



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Public Board Meeting

October 28-29, 2014

Contact Person: Laura Hendricks
(916) 574-7918

This board meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@dca.ca.gov or sending a written request to the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

DATE: October 28-29, 2014

PLACE: Sheraton Park Hotel
1855 South Harbor Blvd.
Anaheim, CA 92802

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(Link to Webcast will not be available until 9 a.m. on October 28, 2014)

NOTE: Pharmacists and pharmacy technicians who attend in person this Board Meeting may be awarded 6 hours of CE, in accordance with the board's CE policy. Sign in and sign out on October 28th are required for the CE credit.

Additionally pharmacists who wish to register with CURES may do so at this meeting by following the CURES Registration Information sheet that follows as the last page of this agenda. Registration will be open from 9:00 a.m.-11:30 a.m. on October 28th and October 29th. Instructions for registration follow this agenda.

For verification of the meeting, call (916) 574-7918 or (916) 574-7900 or access the board's Web site at www.pharmacy.ca.gov.

AGENDA

Tuesday, October 28, 2014

Call to Order

9:00 a.m.

I. GENERAL ANNOUNCEMENTS AND OVERVIEW OF CURES REGISTRATION PROCEDURES FOR BOARD OF PHARMACY

II. TRIBUTE AND RECOGNITION OF CLARENCE HIURA (1934-2014)

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JULY 30-31, 2014

IV. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

V. LEGISLATION AND REGULATION COMMITTEE

Note: There has been no meeting of the Legislation and Regulation Committee since April 2014.

Part 1: Legislation Report

a. Board-Sponsored Legislation

1. SB 960 (Morrell) Pharmacy Licenses: Letters of Admonishment; Chapter 247, Statutes of 2014
2. SB 1466 (Committee on Business, Professions and Economic Development) Omnibus Provision Related to Requirements for a Designated Representative; Chapter 316, Statutes of 2014
3. SB 600 (Lieu) Repeal of Pedigree Requirements, Chapter 492, Statutes of 2014
4. AB 2605 (Bonilla) Requirements for Third Party Logistics Providers; Chapter 507, Statutes of 2014

b. Chaptered Legislation

1. AB 1535 (Bloom) Pharmacists: Naloxone Hydrochloride; Chapter 326, Statutes of 2014
2. AB 1702 (Maienschein) Professions and Vocations: Incarceration; Chapter 410, Statutes of 2014
3. AB 1727 (Rodriguez) Prescription Drugs: Collection and Distribution Program; Chapter 155, Statutes of 2014
4. AB 1743 (Ting) Hypodermic Needles and Syringes; Chapter 331, Statutes of 2014
5. AB 1841 (Mullin) Medical Assistants; Chapter 333, Statutes of 2014
6. AB 2396 (Bonta) Convictions: Expungement: Licenses; Chapter 737, Statutes of 2014
7. AB 2720 (Ting) State Agencies: Meetings: Record of Actions Taken; Chapter 510, Statutes of 2014
8. SB 1039 (Hernandez) Pharmacies: Furnishing Drugs; Chapter 319, Statutes of 2014

9. SB 1159 (Lara) Professions and Vocations: License Applicants: Individual Tax Identification Number, Chapter 757, Statutes of 2014
 10. SB 1226 (Correa) Veterans: Professional Licensing, Chapter 657, Statutes of 2014
- c. Vetoed or Failed Legislation
1. AB 2757 (Bocanegra) Centralized Hospital Packaging Pharmacies: Medication Labels
 2. SB 204 (Corbett) Prescription Drugs: Labeling
 3. SB 1014 (Jackson) Pharmaceutical Waste: Home Generated
 4. SB 1258 (DeSaulnier) Controlled Substances: Prescriptions: Reporting
 5. AB 2058 (Wilk) Open Meetings
 6. AB 2147 (Melendez) Website: Information Practices
 7. AB 2418 (Bonilla / Skinner) Health care coverage Rx drug refills
- d. Discussion of Legislative Proposals for 2015

