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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: October 24-25, 2007

LOCATION: San Jose DoubleTree Hotel
2050 Gateway Place
San Jose, CA 95110

BOARD MEMBERS PRESENT:
William Powers, Public Member, President
Ruth M. Conroy, PharmD
D. Timothy Dazé, Esq., Public Member
Stanley Goldenberg, RPh
Clarence Hiura, PharmD
Robert Swart, PharmD
Andrea Zinder, Public Member

BOARD MEMBERS NOT PRESENT:
Kenneth H. Schell, PharmD, Vice President
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Graul, RPh

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Wednesday, October 24, 2007

CALL TO ORDER

President Powers called the public board meeting to order at 9:08 a.m. on October 24, 2007.

GENERAL ANNOUNCEMENTS

Mr. Goldenberg referenced the recent wildfires in Southern California. He stated that the Board of Pharmacy wanted to encourage pharmacies, especially those located in disaster areas, to receive appropriate help and always take care of the patients first.

Ms. Herold stated that the board had been in contact with California's emergency response agencies, and that many people in the San Diego area had been displaced. Ms. Herold read aloud from language that had just been written and would be sent later in the day via a subscriber alert.

> "California pharmacies are reminded that the Board of Pharmacy has activated its emergency response provisions to all pharmacies under the authority granted it by Business and Professions Code 4062 and its disaster response policy. It is the expectation of the board that patients in or from affected areas will continue to receive prescription medicine, and pharmacists are expected to use professional judgment in providing care. The priority of the board is patient care first. Pharmacists licensed in other states are welcome to help provide pharmacy services to affected patients in California."

ENFORCEMENT COMMITTEE

Enforcement Committee Chairperson Goldenberg advised that several presentations would be made on the status of electronic pedigree implementation.

- **Alien Technology on the Status of RFID Technology**

  Mr. Goldenberg introduced Victor Vega, Director of Technical Marketing of Alien Technology.

  Mr. Vega said that the UHF RFID industry has advanced significantly over the last couple of years because technology has improved and costs have decreased. He gave a multi-media presentation to the board.

  Mr. Vega stressed that UHF RFID is scalable and versatile. The technology is now worldwide and different tags for different countries are no longer needed. Tags are also less expensive as they used to cost around $1 each, but now are under 10 cents each. Mr. Vega stated that for item-level, case-level, and pallet-level tracking, there are three technologies:

1. 2-D matrix barcoding
2. high-frequency (HF) RFID
3. ultra high-frequency (UHF) RFID

Mr. Vega suggested that people could also use some combination of all three technologies throughout the supply chain, but it would be difficult and expensive to set up that type of infrastructure and then maintain that infrastructure. He stated that to scan 2-D barcodes on vials and pill bottles, the barcode may be free, but the time and labor to scan each item is not.

Mr. Vega pointed to various benefits of HF including the ability to "mask in" data, resulting in a unique ID. He stated that no one could divert the data as it can be locked. He gave a demonstration with a box showing a unique ID on the outside label. He added there are adhesive labels that self-destruct if someone tries to remove them from containers. The tags are substantially smaller; tags originally were six inches, then four inches, two inches, and now even less than one inch.

Generally, features and performance have gone up, prices have gone down, and people are realizing they become more competitive by using RFID technology.

Mr. Vega also spoke about the diversity of tag readers available, including handheld readers. He displayed a reader that was pocket-sized. He spoke about the benefits of readers having the ability to singulate items coming down a conveyor belt; the RFID tags do not have to be directly on top of an item or facing forward to be read accurately. He stressed that previous reader problems have been resolved.

Mr. Vega also provided samples of small RFID tags.

Mr. Vega provided an item-level tracking demonstration; he held up one vial at a time, and demonstrated the amount of time it took to read each tag individually. A video display showed one vial at a time. Second, he placed the entire box of vials, each tagged with UHF chips, in front of a reader. The video display showed all vials at one time.

Mr. Vega also provided a demonstration using blister packs of Benadryl. He placed a box of blister packs in front of the reader. A video display showed each blister pack, including a warning that one pack was from a bad lot.

Mr. Vega stressed that readers have advanced so much that now they can read tags on small products, liquid products, and caps with metal in the tops. He performed a demonstration of file management using paper file folders of varying colors. RFID tags affixed to the paper file folders could be read when he placed a stack of the folders in front of a reader. A video display showed each file folder separately, including green folders, red folders, yellow folders, and pink.

Mr. Vega emphasized that there have been considerable advancements in RFID technology. He spoke about RFID tags being able to be read in oil-based liquids, but previously could not be read through water. He said that that problem had been resolved and now tags could be read through water as well. To illustrate his point, he removed an RFID tag affixed to the outside of a water bottle, dropped the tag into the bottle, and then placed the bottle in front of a reader. A video display accurately showed the bottle of water.

Mr. Vega said now is the time to choose “lean” technology over complex technology that gives IT departments job security.

Mr. Goldenberg asked about encryption and battery technology and what the most logical approach would be for a small independent rural pharmacy to be part of this technology.

Mr. Vega responded that a pharmacy can use a simple LAN connection to a reader, and he displayed a small 6” square reader for demonstration purposes. He said it had a circularly polarized antenna, which eliminated external antenna cables. Mr. Vega said that you would not need to go to school to learn about the system – just insert the LAN connection.

Mr. Vega stated that the reader must be connected to a computer to capture the data transmitted, and the reader is probably under $1,000. Purchasing in quantity would result in a dramatic price drop, probably to around $600 each.

Mr. Vega stated that this reader would have approximately 75% of the performance of a high-performance reader, whereas the price for a high performance reader would be around $2,000 for one, with substantial price drops for quantity purchases. He said that a smaller reader would be able to read a tote of 80 items, but for an extremely high volume of tags, a different reader would be best.

Mr. Vega stated that if items are mixed up in tote boxes, with paper in between the tagged items, the reader would still work. He again emphasized the benefits of RFID technology for file management, stating that it can even show when paper files are out of order on a shelf.

Mr. Powers said he appreciated the presentation, which showed that the technology is here now.

Mr. Vega spoke about the challenge of certain biologicals not having been tested with magnetic or ultra high frequency readers, and whether those tests are still on the to-do list. He said he previously worked on biologics, but the data is with that company. The company set up various experiments about four years ago, and no problems were shown.

Mr. Vega commented that there are many other companies doing this type of work; Alien Technology does not have a monopoly. He emphasized that his key message is that if you go with a company that has a proprietary solution, be cautious.

Mr. Vega noted in response to a question that the failure rates for RFID tags of five years ago are no longer a problem. Back then, only 20 percent of tags would read correctly, but now they're close to 100 percent. He added that entire rolls of tags are tested before shipping, so bad tags are removed.

Mr. Vega said that the readers could selectively read UHF RFID tags when other tagged items are nearby. He gave a demonstration of his reader by directing it to show either more items or fewer items, based on a specified distance from the reader. A video display showed file folders, then water bottles, and then vials. He likened the ability to show more or less to a "dimmer on a light switch."

Mr. Room said he heard there could be a limited supply of silicon in the world.

Mr. Vega stated that there is not a shortage of silicon. He added that Alien Technology could build the devices very small, so they are using less silicon anyway.

Mr. Vega responded to a question that the classic squiggle tag is a staple product and has the best price point. He understands that those tags are under 10 cents each, and probably lower when buying in mass quantities.

An audience member asked about counterfeiting and tamper-proofing in packaging.

Mr. Vega responded that with respect to counterfeiting and tamper-proof packaging, when a tag is peeled from a box, the connection is severed, and the reader can lock the data.

Mr. Goldenberg thanked Mr. Vega for his presentation.

- **IBM/AmerisourceBergen on EPCIS (Electronic Product Code Information Services)**

Mr. Goldenberg introduced Craig Asher from IBM and Heather Zenk from AmerisourceBergen.

Craig Asher said he is an IBM product manager, is co-chair of the EPCIS Software Action Group, and co-chair of the Data Exchange. Mr. Asher stated he has been working with EPCglobal and serialization for about three and a half years. He said he wanted to show that EPCIS pedigree and document pedigree can co-exist.

Heather Zenk stated that she works for AmerisourceBergen.

Mr. Asher thanked the board for the opportunity to present. He said he would talk about EPCIS pedigree, and wanted to quickly summarize the California pedigree requirements. He also said there are two different models for pedigree – one is called EPCIS pedigree and the other is called document pedigree. Mr. Asher said that he and Ms. Zenk wanted to convince the board that both models would meet California's requirements. He said that EPCIS pedigree and document pedigree use different data carriers.

Among other issues, Mr. Asher and Ms. Zenk spoke about four product movement events that EPCIS captures:

1. What was the product that moved? (i.e., unit-level EPC number, manufacturing data, transactional data, etc.)
2. Where did the product move? (location, which can be fixed or moving)
3. When did the product move? (event time and record time)
4. Why did the product move? (business process step such as receiving or shipping, product state such as saleable or in transit, current conditions such as temperature)

Mr. Asher emphasized that EPCIS is a standard-based framework that can be implemented by many different parties, and allows tracking of the product. He said that this is the same information that you need for drug pedigree or for EPCIS pedigree. In the pharmaceutical industry, this will show product movement across the supply chain.

Mr. Room asked a question about what information is passed to each trading partner.

Mr. Asher stated that you choose to transfer to the next trading partner. It depends on what the next trading partner wants, but the output of the pedigree is the same. Multiple trading partners will have the same "end point." He added that a pedigree document could be generated at each level of distribution.

Mr. Goldenberg asked about pharmacies that have a desire to transfer products other pharmacies, but the pharmacies are not commonly owned.

Mr. Asher stated that the software provider could establish ways to capture transfers of drugs to other pharmacies that are not commonly owned. For example, if AmerisourceBergen were your pedigree provider, they would enable that as part of their solution to you. If McKesson were your provider, they would enable that as part of their solution to you.

Mr. Goldenberg noted that there is traditional cooperation between pharmacies in supplying consumers with products. The board wants to ensure that transfer of products between pharmacies to alleviate shortages continues.

Mr. Asher said that he's seen a lot of progress, but did not want to present an overly rosy picture. He said that a core group of industry participants are moving ahead now,

and will be moving ahead in 2008 with system implementation and serialization efforts. He believes both EPCIS pedigree and drug pedigree messaging are needed, but he does not believe the industry will be ready by January 1, 2009. He said production implementation of data exchange for serialized items requires 18-24 months, and stressed it takes time to set up the processes.

Mr. Room asked about disappearing trading partners. He asked if under EPCIS, could the pedigree still be assembled if a trading partner is gone?

Mr. Asher answered yes.

Mr. Asher noted that IBM and AmerisourceBergen put together a solution guide for deployment of EPCIS pedigree. He said they want to contribute that guide to EPCglobal soon. They believe that both approaches need a solution guide, so you will have true interoperability.

Mr. Asher said that given the current state of technology that has been evolving rapidly, and given the absorption capability of people in the supply chain since they have other jobs, the industry will not be 100 percent ready by January 1, 2009. He said that production implementation of data exchange, not pilots, requires 18-24 months regardless of which model you use. Mr. Asher presented some questions to the board:

- Do you believe that EPCIS pedigree can enable companies to meet California's requirements in the same manner as the document model?
- What questions do you have about EPCIS, and do you see any shortcomings in EPCIS for pedigree data exchange?
- Do you have any questions about deployment progress?

Mr. Room noted that one of the complaints raised about the document model is that the end user gets all of the data.

Mr. Asher said that if you use EPCIS events, you would only provide the data about the product that was actually shipped.

Mr. Room asked about interoperability problems caused by different vendors configuring data in different ways, and whether there will be difficulty transmitting data downstream and unlocking or unpacking that data.

