



**California State Board of Pharmacy**  
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

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

## Legislation and Regulation Committee

**Stan Weisser, RPh, Chair**  
**Rosalyn Hackworth, Public Member**  
**Greg Lippe, Public Member**  
**Shirley Wheat, Public Member**  
**Tappan Zee, Public Member**

### ***REGULATION REPORT AND ACTION***

#### **A. FOR DISCUSSION: Possible Future Regulation Requirements Specifying Consumer Notice for Language Assistance Interpretative Services Provided in Pharmacies**

At the last two board meetings during discussions to develop the requirements for patient-centered medication container labels, it was strongly suggested that a written notice requirement for pharmacies be established to provide notice to patients regarding the availability of interpretative services.

In the event the board is interested in pursuing this requirement as a future regulation, this item has been added to the agenda for discussion about the specifics of such a requirement. For discussion purposes, staff has prepared an initial proposal for board comment and input.

If the board is interested in pursuing a regulation about this consumer notice, after comments during this meeting, staff will bring more refined language to the July board meeting with the intent that the board finalize it into the text of a proposed requirement, and then initiate a rulemaking and release the proposal for 45 days of public comment.

First, already in the currently noticed text of section 1707.5 is the following paragraph:

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

In New York City, the Department of Consumer Affairs is considering the following language to advise patients about their rights to interpretive services in pharmacies. This language is below (with the exception of the first paragraph which was developed for CA) and provides one way to phrase such a notice.

1707.6 (a) The pharmacy's policies and procedures required by section 1707.5(d) to notify patients with limited or no English proficiency about the availability of interpretative services shall include development and display of a written reference list of languages for which translation services are available, in the specific written language of interpretation. Such a list will enable a non-English speaker to identify his or her language by pointing to the desired language on the reference list of languages.

(b) A pharmacy shall provide the following statement in English and in each of the languages for which interpretative services are available: "Point to your language. Language assistance will be provided at no cost to you."

(c) The statement in each of the required languages shall be in 18-point, bold-face type in a color that sharply contrasts with the background color of the sign. Each such statement shall be enclosed in a box, and there shall be at least a ¼ inch clear space between adjacent boxes.

(d) The statements in all of the required languages shall be printed on one sign that shall be conspicuously displayed on or at each counter near every cash register where prescription drugs are sold and shall be positioned so that a consumer can easily point to the statement identifying the language in which such a person is requesting assistance.

The board may wish to add other parameters; for example,

- how many languages (e.g., five most dominant languages in CA or in the community, those for which MediCal provides written materials)
- require the board to develop the written notice and make available to pharmacies (like we do for the Notice to Consumers posters)

## **B. FOR INFORMATION: Board Approved – Undergoing Administration Review**

### **1. Title 16 CCR Amend Sections 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination; Confidentiality**

#### **ATTACHMENT A**

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items

pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

The formal rulemaking was noticed on October 30, 2009. The 45-day comment period concluded on December 14, 2009, and the board did not receive any comments to the proposed rulemaking. A copy of the board-approved language is attached.

The board adopted this regulation during the January 2010 Board Meeting. This rulemaking file was compiled and submitted to the department in March 2009.

## **2. Title 16 CCR Add Section 1702 – Fingerprint Submissions for Pharmacists**

### **ATTACHMENT B**

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concludes February 15, 2010.

The board adopted this regulation during the February 2010 Board Meeting. The rulemaking file was compiled and submitted to the department in February 2010.

## **C. FOR INFORMATION: Board Approved – Awaiting Notice**

### **1. Title 16 CCR Amend Section 1746 – Emergency Contraception Protocol**

### **ATTACHMENT C**

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004.

Staff recommends that an error be corrected in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." The heading should designate micrograms – not milligrams. While the board deems this to be a typographical error, the regulation (as originally adopted) specified milligrams, not micrograms. As a result, a formal regulation proposal is required to correct this heading.

During the January 2010 Board Meeting, the board voted to initiate the rulemaking process. A copy of the current regulation with proposed amendments is attached. Board staff anticipate releasing this regulation change for comment for adoption during the July 2010 Board Meeting.

