MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: April 3, 2007
LOCATION: Department of Consumer Affairs
1625 N Market Blvd
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Ken Schell, PharmD, Acting Chair
Tim Dazé
Henry Hough

BOARD STAFF PRESENT:

Virginia Herold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Staff Manager

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

Dr. Schell stated that the agenda items were going to be taken out of order and that the first order of business would be a presentation and discussion about Sansum Clinic (Sansum).

Representatives from Sansum provided the committee with a background on the clinic ownership and structure, noting that they currently hold three clinic licenses, one pharmacy license and one wholesaler license.

The wholesale license is used to receive, warehouse and distribute medical supplies for use by the varrious clinic sites and indicated that there is no dispensing at the clinic sites, only administration of the drugs and supplies.

All of the licensed entities share a common ownership.

Representatives from Sansum were requesting board approval to eliminate the wholesale license and replace it with a clinic license. This would eliminate the surety bond requirement currently in effect for wholesalers, as well as relieve some of the pedigree requirements.

Executive Officer Herold stated that the pedigree requirements would still be required and it would be necessary to track the pedigree. The pedigree would need to demonstrate the initial purchase of the drug, however it would not need to trace the movement between the pharmacy and clinic sites.

Dr. John Cronin stated that the proposed clinic is currently JCAHO accredited and that part of that accreditation also requires the tracking of that information.

Chairperson Schell clarified that Sansum's request was to allow the redistribution of the product with a wholesaler license and therefore relieve Sansum from the surety bond and pedigree requirements to a wholesaler license,

Committee Member Hough requested clarification on the necessity to eliminate two of the three existing clinic licenses.

Dr. Cronin stated that Business and Professions Code section 4180 allowed for the transfer of drugs without those permits.

Committee Member Dazé asked if each clinic was a separate corporation.

Representatives from Sansum indicated that the licenses all shared a common ownership.

Supervising Inspector Ratcliff asked if the proposed eliminated clinic sites were still going to have dangerous drugs and stated that if those drugs were going to be in a common stock, the clinic licenses could not be eliminated. Supervising Inspector Ratcliff also stated that a clinic cannot redistribute drugs.

Dr. Cronin asked if a clinic can redistribute if it is done internally.

Supervising Inspector Ratcliff reiterated that the redistribution could not be done by a clinic, but could perhaps be completed by a licensed pharmacy.

Executive Officer Herold indicated that the board would confer with counsel about the legality of the pharmacy redistributing drug product.

Dr. Cronin restated that the goal of this proposal is to eliminate the wholesaler license and that Sansum is seeking guidance from the board on how to meet their goal.

Executive Officer Herold indicated that the board has sufficient information to move forward to evaluate the construct provided and will work within the parameters of the law to make a determination. Ms. Herold committed to assist Sansum in identifying possible solutions.

Approved Regulations

Dr. Schell stated that two regulations were recently approved by the Office of Administrative Law.

Repeal of 16 CCR 1717.2 - Notice of Electronic Prescription Files

The repeal of Section 1717.2 of the California Code of Regulations removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy. This regulation change went into effect March 26, 2007.

Addition of 16 CCR 1784 – Self-Assessment of a Wholesaler

The adoption of this section establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with

legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This regulation will go into effect the end of April 2007.

Board Approved Regulations – Pending Administrative Review

Dr. Schell advised the committee of two regulations that are currently noticed. Dr. Schell provided a brief overview of each of the two rulemakings.

Amendment to 16 CCR 1706.2 - Abandonment of Applications

In 1997, the board established the provisions of 16 CCR1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms "manufacturer," "supplier," "medical device retailer," and "warehouse of a medical device retailer." This proposed regulation change would add veterinary food-animal drug retailer, hypodermic needles and syringes, pharmacist interns and designated representatives to the regulation.

This rulemaking was submitted to the Department on February 16, 2007. The fiscal impact statement was referred to State and Consumer Services Agency on March 27, 2007.

Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

This rulemaking was submitted to the Department on February 16, 2007. The fiscal impact statement was referred to State and Consumer Services Agency on March 27, 2007.

