ms. Herold noted the issue of our large labor expense due to the inspector staff being licensed pharmacists. Because we strongly value the expertise and knowledge of our pharmacist (inspectors), we need to recognize that this will be something we will need to contend with at some point legislatively. Ms. Herold advised the board and a fee audit will

be conducted next fiscal year, to ensure that all of our fees are accurately relative to the cost of delivering the service. She noted that we typically spend 70% of revenue on enforcement, and 30% on applications. The audit provides the board with an independent unimpeachable source that can help with adjusting the fees where appropriate.

Mr. Dazé asked if the board could direct questions to auditors to review certain areas of the budget specifically in order to keep the board sustaining itself.

Ms. Herold responded that that would be the goal. She stated, however, that they already know the expense of the inspector staff exceeds the budgeted expense.

Mr. Dazé asked if it is possible to have the fees set and have the CPI built into the fee so it is automatically adjusted each year.

Ms. Herold responded by providing an explanation of the fee process, which includes a fee cap within the legislation. Ms. Herold referenced the task force created as a result of SB 1270, which will be funded by the general fund because of budget constraints.

Mr. Goldenberg asked about the consideration of more fuel-efficient vehicle purchases for the inspectors.

Ms. Herold responded that the board can only purchase vehicles on the state approved list, which includes fuel alternative vehicles. She noted that we have a couple of fuel alternative vehicles in the fleet. She also explained that the Department of Fleet Administration requires each vehicle to be driven a minimum amount of miles and that some of the staff are not meeting that requirement. She added that the administrator of DFA is taking a close look at whether the state should be purchasing or renting vehicles at all.

Mr. Hough asked if Touro University is an accredited pharmacist school, as he did not see exam results from that school.

Dr. Conroy explained that they have not yet had a graduation class, and the school will become fully accredited at that time.

c. Reimbursement to Board Members

Dr. Conroy indicated that this information is included in the board packet.

d. I-Licensing Progress

Dr. Conroy noted that Ms. Soto discussed this during the presentation. She added that a feasibility study report was approved by the Department of Finance, but there has been a lot of department staff turnover on this project.

B. Recognition of Pharmacists Who Have Been Licensed for 50 Years

Dr. Conroy stated that the board has acknowledged 750+ pharmacists since 2005. She briefly explained the process of recognition.

C. Personnel Update

Ms. Herold explained that the board has now filled all vacant inspector positions and provided their names. She also listed the new staff members since the last board meeting, including position changes and promotions within the department. Ms. Herold recognized the return of Anne Sodergren and her promotion to Assistant Executive Officer. She acknowledged the loss of Kim deLong, but noted her transfer to a position related to her career goal.

Ms. Herold noted the inspector's workshop held in the first week of April in San Diego, and summarized the details of the training, including a mock hearing. She noted various staff members attending training programs to enhance their job-related skills. Ms. Herold concluded by stating that she is pleased to have a full enforcement staff.

Mr. Room stated that, since the mock hearing and training, he is even more cognizant of the need for inspectors to be licensed pharmacists. He added that he appreciates their skill set and understanding of pharmacy law and practices of the pharmaceutical industry, and explained how he sees it as a cost savings for the board by having licensed pharmacists as inspectors.

D. Future Joint Board Meeting in November 2008 with Other Departmental Boards and Bureaus

Dr. Conroy explained that the intent is to have all boards and bureaus hold public meetings at various times throughout the week and at the same location to maximize public participation. She indicated that it is tentatively scheduled for the week of Nov. 17th, 2008 in Southern California, and that the Board of Pharmacy's meeting will be held on Nov. 20th of that week.

E. Third Quarterly Report on Committee Goals for 2007/08

The board meeting packet contained the third quarterly update of the committee's strategic plan.

VIII. Election of Board Officers for 2008-09

President

MOTION: Elect Ken Schell as president of the Board of Pharmacy

M/S: RAVNAN/WEISSER

MOTION: To close further nominations.

M/S: DAZÉ/BURGARD

Vice President

MOTION: Elect Tim Dazé as vice president of the Board of Pharmacy

M/S: GRAUL/HOUGH

MOTION: To close further nominations.

M/S: BURGARD/SCHELL

Treasurer

MOTION: Elect Stan Weisser as treasurer of the Board of Pharmacy

M/S: DAZÉ/SCHELL

MOTION: To close further nominations.

