MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: JANUARY 26, 2006
LOCATION: HOLIDAY INN CAPITOL PLAZA
300 J STREET
SACRAMENTO, CA 95814, (916) 446-0117
1:10 P.M. – 3:50 P.M.

BOARD MEMBERS PRESENT:

JOHN JONES, CHAIR
KENNETH H. SCHELL, MEMBER
DAVE FONG, MEMBER
ANDREA ZINDER, MEMBER

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
JAN PEREZ

The meeting was convened at 1:30 pm

Agenda Item B1 - Legislation

Ms. Perez stated that two bills had been introduced since January 4, 2006 relating to pharmacy law; AB 132 (Chapter 2, Statutes of 2006) Medicare Part D, and AJR 40 (Chan, 2006) Medicare Prescription Drugs.

Mr. Jones stated that the board does not take positions on Resolution bills.

Ms. Perez stated that to date none of the carry over bills from 2005 had been amended or set for committee hearings.

Agenda Item B2 – Legislative Proposals for 2006

Action Item 1. : Request from the Medical Board of California to amend B&P section 4301(e) related to "excessive" furnishing.

Ms. Harris stated that the Medical Board of California (MBC) had dropped its proposal to amend Business and Professions Code section 4301(e) to define the phrase "clearly excessive." The MBC is going forward with other proposals that are not in Pharmacy Law from its Pain Management Task Force. Josh Room (Deputy Attorney General) will review MBC proposal before it goes to Legislative Counsel.

John Cronin, CPhA, stated he was concerned that MBC was pursuing defining "clearly excessive" in B&P 725 and that the term would not be defined in Pharmacy Law.

General discussion on the issue resulted in a wait and see approach to what MBC will introduce; right now there is no bill in print. It available, staff will provide a copy of the January 20, 2006 MBC Pain Management Taskforce minutes, at the Pharmacy Board's February 1, 2006 meeting.

Action Item 2: Request from the Department of Justice to align California's Prescription Monitoring Program (CURES) with the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER).

Mr. Jones stated that DOJ is introducing legislation to conform to Federal Legislation. If CURES does not conform to Federal standards then California will miss an opportunity for Federal money.

Steve Gray, Kaiser Permanente stated that there were several concerns with NASPER and the board should talk to DOJ about modifying their proposed language and cleaning up some sections of the language that are unrelated to NASPER. Mr. Gray stated that the requirement that a patient's telephone number appear on the prescription was problematic. What if a patient doesn't have a telephone number? Can a pharmacist put a patient's telephone number on the prescription? Also problems with date of issue versus date of origin requirement and prescription number consistency.

Mr. Cronin stated that the DOJ should get clarification on terms, or not go after Federal money. Mr. Cronin asked if the Feds had aligned schedule drugs. Ms. Herold stated the Feds had not.

Bob Ratcliff, board supervising inspector, stated there were problems with terms such as date of origin.

George Pennebaker, CPhA, stated there were problems with the terms refill and new prescription and prescription numbering. Mr. Pennebaker would like computer standards consistent with NCPDP standards; some CURES programs do not meet these standards.

Mr. Fong asked if the issue could be raised at next week's NCPDP meeting?

Mr. Gray stated that while the amended language would require weekly reporting there is not equivalent language requiring DOJ to quicken its own reporting time; information from DOJ is often two to three months old.

Mr. Pennebaker stated that technology is available that would prevent excessive prescribing, but CURES is not taking advantage of that technology.

Ms. Harris stated that if the bill does not go through then DOJ will not get grant money. There is grant money for putting patients' reports online. Section 11165 deletes the provision that prevents board funds from being appropriated from to pay the costs of reporting Schedule III controlled substance prescriptions to CURES. Additionally, a feasibility study report (FSR) is going out to study real time data.

Ms. Harris stated there were aspects of the bill that should be looked at – clarify date of origin, refill, and look into change in funding source.

Committee Action – Right now there is no bill in print to take action on or move to the board. The Committee directed board staff to talk to DOJ and author of the proposed bill.

Action Item 3: Proposal to amend B&P sections 4314 and 4315 to authorize the issuance of citations and fines for violation of law related to the voluntary drug repository and distribution program for prescription drugs in county pharmacies.

Committee Action – Approved language and move to the board. The discussion that followed focused on implementing SB 798 (Chapter 444, Statues of 2005).

Mr. Cronin stated that there were problems with SB 798 and implementing it, in light of pedigree requirements and other issues, would be difficult. Mr. Cronin asked if the board could come up with some guidelines for pharmacies that wish to participate in program; the guidelines could be in the form of questions and answers.

Mr. Schell stated that if the board produces guidelines for board inspectors then may be those guidelines could be modified for pharmacy use.

