



California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: April 11, 2008

LOCATION: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, CA 90045

BOARD MEMBERS

PRESENT: Andrea Zinder, Public Member, Chairperson
D. Timothy Dazé, Esq., Public Member
Kenneth H. Schell, PharmD
Robert Graul, RPh
Stanley C. Weisser, RPh

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tina Thomas, Analyst

Chairperson Zinder called the meeting to order at 9:30 a.m.

Chairperson Zinder acknowledged Anne Sodergren's return to the board.

Ms. Herold introduced board staff Anne Sodergren and Tina Thomas.

Dr. Weisser acknowledged Mr. Dazé for assisting in providing the conference room for the meeting.

Legislative and Regulatory Proposals for 2008

SB 1307 Electronic Pedigree

Ms. Herold provided updates on the bill. She stated that amendments have been put in place since the last board meeting to establish staggered implementation dates for the e-pedigree requirements. Ms. Herold noted that there are many manufacturers who feel they will be ready for having their products tagged by 1/1/11. She highlighted that the current implementation timeline would leave the supply chain partners without enough time to implement effectively.

The amendment will allow the wholesalers an additional year and pharmacies will have an additional eighteen months behind the 2011 deadline to implement and stated that there are also provisions for the board to develop regulations for inference. Ms. Herold noted that the current language for grandfathering is difficult to understand and may be slightly revised. She stated that the intent with grandfathering is to provide a grace period in order to run out drugs already in the supply chain prevent, and that it is a short-term implementation issue. Ms. Herold stated that the bill was in hearing Monday and was passed with a 6-2 vote. She commented that the next stop is the Appropriations Committee. Ms. Herold stated that there will be additional amendments to bill, as Senator Cedillo had a competing bill (SB 1270). Senator Cedillo's bill does not have amendments yet.

Dr. Schell asked what the intent is on the grandfathering provision. Ms. Herold responded that on 1/1/01, there will still be drugs manufactured that are not serialized or e-pedigree that could still be moved through the supply chain. She noted that a list has to be developed with regard to turnaround of all such drugs.

Comments/Questions from public:

Kathy Lynch (CPHA) noted that they are in support of SB 1307. Ms. Lynch asked the committee to clarify how inference will be handled. Ms. Herold responded that inference will be done during the regulation process if the bill is passed. Ms. Herold stated that inference comes at the expense of serialization, and that the more inference you give, the less value serialization provides to the security of the supply chain. Ms. Lynch pointed out that they have great concern for the liability involved for their stores. She stated that they appreciate the extra time being provided in order for the pharmacies to comply. Ms. Lynch also stated that she requested that the technology be sightless. Dr. Schell asked if CPHA will be working on developing thoughts around the inference issue, as they should be starting that now. Ms. Lynch responded that they are. Ms. Herold stated that the board shares CPHA's concern about a product going from all the way from the manufacturer to a pharmacy without ever being electronically read, and the issue will be addressed.

SB 1779 (Omnibus Provisions)

Chairperson Zinder stated there have been no new provisions proposed since the last discussion.

Questions/comments from the public:

Steve Gray (Kaiser Permanente) referenced language in section 4110 (Temporary Permit Upon Transfer of Ownership). Dr. Gray suggested that a mobile pharmacy should be allowed in a parking lot during remodel. Ms. Herold agreed that this was a reasonable request and that excluding this event from the provisions was unintentional. Dr. Gray stated his concern over the Board's requirement of an approval process for a new pharmacist-in-charge. Ms. Herold clarified the process for a change of PIC, and stated that a pharmacy permit will not be issued or renewed until the PIC is approved.

MOTION: To ensure the remodel situation is clearly set forth in the amendments to Business and Professions code 4110.

M/S: Weisser/Schell

Support: 4 Oppose: 0

Questions/comments from the public:

Cooky Quandt (Long's) referenced section 4113 (d) and asked for clarification that a pharmacy will need to notify the board in all cases of an interim PIC. Ms. Sodergren pointed out that the language is "may", and that it is not mandatory at this point. Ms. Herold stated that when a pharmacy renews its license an interim PIC must be designated on the renewal. This interim PIC has to be reported to the board.