There were no committee or public comments on these two regulation proposals.

Board Approved Regulations Currently Noticed

Dr. Schell provided a brief description of this proposal.

CCR 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122. 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 Consumer" 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.

Dr. Schell indicated that this proposal will be considered at the April Board Meeting for possible adoption or modification.

Fred Meyer, President PPSI, indicated that he has requested copies of the revised language.

Board staff indicated that they would provide Mr. Meyer with a copy of the proposed language.

Dr. Cronin stated that he submitted comments and was requesting the board's reaction to his comments.

As this was not a regulation hearing, committee members did not respond.

Dr. Steven Gray, representing Kaiser Permanente stated that Kaiser is also concerned about the current language and agrees with the comments submitted by Dr. Cronin.

Kathy Lynch, representing the California Pharmacists Association (CPhA) stated that comments from the CPhA are forthcoming and that the CPhA generally also agrees with the comments submitted by Dr. Cronin.

Board Approved Regulations Awaiting Notice

Dr. Schell briefly discussed the Section 100 Changes (rulemakings without regulatory effect.)

1. Section 100 Changes

- Proposed Amendment to 16 CCR 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"
  In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

- Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material
  Section 1780 sets minimum standards for drug Wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards 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.

- Proposed Amendment to 16 CCR 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"
  In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006.

- Proposed Repeal of 16 CCR 1786 – Return of Exemption Certificates
  This section is outdated and needs to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior pharmacy law which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

- Proposed Amendment to CCR 1715 – Self Assessment Forms
  This self-assessment form is incorporated by reference. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the forms last revision date.

- Proposed Amendment to CCR 1793.8. – Pharmacy Technicians in Hospitals
  This section currently references Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

The committee had no comments on the Section 100 changes.

Dr. Gray questioned if the board considered all of the changes made in the 2005 version of the USP and stated that there could be some unintended consequences to incorporating that version of the USP into regulation. Dr. Gray suggested that board staff review all those changes to ensure the board agrees with the standards established in that version.

Committee members were advised on the status of two additional regulations that were previously approved by the board that are awaiting notice.

Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines
In addition to the Section 100 changes listed above, the board also approved amendments to 16 CCR 1760 – Disciplinary Guidelines.

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. Staff has additional recommendations for changes that will be presented to the board at the June 2007 Enforcement Committee Meeting. No action will be taken on this proposal pending the outcome of the July 2007 board meeting.

Proposed Addition to CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

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

Board Approved Regulation – Awaiting Conformance with the California Building Commission Standards Rulemaking Process.

Dr. Schell provided a brief overview of this proposed regulation change.

At the April 2006 Board Meeting, the board agreed to request amendments to the California Building Code regarding provisions for compounding of injectable medicine from nonsterile components to contain provisions currently required in California Business and Profession Code. Staff will pursue these changes in the new format this year to secure adoption of these standards into the building code.

Board Approved Regulations – Proposed Language to be Developed

Process and Criteria to Approve Accreditation Agencies for Pharmacies

Dr. Schell provided a brief overview of this proposal. Staff will develop the draft language in concert with staff counsel to be provided at a future committee meeting for consideration.

This regulation would formalize criteria the board uses to approve such agencies and would remove the administrative burden placed on the board for such approvals.

Dr. Gray suggested that board staff consider the guidelines recently established by the American Pharmacists Association.

Proposed Legislation – Board Sponsored

Omnibus Provisions

The committee reviewed omnibus provisions previously approved by the board to be introduced this legislative cycle. These provisions include amendments to the following:

B & PC 4084 – Adulterated or Counterfeit Drugs or Dangerous Devices
B & PC 4162 and 4162.5 – Wholesaler Bonding Requirements
B & PC 4314 and 4315 – Citation and Fine for Repository and Distribution Programs for Dangerous Drugs
B & PC 4160(f) and 4161(k) – Temporary License Fee for Wholesalers
B & PC 4208 – Intern Pharmacist License

No comments were made by the committee or public.