## **2. Title 16 CCR Amend Section 1732.2 – Board Issued Continuing Education Credit**

### **ATTACHMENT D**

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete review of examination questions if the committee member is not seeking reimbursement for their time.

Additionally, the board previously voted to award CE for the following:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

This was included into the board's continuing education policy, but was never formally amended into regulation.

During the February 2010 Board Meeting, the board voted to initiate the formal rulemaking process. Board staff anticipates initiating this rulemaking for action at either the July or October 2010 board meeting.

## **D. FOR INFORMATION. Board Approved Regulations – Under Development**

### **1. Proposed Addition to Title 16 CCR Section 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.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period. Subsequent to these actions however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

**2. Proposed Addition of Title 16 CCR §1751.xx – Accreditation Agencies for Pharmacies That Compound Injectable Sterile Drug Products**

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

Staff will be working with counsel to draft language that will be discussed at a future Legislation and Regulation Committee Meeting.

**3. Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material**

CCR §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. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. This subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

# Attachment A

Dishonest Conduct on Exam  
Sections 1721 and 1723.1

**Order of Adoption**  
**Board of Pharmacy**  
**California Code of Regulations**

**To Amend Division 17 of Title 16 CCR §1721 and**

**To Amend Division 17 of Title 16 CCR §1723.1**

**Dishonest Conduct During Examination and Confidentiality of Examination Questions**

**Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1721. Dishonest Conduct During Examination.**

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~and~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

**Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1723.1. Confidentiality of Examination Questions.**

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

---

Virginia Herold  
Executive Officer

---

Date

# Attachment B

Fingerprint Submissions for  
Pharmacists  
Section 1702

**Order of Adoption**  
**Board of Pharmacy**  
**California Code of Regulations**

**To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1702. Pharmacist Renewal Requirements**

- (a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after ([OAL insert effective date]).
- (1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.
- (2) A pharmacist applicant for renewal shall pay, as directed by the Board, the actual cost of compliance with subdivision (a).
- (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

- (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
- (b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$300 not involving alcohol, dangerous drugs, or controlled substances.
- (c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code.

Reference: Sections 490, 4036, 4200.5 4207, 4301, 4301.5, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

---

Virginia Herold  
Executive Officer  
Board of Pharmacy

# Attachment C

Emergency Contraception Protocol  
Sections 1746

**Title 16. Board of Pharmacy  
Proposed Language**

**To Amend Section 1746 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§1746. Emergency Contraception.**

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052 (a)(8)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code section 4052b(3).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

**(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception**

<i>Dedicated Emergency Contraception</i>				
Brand	Manufacturer	Tablets per Dose	EthinylEstradiol per Dose (mg mcg)	Levonorgestrel per Dose (mg)**
<b>One Dose Regimen</b>				
Plan B	Duramed	2 tablets	0	1.5
<b>Two Dose Regimens</b>				
Plan B	Duramed	1 tablet per dose	0	0.75
Preven	Duramed	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg mcg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

**(12) Anti-nausea Treatment Options for use with Emergency Contraception**

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</i>		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.3, Business and Professions Code.

# Attachment D

Board-Issued Continuing Education  
Credit  
Section 1732.2

## **Title 16. Board of Pharmacy Proposed Language**

**To Amend Section 1732.2. of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit hours for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded six hours of continuing education hours for conducting a review of exam test questions as directed by the subcommittee. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions as directed by the subcommittee

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded up to six hours of continuing education on an annual basis. The board shall designate on its public agenda which day shall be eligible for continuing education credit. Pharmacists or pharmacy technicians requesting continuing

education hours pursuant to this subdivision must sign in and out on an attendance sheet provided by the board.

(e) A pharmacist or pharmacy technician who attends a committee meeting of the board may be awarded up to two hours of continuing education on an annual basis. A maximum of four continuing education hours may be earned each year by attending the full meetings of two different board committees. Pharmacists or pharmacy technicians requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet provided by the board.

(f) A pharmacist who completes the Pharmacist Self-Assessment Mechanism (PSAM), administered through the National Association of Boards of Pharmacy, may be awarded up to six hours of continuing education.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200.2, 4231 and 4232, Business and Professions Code.