Dr. Gray shared his concern of the 120-day limit on an interim PIC, and that there is often difficulty for hospitals to find someone who will take the role of permanent PIC. He also explained the concern of compensation in relation to the need to find a permanent PIC. Ms. Herold restated the law from the Pharmacy Lawbook that already requires the designation of a permanent PIC after 120 days. She also noted the fact that a permanent PIC is the cornerstone of pharmacy law. Chairperson Zinder noted that a discussion to consider any change to the permanent PIC law is not appropriate now.

Legislation of Interest

Active bills

AB 501 (Swanson) – Pharmaceutical Devices

Ms. Sodergren stated that the bill was carried over from last year. The bill is designed to provide a safe mechanism for people to dispose of hypodermic syringes and needles and prevent them from being found in landfills, playgrounds, etc. Ms. Sodergren explained the options for ultimate disposal by users.

Board Position: Support

AB 865 (Davis) – State agencies: Live customer service agents

Ms. Sodergren explained that the intent of the legislation is to require state agencies to have all phone calls answered within ten rings by a live operator, and to have a zero-out option to reach a live agent with automated systems. Chairperson Zinder felt that we should not change that position. Ms. Herold emphasized the need for the public to feel that the state agencies are reachable.

Board Position: Neutral

AB 1394 (Krekorian) – Counterfeit: Trademarks

Ms. Herold explained that the bill will enhance penalties against anyone involved in counterfeiting. She explained that it is viewed as theft from manufacturers and thus increased penalties on such theft is appropriate. Ms. Herold noted that there was a slight amendment since the last board meeting.

Board Position: Support

AB 1436 (Hernandez) – Nurse Practitioners

Ms. Sodergren explained that bill was initially introduced to expand to the scope of practice for nurse practitioners. She stated that numerous amendments have been made, and the bill now revises educational requirements for nurse practitioners. Initially the board was watching the bill, however the bill has changed significantly in scope.

Board Position: Watch

AB 1587 (De La Torre) – Personal Information: pharmacy

Ms. Sodergren reviewed the bill and that it would allow the pharmacy to provide drug–manufacturer produced information at the time that a prescription was dispensed. She informed the board that the proposal will not be moving forward.

Board position: Oppose

AB 1947 (Emmerson) – Pharmacy Technicians

Ms. Herold explained that the bill would have required that a pharmacy technician applicant would have to pass an exam that met the requirements of California Business and Professions Code 139 and would also require the technician to earn 20 hours of continuing education credits every two years as a condition of renewal. Ms. Herold stated that the bill has been withdrawn.

Phillip Swanger (CSHP) provided an explanation of the reasons for the bill withdrawal, and explained that there is a plan for all stakeholders to meet in the near future to come to an agreement to rerun the bill in 2009. Dr. Graul asked about the nature of the opposition, and Mr. Swanger responded that it involved financial impact on community and chain pharmacies. Dr. Weisser commented that this is an important issue, and that the Board of Pharmacy should continue to be involved in determining continuing education for the technicians, as they are very involved with the patients and community.

Committee Recommendation: None

AB 2516 (Mendoza) – Prescriptions: Electronic transmission

Ms. Sodergren explained that the bill deals with the electronic transmission of prescriptions. Ms. Sodergren explained further that the bill's intent is to have a physician submit prescriptions electronically to the pharmacy of a patient's choice. Ms. Herold commented on the concern regarding the exemption in section 4072.5, which she will be discussing with legal counsel. Dr. Graul asked if the bill is stating that all prescriptions will be prescribed electronically by 2010. This was confirmed by Ms. Herold and Ms. Sodergren.