Mr. Asher responded that this is why both approaches need a solution guide that all the vendors can adhere to. In that way, there will at least be a broad framework incorporated, so that regardless of which vendor you choose, you know there is going to be the same set of data and elements in the same order. That's what a solution guide would require.

Mr. Asher stated that EPCglobal should develop the solution guide, but it would be good for the board to set the timeline.

Mr. Goldenberg noted that the timeline is in place.

Mr. Goldenberg stated that at a recent NABP meeting, neighboring states were encouraging California's Board to move forward with its requirements.

Mr. Asher responded to an audience member's question regarding a timeline of 18-24 months, that the process of data exchange requires trading partners to cooperate in capturing data, and then getting that data to flow between trading partners, which can take a bit of work. As an example, he said you would have problems getting through a company's firewall, and resolving that one problem can take months. He said that companies are afraid to share data with parties that they do not necessarily know or trust, so just getting holes punched in the firewall can take time.

Mr. Room asked whether the 18-24 month timeframe would include all the manufacturers' work of serializing an individual product, capturing that data, setting up the serialization infrastructure, as well as the plowing of the data exchange furrows between that manufacturer back through the distributor and the retailer.

Mr. Asher responded that this is a process that has to be gone through.

Several board members made comments that the board has watched these presentations, and has seen problems and solutions being brought forward. The board wants every stakeholder to know the board is serious about the implementation date. The board is holding them to that date, and it's the only thing to get stakeholders serious.

Mr. Room asked Mr. Asher whether he agreed that the pace of implementation has been increasing over the past six to twelve months.

Mr. Asher responded, yes. There has been definite acceleration during the last three months.

Ms. Zenk added that she has been receiving an increasing number of questions from their supply chain partners. The questions have increased exponentially, and there are days when she cannot return all phone calls that have come to her. Questions have been coming from all segments of the supply chain as people are becoming more aware and are trying to understand how to move forward.

Mr. Asher asked for the board's help in getting answers to some questions and this would help to move things ahead faster. There would be less on the table for people to worry about.

Ms. Herold stated that questions and answers are being developed. She added that the board has been a big advocate of running pilot studies.

Ms. Herold announced that she was approached by a software vendor interested in talking to a retail chain pharmacy with 200-400 stores that would like to do a pilot in California. Please contact Ms. Herold if you are interested in being put in touch with that vendor.

- **SupplyScape – Drug Pedigree Messaging Standard**

  Mr. Goldenberg introduced Dirk Rodgers from SupplyScape to speak on the subject of the drug pedigree messaging standard.

  Mr. Rodgers said that he had been an active member and participant of the EPCglobal Healthcare Life Sciences (HLS) Group since its beginning four years ago. He said he had also chaired and participated in a number of workgroups in EPCglobal. He added that he currently works for SupplyScape as Director of Industry Standards.

  Mr. Rodgers said he spent the last 17 years designing and integrating IT systems within the pharmaceutical supply chain, and has a personal commitment to making a contribution to the integrity of our drug supply. He emphasized that California's pedigree legislation requires an industry standard solution. The pedigree must be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

  Mr. Rodgers spoke about the benefits of the EPCglobal Drug Pedigree Messaging Standard (DPMS) due to its open format for sharing pedigree information.

  Mr. Rodgers stated that more than 100 companies have implemented the EPCglobal Drug Pedigree Messaging Standard for California compliance. At least 70 of those 100 companies are SupplyScape E-Pedigree customers, and the rest are deploying solutions from three of their competitors.

  Mr. Rodgers clarified that the pedigree standard defines the transaction of record. In contrast, the EPCIS is an interface standard. As an example, he compared an interface standard to a telephone plug; it is defined so that two or more phones can communicate with each other, but the content of that communication is not specified. The phone plug cannot tell you if the incoming information is a voice phone call, a fax, or a computer connection. To define the content of the messages communicated through the phone plug, additional standards and specifications are necessary. Mr. Rodgers said it is the same with the EPCIS standard. Like the phone plug, it only goes so far – computers can communicate between trading partners, but the content is not specified. A standard is an interface specification, not an application. The EPCIS standard is a set of interfaces that support sharing of visibility data.

Mr. Rodgers emphasized that the Drug Messaging Pedigree Standard does the opposite in that it defines the message content, structure, and the usage architecture, but it does not define exactly how the messages might be exchanged or delivered.

Mr. Rodgers said he hoped that everyone could see that these two standards are complimentary. They are not competitive solutions, and he believes that they should work together if the proper standards are built on top of them, but those standards don't exist yet. The EPCglobal standards-making process is a successful way for the pharmaceutical industry to create interoperable standards. It is a collaborative process that encourages debates and experimentation to help participants find the best approach to complex issues. He said that standards created through this process are driven by users and supported by vendors.

Mr. Rodgers asked what it would take to clarify the standards confusion, and spur industry adoption of compliant pedigree solutions for California. He suggested that everyone re-focus on their original commitment to patient safety through supply chain security, and define the missing standards. All trading partners and vendors must participate, present, and discuss alternatives for an EPCIS based e-pedigree solution in an open standards organization.

Mr. Room stated that some of what was in Mr. Rogers' presentation would need to be translated into layperson's terms. He stated that when Mr. Asher from IBM spoke about the ratified EPCIS standard, that that is the data transmission standard and that there is not yet a standard for how the data transmitted will be formatted. Therefore, each type of software that might try to interpret that data could reduce it to its core components in a consistent manner.

Mr. Rodgers responded yes, and EPCIS is a great standard, but there are other standards used.

Mr. Room asked if Mr. Rodgers could give an example of what problems could occur. For example, if an IBM customer transmitted data to a SupplyScape customer, would the SupplyScape software not be able to read data coming in from the IBM EPCIS?

Mr. Rodgers responded that if you don't have a standard for doing that, then that is exactly the kind of interoperable problem that would occur. That is why the right way to approach this is to get the standard nailed down before we have that problem.

Mr. Room followed up by asking if he was referring to what EPCglobal calls track-and-trace standard.

Mr. Rodgers responded yes, that is the term used, but he's not sure it will end up being called that.

Mr. Room recalled that the standard would be sufficiently developed by the end of 2007.

Bob Celeste, from EPCglobal, noted that he hoped people did not get the impression that it would be ready this year, as it is all speculation. He added that if you look at where the process is and the pace it is going and whether it's accelerating or decelerating, he is looking at two years. He has seen more meetings cancelled than have been held. It's an unfortunate situation that we really need to turn around quickly if that standard is to have a hope of participating in compliance for California.

Mr. Room said that the board has difficulty hearing from one vendor who says this is ready to go and then hearing from another vendor that this is not ready to go.

Mr. Goldenberg noted that the board has put a lot of resources behind this endeavor. He said he firmly believes in this project, other states have looked at it, and the FDA has looked at it, and most importantly, consumers in California need this protection.

Mr. Goldenberg added that he often says to students that one person can really make a difference. Each board member is an individual that can really make a better difference in creating a better environment for healthcare to exist, not only in California, but throughout the United States and possibly globally. The resources that California's board is putting behind this are appropriate to the task.

- **EPCglobal on the Status of Standards Development for E-Pedigree**

Mr. Goldenberg introduced Bob Celeste from EPCglobal.

Mr. Celeste spoke briefly about the state of e-pedigree and EPC/RFID standards. He advised that they have been whittling down the standards. The last two standards relate to supply chain integrity – decommissioning of tags and track-and-trace – they had hoped to have those requirements completed by the end of October. The reason for the October date is they have made some changes within the standard setting body and the implementation bodies, and those changes are slated to take place by October 28, 2007.

Mr. Celeste said that he now works for the adoptions part of the company, instead of the standards part. He said that signifies a change in what is happening in that a lot of the standards are being fully realized in commercial products. While they will continue building standards, they are putting more effort into helping companies adopt and understand those standards. Mr. Celeste said it is his job to go forward, working with pilots and adoption in the industry.

Mr. Celeste noted that industry was originally looking and track and trace solutions for efficiency reasons and other reasons, and later moved to the development of pedigree through the messaging standard. Now they have come full circle – the messaging standard was built, and now they're looking again at track and trace solutions in the standard setting body and the adoption body in the United States. They are looking at two different ways of passing pedigrees, and the issue on the table is interoperability.

Mr. Celeste said that they are forming a group called the Pedigree/Track and Trace Group to deal with the issue of interoperability between the two mechanisms. Mr. Celeste noted that they ask companies up front to submit their intellectual property to EPCglobal. Typically, companies come together to develop the requirements and the standards and then it is decided whether there are any patents that sit on the standards. In this case, they ask companies, up front, that if they are going to come into the room and talk, they need to submit their patents to EPCglobal first.

Mr. Celeste noted that guidelines are produced first and standards are developed later. He said he was pleased that there are number of different ways to do this because it adds competitiveness to the industry and lowers the cost of the hardware and software.

Mr. Room asked whether Mr. Celeste could comment on an anticipated timeline of the guideline work and standards work to follow after that, in terms of EPCIS alone, and also EPCIS with the document pedigree messaging standard combined.

Mr. Celeste responded that they received the AmerisourceBergen document about a month ago, and completed an extensive technical review. That information will go into this new team. He said he would provide some information at the board's next Enforcement meeting. By that time, they will have assembled the participants of the group, and will be able to estimate how long the process will take and the steps they will take.

Ms. Herold advised that the next E-Pedigree Workgroup is December 5, 2007 in Sacramento.

Mr. Celeste noted that EPCglobal has been working with Stanford University to see what's been taking place in the industry over the last two years to five years. They are in negotiations with Stanford University to have them look at what has happened in the industry, the products that have been developed under the standards, and put it against a risk model. He believes the board will get a good feeling about things that have taken place and how much safer people are now. He said that sometimes it looks like not much is happening, but a lot really is.

Mr. Goldenberg requested feedback as to the economic impact and outcomes, not only the costs, but what this could do on the positive side of the cost sign.

Mr. Celeste said they have been working with a person who is internationally known and has done a lot of these types of studies.

- **Report and Action of Items Discussed at the Workgroup on E-Pedigree Subcommittee Meeting of September 20, 2007**

Ms. Herold advised that the meeting materials contained information about the results of the E-Pedigree Work Group held on September 20, 2007 in Los Angeles. Several

presentations were made to the Work Group by drug manufacturers, software companies, various associations and pharmacies. Members of the Enforcement Committee were unified in stressing that the implementation date for e-pedigree adoption is January 1, 2009. The members emphasized that pilot projects and cross-company sharing of implementation solutions will be needed to have the e-pedigree requirements in place by 2009, and the board will assist in making implementation smoother.

Mr. Goldenberg added that the committee asked for information about pilot studies and other activities, and he felt encouraged by the commitment of the stakeholders.

- **Board Subcommittee Review of EPCglobal's Electronic Pedigree Standard – Summary of Meeting held on September 27, 2007**

  Ms. Herold noted that the board packet contained information about the meeting held on September 27, 2007 regarding EPCglobal's Electronic Pedigree Standard. President Powers, Board Member Goldenberg, Executive Officer Herold, Supervising Inspectors Nurse and Ratcliff, and Deputy Attorney General Room met with a subcommittee of EPCglobal to refine issues about the EPCglobal messaging standards involving California.

  The issues discussed during the nonpublic meeting on September 27, 2007 were:

  - Unit dose serialization
  - Receipt of partial shipments
  - Drop shipments
  - Signature and certification (inbound)
  - Resale of returned products
  - Intra-company transfers
  - Voided pedigrees
  - Inference

  As a result of the meeting on September 27, 2007, the following five topics will be added as discussion items for future Workgroup on E-pedigree meetings where comments from the industry are sought:

  1. Serialization
  2. Drop Shipments
  3. Management of Returns
  4. Incorrect Pedigree Information (misdeliveries or other errors in pedigree generation or transmission)
  5. Inference

The individuals attending the meeting on September 27, 2007 determined that the board would benefit from, and industry participants may wish to provide, additional input regarding the prevalence of problems and preferred industry solutions in these areas.

