MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: January 8, 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, Legislation and Regulation Manager

Chairperson Schell called the meeting to order at 9:32 a.m.

Approved Regulations

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

1. The "Tech Check Tech" regulation, which amends 1793.7 and adds 1793.8, became effective January 5, 2007.

   This regulation allows for and defines the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting.

   Interim Executive Officer Herold advised the committee that Cedars Sinai Hospital issued a Press Release regarding the Tech Check Tech regulation and its contributions to patient safety by redirecting pharmacists to clinical areas within the hospital.

   It was recommended that a FAQ be developed on the regulation to reiterate that the regulation only applies to acute care hospitals, along with other items generating questions to the board.

   Discussion included questions about how the board will enforce this regulation and whether the regulation should be amended to set a

minimum performance level for the technicians completing the second check.

2. The Automated Delivery Device regulation, which repeals 16 CCR 1717(e) and amends 16 CCR 1713, will take effect January 26, 2007.

   These changes will allow pharmacy patients the ability to use a vending-like machine located near the pharmacy to obtain their refill medication if they choose to do so. This regulation also allows the use of a prescription drop-off box outside the pharmacy as a means to leave a prescription for a pharmacy to later fill.

   Interim Executive Officer Herold indicated that the board will routinely check for problems during the course of routine and complaint inspections and reiterated that the pharmacy is responsible for the security of the drop box and delivery device.

Board Adopted Regulations

The committee was advised that two regulations recently adopted by the board at the October Board Meeting are currently undergoing administrative review.

1. The repeal of 16 CCR 1717.2 was just approved by the Department of Consumer Affairs and will be forwarded to the Office of Administrative Law.

   The repeal of this section 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.

2. The addition of CCR 1784 is still under review by the Department.

   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.

The committee posed questions about the timeframe to complete a rulemaking file and staff provided a brief overview of the process and the current turn around time for department review.

Board Approved Regulations Currently Noticed

The committee was advised that two regulations are currently noticed.

1. Amendment to 16 CCR 1706.2

   In 1997, the board established the provisions of 1706.2 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 update the regulation to add veterinary food-animal drug retailer, hypodermic needles and syringes, pharmacist interns and designated representatives to the regulation.

   The comment period for this proposal will close on February 5, 2007.

2. Amendment to 16 CCR 1775.4

   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.

   The comment period for this proposal will close on February 5, 2007.

According to Department of Consumer Affair's Legal Office, the board may take action on the two pending regulations at the January 2007 Board Meeting as long as a motion is made to adopt the regulations as noticed and no negative comments or substantive changes are recommended.

Discussion included whether the board has the latitude to reschedule the informal office conference referenced in CCR 1775.4 without it counting as a cancellation. Staff will follow up with staff counsel to confirm the language as noticed will allow for this.

MOTION: Recommend that the board adopt of these two regulations at the January 2007 Board Meeting to ensure the timely processing of the rulemaking file and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment

period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

Board Approved Regulations Awaiting Notice

1. Section 100 Changes

The committee discussed previously approved Section 100 regulation changes as well as the process involved in completing this type of rulemaking. Section 100 or rulemaking without regulatory impact changes are made to keep the regulations consistent with statutes. This is an expedited process without a formal notice process.

Items to be included in this rulemaking include, amendment to CCR 1709.1, CCR 1780, CCR 1780.1 and 1781 and CCR 1786. Interim Executive Officer Herold summarized each proposal and discussed the need for each of the changes.

2. Disciplinary Guidelines

The committee was advised that modifications were being made to the Disciplinary Guidelines that will be brought to the April 2007 Board Meeting.

3. California Building Standards

At the April 2006 Board Meeting, the board agreed to request amendments to California Building Code regarding provisions for compounding of injectable medicine from nonsterile components to contain provisions currently required in California Business and Profession Code. Interim Executive Officer Herold provided a brief history and overview of the rulemaking process to modify the California Building Standards Code including that staff will now need to convert these changes into a new format to comply with the Building Standards Commissions' new process and will re-notice the proposal.

Discussion included how the board is notified of changes to the Building Code that the board does not initiate and who is responsible to ensure consistency between requirements in pharmacy law and those found in Building Standards Code.

Supervising Inspector Ratcliff explained that inspectors confirm compliance during routine inspections and complaint investigations. Interim Executive Officer Herold also stated that the Building Standards Commission must also check with the board in advance of making changes that would affect board licensees. Additionally, the board

receives inquiries from architects and others regarding building requirements.

Board Approved Regulations – Proposed Language to be Developed

1. Process and Criteria to Approve Accreditation Agencies for Pharmacies.

   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.

   The committee was provided with a summary of this proposal. Staff will develop the draft language in concert with staff counsel to be provided a future committee meeting for consideration.

2. Notice to Consumers

   The committee was advised that at the next Communication and Public Education Committee Meeting a final draft of the revised Notice to Consumers poster (to make the wording compliant with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) regarding a patient's right to lawfully obtain prescribed medications from a pharmacy) will be discussed. Upon approval by the board, this notice will need to be incorporated into CCR 1707.2 in a future rulemaking.

