



## Legislation and Regulation Committee

**Kenneth Schell, PharmD, Chair**  
**Rosalyn Hackworth, Public Member**  
**Greg Lippe, Public Member**  
**Shirley Wheat, Public Member**  
**Tappan Zee, Public Member**

### **LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION**

Report of the Meeting held on July 14, 2010.

#### **PART 1: REGULATION REPORT AND ACTION**

##### **a. FOR DISCUSSION AND POSSIBLE ACTION**

- 1. Discussion and Possible Action Regarding a Regulation Specifying Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels**

#### **ATTACHMENT 1**

##### Background

On June 10, 2010, the board adopted proposed regulation 16 CCR 1707.5 to establish requirements for a patient-centered prescription drug container label. That regulation is currently undergoing administrative review

The patient-centered prescription label regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested; and also requires a pharmacy to provide oral interpretive services.

During the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of 12-point font, as specified in the adopted regulation. At the April 2010 Board Meeting, staff indicated that draft proposed language to establish consumer notices for these purposes will be provided for the board's consideration and possible action at this meeting. Attachment 1 contains draft proposed text for the board's consideration.

##### Request

Staff is requesting that the board discuss the following:

1. Policy Discussion – Does the board wish to amend 16 CCR § 1707.2 (Duty to Consult; existing consumer notices) to move existing consumer notices from §1707.2 to a new section that also includes notices re: language interpretive services and large font sizes?

2. Review draft text prepared by staff to establish consumer notices to advise patients of their right to the
  - Availability of Oral Interpretive Services; and
  - Availability of 12-Point Font on Prescription Labels

If the board approves the draft text and so chooses, direct staff to take all steps necessary to initiate the formal rulemaking process to add Section 1707.6 to Division 17 of Title 16 of the California Code of Regulations to specify the content of consumer notices related to the availability of interpretive language services for and of the availability of 12-point font on prescription drug container labels. If no adverse comments are received during the 45-day comment period or at the regulation hearing, authorize the Executive Officer to adopt the proposed addition of Section 1707.6 as filed with the Office of Administrative Law.

#### Committee Discussion / Action

This item was not before the Legislation and Regulation Committee for discussion at its recent meeting.

#### Recent Updates

None.

## **2. Future Amendment of 16 California Code of Regulations Section 1793.5 Regarding Modifications to the Pharmacy Technician Application Form**

### **ATTACHMENT 2**

#### Background

Title 16 California Code of Regulations Section 1793.5 was established in 1992 and incorporates by reference the Pharmacy Technician Application. Section 1793.5 was amended in 1995, 2002, and 2004 – primarily to update references to the fee required for obtaining a Pharmacy Technician license. The Office of Administrative Law last reviewed the Pharmacy Technician Application in 1995. Since that time, the Pharmacy Technician Application has been revised by staff to address common deficiencies and to reflect statutory requirements implemented since 1995.

#### Request

Staff is requesting that the board review the proposed changes to § 1703.5 and to the Pharmacy Technician Application. A copy of proposed changes to the application will be provided to the board at the July 2010 Board Meeting.

If the board concurs with the proposed changes and so chooses, direct staff to take all steps necessary to initiate the formal rulemaking process to amend Section 1793.5 to reflect the revision of the Pharmacy Technician Application (Form 17A-5, incorporated by reference) of Article 11 in Division 17 of Title 16 of the California Code of Regulations. If no adverse comments are received during the 45-day public comment period and no hearing is requested, authorize the Executive Officer to adopt the proposed amendment of Section 1793.5 as filed with the Office of Administrative Law.

### Committee Discussion / Action

The Legislation and Regulation Committee did not discuss this item.

### Recent Updates

Recently, counsel advised staff that in order to use a revised Pharmacy Technician Application that the board must amend 16 CCR § 1793.5 (which incorporates the application by reference) and have the application approved through the formal rulemaking process.

Revisions to the application reflect changes in application requirements, as well as reorganization of information in an effort to eliminate the number of applications that are received as deficient.

## **3. Future Update of the Self-Assessment Forms for Pharmacies and Wholesalers (16 California Code of Regulations Sections 1715 and 1784)**

### Background

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms provide references to relevant laws and regulations, and also serve as an easy reference guide for the Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC).