Ms. Herold referred to Page 5 of the Enforcement Committee Report and advised that input can be provided in the form of written submissions to the board in advance of meetings during which these topics are discussed, conforming to the template below:

- Submitted by:
- Problem/conflict with California's law:
- Background: Historical overview/framework of current practices in the industry, what are the different scenarios in which this practice or subject area has arisen already, what are the processes employed to date, and what members of the supply chain are involved?
- Frequency or prevalence of this practice or subject area:
- A specific discussion of the costs of such implementation, on as many variables as possible (per unit, per store, per facility, per company)
- Can compliance with California's law be met? Why or why not?
- Desired Solution:
- Without the desired solution, what is the potential impact?

Mr. Room added that the template is intended to apply to topics of particular areas of implementation. As to the topics, comments should at least include the information in the template and be submitted by representative groups, or an aggregation of groups, trying to resolve certain issues.

Ms. Herold noted that the board is adopting this format because it has started taking questions from stakeholders. It has been approximately a year and a half since the board has answered questions about pedigree, and around 70-100 questions have been submitted. Some of the questions will probably be discussed at the E-Pedigree Workgroup to be held on December 5, 2007. One of the topics that may be addressed is inference.

Ms. Herold emphasized that the board prefers that questions be submitted to board, rather than the board guessing what industry concerns are.

Mr. Goldenberg asked whether there were any other comments on this issue. He said the template is a good idea and they want to get everyone on the same page in giving presentations. He expects the board to receive a lot of comments, and would like those comments to be presented in an organized fashion.

Dr. Swart said the template will help keep the presentations focused and not all over the place.

- **Discussion and Action Regarding Implementation of Electronic Pedigree Requirements for Prescription Medicine in California**

  Mr. Room referred to additional items in the board packet.

  - Excerpts of HR 3580 (Pages 355-358): Federal Requirements for the FDA regarding drug pedigrees
  - Analysis and Summary of HR 3580 as it impact California's requirements

  Mr. Room advised that HR 3580 has become federal law. President Bush signed the 422-page bill to recodify the operations of the FDA with respect to prescription drugs. The excerpted pages apply to electronic pedigrees relative to serialization standards, track-and-trace, and pharmaceutical product security.

  Mr. Room said that the law calls for end-to-end infrastructure. Manufacturers must tag products with unique identifiers. This is primarily technology-development/standards-setting legislation. It is implicitly or explicitly supportive of California's law and timeline, in part, because it responds to the need to enhance security of the pharmaceutical supply chain. It appears that the federal government is piggybacking onto California's legislation.

  Doug Martin came forward with comments. He said he previously worked for IBM and Alien, and also the largest retailer in the world, Albertson's. He is now consulting on his own.

  Mr. Martin said the problem is you need a step by step plan to adhere to, rather than nothing today and everything tomorrow, like a roadmap giving a time for each milestone. He suggested that a timeline have a milestone for each month. He said they did this at Albertson's and it worked for them and their suppliers for RFID tags on their cases and pallets. He said it worked better than a mandate.

  Mr. Martin stated that it would be nice to see the board or someone in the board's administration take the initiative to actually do some sort of staged implementation. What he sees happening, and what he heard on September 20th is that people are saying it can't be done because you need a plan for software, application of tags, and then the actual data exchange. All those things take time. You could do it in stages so that you become more experienced, and then you'll know what you don't know.

  Mr. Dazé emphasized that the board is not cutting the date back from January 1, 2009; he said the board is unified on that date.

  Mr. Martin said it would be much easier to comply with milestones to meet along the way.

Mr. Powers stated that rather than having the board dictate milestones, which may not work for everyone, that stakeholders get together and figure these out for themselves. He said there is certainly enough brainpower, initiative, and experience to get it done. He said the board is depending on American capitalization to figure it all out, while providing a date to get it done.

Mr. Powers added that requirements for pedigrees have been in play for over 20 years. There are those who succeeded in delaying this for 20 years, and the board is not patient anymore.

Mr. Martin said that the hardware and software are all in place, as far as he can tell.

Ms. Herold added that California's requirements were enacted in 2004. She said the past three years would have been a great time for some of these pilots and milestones to be developed. She added that the board is continuing to work and have quarterly meetings to talk about implementation, but the last thing the industry wants is the Board of Pharmacy giving them dates with component milestones. The board has given the industry the one date that matters. How each company gets there will be different for each company.

Mr. Goldenberg asked for input from EPCglobal, and if EPCglobal had thoughts about some facilitator action that might help to ensure implementation is ready by January 1, 2009.

Bob Celeste responded that a group was formed from the members of EPCglobal to talk about issues that were not standards based, but were more adoption and implementation based. He believes that NACDS, HDMA, and a few others came together to have these kinds of discussions. He said that as far as when industry will adopt, it's groups like that that can answer or even address it. He really could not address it.

Mr. Powers suggested that all interested parties attend the next meeting on December 5th to give input.

- **Review of the Modified Disciplinary Guidelines for the Board of Pharmacy**

Mr. Goldenberg referred to the modified Disciplinary Guidelines provided in the meeting materials. He emphasized that it is a very significant document and the first time in his seven years on the board that the board is revising the guidelines. He noted that these guidelines were carefully reviewed at the September Enforcement Committee Meeting.

Mr. Goldenberg asked if there were any comments from the board or the public on the modified guidelines. There were none.

MOTION: Enforcement Committee: Approve the Disciplinary Guidelines as Proposed to be Amended and Move Forward with the Formal Rulemaking Process (Amend 16 CCR section 1760)

SUPPORT: 7 OPPOSE: 0

- **Proposal to Develop an Ethics Course for Pharmacists, Modeled After that Developed by the Medical Board of California**

Ms. Herold noted that the board voted at the April 2007 Board Meeting to form an exploratory subcommittee to examine development of an ethics course for pharmacists as an enforcement option as part of discipline. President Powers appointed Dr. Ravnan and Dr. Swart to the subcommittee.

In June 2007, the subcommittee, along with Ms. Herold and Ms. Sodergren, met with an ethicist who works with the Dental Board. The ethicist provides assessment and individual therapy to respondents referred by the Dental Board. The subcommittee considered whether such counseling could benefit some disciplined pharmacists.

In August 2007, Dr. Ravnan, Ms. Herold and Ms. Sodergren met with representatives from the Institute for Medical Quality, the provider of the Medical Board's 22-hour ethics course. An overview of the Medical Board's program was provided at the January 2007 Board Meeting.

Mr. Goldenberg introduced Jill Silverman, from the Institute for Medical Quality (IMQ).

Ms. Silverman stated that IMQ is a 501(c)(3) subsidiary of the California Medical Association (CMA). She said IMQ originally provided a one-day ethics course for physicians, but the program was revamped and expanded in 2005. She gave an overview of the current program features, and said they could create a separate course that would be relevant to pharmacists. The course would include break-out groups, experimental exercises, and role-playing. The full program would consist of a pre-course personal assessment and testing component, a two-day course, and longitudinal follow-up at 180 days and 360 days. A certificate of completion is issued to those who complete the course and the two assessments. Not everyone completes the course, although typically 90 percent of the physicians do.

Ms. Silverman said the course is paid for by the attendees. The two-day course is $1,900 per attendee, which includes pre-assessment and post-assessment, and includes the 6-month and 12-month follow-up.

Ms. Silverman stated that the course is taught by someone who has a PhD in ethics and theology, and an attorney. Physicians do not provide the instruction.

Ms. Silverman indicated that it would be advantageous to have pharmacists involved in developing the course, but not necessarily involved in teaching it.

Dr. Hiura stated that he wants more information on the matter. He recalled that there was a peer review committee set by the board years ago and the board referred most of the pharmacists recommended to peer review.

Mr. Goldenberg noted that this is a course to try to help people understand the ethics in today's environment.

Dr. Hiura stated that it helped pharmacists understand ethics and morals, which was different than what was proposed here. He added that that type of cost was not involved, and that most universities did not teach ethics. Dr. Hiura asked for more thought and discussion on the matter.

Mr. Powers asked whether he was asking to defeat the motion and go back and reconsider.

Dr. Hiura said he was asking for a no-vote on the recommendation at this time.

MOTION: Enforcement Committee: Develop an ethics course with assistance from the Institute for Medical Quality (IMQ) tailored for pharmacists.

SUPPORT: 6 OPPOSE: 1

- **Request from University Specialty Pharmacy to Waive Provisions of 16 CCR 1713(a) for Betterment of Patient Care**

Mr. Goldenberg said the board received a request from University Specialty Pharmacy to deliver dispensed Synagis prescriptions to a licensed home health (HHA) for administration by the HHA to the patient at his or her residence. Section 1713(a) and (b) provide that:

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

Mr. Goldenberg introduced Glenn Truitt from University Specialty Pharmacy.

Mr. Truitt introduced himself as general counsel and one of the owners of University Specialty Pharmacy, and Jim Pantello introduced himself as one of the owners of University Specialty Pharmacy.

Mr. Truitt stated that they were requesting a waiver to deliver Synagis, advising that many of the patients are migrant. He said the medication requires refrigeration and must be stored either in a refrigerator or a cooler to maintain its integrity. By allowing these medications to be delivered to the administering professional nurses rather than direct delivery to patients, they believe they can avoid accidental and unattended delivery of the drugs (e.g., being left on a doorstep) and the mishandling of the drugs once inside the residence. The drug is viable outside refrigeration for only 24 hours, and they want home health agencies to ensure cold chain delivery to patients.

Mr. Truitt said that transportation of the medicine to the designated nurses would either be by delivery driver or overnight courier. The nurses would, in turn, directly deliver the medicine to the patients' homes upon receipt. He stressed that at all times following delivery, the prescribed medication would be under the direct supervision of the nurse who received it. If consultation is needed regarding the delivered prescription, it would be available through written drug information and a pharmacist would be available at all times for a phone consultation.

Mr. Goldenberg asked if any mixing of the product is done outside the pharmacy.

Mr. Pantello responded, no, it is a liquid drug. The medicine used to be available as a powder, but is no longer, as it is now in a stable solution. It is an expensive medicine as it is $1,500 for a low dose. This is one of the reasons they don't want to leave it on an unattended doorstep.

Mr. Goldenberg asked how temperature monitoring of the package is performed.

Mr. Pantello responded that the medicine's container is on ice and they use refrigeration during shipping.

Mr. Pantello stated that currently the pharmacy ships Synagis throughout the state, normally by way of a local driver, to a patient's home. The injections, however, must always be administered by a nurse.

Mr. Huitt emphasized that the medicine is never administered by a parent of a patient.

Mr. Goldenberg asked whether, if the board grants a waiver specifically for this company, would every other pharmacy need to present before the board.

Ms. Herold said yes. This request is not only company-specific, but drug-specific.

Mr. Goldenberg noted that a previous waiver was granted when the medicine was a powder and more unstable. He asked whether the board wanted to create a more level playing field for all pharmacies.

Ms. Herold clarified that that would require an amendment to the regulations.

Mr. Room noted that University Specialty Pharmacy is a Medi-Cal and Medicare provider for this drug.

Mr. Powers suggested that a waiver be considered only as to this specific drug, and Mr. Dazé suggested that the waiver be considered with a limit of three years.

MOTION: Grant a three-year waiver of 16 CCR section 1713(a) to University Specialty Pharmacy to allow delivery of Synagis to licensed home health agencies (HHAs) for administration by HHAs to patients at their residences.

M/S: DAZÉ/ZINDER

SUPPORT: 7 OPPOSE: 0

- **Former Board of Pharmacy President in Attendance**

Mr. Powers recognized a former Board of Pharmacy president who was in attendance at the meeting. Glenn Yokoyama, PharmD, was in the audience, along with students from the UCSF School of Pharmacy.