Questions/comments from the public:

Dr. Gray (Kaiser Permanente) shared concerns with the bill. Dr. Gray first indicated that the law already states that prescriptions are to be sent to the patients' pharmacy of choice. Dr. Gray stated his concern over the intent of the bill and whether liability would lie with the prescriber or the pharmacy when a prescription is not prescribed electronically. Dr. Gray was also concerned over proper enforcement from other boards involved (i.e., Medical, Dental Boards). Dr. Gray also stated concern over the date of the implementation and the lack of technology in place to have all pharmacies receive prescriptions electronically from large hospitals, such as Kaiser Permanente. Dr. Gray and Dr. Graul both raised the issue of poor legibility on faxed handwritten transmissions and other types of transmissions and that it doesn't seem realistic to have e-prescribing in place by the implementation date of the bill. Ms. Herold stated that further investigation of the bill by board staff is necessary.

Stacy Noroni (health care attorney) stated that the regulations are not clear on some issues, including the lack of distinction between new and renewal prescriptions. She also discussed the issue of regulations being specifically addressed towards skilled nursing facilities (but not other entities), which billers are using against the skilled nursing facilities to withhold payments. Ms. Herold requested that Ms. Noroni place her issues in writing and submit them to the board. She noted that the e-prescribing law has been in place since 1994, and that it may be time to take a look at whether the law is still adequate based on current technology. Ms. Noroni stated that

she will submit the issue in writing. It was noted that the board will conduct further analysis on the bill before taking a position, as additional information is needed.

Committee Recommendation: None

AB 2643 (Cook) - Drugs and Devices

Ms. Sodergren explained that the bill would have replaced the references to USP to the name of the publication Drug Points. She noted that the hearing was cancelled, and that the sponsor will not be moving on this legislation

Committee Recommendation: None

AB 2756 (Duvall) – Pharmacists: Furnishing Drugs During and Emergency

Ms. Herold invited the California Retailers Association to speak on behalf of the bill, as they are the sponsor of the bill. Heidi Barsuglia (CRA) explained that the bill is currently a spot bill, but amendments should be in print by Monday. She explained the details of the bill as it relates to natural disasters and the ability to dispense in such an event, rather than having to wait until a Governor declaration is issued. Dr. Schell asked who would determine the emergency. Ms. Barsuglia clarified that this would refer to the natural disaster, rather than an emergency. Dr. Graul clarified that the changing of language would involve adding “natural disaster” to the current language. Ms. Herold recommended that the board wait until we have the bill in front of us before taking a position.

Committee Recommendation: None

SB 963 (Ridley – Thomas) – Regulatory Boards: Operations

Ms. Herold explained that the bill deals with the Sunset Review process. She informed the board that there will be changes in the bill, and that amendments are not yet available. Ms. Herold recommended that the board not take a position until we have the changes. She stated that the information provided is for information only. Ms. Herold did emphasize the importance of bill.

Committee Recommendation: None

SB 1096 (Calderon) – Medical Information

Ms. Sodergren explained that the bill would allow a pharmacy, or an entity authorized by a pharmacy, to mail written communications to a patient pertaining to the prescribed course of their treatment, without patient authorization. Ms. Sodergren noted that the board took an oppose position at the January 2008 board meeting and concerns from the board are detailed in the comments of the bill analysis.

Comments from the sponsor:

Dan Ruben (Adheris), sponsor of the bill, provided the background and purpose for the bill. Mr. Ruben reviewed specific points they would like the board to keep in mind when evaluating the bill, including the issue of lack of patients’ adherence to taking their medications, the need for ongoing management of chronic health, and programs providing education and reminder messaging about patients’ prescribed therapy. Mr. Ruben also listed programs not being offered to citizens in California. Mr. Ruben emphasized several requirements that must be met before the written communications would occur. He also stated that Adheris disagrees with concern by some parties that the written communication programs could interfere with the patient-physician

relationship, by pointing out that the information being provided in writing only relates to drugs already prescribed by the physician.