Changes to CURES enacted by AB 2986 (Chapter 286, Statues of 2006)

Executive Officer Herold provided an overview of the implementation issues arising from changes enacted in 2006 to the CURES program expanding reporting requirements to include Schedule IV controlled substances. In addition, the legislation expanded the reporting elements to include a patient's phone number and increased the frequency with which this data must be submitted. Staff is proposing a transition period for implementation of the new reporting requirements for CURES.

Ms. Herold stated that initially the Department of Justice was going to sponsor the proposed legislative changes, however because of the change in administration at that agency, it was unable to do so. The board was going to carry these changes, but lost

the author. As such the only mechanism the board had to pursue these changes would be through an omnibus bill, but that could result in a triple referral of the omnibus bill.

Ms. Herold indicated that the board has not heard from the industry that the changes enacted by AB 2986 are problematic.

Dr. Schell sought clarification about the requirement to obtain a patient's phone number and indicated that not all patients have a phone number. Dr. Schell indicated that there needs to be a workaround.

Ms. Herold stated that the current state requirement mirror those found in federal legislation and stated that the DOJ must be fully compliant with the federal requirements to receive federal grant money. DOJ has offered some solutions to the phone number requirement including the use of all 9's in that field, a fictitious phone number or the pharmacies phone number. The board is not involved in identifying such workarounds.

Maria Serpa, representing the California Society of Health-Systems Pharmacists (CSHP), commented that small pharmacies do not report electronically to CURES and that the weekly reporting requirement is problematic for such pharmacies. Ms. Serpa requested clarification on whether the board had a plan to communicate to pharmacies that do not have on-line capabilities.

Ms. Herold restated that the requirement is to report CURES data weekly and suggested that Ms. Serpa contact the Bureau of Narcotic Enforcement for guidance.

Ms. Serpa also indicated that the current proposed language is a little bit prescriptive in specifying the exact day of the week the weekly CURES information is to be transmitted.

Dr. Gray stated that the intended changes were designed to clarify the changes enacted by AB 2986 and stated that there is a lack of information coming from the DOJ. He stated that Kaiser can live with the existing language as long as the CURES enforcement is reasonable.

Dr. Gray also stated that there are problems with incomplete submissions being kicked back from the vendor (Atlantic and Associates) and stated that the requirement for the weekly transmission to occur on Monday is also problematic for Kaiser.

Ms. Herold stated that some of the transmission issues may be resolved when the new contract with Atlantic and Associates goes into effect.
There were no additional comments from committee members or the public.

Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Executive Officer Herold advised the committee of the five possible positions the committee can recommend to the board for consideration: Oppose, Oppose with Amendments, Support if Amended, Support, and Neutral.

Dr. Schell provided a brief overview of each of the relevant bills, as well as the author's intent.

AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

This proposal would allow for the use of General Fund money to purchase needles for NEP programs.

Committee Member Hough stated the effectiveness of the current law.

Executive Officer Herold clarified that this proposal would allow the use of General Fund money to purchase needles for NEP programs.

Committee Member Dazé stated concern that the General Fund money could be used in another fashion and that the proposed funding should be done on at the county level.

Committee Member Hough agreed.

Fred Meyer, PPSI, stated that NEP's are effective and save lives. He stated that the government should step in.

Committee Member Dazé stated that the committee is not recommending that the board take an oppose position.

Committee Recommendation: Watch

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

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

Committee Recommendation: Support

No comments from the committee or public.

AB 501 (Swanson) Pharmaceutical Devices: Hypodermic Needle and Syringe Disposal

This proposal would require every pharmaceutical company whose product requires the use of prefilled syringe, prefilled pen needle or other prefilled injection device to provide a method for California patients to dispose of the device.

Committee Member Hough requested an explanation of a sharps container.

Dr. Schell indicated that it is a container designed to protect people from inadvertently sticking themselves with a needle.

Fred Meyer, PPSI, stated that the changes should require the manufacturer to pay for the container.

Committee Member Hough stated that with the escalating costs of health care, who would pay for this. If it is required that the manufacturer pay for this container, it will result in the manufacturer raising their price. Mr. Hough also questioned if there is a problem with disposing of used needles in another fashion such as a milk bottle.

A representative from the Gray Panthers stated that this legislation is needed.