- **Proposed Self-Assessment Form for Veterinary Food Animal Drug Retailers and Addition of 16 CCR section 1785**

Mr. Goldenberg referred to the proposed Self-Assessment Form for veterinary food animal drug retailers provided in the meeting materials, specifically proposed language to add section 1785 to 16 CCR:

(a) The designated representative-in-charge of each veterinary food animal drug retailer as defined under sections 4041 and 4196 of the Business and Professions Code shall complete a self-assessment of the veterinary food animal drug retailer's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food animal drug retailer permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a veterinary food animal drug retailer is responsible for compliance with this subdivision
(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form XXXXX (rev. 10/24/07) entitled "Veterinary Food Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed veterinary food animal drug retailer premises for three years after it is completed.

(e) The veterinary food animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4041, 4042 and 4196-4199 Business and Professions Code

Mr. Goldenberg asked if there were any comments from the public. There were none.

MOTION: Adopt the Veterinary Food Animal Drug Retailer Self-Assessment Form as section 1785 to 16 CCR and move forward with formal rulemaking process; release for required 45-day public comment period.

M/S: DAZE/HIURA

SUPPORT: 7 OPPOSE: 0

- **Requirements of the Center for Medicare and Medicaid Services to use Security Prescription Pads for Prescriptions**

Mr. Goldenberg stated this item was for information only. Federal legislation would have required that Medicaid-funded prescriptions be written on security prescription forms if they are not issued orally or electronically. Subsequent federal legislation delayed implementation of the requirements until April 1, 2008. Medicaid-funded prescriptions must have at least one of three security features by April 1, 2008, and possess all three security features by October 1, 2008.

A chart was provided in the meeting materials outlining the new CMS requirements, and the corresponding protective tamper-resistant features of California's controlled substance prescription forms.

Mr. Goldenberg noted that prescribers will have to remember which prescription pad to use, whether it be a subscription pad for MediCal patients or a security prescription pad for controlled substances. Prescribers will have to remember which pad to use because the prescription pad for controlled substances in California is more costly.

- **Enforcement Statistics**

  Mr. Goldenberg noted that Enforcement Statistics for the first quarter of 2007/08 were provided in the meeting materials. He asked if there were any questions from the board or the public on the statistics. There were none.

- **First Quarterly Update on the Enforcement Committee Goals for 2007/08**

  Mr. Goldenberg noted that the First Quarterly Update on the Enforcement Committee Goals for 2007/08 were provided in the meeting materials. He asked if there were any questions or comments from the board or the public on the update. There were none.

RECOGNITION OF PHARMACISTS LICENSED WITH THE BOARD FOR 50 YEARS

President Powers stated that the board continues to honor pharmacists who have been in the profession for 50 years. Pharmacists that have been licensed to practice for 50 or more years are sent a certificate from the board, and are invited to attend a board meeting for public recognition.

- **Milt Levinson**

  Mr. Goldenberg introduced Milt Levinson by reading aloud from a letter from former Board of Pharmacy President Robert Elsner as follows:

  > "Dear Milt: Congratulations on being honored today by the State Board of Pharmacy for your much deserved contribution to the profession of pharmacy over the past 50 years. During my tenure on the Board of Pharmacy, I came to have even greater respect and appreciation for pharmacists and their increasingly demanding and critical role in patient care today. Milt, you epitomize the ideals of professionalism for pharmacies and pharmacists. I regret I cannot be in San Jose today to join the board and your colleagues in honoring you today for your half-century of service to Californians. Since retiring and moving to Palm Springs, I consider having met and worked with you in our Rotary Club to be one of the best things that could have ever happened. You are an asset, not only to the profession of pharmacy, but to your community. Congratulations again Milt, for this much deserved recognition by the State Board of Pharmacy."

  Mr. Goldenberg noted that the board recently created a 50-year pin, and Milt would be the first honoree to receive the pin. He presented Mr. Levinson with the pin, and congratulated him for his accomplishment.

Mr. Levinson stated that it was an honor to be recognized by his peers. He noted that there have been other pharmacists that have served more than 50 years and have the varicose veins to prove it. He said he enjoyed working in the community and getting to know people quite well. He said it has been a lot of fun meeting and serving the families in his community, including many children and grandchildren, over the years.

- **Arthur Davis**

  Dr. Conroy presented Arthur Davis with his 50-year pin.

  Mr. Davis thanked the board for recognizing him, and added that this was the first Board of Pharmacy meeting that he had the opportunity to attend.

  Mr. Davis has been a licensed pharmacist since 1953, and has worked for Thrifty Drugs for 35 years. He is a member of APhA and CPhA.

- **John Kurilich**

  Dr. Swart presented John Kurilich with his 50-year pin. He stated that there were many students of pharmacy in attendance, and that pharmacists with 50 years of service serve as an inspiration to those students. He added that we thank these pharmacists for how they have helped shaped the profession.

  Mr. Kurilich thanked the board for this recognition. He said it was a real honor to speak today, and to observe what the Board of Pharmacy accomplishes during its meetings. He said he had often wondered what it would be like to attend a meeting. Like Arthur Davis, he was finally able to attend a meeting. He said he is now retired, so he had time to do that.

  Mr. Kurilich said that, as Milt Levinson stated earlier, he gained varicose veins and lost his hair during his 55 years of practice. He added that he enjoyed every minute of his practice.

  Mr. Kurilich has been licensed since 1952. He previously owned an independent pharmacy, and also served as pharmacist in other independent and chain drug stores.

LICENSING COMMITTEE

Chairperson Conroy provided a report of the Licensing Committee Meeting held September 5, 2007.

- **Proposed Regulation Requirements for Pharmacies that Compound Medication and Sterile Injectable Medication (Amendments to 16 CCR sections 1716.1, 1716.2 and 1751-1751.8, and Adoption of sections 1735-1735.8)**

  Chairperson Conroy noted that the board has been refining regulation requirements for pharmacies that compound. Proposed amendments to the regulations were developed during the March, May, and September 2007 Licensing Committee Meetings.

  The proposed regulatory language now establishes requirements for all pharmacies that compound any medication in Article 4.5. Pharmacies that perform sterile injectable compounding must also comply with provisions in Article 7.

  Dr. Conroy noted that the revised language was provided in the meeting materials.

  Mr. Room stated that the basic structure of the regulation is that Article 4.5 will apply to all pharmacies that compound across the board. Article 7 contains additional requirements that will apply only to sterile injectible compounding. The purpose of reconciling these two articles is to prevent confusion and avoid duplication. There will be one unified set of regulations to set a baseline, a "floor" of competence and recordkeeping, and personnel and physical conditions under which compounding is performed.

  Dr. Conroy asked if there were any questions or comments on the language.

  Mr. Goldenberg asked two questions. In the context of pedigree regulations, will the raw products that pharmacies buy to compound drugs come under the requirements for drug pedigree? Will the final product produced by the compounding pharmacy require a pedigree?

  Mr. Room responded the pedigree requirement ends at the pharmacy.

  Dr. Conroy asked for comments from the public.

  Victoria Ferraresi, representing the California Society of Health-System Pharmacists (CSHP), presented a letter dated October 23, 2007. The CSHP has concerns about the general compounding language. She read aloud excerpts from the letter stating that they are concerned that the added documentation will delay the preparation and delivery of urgently needed medications in acute care facilities, without benefiting patient care.

  Dr. Ferraresi detailed the suggested addition of a new subdivision "b" to Section 1751.1.

  Ms. Herold asked for confirmation from Ms. Ferraresi that CSHP's concerns were not about bulk compounding. Instead, they were proposing regulatory language for short-term single-use doses on an emergency basis, and it would be very limited. She also

assumed that procedures were already in place in the hospital regarding documentation on medications.

Dr. Ferraresi said she could not say that it wouldn't be different from institution to institution, but it was very standard practice that hospitals do have these procedures in place.

Ms. Herold noted that in all likelihood, if there was a problem with a compounded medicine, it would already have been administered to a patient, and you would find out about it post-administration.

Dr. Ferraresi responded that that was correct. She also read aloud from their letter regarding their suggested amendments to subsection (a) in Section 1735.3. She asked that their suggestions be submitted to the board for consideration.

Dr. Conroy asked for clarification that they are requesting that CSHP only wants documentation to be on the patient-specific product label, which goes with the product to the patient.

Dr. Ferraresi responded, yes, and if there were problems later, for example a recalled drug, that information would be available in the patient's records.

Mr. Room said that Section 1735.3 requires that the information be kept in the pharmacy records. He asked whether she was saying that all this information is already in the pharmacy records or is it in the patient medical records.

Dr. Ferraresi responded it would be in both. The pharmacy keeps records on the drugs they have in stock, and the patient's records would have a record of who received what. The pharmacy also would have a record of what was dispensed because of the patient profile.

Mr. Room asked Dr. Ferraresi to identify which particular informational item in that list they were seeking an exemption from in Section 1735.3.

Dr. Ferraresi responded that they are just asking that they not have to keep a separate additional record each time they make one of these products.

Dan Wills clarified that he believed CSHP was objecting to having a separate master formula with all the records, when you already have the records in the pharmacy.

Dr. Ferraresi responded that that is correct.

Mr. Room stated the item should go to the committee, as there was a lot of information to try to consolidate under these conditions.

Dr. Ferraresi emphasized that CSHP is concerned that this extra record keeping at the time that the product is made will delay dispensing to patient who may need it in a matter of minutes.

Ms. Herold asked for clarification that her concern is about the wording for each compounded drug product in the pharmacy records, instead of the hospital records. She asked if we were to walk into a pharmacy and request the records, would they be pointing us to another section of the hospital?

Ms. Ferraresi responded no, they would have the records of how they made the drug.

Ms. Herold noted that they would have the master formula record and they do not have to rewrite the master formula each time a dose of the drug is prepared.

Mr. Room asked whether they were asking about drugs for which they have not previously developed a master formula, and if they are asking for the ability to do that simultaneously with the preparation of the drug. He said that may require different language.

Ms. Herold asked about compounding pursuant to a prescriber's order.

Mr. Room suggested that it may be a timing situation, and the record would be written after the fact.

Mr. Goldenberg noted that in the compounding regulations, especially sterile compounding, there are examples such as emergency kits and crash carts in a nursing home where a nurse would do the compounding. If a nurse does the compounding, is that exempt from this regulation?

Mr. Room responded that we do not regulate nurses.

Ms. Herold added that that is a Department of Health Services issue.

Mr. Wills commented on self-assessment form, number two, regarding the expiration dates. He said the law allows for a longer expiration, but it's not in the self-assessment so the board may want to take a look at that because part of the concept is missing. Also, there is a part that really concerned him and a pharmacist from the Academy of Compounding Pharmacist met with him on the matter. In Section 1751.7 Sterile Injectible Compounding Quality Assurance and Process Validation, a line was deleted. He believes #5 was added to replace that. He said that was a big controversy when they were putting together the sterile compounding laws. The problem with the way it is now is that it could be interpreted exactly as the way it was originally, or a new interpretation could be given that every product needs to have end product testing. That would shut down community compounding pharmacies. He recommended not striking it, but instead just leaving that sentence.

Mr. Wills also commented on Section 1735.1 under quality in the absence of harmful contaminants. He had concerns about the language because quality means in the absence of “harmful levels” of contaminants.

Ms. Herold stated that harmful is harmful, but the board was trying to keep the number of words down. It depends at what point the level becomes harmful.

Mr. Wills responded that their concern is about “decomposed” substances. For example, there are endotoxins in sterile compounding that are harmful, but they are only harmful if the amount gets to a certain level. If a substance is harmful but is only one part per billion, it’s not going to do harm.

