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

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LEGISLATION AND REGULATION COMMITTEE July 5, 2007 1:00 p.m. – 5:00 p.m. Department of Consumer Affairs Hearing Room

epartment of Consumer Affairs Hearing Roon 1625 North Market Blvd. Sacramento, CA 95834

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Gloria Schultz at (916) 574-7912, at least five working days prior to the meeting.

Opportunities are provided to the public to address the committee on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

*Times are approximate and are subject to change

- A. Call to Order 1:00 p.m.
- B. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction
 - 1. Proposed Legislation Board Sponsored
 - a. Omnibus Provisions
 - Adulterated or Counterfeit Drugs or Dangerous Devices B&PC section 4084
 - Wholesaler: Bonding Requirements B&PC sections 4162 and 4162.5
 - Citation and Fine for Repository and Distribution Programs for Dangerous Drugs B&PC sections 4314 and 4315
 - Temporary License Fees for Wholesalers B&PC section 4160(f) and 4161(k)
 - Intern Pharmacist License B&PC section 4208
 - Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board B&PC section 4101
 - Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient;
 Requirements B&PC section 4068
 - 2. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction for Committee Consideration
 - a. Active Bills with Positions Taken by the Board
 - 1. AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects
 - 2. AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

- 3. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure
- 4. AB 1025 (Bass) Professions and Vocations: Denial of Licensure
- 5. AB 1587 (De La Torre) Personal Information: Pharmacy
- 6. SB 472 (Corbett) Prescription Drugs: Labeling Requirements
- 7. SB 606 (Scott) Pharmaceutical Information: Clinical Data Trial
- 8. SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program
- 9. SB 963 (Ridley-Thomas) Regulatory Boards: Termination
- 10. SB 966 (Simitian) Pharmaceutical Drug Disposal
- b. Inactive Bills with Positions Taken by the Board
 - 1. AB 501 (Swanson) Pharmaceutical Devices
 - 2. AB 851 (Brownley) Prescription Drugs: Informational Insert
 - 3. AB 865 (Davis) State Agencies: Live Customer Service Agents
 - 4. AB 1276 (Kamette) Pharmacies: Prescription Containers: Labels
 - 5. AB 1399 (Richardson) Pharmacies: Prescription Labels
 - 6. AB 1436 (Hernandez) Nurse Practitioner: Scope of Practice
 - 7. SB 809 (Ashburn) Nurse Practitioners
 - 8. SB 993 (Calderon) Psychologists: Scope of Practice: Prescribing Drugs

3. Other Legislation Introduced (for Information Only)

- a. Active Bills
 - 1. AB 14 (Laird) Discrimination: Civil Rights Act of 2007
 - 2. AB 64 (Berg) Uniform Emergency Volunteer Health Practitioners Act
 - 3. AB 106 (Berg) Immunizations
 - 4. AB 329 (Nakanishi) Chronic Diseases: Telemedicine
 - 5. AB 1302 (Horton) Health Insurance Portability and Accountability Act
- b. Inactive Bills
 - 1. AB 374 (Berg) California Compassionate Choices Act
 - 2. AB 436 (Salas) Health Insurance Portability And Accountability Act Of 2001
 - 3. AB 555 (Nakanishi) Healing Arts: Medical Records
 - 4. AB 703 (Ruckin) Social Security Numbers
 - 5. ACR 9 (Dymally) Legislative Task Force on Substance Abuse
 - 6. SB 254 (Aanestad) Health Facilities: Licensure
 - 7. SB 907 (Calderon) Physicians and Surgeons: Referrals

C. Approved Regulations

- 1. Proposed Adoption of 16 CCR 1784 Self-Assessment of a Wholesaler by a Designated Representative-in-Charge
- 2. Proposed Amendment of 16 CCR 1706.2 Abandonment of Application Files

D. Board Adopted Regulations – Pending Administration Review

- 1. Section 100 Changes
 - Proposed Amendment to 16 CCR 1709.1 Replace the Term "Exemptee-in-Charge" with "Designated Representative-in-Charge"
 - Proposed Amendment to 16 CCR 1780.1 and 1781 Replace the Term "Exemptee" with "Designated Representative"
 - Proposed Repeal of 16 CCR 1786 Return of Exemption Certificates
 - Self Assessment Forms for Pharmacies 16 CCR 1715

- Pharmacy Technicians in Hospitals 16 CCR 1793.8
- Waiver Requirements for Off-Site Storage of Records 16 CCR 1707
- Authorization to Distribute Dialysis Drugs and Devices 16 CCR 1787
- Assembling and Packaging 16 CCR 1790
- Pharmacy Practice 16 CCR 1719
- 2. Addition to the California Building Code 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies

E. Board Approved Regulations Currently Noticed – Action Recommended at July 2007 Board Meeting

- 1. Proposed Amendment of 16 CCR 1707.2 Notice to Consumers
- 2. Proposed Amendment of 16 CCR 1749 Fee Schedule

F. Board Approved Regulations Awaiting Notice

- 1. Section 100 Changes
 - Proposed Amendment to 16 CCR 1780 Update the USP Standards Reference Material
- 2. Proposed Amendment to 16 CCR 1760 Disciplinary Guidelines
- 3. Proposed Amendment to 16 CCR 1785 Self-Assessment of a Veterinary Food Animal Drug Retailer

G. Board Approved Regulation – Proposed Language

1. Proposed Addition to 16 CCR 1752 - Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Adjournment: 5 p.m.

Committee materials will be available on the board's Web site by June 29, 2007.