California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES

DATE: December 9, 2008

LOCATION: Department of Consumer Affairs
Hearing Room, First Floor
1625 N. Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT: Robert Swart, PharmD, Chairperson
Stanley C. Weisser, RPh
James Burgard, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Schieldge, Senior Staff Counsel

Chairperson Swart called the meeting to order at 9:36 a.m.

1. Update on the Implementation of Drug Take Back Programs from Patients (SB 966 Chapter 542, Statutes of 2007)

Chairperson Swart provided an overview and background of the bill and highlighted the comments submitted by Executive Officer Herold to the California Integrated Waste Management Board (CIWMB). Many of the board's comments were not incorporated into the new guidelines. However, because many comments were received from other agencies as well, CIWMB will consider all comments at its meeting on December 19, 2008.

The committee discussed additional concerns including the diversion of the returned products and how to keep the pharmacy clean. Ms. Herold also advised the committee about the introduction of SB 26 (Simitian, 2009) which requires the board to work with other agencies to develop regulations for the drug-take back programs.

Ms. Herold introduced Jim Cropper (CIWMB) and requested process clarification on the CIWMB process for changing the adopted guidelines.

Jim Cropper stated that board comments were not received and therefore were not incorporated into the final draft model programs. He stated that the comments which were received were placed in a metrics to allow for quick review. Mr. Cropper indicated that the metrics will be released at the end of the week. Three or four primary comments will be reviewed during the December 19, 2008 meeting and recommendations will be made. The CIWMB will consider the revised requirements at its February 2009 Board Meeting.

Mr. Cropper indicated that about 10 different organizations submitted comments representing the public, cities that have collection programs, etc. Chairperson Swart expressed concern that the board's comments will not be included, especially given that the board is responsible for enforcement of some of the provisions.

Stan Weisser expressed concern also that some of the issues raised by the board were not included and highlighted. He noted one in particular, that being the inability of a pharmacy to recoup the costs for collection and disposal.

Jim Cropper responded that the legal mandate was that the program needed to be at no cost to consumers. The document does include possible ways to recover some of the costs such as applying for grants, clean water programs funding, etc.

John Cronin stated that he was involved in this issue when the original bill, SB 966, was being passed. The impression at that time was that these programs are being rushed. Dr. Cronin stated concern that, based on the current program specifications, there will not be wide adoption. Dr. Cronin suggested that everyone take a step back and review the whole program rather than just throwing together these model programs.

Executive Officer Herold provided an overview of SB 26 (Simitian, 2009) which puts the board squarely in the middle of the implementation of the drug-take program. Ms. Herold read section 4001.1 from the bill, which requires the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes. Board staff will need to speak with Senator Simitian's staff as well as complete a full bill analysis. This will be provided at the January 2009 Board Meeting.

2. Discussion of Sharps Take Back by Pharmacies

Chairperson Swart discussed the board's policy with respect to pharmacies accepting the return of used needles in sharps containers. The policy statement will be included in the January 2009 *Script* newsletter.

The board agreed, at its October 2008 Board meeting, to pursue a statutory change to authorize the pharmacy to take back used syringes. A similar provision is contained in SB 26.

Committee discussion included the question of the cost. While some counties are providing grants to cover the costs, typically 1-2 years of grant money is required to establish the program. At that point, however, the grant money is gone.

Members of industry indicated that they are complying with local ordinances in conformance with sharps take back requirements. Longs, specifically, indicated that they are receiving not only returned needles, but also drugs. In addition, needles are being returned in unauthorized containers. While Longs Drugs have sharps containers available for sale, many consumers are not returning the used needles in sharps containers. San Luis Obispo (SLO) is providing Longs with containers to place the sharps units directly into the container. Longs keeps them behind the pharmacy counter, theoretically, when the pharmacy is closed, should someone could come back and try to access the container. Consumers do put other items in the containers. SLO is also arranging for the disposal of the needles and is paying for it with a two year grant. Marin County has a similar program and also pays for the disposal. In Marin County, the county also pays for the sharps container so the disposal is not the same issue as in SLO.