A person from the audience approached the board stating that she was a pharmacist with more than 20 years experience in the pharmaceutical industry. She said she has been doing consulting, helping pharmacies get into the business of compounding. She expressed concerns regarding 1735.2, as the policies and procedures appeared to be for each formula, and pharmacies can have upwards of 5,000 formulas. She questioned what constitutes a quality review for each of these formulas. She was also concerned about compounding pharmacies that have limited room and stated that often, pharmacies are pigpens with food, powders, chemicals, and hot plates all over.

Ms. Herold requested that the board be notified of such pharmacies as pharmacies are providing these services to patients, and patients have the right to get a pharmaceutically-elegant product from a pharmacy. A pharmacy that is totally out of control is a public health issue. The board relies on people to report such occurrences to the board. There are provisions in the regulation that deal with the issue. The regulation is to ensure pharmacies safely compound drugs for patients.

Ms. Herold stated that the board has been working on this regulation since 2004. Further delays could result in opinions by the FDA about what pharmacies can and cannot do. The board is proposing regulations that have had generally solid agreement for years. The proposal will ensure the compounding of medicine under consistent standard requirements that will provide good patient safety.

Mr. Wills suggested taking sterile record keeping for cleanliness and adding it to the general section.

The audience member also had concerns about 1735.3(a)(7) that pharmacies would need to document the equipment used in compounding the drug product. She understands that that has already been discussed, and she understands the rationale, but it will be problematic.

Ms. Herold noted that if you weigh a substance on balance A and balance B and you have calibrated those balances, we are looking at the type of equipment used, not the specific piece of equipment.

The audience member asked a question about 1735.4(c), and whether a pharmacy would need to label each syringe that contains multiple doses. For example, if a pharmacy is delivering Estrogren 0.2 mL and she puts it in a 1 mL syringe, she does not need to label that.

Mr. Room said that that would be subject to all normal labeling requirements. It's the unit dose that has some of the exemptions from the general labeling requirements. Any multiple dose carrier would have to be subject to the general labeling requirements.

Dr. Conroy asked if there any other public comments. There were none.

Mr. Dazé asked whether it was possible for the board to move the regulation to hearing for resolution.

Mr. Room responded that the only way to do that would be to move the whole thing to a regulation hearing, and then through the regulation hearing process, deal with each individual item that has been raised.

Mr. Dazé expressed an interest in doing that so that the process does not go out several more months or a year. He believed the comments made today were excellent, and we can address those amendments.

Ms. Herold said that this is the way most regulations have been done, but recently the board has waited until the regulation is "perfect" before putting it into the rulemaking process, so there are not any 15-day comments because we've already taken care of the comments at the front end. She stated though, that may be a good solution because we can start the formal comment period, though it will make the rulemaking a little more complicated. Most agencies do rulemaking that way.

MOTION: Licensing Committee: Approve the proposed new amendments to 16 CCR sections 1716.1, 1716.2, 1751-1751.8 and adoption of section 1735-1735.8 (including the self-assessment form) and initiate the formal rulemaking process

SUPPORT: 7 OPPOSE: 0

- **Legislative Proposal: Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices by amending B&PC Section 4052 and Addition of Section 4052.8**

Jeff Goad, professor at USC, spoke in support of the proposed state protocols. He said that everyone was very enthusiastic to have pharmacists participate in immunization in a more accessible format. There is a strong vocal force, both on the state and local level.

Dr. Goad referred to the Advisory Committee on Immunization Practices (ACIP) and the CDC's three immunization tables. He referred to a formalized and standardized process for immunizations. He said that rabies and other specific immunizations like travel meds would not be included in the immunization set, although an individual prescriber could still set up a protocol with pharmacists to administer these immunizations.

Mr. Goldenberg said there are a variety of companies involved in the vaccination process that do not involve pharmacists, such as nurses going to sites to give flu vaccines.

Dr. Goad responded that those are "mass vaccinators" consisting mostly of nurses and medical assistants. Pharmacies host mass vaccinations.

Dr. Swart added that Safeway and Vons stores give around 200,000 vaccinations. People do not have to go on a certain day. They can get vaccinated when it's convenient.

Dr. Conroy noted that seeing the friendly face of a pharmacist is good, and it is "on demand" so people can get vaccinated any day, instead of having to go on a certain day.

Dr. Goad said the trend in family medicine is that nurses don't work there. They have LVNs and MAs. The landscape has changed, so pharmacists are well positioned to provide these immunizations.

Mike Cantrell, representing Longs, asked if pharmacists could vaccinate in the event of an emergency like the pandemic flu.

Mr. Room clarified that this is for vaccines on the CDC schedule only. The Avian flu vaccine is not on the schedule.

Dr. Goad noted that those products are also not FDA approved.

Mr. Goldenberg asked whether students in pharmacy schools are certified to give vaccines.

Dr. Goad responded that to some degree, yes, but only a couple of schools provide training. Three CE units are required every year, on top of the immunization certificate program.

Ms. Herold suggested that stakeholders write support letters for this legislation, which will be a stand alone bill.

- **Legislative Proposal: Licensing of Mobile Locations by the Board of Pharmacy for Emergencies by amending Business and Professions Code Section 4062 and Business and Professions Code Section 4110**

  Dr. Conroy noted that this item is timely due to the recent California wildfires. The board received a request for guidance from Ralphs Grocery Company about the appropriate use of mobile pharmacy trailers. Ralphs would like to use trailers under emergency conditions or in the event an existing pharmacy is damaged or closed. The use of mobile trailers is consistent with the NABP recommendation that pharmacies have mobile units available in the event of a declared disaster.

  Department Counsel Spencer Walker advised the committee and board staff that statutory changes would be necessary to allow for the use of mobile trailers.

  Dr. Conroy advised that draft statutory language was developed after the last Licensing Committee Meeting and was provided in the meeting materials.

  Mr. Room asked whether there was a need to further define the term "mobile pharmacy" unless everyone in the industry assumes that the term means a trailer or RV, and not a car.

  Dr. Swart responded that if there is an emergency, someone may need to use their car as a mobile pharmacy.

  Mr. Room noted that Section 4062 is for emergencies. Section 4110 may not be an emergency; it may only be the destruction of an individual pharmacy, which could be an "emergency" for individual patients of that pharmacy, but it would not be a declared disaster area.

  Mr. Powers added that this will go through the legislative process and there will be hearings and opportunities to add language; for example, if refrigeration is necessary in the mobile pharmacy.

  Dr. Conroy asked if there were any public comments on the legislative proposal. There were none.

  MOTION: Approve a legislative proposal to authorize the licensing of mobile locations by the Board of Pharmacy for Emergencies by amending Business and Professions Code Section 4062 and Business and Professions Code Section 4110

  Business and Professions Code Section 4062

  (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription

during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency the board will allow for the deployment of a mobile pharmacy to impacted areas to ensure the continuity of patient care if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing as required in subdivision (a);

(3) A licensed pharmacist is on the premises, and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed;

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared disaster area or affected areas; and

(6) The mobile pharmacy ceases the provision of services within forty-eight (48) hours following the termination of the declared emergency.

Business and Professions Code Section 4110

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to

another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permit-holder or service by certified mail, return receipt requested, at the permit-holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permit-holder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy, when a pharmacy is destroyed or damaged and when needed to protect the health and safety of the public and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the Pharmacist-in-Charge of the pharmacy that was destroyed or damaged

(3) A licensed pharmacist is on the premises while drugs are being dispensed;

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy;

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage and an expected restoration date;

(6) Within three (3) calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration to the permanent pharmacy;

(7) The mobile pharmacy is not operated for more than forty-eight (48) hours following the restoration of the pharmacy.

M/S: POWERS/GOLDENBERG

SUPPORT: 7 OPPOSE: 0

- **Update on Emergency Preparedness for California Pharmacy**

  Dr. Conroy advised that this was an informational item. Disaster and emergency preparedness continues to be an important initiative of the Schwarzenegger Administration. Dr. Conroy summarized the following items reviewed at the September 5, 2007 Licensing Committee Meeting.

  Rough and Ready 2007

  A disaster drill was performed in Orange County in August, and a major component was the demonstration of the state's three mobile hospitals. Dr. Conroy attended this session as an observer.

  California Medical Volunteers

  Board staff participated in the evaluation of the contract proposal for the implementation and operation of California's Emergency System for the Advanced Registration of Volunteer Health Professionals. The system is known as the California Medical Volunteers, and will play an important role in deployment of registered health care professionals responding to disasters and terrorist events.

  Ms. Herold advised that a contract was awarded that allows the pre-registration of health care professionals. In an event of an emergency or disaster, there will be pre-screened individuals who can immediately be called upon to respond. Ms. Herold added that she will keep will keep the board apprised of this matter as it moves forward. She noted that in the last three newsletters, the board has encouraged pharmacists to contact their local agencies to become trained as emergency responders. In the event there is a need for medical or mass public intervention for healthcare, the board wants pharmacists to be able to respond and provide the services of pharmaceutical management that need to be done in a disaster. The California Pharmacists Association (CPhA) has asked Ms. Herold to speak at their November 8, 2007 meeting on the subject of disaster response.

  Kathy Lynch, CPhA, noted that CPhA is working to get pharmacists in contact with their local agencies to get more involved in disaster response.

  Ms. Herold said that federal emergency and disaster planning did not originally include pharmacists; they included mental health professionals, but not pharmacists. She will continue to stress the need for pharmacists to be trained as responders.

- **California Schools of Pharmacy Proposal to Identify the Professional Competencies that Should Be Achieved by the End of Basic Intern Experiences**

  Dr. Conroy summarized this informational item.

The board has been participating in a joint project of California's pharmacy schools to develop and assess the competencies that pharmacy students should achieve by the end of the introductory pharmacy experience of 300 hours. This is part of changes to intern experience objectives from the Accreditation Council for Pharmacy Education, which accredits US schools of pharmacy. Susan Ravnan, Virginia Herold, and Anne Sodergren attended three work sessions held for this purpose. The next phase of the project involved the schools developing an exam to assess student achievement of the basic competencies. The workgroup hopes to complete the process in time for incorporation during the 2007/08 academic year.

A copy of the proposed competencies developed by the workgroup, as well as a letter from Mary Ann Koda-Kimble of UCSF's School of Pharmacy, were provided in the meeting materials. Dr. Koda-Kimble requested that the board affirm its agreement with this document. Discussion at the September 5, 2007 committee meeting included concern about the board's role in affirming agreement with this document, as the board does not normally become involved in curriculum development. The committee's recommendation was that Dr. Koda-Kimble's letter be forwarded to the board for discussion.

Ms. Herold added that the letter from Dr. Koda-Kimble strongly requested that the board agree to accept the competencies. She said that she recently attended the California Society of Health-System Pharmacists meeting where she was approached by the dean of another school of pharmacy requesting that the board send a statement to ACPE basically saying that the Board of Pharmacy, which licenses pharmacists, does in fact recognize these as legitimate competencies.

Ms. Herold drafted language for the board's consideration regarding Dr. Koda-Kimble's request. She read aloud from a draft response to that letter as follows:

> "The California Board of Pharmacy recognizes these competencies as appropriate competencies for a California licensed pharmacist to possess, and the board strongly supports the need for interns to develop and expand their competency in these areas as core responsibilities of pharmacists."

Dr. Swart commented about "core responsibilities" and meeting minimum standards. When minimum standards change over time, it could pigeonhole the board because it will appear that the board said these were the only things that were important.

Ms. Herold responded that the wording could be changed to "among" the core responsibilities of pharmacists.

Dr. Conroy asked what action the board needed to consider taking on this issue.

Ms. Herold suggested that the board request she send a letter to the chair of the person who is coordinating the project stating that the board at its October 24th meeting reviewed the competencies and voted to acknowledge support.

Dr. Conroy asked if there were any comments.