M/S: GRAUL/SCHELL

MOTION: Vote as a group for above nominations

SUPPORT: 11 OPPOSE: 0

Ix. Public Comment For Items Not On The Agenda/Agenda Items For Future Meetings:

Lucy Saldaña and Eileen Turner - Centers for Medicare and Medicaid Services

Ms. Saldaña began the presentation by explaining her purpose for presenting, which is to inform the board of a new Medicare program known as DMEPOS (Durable Medical Equipment Prosthesis Orthotics and Supplies). She noted that these items are covered under Medicare Part B, which includes walkers, power wheelchairs, hospital beds and other accessories.

Ms. Saldaña explained that the program would affect how Medicare patients pay for these supplies and provided and overview of the new competitive bidding program. She explained that the program only applies to patients who already have Medicare and reside (or travel) within the initial designated areas. The designated areas were listed as being Riverside, Ontario and San Bernadino counties. Ms. Saldaña also reviewed the benefits of the program to the Medicare patients.

Ms. Saldaña explained the 10 categories of products included in the competitive bidding. She also noted non-DMEPOS items (those not included). She stated that the program does not affect a patient's choice of physician or hospital. Ms. Saldaña stressed that some will need to change DMEPOS suppliers in order to continue Medicare coverage.

Ms. Saldaña provided the beginning effective date, but explained that patients receiving supplies contracted prior to this date will still be able to receive those supplies in the current manner for a given period of time.

Ms. Saldaña gave an overview of the bidding process for suppliers. She explained that if you have not yet submitted bids, it is too late for "Round 1". Suppliers would need to submit an accreditation application before May 9, 2008 in order to be included in "Round 2" for July 1, 2008. Ms. Saldaña listed the National Accreditation Organizations to accredit DMEPOS suppliers.

Ms. Saldaña reviewed the benefits of the new bidding process, including lower cost for Medicare patients, improved access to certain suppliers, and the reduction of fraud, waste and abuse.

Ms. Saldaña gave an overview of the DMEPOS Accreditation, which is a completely different program from competitive bidding. She explained that if providers dispense or sell DMEPOS products and have a Part B provider number, they will need to receive accreditation by September 1, 2009. She noted that without accreditation, providers can still dispense or sell DMEPOS products, but they will not be reimbursed by Medicare. Ms. Saldaña noted there is an expense with the accreditation. She provided resources and websites to assist providers with determining whether the products they sell are under the DMEPOS category, as well as other valuable information.

Eileen Turner gave additional comments. She noted that they are currently still working on Round 1. Ms. Turner discussed the grandfathering provision in order to ensure clarity. She explained that as long as the existing arrangement with suppliers was in effect prior to July 1, 2008, they will be able to continue with that arrangement or service. She noted that the same is true for the supply of oxygen, however the rate will change.

Jennifer Delaney

Ms. Delaney indicated that she took the CPJE on April 9th. She stated that she saw the notice on-line indicating that a Quality Assurance review was underway on April 1st, and that the results may not be available until July, 2008. Ms. Delaney stated her frustration over scores being held to assure the quality of the exam, and requested an explanation. She indicated that the delay is affecting her ability to accept job positions currently being offered.

Ms. Herold responded by explaining the board's requirement to provide valid job-related exams. She stated that the board contracts with a psychometrician firm which handles all matters relating to the validity and reliability of the exam questions. Part of the firm's process requires a periodic quality assurance review, and exam scores cannot be released during that time. Ms. Herold explained that if the exam results were provided to applicants following their exam, and the result of the QA indicated a problem which affected the score of the applicants during the QA period, the applicant's license would need to be revoked by taking the applicant to the Attorney General's office under the form of discipline. Ms. Herold stated that they recognize the difficulty this places on applicants affected by the QA period, and the board releases those scores following the QA period as quickly as possible. She noted however that is would be irresponsible and against their public protection mandate to release those scores until the vendor is able to stand behind them.

Ms. Delaney noted that the on-line bulletin states that you will be informed prior to the exam of the possibility of a Quality Assurance hold. She asked about the board announcing the QA prior to the beginning of the review period. Ms. Herold stated that the announcement should have been placed a bit sooner, but that the board cannot anticipate the specific date upon which a QA review will begin.

Mr. Room suggested that the topic be agendized for a future board meeting as the topic may apply to other applicants as well.

Ms. Schieldge indicated that, because the item has become a topic of discussion between the board and the individual, it is no longer appropriate for this area of agenda. Ms. Schieldge stated that Ms. Delaney should continue the discussion with Ms. Herold following the board meeting. The board encouraged Ms. Delaney to attend future board meetings.

Meeting was adjourned at 4:27p.m.