Board Comments:

Stan Weisser asked if similar problems are occurring for entities using mail back containers.

In response, Mr. Weisser was advised that patients appear resistant to purchase mail back containers, which cost over $20.00. Also, there is a company that is promoting the ability of pharmacies to melt sharps units. To do this, a specific sharps container is used, that when returned by the customer, can be melted at the pharmacy. The cost of each unit is about $1800 and the pharmacy would be left with the cost to implement.

Longs provided some “lessons learned” from their efforts in various parts of the California and stated that the costs for these solutions make the programs cost prohibitive.

Clarification was provided on the containers provided from SLO. They are round containers without a lid, similar to a garbage can. The public has become very familiar with the process in Marin County. Longs indicated that public education is a key component to ensure that needles are returned in sharps containers. Longs suggested that there be a uniform public education and outreach.

John Cronin reiterated the importance of dealing with the costs of this program. He added that CIWMB may not be aware of some of the hidden costs and all of the different laws that cover such disposal.

The committee asked for clarification of disposal options of these returned products. Jim Cropper (CIWMB), Kelvin Yamada (Department of Public Health (DPH)) and Steve Kubo (DPH) described the three methods: Household Hazard Waste collection facilities, use of mail back container or collection at consolidations centers (including pharmacies).

DPH advised the committee that individual agencies can have the products sent to an incineration facility. DPH also highlighted some problems during transportation of the products, including occasional cases where returned product has fallen off the truck. There are also investigations resulting from stolen containers and sharps showing up at recycling centers because people put them in bottles that are turned in to the recycling center. DPH anticipates seeing more problems now that the ban has been implemented.

DPH is aware that SLO is providing the sharps containers to consumers, however they are unclear on the continued funding. Some counties are offering sharps containers at no cost, however there is no widespread advertising.

Lynn Rolston (CPhA) informed the board that CPhA has made waste the highest priority and will be meeting with all stakeholders. Ms. Rolston requested to meet with Ms. Herold to put forward a coordinated effort to address all concerns and find a true solution that also manages the cost, especially given the current economy.

3. E-Prescribing Discussion

Chairperson Swart highlighted the two forums, a board-sponsored forum as well as one sponsored by the California Healthcare Foundation that both occurred on November 20, 2008 to discuss E-prescribing. The forums were very similar in structure and both allowed for public input. Dr. Swart stated that E-prescribing is a priority of the administration.

Dr. Swart discussed the DEA proposed changes to allow for E-prescribing of scheduled drugs and the issues were raised specific to the proposed rules for E-prescribing. The DEA has not responded to the board's comments. It is unclear when or how the DEA will proceed with the proposed rule and stated that there is considerable momentum to push for E-prescribing. He noted, however that the inability to e-prescribe scheduled drugs is a large barrier to full implementation.

The California Healthcare Foundation and Ms. Herold will share results from both forums. Ms. Herold will provide the board with an update at the January 2009 Board Meeting.

John Cronin stated that one outcome pharmacists are reporting is that medication errors are not necessarily being reduced, rather that the type of errors that occur is changing. Dr. Cronin recommended that the board track this information and move slowly. Dr. Cronin highlighted issues with privacy and the interface with medical records and advised the committee that there are some government agencies looking at these issues.

No committee action was taken.

4. Fingerprinting Initiative of the Department of Consumer Affairs for Health-Related Boards

Chairperson Swart discussed recent changes to fingerprinting and provided a summary. For a number of years the board has fingerprinted all applicants to secure criminal background information before issuing a license. On November 4, 2008, Director Carrie Lopez issued a memo to all Executive Officers and Bureau Chiefs under the department's purview, setting out expectations for enforcement and public disclosures. One of the specific requirements detailed by the Director is that all health boards within the Department implement a plan for securing fingerprints from all licensees regardless of when they were first licensed.

When researching the possible impact to board operations to implement such a change, staff learned that the board was fingerprinting pharmacist applicants as early as September 1949, and we estimate that approximately 150 currently licensed before this date were not fingerprint cleared with the Department of Justice. It is unclear when the board began requiring fingerprints for business owners.