Committee member Dazé stated that individuals would be damaged by the improper disposal of a needle and expressed support for the legislation.

Dr. Phillips stated that inadvertent needle sticks is a big problem that results in emergency room visits.

Dr. Schell stated that this proposal provides a mechanism for disposal, but that this may not be the best solution.

A representative from the Gray Panthers suggested that perhaps the sharps container should be provided at cost.

Supervising Inspector Ratcliff stated that he is concerned about the potential impact on pharmacies and cited the scenario of a pharmacy dispensing a starter kit.

Committee Recommendation: Support

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would standardize the licensing requirements for ambulatory surgical centers.

Bryce Docherty representing the California Ambulatory Surgery Association provided a brief overview and history of this proposal and stated that this is similar to the legislation introduced last year that was vetoed by the governor.

Committee Member Dazé asked if the comments addressed in the governor's veto message have been addressed.

Mr. Docherty summarized the reason for the veto last year and stated that these concerns have been addressed in this new legislative proposal.

Dr. Schell indicated that the board anticipates a fiscal impact should this proposal be signed by the governor and asked if the current proposal includes money for the board.

Mr. Docherty responded that it is unclear how many new ambulatory surgery centers would seek licensure from the board and stated that he would need a cost breakdown from the board.

Executive Officer Herold stated that the board would require new staff.

Mr. Docherty stated that he would work with the board to secure the staff needed.

Executive Officer Herold asked if the Department of Health Services (DHS) is in support of this proposal.

Mr. Docherty stated that the DHS does not have a formal position on this bill.

Executive Officer Herold requested clarification on how a clinic becomes Medicare Certified.

Mr. Docherty stated that he understands the need for clarification.

Dr. Gray stated that the board's license would allow for a common stock of medications and would allow for a clinic to obtain a DEA permit and therefore allow for the dispensing of controlled substances.

Committee Recommendation: Support

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

This proposal would require all state agencies to answer public telephone lines within 10 rings.

Committee Member Dazé is concerned about an unfunded mandate on the profession and stated that he would not support this bill as written.

Committee member Hough stated that this bill could prove cost effective and that a consumer's time is worth something.

Committee Member Dazé stated his support for a similar requirement in Illinois that allows for a "zero out" option, rather than the bill in its current form.

Executive Officer Herold suggested that the board's concerns could be forwarded to the Department of Consumer Affairs (DCA).

Committee Recommendation: Neutral – forward concerns to the DCA

AB 1025 (Bass) Professions and Vocations: Denial of Licensure

This proposal would prohibit the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside or for an arrest where a final disposition has not occurred within one year.

Board staff indicated that this bill could pose a threat to public safety by curbing the board's ability to pursue administrative action.

Committee Member Dazé stated that it is a problem to deny a license if a conviction is not in place as an individual is innocent until proven guilty.

Executive Officer Herold stated that staff will seek clarification from counsel.

Committee Recommendation: None – seek clarification from counsel

AB 1587 (De La Torre) Personal Information: Pharmacy

This proposal would make exemptions to the definition of marketing materials.

Committee Recommendation: **None**

SB 963 (Ridley-Thomas) Regulatory Boards: Termination

This proposal would remove the Department of Consumer Affairs as the automatic successor in the event a board is "sunsetted."

Committee Recommendation: **None**

SB 966 (Simitian) Pharmaceutical Drug Disposal

This proposal would require pharmacies to accept then dispose of returned unused medications.

Committee Member Dazé stated that this bill is imposing a government mandate without funding. The solution could be to educate the public on the proper disposal of unused medications.

Board staff indicated that the author's office held a meeting with stakeholders to try to eliminate potential opposition to the bill. In addition board staff advised the committee of some amendments that were forthcoming.

Kathy Lynch, representing the CPhA stated that their organization has not taken a formal oppose position on this bill, but has identified several problems including the possible liability pharmacies would incur, the lack of funding for implementation as well as concerns about the disposal mechanism. She stated that the CPhA is looking for a workable solution.

Dr. Schell requested the CPhA's concerns in writing.

Dr. Cronin suggested that the board should reconsider its fiscal impact.