Dr. Graul confirmed that the program is an “opt out” program. He asked what the time frame is for opting patients out currently under the program. Mr. Ruben indicated that a toll-free phone number is available for the patient to call in order to opt-out, at which point they are removed from any further written communication immediately. Dr. Graul also asked about the confidentiality concern over written communication being sent. Mr. Ruben stated that all written communication is sent by first class mail. Dr. Graul also confirmed with Mr. Ruben that the program is currently being funded by pharmaceutical companies.

Dr. Schell asked if they have any evidence that suggests a greater problem with medication adherence in California compared to the rest of the United States. Mr. Ruben responded that he doesn't think it is better or worse. Dr. Schell commented that maybe the reason adherence is not worse in California is because such patient mailings do not work. Mr. Ruben clarified that he was speaking globally.

Mr. Dazé asked about the option of doing an “opt-in” program rather than an “opt-out”. Mr. Ruben responded that no bill is needed for an “opt-in” program, but there are limitations to such a program. He stated that in the case of an “opt-in” program, it is difficult to get patients to “opt-in,” and they tend to be only the most compliant patients. Mr. Dazé stated that people simply may not want the information, and that is why they wouldn't “opt-in” if they have the choice.

Chairperson Zinder asked what additional information is provided through Adheris's service that is not provided at the pharmacy. Mr. Ruben responded that additional information includes the printing out of a drug monograph in a more patient-friendly manner. He also stated that refill reminders will come in the mail to them as well. Ms. Herold requested copies of the letters that are used for written communication in other states. The board agreed on the request. Mr. Ruben will send this material to the board.

Dr. Schell requested a better overview on how the system knows to stop sending information when there are no refills. Mr. Ruben that all the communications are triggered based on refills remaining. He also noted that an additional letter may be sent out for patients using medication on a long-term basis, indicating the recommendation to contact their physician routinely. Chairperson Zinder asked who the mailing comes from. Mr. Ruben indicated that it appears to come from the pharmacy.

Dr. Graul asked for the “opt-out” rate. Mr. Ruben indicated it was 3 percent. Ms. Sodergren and Mr. Dazé asked if Adheris receives the patient information, and whether that is without the acknowledgement of the patient. Mr. Ruben responded that that is correct in some cases. Dr. Graul how much money is involved in the transactions, and whether it is a significant cash flow to the pharmacies. Mr. Ruben responded that there is reimbursement for services involved for help in printing out the letters.

Questions/comments from the public:

Dr. Gray voiced Kaiser Permanente's concern over the bill. He stated that Kaiser Permanente's view is that the bill places severe limitations on written communication to patients from the pharmacy, and limits that communication to only being that which has prior authorization. Dr. Gray pointed out that they cannot provide non-drug information or information on other drugs not prescribed, and can only provide what's in the medication insert of the drug being prescribed. Dr. Gray noted that the confidentiality law is extremely complex, but Kaiser

Permanente is concerned that this bill would inhibit pharmacies to participate fully in what they can and cannot communicate in writing. Dr. Gray encouraged the board to look at this bill carefully, and feels that there should be more communication, not less.

Mr. Dazé asked if Kaiser Permanente has communicated their concerns with the sponsor. Dr. Gray responded that they have not, but they are beginning that process. Mr. Dazé noted that if there is a positive impact to mailings, then we should take a look at it. However, the board needs to address this if it will hinder the other types of communications Dr. Gray mentioned, including medication adherence. Dr. Graul clarified that this bill would narrow the scope of communication between a pharmacy and a patient to one drug being prescribed, and would not allow the pharmacist to discuss other drug options or otherwise, for example. Dr. Graul stated that he is not opposed to compliance programs, but that something is needed to improve and protect the patients when they don't know that they should not continue on a drug. Dr. Gray stated that substantial funding for some of those programs comes from the pharmaceutical companies, and it usually comes from a company of a patented, branded drug. They are rarely sponsored by a generic drug company. This raises the question of intention of some of the trade name companies, so that the pharmacists are unable to communicate generic drugs options to patients in low-income situations.