Glenn Yokayama stated that this is a public health issue, and he wanted to make a comment on his own behalf, not on behalf of the school. He spoke in favor of the board taking action accepting the concepts of the precepts at these schools of pharmacy.

Mr. Goldenberg noted that at the recent NABP Regional meeting in Oregon a presenter spoke about students at the University of Oregon College of Pharmacy. First year students are required to go to elementary schools and review healthy eating habits and wellness of the school children. Second year students look at junior high schools, and third year students look at high school students. Fourth year pharmacy students circle around and participate in community activities.

Mr. Goldenberg said he believes there is a situation of underserved community groups and ethnic groups where certain disease states are becoming public health issues. In the Latino community, obesity, diabetes, hypertension, and cardiovascular diseases are occurring. Stan thought it was excellent for the public to try to have an effect on kids at the right age, as well as being a rewarding experience for the students. He said it was the third year the students were doing this, and it was extremely well received by the students and the community. He noted that students in Arizona are also involved with American Indians and their health. He saw this as an organized, well-thought-out program, with good outcomes.

Ms. Herold said she will ask Hope Tamraz to interview Mr. Goldenberg and Dr. Conroy for a newsletter article in January's *The Script*. It will be a good way to get the information out there. Public outreach is one of the competencies that are a basic level skill set.

MOTION: Request that a letter be sent from Executive Officer Virginia Herold responding to Dr. Koda-Kimble regarding professional competencies that should be achieved by the end of basic intern experience. The letter shall include this language:

"The California Board of Pharmacy recognizes these competencies as appropriate competencies for a California licensed pharmacists to possess, and the board strongly supports the need for interns to develop and expand their competency in these areas as among the core responsibilities of pharmacists."

M/S: GOLDENBERG/SWART

SUPPORT: 7 OPPOSE: 0

- **Request to Add the Exam for the Certification of Pharmacy of Pharmacy Technicians**

  Dr. Conroy summarized this informational item. Since October 2006, the board has sought a psychometric evaluation of the ExCPT examination to assure that the exam fits the requirements of Business and Professions Code section 139 for job relatedness. A solicitation for an independent contractor to review materials for the ExCPT and PTCB exams began, to assure that both exams are job related. To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or a regulation amendment needs to be adopted.

  The CSHP and CPhA are initiating a study of intern qualifications and experience, and whether current requirements are sufficient to adequately prepare pharmacy technicians for the responsibilities of working in a pharmacy. The Licensing Committee tabled this matter pending the recommendations for changes in pharmacy technician currently underway.

- **Competency Committee Report**

  - Examination Statistics

    Dr. Conroy advised that the biannual examination statistics for the CPJE and for those qualified in California who have taken the NAPLEX were provided in the meeting materials. The period of this report encompassed April 1, 2007 to August 31, 2007.

    Currently underway is a quality assurance review of the examination that was initiated on September 1, 2007. The required review is nearly completed and the board hopes to be able to release results in early November 2007.

  - NAPLEX Compromised, Suspended, and Reactivated

    In August 2007, the National Association of Boards of Pharmacy learned that the NAPLEX had been compromised, and ceased administration of this examination nationally on August 25, 2007. The compromise occurred in Georgia, and also resulted in the suspension of the administration of the Georgia MPJE. On October 5, 2007, national administration of the NAPLEX resumed.

    Dr. Conroy advised that material regarding the NAPLEX compromise was provided in the meeting materials.

- Proposed Amendment to 16 CCR Sections 1721 and 1723.1 Regarding Dishonest Conduct on a Pharmacist Licensure Examination

The Competency Committee submitted 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.

Dr. Conroy advised that the proposed language was provided in the meeting materials. The Licensing Committee considered the proposed amendments and recommended that the board approve the proposed language.

Ms. Herold noted that this issue was initiated in August with the Competency Committee, prior to an incident when a California student left the NAPLEX examination site, went to her car, and came back to complete the exam. There is an interest to protect the exam and maintain exam security. Compromised test items pose not only a financial loss to the board as the cost to generate each new test item is $2,000 (according to the board's exam contractor), but also inhibit the board's ability to test for minimum competency.

Dr. Conroy asked if there were any comments from the board or the public on this item. There were none.

MOTION: Licensing Committee: Approve proposed amendments to 16 CCR sections 1721 and 1723.1 regarding dishonest conduct on a pharmacist licensure examination as follows:

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

1723.1 Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination room or area, or who conveys or exposes all

or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

SUPPORT: 7 OPPOSE: 0

- **Creighton University's Web-Based PharmD Program**

  Dr. Conroy advised that information regarding Creighton University's Web-Based PharmD Program was included in the meeting materials. The online program began in 2000, and ACPE determined that this education pathway follows the same standards as the traditional PharmD program and as such, obtained the same approval and accreditation as the traditional program. The Licensing Committee reviewed these materials without comment.

  This material was provided to the board for informational purposes only.

- **Meeting Summary of the September 5, 2007 Licensing Committee Meeting**

  The minutes of the September 5, 2007 Licensing Committee Meeting were provided the meeting materials.

- **Licensing Statistics**

  The licensing statistics describing the Licensing Unit's processing activities for the first quarter of Fiscal Year 2007/08 were provided in the meeting materials.

- **First Quarterly Report on Licensing Committee Goals for 2007/08**

  The first Quarterly Report on Licensing Committee Goals for 2007/08 was provided in the meeting materials.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

President Powers advised that Chairperson Kenneth Schell was unable to attend this board meeting due to the wildfires in Southern California.

Ms. Herold chaired this portion of the meeting. She advised that the Communication and Public Education Committee met on September 14, 2007 and several action items resulted from that meeting.

- **Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care**

  The board has been working exclusively with UCSF's Center for Consumer Self Care to have their interns develop fact sheets for consumers. Several fact sheets have been completed since the project was initiated, but the project has not progressed as quickly or as expansively as the board had originally hoped.

  The fact sheets contain "quick-hits" of topical information that are distributed online and at consumer fairs. Over time, UCSF has been unable to commit resources to complete this project.

  In August 2007, Chairperson Schell and Ms. Herold met with Dr. Soller at UCSF regarding this project. During that meeting, Dr. Soller advised that some projects that were formerly produced without a stipend could no longer be pursued. USCF suggested that a contract be developed to produce 16 fact sheets over the next year for a fee of $25,000.

  The Communication and Public Education Committee recommended that the project be opened up to interns at other schools of pharmacy. Board Members Schell and Ravnan and Executive Officer Herold have since contacted six other schools of pharmacy, and most of them expressed interest in working with the board on intern projects to develop consumer fact sheets. Ms. Herold emphasized that the board's consumer protection mandate requires development of topical consumer education about drug choices in the marketplace. There were two proposals for consideration by the board on this issue:

  - ❖ <u>Extend project to other schools and provide a template for students</u>

    Does the board wish to extend the fact sheet series project and offer it to other schools of pharmacy, and provide a template-type structure? A template would guide students in the parameters including footnoted and documented fact sheets (as well as unfootnoted versions for consumers) so the board can track each element and verify the information contained therein.

  - ❖ <u>Acknowledge the students through a competition</u>

    Does the board wish to offer an award, (e.g., certificate) to students producing the best consumer fact sheets?

Mr. Dazé said he supported Board Member Hough's idea to make a contest out of it. He said there are very creative, young, bright men and women who are interns and who will produce top fact sheets. He also supported giving the students parameters as to what the board wants for consumers. The board can give a certificate as a first place award. Mr. Dazé did not recommend paying $25,000 to produce the fact sheets when other students can benefit from developing them, at no cost to the board.

Dr. Swart suggested publishing the names of the student competition winners in *The Script*. He added that the board could acknowledge the students at board meetings, and present them with a certificate.

MOTION: Extend the Consumer Fact Sheet Series to other schools of pharmacy, provide a template to guide students about the topics and annotation requirements, and acknowledge students through a competition to produce relevant and meaningful consumer fact sheets for the public.

M/S: DAZÉ/ZINDER

SUPPORT: 7 OPPOSE: 0

Ms. Herold noted that the Communication and Public Education Committee strongly supported the idea of a competition among students. She also noted that opening up the project to other schools of pharmacy would not preclude UCSF students from participating.

Ms. Zinder added that UCSF students are welcomed to participate on a voluntary basis, but she did not support UCSF's involvement at the expense of a stipend.

- **Update on *The Script***

Ms. Herold noted that board staff was in the final stages of the developing the next issue of *The Script*, which will be published and mailed in January 2008. The focus of that issue will be consumer law. It will also include an interview of Mr. Goldenberg about NABP and what Oregon is doing with their students. The issue will also contain information about pedigree, and regulations and statutes.

- **New Board Web Site Under Development**

Ms. Herold noted that the board's redesigned Web site must be up by November 1, 2007. This deadline will meet Governor Schwarzenegger's requirement that state government Web sites conform to a new look and format.

Ms. Herold said that board staff has been working on the redesigned Web site, and they expect to meet the Governor's deadline. Once the Web site is up, a portion of the site will be devoted to e-pedigree and another portion to a resource center about prescription errors for pharmacists and for patients.

Mr. Powers asked if this was the third time that the board's Web site had been redesigned.

Ms. Herold responded that there have been at least three separate updates that she has been aware of. The first Web site did not have a particular format. Later, Governor Davis asked state agencies to conform to a particular format. Most recently, Governor Schwarzenegger asked for additional changes to be made by November 1, 2007.

A subscriber alert will be sent once the redesigned Web site design is in place.

- **Development of New Consumer Brochures**

The board has developed new informational brochures. Board Analyst Karen Abbe set up a display highlighting some of the board's brochures and materials outside the meeting room. Two recently finalized brochures were on display, including a brochure that serves as an overview of the board's functions and activities, and another on the board's consumer complaint process.

Undergoing final review at this time are four documents:

- Prescription Drug Discount Program for Medicare Recipients

  This is an update of the board's informational brochure about the state's program for Medicare-eligible patients to obtain the MediCal price for prescription medicine if they must pay out of pocket (SB 393, Speier, Chapter 946, Statutes of 1999). The Department of Health Services is reviewing the updated brochure.

- Fact sheet for consumers on Traveling Medicine Chest

  This information was developed from a list from Board Member Graul, with input from Board Member Ravnan.

- Fact sheet for consumers on Vaccinations and Travel Outside the US

  This information is intended to encourage travelers to plan ahead for vaccinations they may need before leaving on a trip outside the United States.

- **Information for Examination Applicants**

  Ms. Herold wrote an article for the CSHP Journal with an insider's view of applying to become a pharmacist in California. This article will be reformatted into a board fact sheet or brochure for applicants. The article was provided in the meeting materials.

  Ms. Herold noted the intent of the fact sheet will be to help applicants get through the process with less hassle and more expediency. The information will address how long the process takes, helpful tips, what typically goes wrong during the process, and how can applicants can provide a complete application to the board.

  Providing a complete application to the board is important because since 2001, budget cutbacks have prevented board staff from being able to provide application status checks. This can be frustrating to applicants when they do not hear from the board regarding the status of their application. When an application is submitted, the board processes the check in a timely fashion. Applicants can check with their bank to see if their check has been cashed, and that will help determine whether the board has received their application. Another way for applicants to check to see whether the board has received an application is for the applicant to attach a postcard with the application; when the cashier cashes the check, they can send the postcard back to the applicant.

  Once the brochure (or fact sheet) pertaining to information for examination applicants is completed, it will be posted on the board's Web site.

- **National Council on Patient Information and Education's Medication Adherence Report**

  Ms. Herold advised that this item was provided for information only. The National Council on Patient Education and Information (NCPIE) released a report on medication adherence entitled *Report on Enhancing Presciption Medication Adherence: A National* Problem. The report was provided in the meeting materials.