Mr. Docherty, representing the CSHP stated that CSHP also shares the concerns of CPhA and offered that a voluntary take back program may be a better solution than a mandatory one. Mr. Docherty also stated that CSHP would like a definition of "retailer" and asked what would be the ramifications on a pharmacist that refuses to take back the medications.

Dr. Gray stated that physicians and dentists also dispense medications and was questioning if they would also be required to take back unused medications.

Executive Officer Herold stated that several issues need answers and also expressed support for stakeholders attending a meeting with the author's office.

Committee Recommendation: None

AB 851 (Brownley) Prescription Drugs: Informational Insert

This proposal would require the inclusion of a large font informational insert with all prescription medications that could adversely interact with alcohol and/or other prescribed or over-the-counter medications.

Dr. Gray stated that there are currently certain requirements in the law to notify consumers, however this proposal expands those requirements to include over-the-counter medications. Dr. Gray indicated that this could be problematic. Dr. Gray indicated that there could be a fiscal impact.

Dr. Cronin stated that this information is already provided on the label and that perhaps consumer outreach is needed to have consumers learn about their medications.

Dr. Schell stated that he shares the concerns with this bill.

Executive Officer Herold reiterated the problems expressed and suggested that board staff talk to the author's office to help them refine the requirements.

Committee Recommendation: No Position

AB 1276 (Karnette) Pharmacies: Prescription Containers: Labels

This proposal would require the prescription label to include the intended use for the medication if noted on the prescription by the prescriber.

Kathy Lynch, CPHA stated that they support the findings of the Medications Error Panel Report and that the CPhA is working with the authors' offices on SB 472, AB 1276, AB 1399 and AB 851 but that the CPhA is concerned about four proposed unfunded mandates.

Dr. Gray suggested that all four proposals and the issue itself should be looked at in their entirety. Dr. Gray stated that currently there is no requirement to include the phone number of the dispensing site on the label.

Mr. Meyer stated that errors can be reduced with better prescription labels but that uncompensated mandated does not work. Mr. Meyer stated that pharmacists need to provide patient consultation.

Committee Recommendation: None

AB 1399 (Richardson) Pharmacies: Prescription Labels

This proposal would require a pharmacy to provide a prescription label that is readable by an assistive technology device if requested.

Dr. Gray stated that this requirement is already in federal law.

Board staff requested clarification as some chain pharmacies recently surveyed to do not currently use such technology.

Committee Recommendation: None

SB 472 (Corbett) Prescription Drugs: Labeling Requirements

This proposal is still in the drafting phase, but the intent is to ensure standardization of prescription labels.

Dr. Schell stated that this bill may be a vehicle to address the issues and intent of all four bills dealing with prescription labels and requested that the public provide their comments and concerns in writing for board consideration.

Committee Recommendation: None

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

This proposal would establish a scholarship and loan repayment program for pharmacy technicians and require all pharmacy technicians as well as pharmacies to contribute $10.00 at the time of renewal.

Committee Recommendation: None

SB 809 (Ashburn) Nurse Practioners

This proposal would expand the scope of practice for nurse practitioners to include, among other things, the independent prescribing and dispensing of medications.

Committee Recommendation: None

SB 822 (Aanestad) Psychology: Scope of Practice

This proposal would create a prescribing psychologist certification to allow the prescribing of limited medications by a certified psychologist.

Committee Recommendation: None

SB 993 (Calderon) Psychologists: Scope of Practice: Prescribing Drug

This proposal would expand the scope of practice for psychologists to include prescribing medications for specially trained and certified psychologists.

Committee Recommendation: None

Discussion and Public Comment on Pill Splitting

Dr. Charles Phillips provided information on the problems associated with pill splitting and stated that when a consumer splits pills, the medication does not split evenly. Dr. Phillips provided additional information about the problems with the practice of pill splitting and urged the board to prohibit the global practice.

Dr. Schell asked for comments on this topic in writing.

Due to time constraints, discussion on some of the pending legislation, as well as the topic of pill splitting did not occur.

Adjournment

The committee adjourned around 1:30 p.m.