Section 1715 of Title 16 Cal. Code of Regs applies to the self-assessment of a pharmacy by the Pharmacist-in-Charge. The regulation was established in 1997 and was last amended in 2009. The following self-assessment forms are incorporated by reference in § 1715:

17M-13 (Rev 10/08) "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment"  
17M-14 (Rev 10/08) "Hospital Pharmacy and Self Assessment"

Section 1784 of Title 16 Cal. Code of Regs applies to wholesalers. This regulation was established in 2007 and was last updated in 2009. It incorporates by reference the following self-assessment form:

17M-26 (Rev 10/08) "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment"

After the conclusion of the 2009/2010 Legislative Session, board staff will draft changes to the self-assessment forms to reflect statutory changes for the board's consideration at a future meeting.

### Committee Discussion / Action

The Legislation and Regulation Committee did not discuss this item.

**b. RECENTLY APPROVED REGULATIONS**

Adopt New Section at Title 16 California Code of Regulations Section 1702 – Fingerprint Submissions for Pharmacists

**ATTACHMENT 3**

The Office of Administrative Law approved and filed with the Secretary of State a new Board of Pharmacy regulation regarding fingerprint submissions for pharmacists. Title 16 California Code of Regulations Section 1702 is effective on December 7, 2010.

The regulation 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. Attachment 3 contains a copy of the approved regulation.

Committee Discussion / Action

Chair Schell advised that board staff will be developing an implementation plan and hopes to advise all affected licensees by late summer of the fingerprint requirements. An article also will be included in the next version of *The Script*.

**c. BOARD APPROVED REGULATIONS UNDERGOING ADMINISTRATIVE REVIEW**

1. Adopt Sections 1721 and 1723.1 in Division 17 of Title 16 of the California Code of Regulations Regarding Dishonest Conduct During a Pharmacist’s Licensure Examination / Confidentiality

**ATTACHMENT 4**

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.

The formal rulemaking was noticed on October 30, 2009, and the board did not receive any comments to the proposed rulemaking during the 45-day public comment period.

The board adopted this regulation at its January 2010 Board Meeting. The rulemaking file was compiled and submitted to the department for review in March 2010 and staff was advised in early July of the department’s approval. The rulemaking was filed with the Office of Administrative Law on July 9, 2010, where it is currently undergoing administrative review. A copy of the adopted text is provided in Attachment 4.

2. Adopt Section 1707.5 in Division 17 of Title 16 of the California Code of Regulations Regarding Patient-Centered Prescription Drug Container Labels

**ATTACHMENT 5**

During the June 2010 Board Meeting, the board voted to adopt proposed 16 CCR Section 1707.5 creating the patient-centered prescription label requirements. A copy of the adopted text is provided in Attachment 5.

The formal rulemaking was noticed for the 45-Day comment period on November 20, 2009 and a regulation hearing was held on January 20, 2010. The first 15-day comment period started on February 22, 2010, and the second 15-day comment period began on April 28, 2010. The board received about 1,200 comments. The board adopted the final text at its meeting held June 10, 2010.

As directed by the board, staff prepared the Final Statement of Reasons and compiled the rulemaking file. The rulemaking was submitted to the department for review on July 12, 2010. The file will be reviewed by the Department of Consumer Affairs, the Department of Finance (fiscal), and State and Consumer Services Agency. Upon approval by department/agency, the rulemaking will be filed with the Office of Administrative Law for further administrative review.

**d. BOARD APPROVED REGULATIONS – AWAITING NOTICE**

1. Amend Title 16 of the California Code of Regulations Section 1746 Regarding Emergency Contraception Protocol (to include correction of typographical error: Mcg instead of Mg)

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.

Committee Discussion / Action

Chair Schell advised that at the January 2010 Board Meeting, the board voted to initiate the rulemaking process. He stated that board staff had anticipated releasing this regulation change for comment for adoption prior to the July 2010 Board Meeting, however, because of competing priorities, has been unable to do so.

Ms. Herold suggested that the board consider forming a committee to update the regulation as after six years, the medication may have changed.

2. Amend Title 16 of the California Code of Regulations Section 1732.2 Regarding Board Accredited Continuing Education

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 approved a recommendation from the Licensing Committee to award Competency Committee members 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).