Part 2: Regulation Report

- a. Board Approved – Undergoing Administrative Review (Information Only)
Update on Rulemaking to Amend Title 16 CCR Section 1707.5 Regarding Patient-Centered Labeling Requirements
- b. Board Approved – Awaiting Notice
 1. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements
 2. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education
 3. Proposal to Amend Title 16 CCR Section 1703 Related to “Section 100” Regulatory Actions
- c. Regulation Proposals – Possible Action Items
 1. Recommendation to Amend Title 16 CCR Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14, 17M-26 and 17M-35
 2. Recommendation to Further Amend Title 16 CCR Section 1732.5 Related to Renewal Requirements for Pharmacists – Continuing Education

VI. LUNCH

A lunch break will be taken at some point during the day’s meeting.

VII. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE

Report of the Meeting Held August 26, 2014.

3. Report on California’s Opioid Misuse and Overdose Prevention Work Group Prescription Drug Headed by the Director of the State Department of Public Health
4. Summary on CURES Data Regarding Controlled Substances Dispensed in California and Controlled Substance Diversion for Fiscal Year 2013-14; and Board Funding for CURES
5. Discussion About Recommendations Developed by the National Council for Prescription Drug Programs (NCPDP) for Improving Prescription Drug Monitoring Programs
6. Review of Red Flags Video on Corresponding Responsibility Produced by the National Association of Boards of Pharmacy (NABP)

7. Summary of the September 2014 Meeting of the Medical Board of California's Prescribing Task Force
8. Summary of a Presentation by Angela Crispo, PharmD, on Counseling Tips for Pharmacists on Opioid Prescriptions
9. Summary of a Presentation by Consumer Reports on the Dangers of Painkillers Presented by Doris Peter, PhD.
10. Summary of a Presentation on Opioid Addiction, Recovery and the Personal Experiences of Jason Smith
11. Report on the Joint DEA/Board of Pharmacy CE Program on Drug Abuse and Corresponding Responsibility in Santa Barbara on September 2 and 3, 2014
12. Report on the DEA Drug Take Back Event Held on September 27, 2014
13. Summary of Additions to the Board of Pharmacy Prescription Drug Abuse Prevention Website Page
14. Review of Articles Documenting Issues of Prescription Medication Abuse
15. Review of Public Outreach to Address Prescription Drug Abuse

VIII. SB 493 IMPLEMENTATION COMMITTEE

Report of the Meeting held August 6, 2014.

- a. Review of a Proposed Project Plan for Implementation of SB 493
- b. Discussion Regarding Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:
 1. For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices
 2. For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US
 3. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies
- c. Summary of the Discussion on the Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols
- d. Summary of the Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols
- e. Summary of the Discussion on Application Requirements of the Advanced Practice Pharmacist License
 1. Board of Pharmacy Specialties Certification Programs
 2. Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy)
 3. Other Programs Envisioned or Under Development
- f. Development of Elements for Advanced Practice Pharmacist Licensure
 1. Initiation of Rulemaking to Identify Certificate Programs of the Board of Pharmacy Specialties

IV. ENFORCEMENT AND COMPOUNDING COMMITTEE

Report of the Meeting Held September 16, 2014.

Part 1: Enforcement Matters

- a. Discussion and Possible Action to Modify 16 California Code of Regulations Section 1744 Regarding Required Warning Labels on Prescription Container Labels
- b. Discussion and Possible Action to Seek Repeal of Health and Safety Code Section 11164.5(a), Approval to Receive Electronic Prescriptions for Controlled Substance Prescriptions
- c. Discussion and Possible Action on a Proposed Regulation for Community Pharmacies Aimed at Reducing Losses of Controlled Substances
- d. Discussion Regarding the Future Demonstration of the Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for Identification of Medication Diversion from These Units
- e. Discussion Regarding the Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication
- f. Discussion of the Federal Rescheduling of Hydrocodone to Schedule II
- g. Discussion of the Federal Rescheduling of Tramadol to Schedule IV
- h. Update on the Alternative Process for Pharmacists to Become Registered to Access CURES
- i. Summary of a Presentation by Rita Shane, PharmD, FASHP, FCSHP on Medication Reconciliation in Health Care Facilities
- j. New Committee Issues Scheduled for Board Discussion at This Meeting (Not Discussed at the September 2014 Meeting)
 - 1. DEA Release of Drug Take Back Regulations
 - 2. FDA Guidance on Drug Supply Chain Security Act
 - 3. Publication of a Board Appeal Decision Involving License Revocation Involving Fraud
 - 4. National Transportation Safety Board and its "Drug Use Trends in Aviation: Assessing Pilot Impairment"
- k. Enforcement Statistics, 1st Quarter 2014-15