Ms. Harris stated that board President, Stanley Goldenberg, was talking to the Long Term Care Council. Ms. Harris suggested that the board watch Santa Clara County's implementation of SB 798.

Ms. Herold stated that it might be an issue to take up in the board's pedigree taskforce.

Action Item 4. Amend B&P section 4162, resident wholesalers, to waive the surety bond requirement for government owned and operated wholesalers.

Ms. Harris stated that government agencies do not pay fees and they are self-insured.

Mr. Gray asked to have intent clarified.

Ms. Herold stated that there are eight government owned wholesalers in California two of which have drugs stored for disasters. As a "professional courtesy" government agencies don't charge each other fees. The board would like the law to be clear that we do not expect government agencies to provide a surety bond.

Committee Action – Approve language for board consideration.

Item 5: At the Legislation and Regulation Committee meeting in October, the Committee approved three Legislative proposals. At the February board meeting, the board needs to approve each of the legislative proposals. These proposals are provided for information.

Mr. Gray, with regards to 4182would like it if it was required that a copy of the consulting pharmacist certification was be sent to the director of the clinic. Mr. Gray would also like an amendment to 4182(c) to add the word "respectively" to the section.

Not on the Agenda, late arrival received by staff via e-mail, was brought to committee for committee information. California Chapter of the American College of Emergency Physicians is considering a minor legislative modification to clarify B&P section 4068 related to the dispensing of pre-packaged 'starter packs' to selected emergency department patients.

A representative from the American College of Emergency Physicians was not at the meeting. Ms. Harris stated that she had not heard of any complaints from hospitals regarding this problem.

Mr. Ratcliff stated that the Pharmacy Law does not define "out patient" pharmacy.

Maria Serpa stated that the proposal may be in response to dispensing machines.

Candace Fong, Sutter Roseville Medical Center, would like to see exclusion even if the hospital has a 24-hour pharmacy. Ms. Fong would like to have pre-packaged meds available so they do not have to go through the "pharmacy system."

Mr. Gray questioned if this were to go through, who would do the dispensing in a busy emergency room? Unlikely a doctor or RN would dispense meds.

A gentleman from Sutter Saint Luke's in SF stated that they hold patients in the emergency room until the patient has taken their medication.

Ms. Serpa stated that if the proposal were to go through then the emergency room would loose pharmacy counsel.

Mr. Schell recounted his experience working in a hospital where he said a pharmacist was not always able to get to the emergency room in quick time; this is why the proposal was likely brought forward.

Mr. Gray stated that RNs are allowed to dispense in clinics, but not in the ER; there might be a solution here to have RNs dispense.

Mr. Pennebaker, what about hospitals without 24 hour pharmacist?

Mr. Gray stated that DHS should look at the proposal because ER patients are an anomaly, in that they are patients that are not admitted to the hospital.

Agenda Item C1 – Regulation Update

Committee Approved -1760, Disciplinary Guidelines.

Mr. Cronin stated that the wording after the double dashes [--the presence of mitigating factors; the age of the case; evidentiary problems] could be deleted.

Ms. Harris said she would check with Mr. Room.

Committee Approved -1784, Self-Assessment of a Wholesaler by the Designated Representative-In-Charge, language.

Agenda Item C2 – Regulation Proposals for 2006

Action Item 1: Request from the California Society of Health-System Pharmacists to amend 16 CCR section 1793.7 and 1793.8, to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes.

Susan Ravnan, California Society of Health-System Pharmacists (CSHP), read testimony and provided the board with a handout of background information. [This handout will be part of the board packet for the board's February 1, 2006 board meeting.] Ms. Ravnan would like the committee to forward the proposal to the board for consideration.

Mr. Pennebaker presented a letter to the board from Lynn Rolston, CEO CPhA. [This letter will be part of the board packet for the board's February 1, 2006 board meeting.] Mr. Pennebaker would like TCT a with pharmacy service plan, only in acute care hospital settings.

Ms. Judith Wolen, California Hospital Association, supports CSHP's proposal.

Ms. Harris stated that the committee has the language from CSHP and letter from CPhA, what direction would the committee like to take.

Ms. Zinder would like the committee to work on resolving differences between CSHP and CPhA prior to moving the proposal to the board.

Committee Action – Approve to move the proposal to the board. Mr. Jones, Mr. Fong, and Mr. Schell, voted in favor and Ms. Zinder voted against the motion. Mr. Jones asked CSHP and CPhA to work on amending the proposal for next week's board meeting.

Action Item 2. Proposal to repeal 16 CCR section 1786 - An outdated provision related to exemptees.

Committee Action – Approve language for board consideration.

Action Item 3. Revised language incorporating comments from the October 2005 public hearing to repeal 16 CCR section 1717(e) and to add 16 CCR section1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions.