In 2001, the Department of Justice began transitioning to electronic submission of fingerprints (LiveScan). Fingerprint background information collected since that time is stored electronically. However, pre-existing fingerprint information was not converted into this electronic format. Given that full conversion of previous records is unlikely to occur, the committee should consider a recommendation to require licensees to resubmit fingerprints as a condition of renewal. Ms. Herold highlighted that the majority of the board's licensees are currently not in the automated system because they were fingerprinted before the implementation of LiveScan.

Ms. Herold also discussed the creation of the Criminal Conviction Unit to address current workloads and centralize the functions of background check review and investigations. Ms. Herold recommended that the Public Education Committee develop informational brochures to educate licensees on the process should the board move forward. Also, Ms. Herold advised the committee that renewal notices will now require the licensee to indicate whether or not they have been convicted or disciplined during the last renewal cycle.

Public Comments:

John Cronin expressed concern about the requirement to post all pending accusations on the board's Web site as detailed in the director's memo.

Ms. Herold clarified that the board will be posting the accusation after it becomes a public document.

Dr. Cronin also expressed concern over the administrative process in general and that regulatory agencies may be misusing this.

Staff counsel advised that the Department of Consumer Affairs legal office is drafting language that explains what an accusation is and what it means.

There were no additional public comments and no committee action.

5. Citation and Fine Program Overview 2007-2008

Bob Ratcliff, Supervising Inspector, provided a power point presentation on citation and fines issued and provided a comparison by fiscal year. The presentation included a breakdown of citations issued by sites as well as the top five violations charged to licensed sites, pharmacists-in-charge, and individual pharmacists. Supervising Inspector Ratcliff also provided a breakdown of the range of fines issued for the license category.

Public Comments:

Dr. Cronin wanted to ensure that the board understands how the program is perceived and provided his historical perspective on why the board implemented the program. Dr. Cronin stated that he believes the program was never intended to be used as a first line of action by the board, rather as an opportunity to allow a licensee to correct a problem and if the licensee failed to do so, then board could pursue a citation and fine. Dr. Cronin also stated that the most common complaint that he receives in his role is surrounding the citation and fine program. He expressed concern over citations being issued for multiple violations and that the totals are beginning to be very substantial. He encouraged the board to reconsider that the administrative process is to gain compliance and is not designed to be punitive. He encouraged the board to look at the roots of the program.

Dr. Cronin expressed concern over medication errors and the investigations that result from a consumer alleging such an error.

Chairperson Swart agreed with some of the statements made by Dr. Cronin including the issue of medication errors.

Ms. Herold responded to these concerns, highlighting that it is not unusual for the board to close a case due to insufficient evidence. The board does not issue a citation and fine if we are unable to substantiate the error. Ms. Herold also underscored the value of the office conference appeal, which many times allows the licensee the opportunity to provide additional information, as well as establishes an educational opportunity.

Chairperson Swart recommended that the board should take into consideration whether the licensee's history can be factored into whether the citation is issued.

Ms. Herold made distinction that the board is a consumer protection agency and does not have a provision to allow for a "free pass" for a first offense. A medication error is very relevant to the consumer that it happens to. Inspectors are trained to look at the QA program to see how serious the program is being used and whether changes were made to prevent future errors.

Lynn Rolston, CPhA, acknowledged the board's consumer protection role. Pharmacists are concerned about public trust and keeping people safe. Ms. Rolston stated that she believes most behavior change takes place because someone has been sensitized to the information and shared that this issue was brought to President Schell. Ms. Rolston stated that education will help pharmacists avoid the mistakes and would appreciate the opportunity.

Ms. Herold highlighted the presentation given at the July 2008 Board Meeting, focusing on medication errors. She shared that the January 2009 issue of *The Script* will include some investigation results but reiterated that the Institute of Safe Medication Practices and others may have better resources to help educate licensees to prevent future errors. The board does try to provide education outreach.