Mr. Ruben responded to Dr. Gray's comments, and stated that there was nothing in the bill which was meant to limit what can be done. They viewed the bill as a starting point, and are not against allowing other communication. Mr. Ruben defended the concern over any intention of branded companies to disallow communication on generic drugs.

Mr. Dazé suggested that Adheris and Kaiser Permanente work together to address the concerns. Mr. Dazé also noted that no one is opposed to having information going to consumer, or to have information restricted to only one channel.

Chairperson Zinder noted that the board has taken an opposed position. Ms. Herold explained the reason for the opposed position involved (1) financial reimbursement to the pharmacy for providing this service, compromising the role of the pharmacist, (2) the opt-out nature of the process and as well as (3) patient confidentiality being violated by a third party.

Questions/comments from the public:

Dr. Gray addressed the board's concern regarding the sharing of information to third parties. He feels that this issue is already well regulated, and Kaiser Permanente's opposition to the bill is not related to this. Dr. Gray noted Kaiser Permanente's communications to patients in an attempt to discourage patients to continue on medication that they should not be using, and that this is another reason for their opposition

Board Position: Oppose

SB 1270 (Cedillo) – Pharmacy: Dangerous Drug and Devices Pedigree

Ms. Herold summarized the bill. She stated that the bill was amended on March 27th, and explained that it deals with the normal distribution channel of e-pedigree. She noted that amendments to the bill just came out April 11th, and that the bill will be heard by the Business & Professions Committee on April 14th. Ms. Herold stated that everything in the bill related to normal distribution channels has been removed, and replaced with a task force to help aid the board in advising it about implementation of e-pedigree requirements. Ms. Herold advised the committee to wait to take a position on the bill until the amended copy is available to review.

Committee Recommendation: None

SB 1504 (Ridley – Thomas) – Antiepileptic Drug Products: Substitution

Ms. Sodergren explained that the bill dealt with prohibiting generic substitutions for antiepileptic drugs. She stated that the bill is not moving forward.

Committee Recommendation: None

SB1594 (Steinberg) – Bleeding Disorders Clotting Products

Ms. Herold explained that the bill involves specific regulations on blood clotting products for home use. The Senate Health Committee had requested that amendments be added to allow the Pharmacy Board to enforce the regulations with respect to pharmacies. Ms. Herold that the board staff should be able to ensure the safety of these patients. Ms. Herold stated that the bill was amended on April 9th, and the board has not had a chance to work with the Dept. of Health Care Services to work out the details. Ms. Herold suggested not recommending a position on the bill.

Dr. Graul raised the question of whether the bill would allow for jurisdiction by the Board of Pharmacy over non-licensed persons involved as well.

Dr. Schell asked what the genesis of the bill is. Ms. Herold responded that the bill aimed at improving the quality of service for patients that require hemophilia drugs. Dr. Schell questioned whether the quality of services is currently an issue. Kathy Lynch (CPhA) indicated that CPhA is taking a neutral/watch position on this bill right now. She explained the issues behind the bill with respect to the container of the drug, as well as the need for standards. CPhA feels that the pharmacies are already abiding by these standards, and that it is the hemophilia groups' intention to have something in place that will be enforced. Dr. Schell's shared his concern on overregulation, and that we may simply be adding another, and an unnecessary layer. Ms. Lynch pointed out that standards similar to those being attempted in California have been set in other states. She also noted that hemophiliac groups are seeking some amendments, but she is not sure what they are.

Dr. Gray provided background on hemophiliac drugs, including cost. He noted that a very well organized consumer group is involved in developing this bill.

Ms. Lynch described an instance where a specialty pharmacy was trying to force a patient to move over to another drug because they did not want to supply the original drug that the patient has been taking for many years. She stated that this is an important aspect to consider for this bill and group.

Ms. Herold wants to clarify specifics around this bill by those with expertise in this area, so that the board can properly enforce regulations for these sensitive patients. Ms Herold added that the board does not need to be the lead agency, but that we should participate. The committee indicated that they will need more information before taking a position on the bill.