Part 2: Compounding Matters

- a. Discussion Regarding FDA's Expectations for Human Drug Compounders
- b. Results of the Board's Implementation and Inspections of California Sterile Compounding Facilities
- c. Data on Violations Found During Out of State Compounding Inspections
- d. Recalls of Compounded Drugs Throughout the United States
- e. Future Meeting Dates

X. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

ADJOURNMENT FOR THE DAY

Wednesday, October 29, 2014

XI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

RESUMPTION OF OPEN SESSION

9:00 a.m.

XII. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

XIII. LICENSING COMMITTEE REPORT

Note: There has been no Licensing Committee Meeting since June 26, 2014.

- a. Request from West Coast University Possessing ACPE “Pre-Candidate” Accreditation for Recognition by the Board of Pharmacy Under Section 16 CCR § 1719 for Purposes of Issuing Intern Licenses
- b. Discussion and Possible Action on Requests for Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Sections 4128 et seq., From Palomar Medical Center
- c. Discussion and Possible Action to Seek Amendments to Business and Professions Code Section 4209 Relating to Intern Experience Requirements, and to Title 16 California Code of Regulations Section 1728. Also Relating to Intern Experience Requirement
- d. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs for the Board
- e. Proposed Amendment to Title 16 California Code of Regulations Section 1793.5 to Update the Pharmacy Technician Application Form
- f. Competency Committee Report and Examination Statistics
- g. Licensing Statistics

XIV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Report of the Meeting Held September 18, 2014.

- a. Discussion Concerning the Parameters for Patient Consultation as Required by 16 California Code of Regulations Section 1707.2
- b. Discussion and Possible Action on the Resumption of the Board’s Assessment of California’s Patient-Centered Labeling Requirement
 1. Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer’s Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?
 2. When a Generic Drug Is Dispensed, Should the Brand Name of the Generic Equivalent Be Included on the Label Phrased as “Generic for _____”?
 3. Should Purpose or Condition Be a General Requirement for Labels?
 4. Should the Existing Requirements for “Added Emphasis” in the Patient-Centered Area of the Prescription Label Be Modified?
 5. Translations on Labels:

- A. Translated Directions for Use Are Available on the Board’s Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
- B. Should There Be a Specific Requirement for Labels to Be Translated?
- 6. Should the Board Adopt Liquid Measurement Standards as recommended by NCPDP?
- 7. Should the Board Consider Technology Standards to Enhance the Patient-Centered label?
- c. Discussion and Possible Action to Adopt a Board Policy Statement Recommending the Elimination of Tobacco and E-Cigarette Sales from California Pharmacies
- d. Update on The Script
- e. Update on the Board’s Consumer Education Brochure on Counterfeit Drugs
- f. Update on Media Activity
- g. Report of Public Outreach Activities Conducted by the Board
- h. Review and Discussion of Articles on Issues of Interest
- i. Discussion of the 43rd Annual Report of the Research Advisory Panel of California

XV. ORGANIZATIONAL DEVELOPMENT COMMITTEE

Note: Several ad hoc teleconference meetings of the Organizational Development Committee have occurred to discuss items that required immediate attention.