Ms. Rolston restated her previous request for a new effort be put forth to better educate licensees. Ms. Rolston expressed concern that *The Script* is only provided to facilities and may not be passed on to individual licensees.

Supervising Inspector Ratcliff indicated that inspectors have a lot of enforcement discretion when it comes to routine inspections and that these inspections present a good educational opportunity. He also stated that the board has historically used its enforcement discretion when a new mandate goes into effect to allow for industry to implement. However, after a period of time, the board must begin to enforce against it. We do not have a lot of enforcement discretion when the investigation/inspection is a result of a consumer complaint. If the board substantiates findings, they must take action.

There was no further committee discussion or action on this item.

6. DEA Policy on Correcting Schedule II Prescriptions

Chairperson Swart provided background on this topic. In October 2008, the board received clarification from the Drug Enforcement Administration on the final rule, entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) as it relates to the changes that can be made by a pharmacist.

As highlighted by the DEA, the preamble to the final rule is in conflict with information posted on the DEA's website regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

In light of this confusion, the DEA is instructing pharmacists to adhere to state regulations or policy until this matter is resolved through a future rulemaking.

Public Comments:

John Cronin stated that when the triplicate law change occurred, the board developed Frequently Asked Questions (FAQs) that do not appear to be updated. He requested that the FAQs be updated. Also, he stated that he recently received a call on a Q&A from CPhA regarding the use of the tamper resistant forms satisfying the requirement.

7. Theft of Dangerous Drugs from the Pharmaceutical Supply Chain

Chairperson Swart provided an overview of the topic. California Pharmacy Law requires that all deliveries of dangerous drugs and devices may only be received by and signed for by a pharmacist or designated representative. Further, the law specifies that delivery of such products to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the products. (Business and Professions Code Section 4059.5(a) and (c))

Board staff received correspondence from Kaiser Permanente, requesting the board's assistance in communicating the delivery requirements for dangerous drugs and devices to pharmacies. According to information received from Kaiser, despite numerous attempts to address this issue with common carriers like Fed Ex and UPS, deliveries are still made to unauthorized locations.

The board does not regulate common carriers, nor is there any requirement in pharmacy law requiring such licensure to handle dangerous drugs and devices. However, board licensees are responsible for ensuring the appropriate delivery, receipt and handling of such products.

This is an issue for many pharmacies that use common carriers. It is easy to identify the problem, however the solution is difficult.

Ron Bone, McKesson Corporation discussed this issue last week. Healthcare Distribution Management Association, the trade association and McKesson are all very concerned with this issue. They are educating the driver community as well as addressing other security issues that cannot be shared publicly.

John Cronin stated that UPS and other common carries probably do not know the law requiring that the products be delivered directly to the pharmacy. He stated that this may be a good topic for the board to provide direction to licensees. He complained that *The Script* article did not provide any realistic solutions. Dr. Cronin expressed the need for some clarity and that pharmacists look to the board for clarity and stated that drugs get diverted from other sources, such as mail carriers and common carriers as well as from a licensed person or site.

Chairperson Swart requested guidance from counsel on how to proceed.

According to counsel, it is incumbent upon the wholesaler to ensure the appropriate delivery of the product. It appears that this could be a contractual issue between the wholesaler and the common carrier. Legally, the board does not have any authority over the common carrier. Business and Professions Code section 4166 imposes a legal obligation on the wholesaler to ensure the appropriate delivery of the products. Counsel advised that the board could consider convening a subcommittee to further explore if any additional changes need to be made in our law.

Stan Weisser stated that an organization that maintains a contract with the common carrier holds the hammer and can make results happen.

Jim Burgard shared a similar scenario which occurred with hazardous materials when establishing the chain of custody and stated that when parameters were established, it became a straight forward process.

Chairperson Swart also indicated that the store could send the delivery back if it is not delivered appropriately. Chairperson Swart requested that this item be brought to the full board for consideration and to gain input on what can be done.

8. Public Comment for items Not on the Agenda

No additional public comment was provided.

The meeting was adjourned at 12:23 p.m.