Proposed Legislation

1. 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

   Interim Executive Officer Herold summarized each proposal as well as the need for each of the changes. At the October Legislation and Regulation Committee Meeting, staff had recommended revisions to B & PC 4312, but after further review and discussion, removed this request.

Ms. Herold explained what constitutes an omnibus provision and indicated that the board has an author to carry this legislation.

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

Interim 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.

An article is included in the newest version of *The Script*, which will provide information to licensees about the board's intent to enforce these new CURES requirements via an educational emphasis for the first six to 12 months.

Discussion from the public included frustration on the part of pharmacies who are receiving unclear information from the DOJ about the expansion as well as new software standards that are required, but are not included in the legislation.

A representative from the DOJ indicated that they are receiving a lot of calls from individuals about the new requirements. The DOJ is currently working the contractor responsible for accepting the data to ensure conformity with these new requirements, but a new contract has not been obtained.

A concern was expressed that the board will be aggressively enforcing this new requirement. Interim Executive Officer Herold responded that the board intends to take a transitional and educational approach with licensees. Supervising Inspector Ratcliff reiterated that board inspectors will provide guidance, not aggressive enforcement to ensure compliance for the first six to 12 months.

Discussion also surrounded a recommendation to pursue emergency legislation to achieve some of these changes because of a potential violation of HIPAA. Interim Executive Officer indicated that it may not be possible to demonstrate the urgency and that to be successful a coalition would need to advocate for the change.

Comments from the public indicated that the proposed changes make the requirements clear however there is still an outstanding issue about the

inconsistency between state and federal classifications of some drugs, and which schedule determines if a drug should be reported to CURES.

Interim Executive Officer Herold that staff will seek input from counsel.

The DOJ indicated that they hope to have pharmacies compliant with the new ASAP software requirements by July 2007.

A representative from Longs expressed concern about the ASAP software requirements as they had not been made aware of the requirement.

MOTION: Recommend to pursue changes with the understanding that staff will continue to work on the language with interested stakeholders.

3. Licensing of Headquarters for Chain Pharmacies

Interim Executive Officer Herold explained that the board currently has an informal process already established for chain store pharmacies, to renew and purchase pharmacies; however the law does not recognize the construct of "headquarters." This could be considered an underground regulation. This proposal would authorize a headquarter to enable a chain to renew 15 to 800 licenses all at one time, which greatly simplifies processing for licensees as well as the board.

Dr. Schell indicated that the proposal seemed reasonable but expressed concern that the board could potentially revoke a headquarters license. Ms. Herold explained that currently a headquarters is more of a convenience. If the board were to discipline a headquarters, if would do so. If revocation were pursued, it would mean revocation of all pharmacies in the state owned by the Corporation. The board has the authority to do this now; it would just have to be done on a store by store basis.

Board staff will continue to explore this issue and will present a recommendation at a future committee meeting if appropriate.

Proposed Regulations

1. Section 100 Rulemaking without Regulatory Effect

Board staff presented two additional Section 100 changes for committee consideration: amend CCR 1715 – Self Assessment Forms to update changes in pharmacy law since the last revision of this form, and amend CCR 1793.8. 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.

MOTION: Recommend the board accept these proposals at the January 2007 board meeting.

2. 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 process for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with California 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.

MOTION: Recommend the board approve this proposal at the January 2007 board meeting.

Public Requests for Future Legislation and Regulatory Proposals

1. Supervising Inspector Ratcliff requested the committee to consider an amendment to CCR 1707.3. Currently this regulation requires a drug utilization review on a new prescription. The recommendation proposed would require this review on all prescriptions, new or refill.

   Supervising Inspector Ratcliff reiterated that this proposal is not to require consultation on all prescriptions, rather just that a drug utilization review be completed in advance of dispensing the medication.

   Comments from the pubic indicate that several organizations already do this.

2. Steve Gray suggested that the board repeal the section of the Health and Safety Code that requires the board to approve a pharmacy's computer system for controlled substances.

   Staff will work on this proposal with Dr. Gray and bring it to the next Legislation and Regulation Committee Meeting.

3. Steve Gray requires that the board pursue legislation that would require that a criminal background check be required on a pharmacy technician trainee.

Interim Executive Officer Herold requested that Mr. Gray provide a draft of his proposal for consideration.

4. Interim Executive Officer Herold proposed that the board consider developing a protocol consistent with CDC guidelines for pharmacists to provide immunizations for flu vaccines according to a state protocol developed as a regulation, similar to the process used for the emergency contraception state protocol.

   Discussion on this topic included that this would be important in response to a disaster and that a coalition may need to be formed to ensure the success of this proposal.

New Business

Dr. Gray requested clarification of a new law that allows a physician to write a prescription for a patient's partner with a communicable disease. Dr. Gray asked for guidance on how this law will be implemented specifically for how to label the container for the partner and suggested that a newsletter article discussing this topic would be valuable.

Adjournment

The committee adjourned at 11:55 a.m.