  According to NCPIE, the lack of medication adherence results in $177 billion annually in direct and indirect costs to the US economy, plus an additional $47 billion each year for drug-related hospitalizations, 40 percent of admissions to nursing home, and $2,000 a year per patient in medication costs for medical doctor visits.

  Ms. Herold noted that the NCPIE report was one of the documents that the board will be looking at more closely when the board takes on the project of designing a standardized prescription container label pursuant to SB 472 (Corbett). This is a related issue to patients understanding what is on the label.

- **Update on Public Outreach Activities**

  Ms. Herold advised that the board continues to have a vigorous public outreach program. From June to October 2007, the board provided three CE presentations to professional associations, four presentations at major conferences (EPCglobal's annual meeting, and a RFID conference for wholesalers, and another RFID conference for manufacturers), three presentations at meetings involving public policy discussions, and staffed booths at five public information fairs. A list of the board's outreach activities was provided in the meeting materials.

  Karen Abbe helped staff a booth at the Marin Senior Information Fair on October 10th, and Fred Mayer of PPSI participated in the event as well. Interns from schools of pharmacy also participated in the event, which was very well attended.

  Dr. Mayer subsequently faxed a document to Ms. Herold and requested that she share it with everyone. He would like us to discuss what the board is doing about Medicare prescription issues and also the SCR 49 Committee, which dealt with prescription errors. Ms. Herold noted that the board has seen most of this material before, but she provided photocopies of the material during the meeting as it was not provided in the board packet.

- **Discussion and Action on the Board's Proposed Public Forum on Medicare Prescription Drug Plans**

  The board has been working with various stakeholder groups to aid patients in receiving benefits under the federal Medicare Modernization Act, and specifically the Medicare Part D plans implemented in January 2006. The board has held six public forums during the last two years to discuss difficulties that patients and providers have had with the plans, in hopes of finding resolutions. However, structural changes to the program need to be made at the federal level.

  Ms. Herold advised that at the April 2007 Board Meeting, the board directed staff to convene a public forum, in conjunction with members of the California Congressional Delegation. President Powers and Ms. Herold subsequently discussed issues with the Part D plans and the board's hope to initiate changes that would benefit patients with Congressman Pete Stark. A copy of the problem statement that was sent to Congressman Stark was provided in the meeting materials.

  Mr. Powers commented that Congressman Stark is extremely interested in how the Part D program is working. Unfortunately, Congressman Stark believed that this administration was not going to change any element of the program at this time. This administration had resisted and threatened vetoes of any proposed legislation, particularly in regard to Medicare being able to negotiate for lower prices.

Mr. Powers added that Congressman Stark encouraged the board to continue efforts to get information out. The new enrollment period starts December 15th and runs to the middle of January. Mr. Powers believed that the board could get input on what is happening on the program and bring it to the attention of the congressional delegation that there are still problems with the problem.

Mr. Goldenberg commented that part of what he's been hearing from the senior community, as well as from long-term care, is that there will be some very significant formulary changes in all of the plans. He was not sure that seniors understood that this is a year-to-year contract that should be re-evaluated. Seniors should review their prescription plans from year to year, and it's not clear the plans go out of their way when they send out their paperwork that consumers should reevaluate. Some drugs that are covered this year, but may not be covered next year, or maybe the plan will no longer automatically accept dual-eligibles, and so on.

Mr. Goldenberg foresees some challenges coming January 1, 2008, and he wants to be sure that we bring these concerns to the attention of the federal government so they can see that these problems have not been fixed.

Mr. Powers recommended that information be put out in the next *The Script* that the next enrollment period is coming up and that they should encourage patients to check the medications on the plan formulary.

Mr. Goldenberg noted that the next newsletter would not be produced in sufficient time.

Mr. Powers clarified that there will be an extended enrollment period, so there will be time.

Dr. Swart stated that he has seen many companies that are offering Part D plans and have brochures available. There is a heightened awareness that enrollment period is coming.

Ms. Herold commented that she believes she saw an article that prices for the medicines or their overall co-payments were going up 20 percent.

Mr. Goldenberg responded that a lot went down, but a lot have gone up. His understanding is that industry wanted to see as many people enroll in what they called MAPDs, full plans, where the patients assign all their Medicare benefits. There's the medical side (doctor side) and the pharmacy side. Industry has many years experience in how to handle on a profitable basis the medical side. So they "gave away" the pharmacy side, hoping to recruit enough people into the full MADP. That has not occurred to their level of satisfaction, so now the pharmacy side has to become profitable on its own. Industry now wants the stand alone drug coverage programs to become profitable. It's become big business, and consumers familiar with government plans are used to programs that don't change, and consumers are getting a lot of mail that is not clear about these changing plans.

Mr. Goldenberg emphasized that when he talks to seniors, he advised them to take the letters and information they are receiving from their Medicare plans to their pharmacies. He advises people to pay particular attention to letters that refer to changes in formularies. Mr. Goldenberg believes there is still a lot to be desired to make a program that works, but on the plus side, a lot of seniors have saved a significant amount of money so far.

Mr. Powers commented on fraudulent activity that has been going on as well in signing up patients.

- **Accuracy of Oral Liquid Measuring Devices**

  Ms. Herold advised that at the CSHP annual meeting over the weekend, a study was presented about oral medications administered to infants. A copy of the one-page comparison was provided as a handout. The comparison showed a distribution diagram using a cup, a syringe, and a spoon. The results showed that using a syringe may cause underdosing, and using a cup may cause overdosing.

- **Meeting Summary of the September 14, 2007 Communication and Public Education Committee**

  A copy of the Meeting Summary of the September 14, 2007 Communication and Public Education Committee was provided in the meeting materials.

- **First Quarterly Update on Communication and Public Education Committee Goals for 2007/08**

  A copy of the First Quarterly Update on the Communication and Public Education Committee's Goals for 2007/08 was provided in the meeting materials.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

1. **Regulations Submitted to the Administration for Approval**

   The following pending regulations were adopted by the board at the July 2007 Board Meeting.

   a. Proposed Amendment of 16 CCR 1707.2 – Notice to Consumers

Ms. Zinder noted that the revised language of this regulation is currently undergoing review by the Office of Administrative Law (OAL).

Section 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122 (unless printed on the back of receipts). Assembly Bill 2583 (Chapter 487, Statutes of 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to amend the Notice to Consumers to include a statement that describes a patient's right to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication is required.

Ms. Sodergren said OAL notified her that after the board takes action on the minutes from the last board meeting during this meeting, the language should be approved on October 31, 2007.

Ms. Herold thanked Ms. Sodergren for her efforts on the Notice to Consumers.

b. Proposed Amendment of 16 CCR 1749 – Fee Schedule

Ms. Zinder said this rulemaking file was submitted to OAL on October 9, 2007. Section 1749 establishes specific application and renewal fees for licensees according to the range set forth in Business and Professions Code. This proposal will raise board fees to their statutory maximum. This proposal is necessary to ensure revenue to maintain current board operations.

c. Section 100 Technical Changes

Ms. Sodergren advised that the Section 100 items had to be withdrawn from OAL, primarily because of technical issues referencing laws on the self-assessment form. The board must provide historical references as to when each law referenced on the pharmacy self-assessment form was enacted. Ms. Sodergren added that she hopes to have this done by the end of October, and then resubmit the rulemaking file to OAL.

The specific changes are:

(1) Proposed Amendment to 16 CCR § 1709.1 – Replace the Term "Exemptee-in-Charge" with "Designated Representative-in-Charge"
(2) Proposed Amendment to 16 CCR § 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"
(3) Proposed Repeal of 16 CCR § 1786 – Return of Exemption Certificate
(4) Proposed Amendment to 16 CCR § 1715 – Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law

(5) Proposed Amendment to 16 CCR §1793.8 to Update Regulation Reference to Recodified Business and Professions Code § 4052
(6) Proposed Amendment to 16 CCR § 1707 Waiver Requirements for Off-Site Storage of Records
(7) Proposed Amendment to 16 CCR § 1787 Authorization to Distribute Dialysis Drugs and Devices
(8) Proposed Amendment to 16 CCR § 1790 Assembling and Packaging
(9) Proposed Amendment to 16 CCR § 1717 Pharmacy Practice

d. Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions: Technical Changes to the Building Code Relating to Pharmacies

At the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. Thereafter, the Building Standards Commission advised the board of a new process to submit items into the California Building Code. These changes were submitted to the Buildings Standards Commission in compliance with their rulemaking procedures.

Ms. Sodergren advised that this item was submitted to the committee, but unfortunately left out of the rulemaking. An errata sheet by the Building Standards Commission is being prepared for this item.

2. Board-Approved – Awaiting Public Notice

Ms. Zinder advised that the following items were board-approved regulations, and are now awaiting public notice.

a. Proposal to Require the Self Assessment of a Veterinary Food Animal Drug Retailer Premises, Addition of 16 CCR § 1785

During the Enforcement portion of this meeting, the board voted to adopt the Veterinary Food Animal Drug Retailer Self-Assessment Form and move forward with formal rulemaking process. The form and proposed regulatory language adding section 1785 to 16 CCR will be released for the required 45-day public comment period, at which point the matter will be brought back to the board.

b. Proposed Amendment to 16 CCR § 1760 – Disciplinary Guidelines

Ms. Zinder noted that the board took action earlier to approve the Disciplinary Guidelines and move forward with the formal rulemaking process to amend 16 CCR section 1760. This rulemaking will allow the board to use the revised 2007 edition of

this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law.

c. Section 100 Change: Update 16 CCR § 1780 – USP Standards Reference Material CCR

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 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.

Ms. Sodergren noted that 16 CCR § 1780 was initially to be included as a Section 100 change. However, public comments during a committee meeting noted concern about the reference to the USP version. The board is reviewing it in a subcommittee.

d. Proposed Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies that Compound Sterile Injectable 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.

Legislation Report and Action

3. Board-Sponsored Legislation

Omnibus Provisions Contained in SB 1048

The board's omnibus provisions for 2007 were carried in SB 1048 (Chapter 588, Statutes of 2007), a committee bill containing provisions for several other boards within the DCA. The Governor signed this legislation, and all of its provisions will become effective January 1, 2008. These changes will be highlighted on the Board's Web site as well as in the next issue of *The Script.*

The specific changes are:

Business and Professions Code Section 4068
Revises this section to add Schedule IV controlled substances to the CURES reporting requirements for hospitals.

Business and Professions Code Section 4084
Allows board inspectors to embargo a prescription drug when the inspector has probable cause to believe that it is misbranded.

Business and Professions Code Section 4101
Replaces the term “exemptee” to “designated representative.”

Business and Professions Code Sections 4160(f) & 4161(k)
Specifies a temporary license fee of $550 for drug wholesalers and nonresident wholesalers.

Business and Professions Code Sections 4162 and 4162.5
Extends bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement e-pedigree requirements, (restoring provisions in SB 1476 chaptered out in 2006 by SB 1475).

Business and Professions Code Sections 4200 – 4200.2
Changes the name of the pharmacist exam to more accurately reflect the requirements described in B&P 4200.2. The new name will be the “California Practice Standards and Jurisprudence Examination for Pharmacists” but the acronym will remain as CPJE.

Business and Professions Code Section 4208
Revises requirements for intern licenses to allow the board discretion to extend the duration of an intern license.

Business and Professions Code Sections 4314 and 4315
Allows the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

A partial copy of the chaptered bill containing the board provisions was provided in the meeting materials.

4. Enrolled Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

Bills with Positions Taken by the Board

In the meeting materials were copies of chaptered and vetoed bills impacting the practice of pharmacy or the board's jurisdiction. SB 472 and SB 966 are two major pieces of legislation that were chaptered that will significantly impact board resources.

SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements

Ms. Herold said this bill requires prescription label redesigning, and she displayed a prescription bottle from Target as an example of an effort to provide clear labeling for patients.