Ms. Perez read the following description of the proposal: The Legislation and Regulation Committee is considering a proposed regulation for prescription drop boxes and automated delivery devices. This proposed regulation is based on public comment and board discussion received at the board's October 25, 2006 meeting, on the October 19, 2005 version of the regulation. The January 26, 2006 version of the regulation further strengthens consumer protections from earlier versions of the regulation. Specifically, the new language would require:

1) a consumer to sign a consent form stating that the consumer has chosen to use the delivery device;
2) a pharmacy to provide a means for each patient to obtain an immediate consultation with a pharmacist via phone or in person if the patient request a consultation;
3) complaints received from patients to be reviewed as part of a pharmacy's quality assurance program;
4) pharmacies to have procedures in place to notify patients when expected prescriptions are not available in the device; and
5) pharmacies to have producers in place to ensure the delivery of prescriptions to patients in the event that a device is disabled or malfunctions.

Ms. Harris stated that the word "adjacent" comment from October 25, 2005 was not incorporated into the new language.

Ms. Zinder stated that she thought the board was not going forward with this regulation. She asked where the proposal came from.

Ms. Harris stated that Asteres Inc. and others had asked that it be brought back to the committee as a new proposal. Ms. Harris and Ms. Herold clarified that at the board's October 25, 2005 meeting the board motioned to table the discussion.

Mr. Cronin stated that he would like his comments from October 2005 reflected in the new proposed language. Mr. Cronin stated that section 1713(e)(6) should be strengthened to state specifically how a patient would receive meds in the event that the device is disabled or malfunctions. Mr. Cronin suggested that language similar to SB 644 (Chapter 417, Statutes of 2005) could be added that would require a pharmacy to direct a patient to the nearest pharmacy where their prescription could be filled.

Mr. Fong stated that there could be a 1-800 number available on the machine for patients to call when the machine does not dispense their meds.

Mr. Ratcliff stated that the situation is no different than if the power goes out in a pharmacy; patients would not be able to get their prescriptions in that case. Mr. Radcliff stated that the language was generic enough that a pharmacy could come up with the procedures that would work best for that particular pharmacy. Additionally, if the board were to investigate consumer complaints about the machines the board would focus on if a patient was able to get their prescription in a reasonable length of time.

Mr. Gray stated that pharmacies that use the machines would be held to a higher standard. Right now if a pharmacy decides to close early for the day, then patients are not able to get their prescriptions; the law does not require the pharmacy to have procedures in place for patients to get their prescriptions if the pharmacy closes early.

Bob Hansen, Vice President Pharmacy Services, Asteres Inc., stated that the machines have a back up battery to operate and once they are down, they can reboot on their own, however, if the power in the pharmacy goes out, then the pharmacy's computers will have to be turned on/rebooted by some one so that pharmacy's computers can talk with the ScriptCenter®.

Ms. Cooky Quandt, Corporate Pharmacy Compliance Manager, Longs Drugs, asked what was meant by the word "omissions" in 1713(d)(9)? Based on usual quality assurance? Additionally she asked the purpose of adding "notifying patients when expected prescriptions are not available in the device," to section 1713(e)(5).

Mr. Jones stated that section 1713(e)(5) was in case a medication was not in stock or a pharmacist wants to consult with a patient.

Mr. Schell stated that the procedures should be the same as if meds are not available from the pharmacy.

Ms. Quandt stated that it seemed a higher standard was being placed on the machines then the pharmacy.

Mr. Jones stated that the board might have higher expectations for the machines.

Mr. Hansen stated that in addition to the states he listed in his letter to the board, there are four additional states that have regulations pending for the use of the machines.

A discussion then took place between Mr. Cronin, Mr. Jones, Mr. Fong, Ms. Harris, and Ms. Zinder on what comments from the October 2005 board meeting had been incorporated into the new language.

Ms. Zinder asked about Pharmacy Service Plans and that not incorporating the plans into the new language was a major omission.

Mr. Jones stated that the board discussed Pharmacy Service Plans.

Mr. Cronin requested that the committee have an informational hearing on the proposed language at the next committee meeting.

Committee Action - Support the proposed language, move to the board. Mr. Jones, Mr. Schell, and Mr. Fong voted in favor. Ms. Zinder voted No.

Agenda Item D. Overview of the Board of Pharmacy's Sunset Review Process

The board will undergo sunset review this year. The board's Sunset Review Report is due to the Legislature by September 1, 2006.

Mr. Jones asked if there was any public comment for items not on the agenda. None.

Next Legislative and Regulation Committee Meeting

The next meeting is set for April 19, 2006 from 10am-1pm in Sacramento.

Adjournment

The committee adjourned at 3:50 pm.