Committee Recommendation: None – seeking more information

AB 2122 (Plescia) – Surgical Centers: Licensure

Ms. Sodergren noted that the bill is similar to AB 543 from 2006, which the board had supported. Ms. Sodergren explained that the bill standardizes the operating standards for a

surgical clinic, and would allow the board to issue a surgical clinic license to anyone who is accredited by an approved agency or is certified to participate in the Medicare program.

Dr. Graul asked if the bill cleared the bar that the Governor has set in his veto message, or whether the language is substantially different. Ms. Sodergren stated that the language is very similar to AB 543. Ms. Herold and Ms. Sodergren provided more clarification on the details of the bill. Dr. Weisser asked for clarification on language of “operation staffing” and acute facilities. Dr. Weisser stated his concern over an attempt by this bill to dictate staffing ratios in acute facilities.

Dr. Gray provided background on the bill with relation to licenses and staffing. Dr. Gray encouraged the board to support the bill.

Motion: Support AB 2122.

M/S: Graul/Dazé

Support: 4 Oppose: 0

AB 2425 (Coto) – Dept. of Public Health: Water Quality: Purity

Ms. Sodergren summarized the bill, which would require any pharmaceutical manufacturer doing business in California whose products have been detected in the drinking water, to file a report with the State Public Health Officer as specified. She explained that the intent is to determine how pharmaceuticals are entering the water supply and then what will be done to remove them. She noted that there is a six-year window for this process.

Ms. Herold noted that this bill was intended for information purposes.

Dr. Graul stated a concern with subsection b in regards to the methods of preventing the drugs from entering the water, as it is unclear how that will be identified. Ms. Sodergren responded that the intention is for the manufacturers to make recommendations on how to prevent residue from occurring.

Committee Recommendation: None

Public Requests for Future Legislation and Regulatory Proposals:

Heidi Barsuglia (CRA) asked the committee to put SB 1702 (Machado) on their watch list. She explained that it would trigger additional MediCal audits of any MediCal provider who supply a service or product to a certain percentage of out-of-county MediCal beneficiaries. Pharmacists are concerned that if they have patients near a county line, patients would be effected. The recommendation has been to address the issue as a “service area” instead.

Dr. Gray (Kaiser Permanente) asked the board to put AB 2661 on a watch list. He explained that this bill changes the definition of California law on telemedicine, and removes the exemption of phone calls. He stated that this would instead impose requirements on how telemedicine could be done, records kept, etc.

Phillip Swanger (CSHP) spoke regarding their sponsorship of AB 1947 (Emmerson). Mr. Swanger provided a brief history as well as an explanation for their language of the bill. He detailed the creation of a task force, and their development on addressing the requirements for

pharmacy technician training and education. Mr. Swanger reviewed issues determined by the task force, including having pharmacy technicians pass a certification exam, and completion of standardized training. CSHP is asking the board to consider co-sponsoring the bill to protect consumers.

Board Approved Regulations – Awaiting Notice (Status Update:)

Repeal of Title 16, CCR sections 1716.1 and 1716.2 and amendment to sections 1751-1751.8 and adoption of sections 1735-1735.8.

Ms. Sodergren stated that there was a vote on the compounding regulations at the January 2008 board meeting to do a 15-day notice, which has not yet been done.

Ms. Sodergren reviewed the regulations awaiting notice as:

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

Title 16 CCR section 1780 – Update the USP Standards Reference Material

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

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

Ms. Sodergren noted that all of the regulations are awaiting notice, and that the specific language is provided.

Regulations Currently Noticed (Status Update)

Ms. Sodergren stated that the Disciplinary Guidelines are currently noticed, that the comment period was reopened until the regulation hearing, which will occur at the April Board Meeting.

Board approved – Regulation Language to be Developed

Ms. Sodergren explained that the language needs to be developed for the ethics course. She stated that the concept was approved at the board meeting in October 2007.

Chairperson Zinder adjourned the meeting at 12:08 p.m.