Mr. Powers appointed Board Members Kenneth Schell, Ruth Conroy, and Robert Swart to the subcommittee, as well as himself. Dr. Schell is the chairperson of the Communication and Public Education Committee, and will also serve as chairperson of this subcommittee.

This legislation requires the board to hold a series of public meetings to elicit comments and suggestions about how to standardize the prescription label and make it patient-centered. These meetings will occur throughout 2008. At the conclusion of these public meetings, the board will need to promulgate regulations. The legislation requires that the standardized label be in place no later than January 1, 2011, giving industry time to comply with the new requirements. Board staff will work with the subcommittee and the bill's sponsors to identify key locations to conduct these meetings and to ensure that identified groups, such as seniors, are represented at the meetings.

Board Position: Support

SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal

Ms. Herold said that Senator Simitian held a There-Ought-To-Be-A-Law contest, and SB 966 was a result of that contest. The Integrated Waste Management Board is the lead agency in developing the requirements, but the board will provide input to the developing requirements.

This law allows for the creation of voluntary pharmaceutical drug take-back programs. A key goal of this legislation is to provide consumers with a way to discard unused medicines in an environmentally friendly way. The development of the models for the take-back programs will be established by the Integrated Waste Management Board, who is required to work closely with the Department of Toxic Control Substances, the State Water Resources Control Board, our board, and other local, state and federal agencies. These model programs must be available no later than December 2008. Board staff will work closely to ensure that the model programs will safeguard the handling and proper disposal of returned medicines and to prevent these returned medicines from reentering the supply chain.

Drew Donovan, from CPhA, suggested an alternative approach used in his community. Law enforcement set aside a certain day for consumers to bring in unused

prescriptions. He said the program worked efficiently, and they took back all types of medications. He said that approach would take away the burden from pharmacists.

Ms. Herold advised that not all law enforcement agencies will take back unused medications. In addition, this program excludes controlled substances.

Dr. Hiura asked what the law enforcement officials did with the medications received.

Mr. Donovan said they probably took it to disposal sites.

Ms. Zinder asked whether pharmacists will have to go through each vial to see if there are any controlled substances in each bottle.

Mr. Room responded that the Integrated Waste Management Board will develop protocols.

Ms. Sodergren clarified that protocols will be established, and then pharmacies that volunteer to be part of the program will have to adhere to those protocols.

Board Position: Support

AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

This legislation allows for use of General Fund money to purchase needles for NEP programs.

Board Position: Support

AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

This proposal would have prevented all health care practitioners from including a "gag clause" in a civil action.

Board Position: Support
Status: Veto. The veto message was included in the board packet.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would have standardized the licensing requirements for ambulatory surgical centers and would have allowed the board to issue clinic licenses to clinics that Medicare certified or accredited.

Board Position: Support
Status: Veto. The veto message was included in the board packet.

AB 1025 (Bass) Professions and Vocations: Licensure

This proposal would have prohibited the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside under certain circumstances.

Board Position: Oppose
Status: Veto. The veto message was included in the board packet.

SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data

This proposal would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial or bioequivalence study, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the company initiates or sponsors the initiation of, but does not complete.

Board Position: Support
Status: Inactive File

SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program

This proposal would have established a scholarship and loan repayment program for pharmacy technicians.

Board Position: Oppose
Status: Veto. The veto message was included in the board packet.

5. First Quarterly Report on Legislation & Regulation Committee Goals for 2007/08

The first quarterly report on the committee's strategic goals for 2007/08 was provided in the board materials.

ADJOURNMENT

President Powers recessed the meeting at 4:50 p.m. to allow the Legislation and Regulation Committee to conduct its meeting at 5:00 p.m.

Thursday, October 25, 2007

CLOSED SESSION

At 8:00 a.m. on October 25, 2007, the board moved into closed session pursuant to Government Code section 11126(c)(1) to discuss and evaluate administration of the pharmacist licensure examination. The board also deliberated on disciplinary matters pursuant to Government Code section 11126(c)(3).

CALL TO ORDER

President Powers called the public meeting to order at 9:19 a.m.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Conroy noted that the Organization Development Committee met on October 16, 2007. A summary of this non-public meeting was provided in the board packet.

- **Budget Update and Report**

  a. Final Budget Report for 2006/07

     Ms. Herold noted that the fiscal year ended June 30, 2007. Detailed information regarding the final budget report was provided in the board packet. The total revenue received during Fiscal Year 2006/07 was $10,808,471 which included the final repayment of a 2001 General Fund loan.

     Ms. Herold added that the requested fee increase was put through to OAL, and no negative comments were received. The revenue for the year also included additional amounts for cost recovery and citations and fines. During the fiscal year, the board collected $436,711 in citations and fines and $130,277 in cost recovery. Ms. Herold referred to graphic displays of the revenue in the board materials.

  b. Budget for 2007/08

     Ms. Herold advised that the board's budget for 2007/08 includes projected revenue of $6,776,000 which assumes that the fee increase begins on January 1, 2008. The expenditures projected are $9,383,000 which includes the approved budget change proposals (BCPs).

     Ms. Herold noted the 2007/08 budget includes an augmentation of $576,000 for a recruitment and retention differential for board inspectors, and restoration of three positions (licensing expediter, enforcement analyst, and receptionist). The positions

were restored without an increase in the board's expenditure authority, meaning that the board must find funding for the positions within its budget.

c. Fund Condition Report

Ms. Herold noted that according to a fund condition report prepared by the department, if the board increases fees to the statutory maximum on January 1, 2008, the board will have the following fund conditions at the end of the identified fiscal years:

2006/07	$10,914,000	14.1 months in reserve (actual)
2007/08	$8,369,000	10.6 months in reserve
2008/09	$6,424,000	8.1 months in reserve
2009/10	$4,313,000	5.4 months in reserve

These estimates are built upon a conservative estimate of revenue (typically the board collects about 10 percent more revenue from licensing fees than it estimates), and revenue does not include cost recovery or cite and fine revenue collected during the year.

d. Inspector Recruitment and Retention Salary Differential

The board's $2,000 monthly differential became effective July 1, 2007 for inspectors and supervising inspectors. Inspectors received their compensation adjustments in mid-October.

e. Reimbursement to Board Members

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

f. Cashiering Update

Ms. Herold said things have improved in the department's cashiering unit, but problems remain. Ms. Herold contacted the department's new head of Administration in an attempt to gain resolution of remaining items. The department has hired consultants to review all cashiering processes, training, and classification of staff used.

g. I-Licensing Project Update

I-Licensing will allow online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future. Delays in securing vendors and new staff overseeing the project have delayed I-Licensing six to nine months, so the board is about two years away from implementing I-Licensing here. Ms. Herold serves as an executive sponsor on the project.

Mr. Spencer advised that he serves as an attorney on I-licensing, and several issues are at hand. The Department of General Services is revising an RFP, and will send it to DCA for correction. The RFP is complex, and the project has been riddled with problems. Four of the DGS project managers were killed in a plane crash, and someone else lost the RFP from her computer.

Ms. Herold emphasized the importance of getting on-line renewal for the board as a major priority.

- **Recognition of Pharmacists Who Have Been Licensed 50 Years**

  Since July 2005, the board has acknowledged 692 pharmacists with 50 or more years of licensure. Eighteen pharmacists reached this milestone between August and November 1, 2007, and each were sent a certificate and invited to a future board meeting for public recognition.

- **Board Recognition of Notable California-Licensed Pharmacists**

  The July 2007 issue of *The* Script solicited nominations from pharmacists to recognize exceptional California preceptors. The board subsequently received the nomination of one preceptor, along with letters of nomination from a school of pharmacy and three pharmacists who work with him and know of his work with interns.

  Board Member Dazé suggested that the preceptor receive acknowledgement from the board at a meeting somewhere near the school of pharmacy where he or she serves as preceptor.

  President Powers suggested another pharmacist for recognition who had been acknowledged by Senate Pro Tem Perata. Staff will research this matter.

- Personnel Update and Training Report

  a. Staff Changes

     Ms. Herold said the board has four inspector vacancies and one supervising inspector vacancy. New civil service lists were established and interviews for inspectors will take place in late October. Supervising inspector interviews will be conducted in November. Since the July 2007 Board Meeting, the board hired staff and promoted others as follows:

- Brandi Neubauer-Scott is the board's new receptionist.
- Bridgette McFarland was hired to process examination applications for pharmacists and issue pharmacist licenses.
- Amber Crosby, who formerly processed examination applications for pharmacists, is now one of the board's two cashiers.
- Akisha Marshall recently started work as a file technician for the Licensing Unit.
- Jennifer Sevilla is the new public records request analyst in the Enforcement Unit.
- Lori Haley was recently transferred into a permanent position in the Licensing Unit to respond to e-mail inquiries regarding applications.
- Enforcement Coordinator Susan Cappello and Enforcement Analyst Kim DeLong received recent promotions to the associate analyst level.

The board has the following staff vacancies and recruitment is underway:

- enforcement analyst to perform administrative work for our enforcement program
- administrative assistant for executive office
- assistant executive officer
- technician for reviewing criminal conviction reports
- full-time receptionist
- four inspector positions
- one supervising inspector

b. AEO Reclassification

The board's request to reclassify the assistant executive officer's position was submitted to the Department of Consumer Affairs in June. DCA submitted the proposal to the State Personnel Board at the end of September. No additional information is available at this time.

c. Inspector and Supervising Inspector Examinations

The examinations have been conducted and the board will conduct employment interviews in October for inspector positions and interviews for supervising inspectors in November.

d. Required Sexual Harassment Prevention Training for Board Members

Ms. Cates advised that a vendor was identified to provide on-line sexual harassment prevention training and that information will be forthcoming via e-mail. Board members are required to receive sexual harassment prevention training every two years, as are all managers and supervisors.

e. Privacy Training for Board Members

DCA notified all board members of the need to complete privacy training before the end of September 2007. A copy of the letter was provided the board materials**.**

- **NABP District 7 and 8 Meeting**

Board Member Stan Goldenberg represented the board at the NABP District 7 and 8 Meeting in Ashland, Oregon. Vice President Ruth Conroy also attended the meeting. The topics discussed at the NABP meeting included remote supervision by pharmacists via cameras.

Dr. Swart noted that telepharmacy is currently being practiced in Ketchikan.

Mr. Goldenberg discussed a program implemented at the University of Oregon College of Pharmacy where first year students talk to school children about healthy eating and other health factors. He said it was an excellent program to educate students from an early age. He said the program is in its third year, and is well received by the students and the community.

Mr. Goldenberg also spoke about presentations given at NABP regarding underserved communities, including neighboring states that have pharmacist interns in rural pharmacies.

- **Approval of the full Board Minutes of July 24 and 25, 2007**

The minutes of the meeting of the Board Meeting of July 24-25, 2007 were provided in the meeting materials.

MOTION: Approve the Minutes of the Board Meeting of July 24-25, 2007.

M/S: DAZÉ/SWART

SUPPORT: 7 OPPOSE: 0

Mr. Dazé recommended that the board approve minutes on the first day of two-day board meeting, so that the board can move forward with other items.

- **First Quarterly Report on the Organizational Development Committee Goals for 2007/08**

The First Quarterly Report on the Organizational Development Committee Goals for

2007/08 was provided in the meeting materials.

ENFORCEMENT WORKSHOP

Ms. Cates and Mr. Room gave a presentation about the board's administrative disciplinary processes, including the Administrative Procedure Act, which governs the disciplinary process.

PETITION FOR REINSTATEMENT

The board heard testimony from Mary French, who petitioned for reinstatement of her license.

CLOSED SESSION

The board moved into closed session pursuant to Government Code Section 11126(c)(3) to deliberate on the petition for reinstatement.

ADJOURNMENT

There being no further business, President Powers adjourned the meeting at 1:30 p.m.