- a. Future Board Meeting Dates for 2015
- b. Budget Update/Report
 - 1. Budget Report for 2014/2015
 - 2. Final Budget Report for 2013/2014
 - 3. Fund Condition Report
 - 4. Fee Audit Underway
 - 5. Update on BreEZe, DCA’s New Computer System
 - 6. Board Member Reimbursement and Mail Vote Information
- c. Personnel Update
 - 1. Board Member Update
 - 2. Board Staff Update

XVI. LUNCH

A lunch break will be taken at some point during the day’s meeting.

XVII. EXECUTIVE OFFICER’S REPORT

- a. Medical Board Update
- b. PEW Trust Meeting on Compounding
- c. NABP Hosts Its Executive Officer Conference
- d. Board Inspector Meeting Held October 6-9, 2014 Including a Joint Meeting Between Board Inspectors and CDPH Consultants
- e. Duty Inspector Reinstated
- f. 2015 Meeting Calendar for Committees Under Development
- g. Changes for Board Members Making Travel Arrangements

ADJOURNMENT

Sign up for CURES

Board of Pharmacy now taking CURES registration materials

The California State Board of Pharmacy wants to help pharmacists register to access CURES and has created a procedure to do just that.

CURES is California's prescription drug monitoring program for controlled substances and is operated under the California Department of Justice. Effective January 1, 2016, all California licensed pharmacists must be registered to access CURES (as required by section 209 of the California Business and Professions Code).

To aid pharmacists and the California Department of Justice in meeting this deadline, the board is offering to assist in the registration of pharmacists. The information below advises pharmacists on how to register in CURES in order to access patient activity reports.

There are now three ways for pharmacists to register for CURES.

1. Via the Board of Pharmacy

STEP 1. PREREGISTRATION: To start the process, go to oag.ca.gov/cures-pdmp. Click on PDMP registration on the right hand side of the page.

Select "pharmacist," then:

1. Complete the online application form
2. Print out the completed form, then sign and date it
3. Attach a copy of:
 - Your CA pharmacist license
 - DEA controlled substances registration (if you possess one)
 - Driver's license or other photo government identification

STEP 2. Personally hand the completed application package to a board inspector or personally bring the completed packet to the Board of Pharmacy office in Sacramento, at 1625 N. Market Blvd., Suite N-219.

STEP 3. A CONFIRMATION from the DOJ takes the form of a link to the password establishment routine. Once registrants complete that step, they have access to the system.

- ### 2. Pharmacists can go online to oag.ca.gov/cures-pdmp and complete and mail to the DOJ a notarized packet. Instructions are online at this website.

3. Group Registration by the Department of Justice

The DOJ CURES Program offers outreach registration to interested prescriber and pharmacist groups.

If a site can present at least 20 prescribers or pharmacists who have completed registration applications in hand – including the completed, downloadable application form; pertinent California professional license; DEA Controlled Substance Certificate (if there is one); and a driver's license or government photo identification – then CURES staff will personally attend and accept the application packages at the site in place of the mail-in process that requires a notary to authenticate the identity of the applicant and required documentation.

Registration applications are available at oag.ca.gov/cures-pdmp.

CURES outreach staff will also provide a short CURES briefing to the group.

To arrange for a sign-up event, contact Mike Small at (916) 227-3324 or mike.small@doj.ca.gov; or Tina Farales (916) 227-3436 or tina.farales@doj.ca.gov.

NOTE THE FOLLOWING

If you do not have a pharmacy DEA number, you do not need to provide one. CURES passwords MUST BE renewed every six weeks.

Check your SPAM filter if you do not receive a confirmation after submitting your application form.

After receiving your confirmation email, you must reply within 72 hours.

If you forget your password, use the CAPTCHA function described at the end of the application. Some pharmacists simply renew their passwords on the first of each month. While you CAN use the same password every time, you need to re-fresh/re-new before the password expires.

Keep a copy (screenshot) of your original responses to the security questions before submission. If your password expires, it can be difficult to reset if you did not save all the questions you answered on the original application – which must be entered exactly as you initially entered them – including capitalization and spacing.