The provisions above were included in the board's continuing education policy, but never formally amended into the regulation

Committee Discussion / Action

Committee Chair Schell advised that at the February 2010 Board Meeting, the board voted to initiate the rulemaking process. He stated that board staff anticipates initiating the rulemaking for action at the October 2010 board meeting.

**e. BOARD APPROVED REGULATIONS – UNDER DEVELOPMENT**

1. **Title 16 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 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 those actions however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The board was advised at its Board Meeting in April 2010 that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program, and that staff does not anticipate proceeding with this regulation until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

### Committee Discussion / Action

The committee was advised that this regulation has been tabled until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Retailer program.

## **2. Title 16 CCR § 1751.9 – 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 language will specify the criteria the board will utilize to consider approval of accrediting agency requests.

### Committee Discussion / Action

Ms. Herold advised the committee that at least one of the accreditation agencies seeking board recognition will be in attendance at the July 2010 Board Meeting to seek accreditation from the board.

## **3. Title 16 CCR § 1780 – Update the USP Standards Reference Material**

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

### Committee Discussion / Action

Chair Schell provided that because of stated concerns about whether referencing the 2005 USP standards would be 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.

Chair Schell indicated that a subcommittee had been established; but, as a result of recent vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change. Public comment suggested that the subcommittee seek some additional assistance in order to fully evaluate the standards.

# **ATTACHMENT 1**

# Attachment 1

*Possible Text  
for  
Notices to Consumers*

*Availability of  
Oral Interpretive Services*



*Availability of 12-Point Font*

**Potential Regulatory Proposal(s) re: Notices to Consumers**

**Add 1707.6. Posted Notices Required in Pharmacies.**

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, notices containing the text in subdivisions (b), (c), (d) and (e). The board has previously developed and distributed standardized posters for the notices that are required by subdivisions (b) and (c). The board shall similarly develop a standardized poster for the notice required by subdivision (d). For the notices required by subdivisions (b), (c), and (d), the pharmacy shall display the poster developed by the board, or a full-color duplicate thereof.

As an alternative to printed notices, the pharmacy may display one or more required notices on a video screen located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, where the video screen display meets the following requirements:

- (1) The video screen is at least 30 inches, measured diagonally;
- (2) The text and format of the notice(s) is the same as it would be in printed form, including the size of the notice(s), the size of the text, and the colors utilized;
- (3) The text of the notice(s) remains on the screen for a minimum of 30 seconds;
- (4) Where the entire text of a notice does not fit onto a single screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least 30 seconds; and
- (5) No more than four minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

*Staff Note: Subdivision (b) is the Notice to Consumers currently at § 1707.2(f)*

(b) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?

How and when do I take it - and for how long? What if I miss a dose?

What are the possible side effects and what should I do if they occur?

Will the new medicine work safely with other medicines and herbal supplements I am taking?

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

*Staff Note: Subdivision (c) is the Notice to Consumers currently at § 1707.2(g)*

(c) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy,
2. The pharmacist, based upon his or her professional judgment determines providing the item:
  - is against the law,
  - could cause harmful drug interaction, or
  - could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

(d) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

The container label for your prescription medication contains vital information. Please take a moment to check the container label before you leave the pharmacy to be sure that:

The container label has the correct patient name;

The container label has the correct medication name and strength;

The container label has the correct directions for use; and

The container label includes the purpose or condition for which the medication was prescribed, if that information was included in the prescription.

All of these four categories of information must be clustered into one area of the label, and must appear on the label, in the order given above, in at least a 10 point font.

If you would like the text on your container label to be larger, please ask. Upon request, the pharmacy will print a label with the text for these four categories of information in at least a 12-point font. This may result in use of a larger label and/or a larger container.

If you have questions about any of the information on the label, ask the pharmacist.

(e) There shall be a notice containing the following text, repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice:

NOTICE TO CONSUMERS

It is very important that you understand the information on the container label for your prescription medication. If you have trouble reading or understanding English, this pharmacy will make interpretive services available to you in your own language.

(f) The pharmacy shall also post or provide the following statement, repeated in English and in each of the languages for which interpretive services are available, written in at least an 18-point boldface type in a color that sharply contrasts with the background color of the statement, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This statement, repeated in all available languages, may be made available by posted notice or by video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance.

If the posted notice or video screen is not positioned so that a consumer can easily point to and touch the notice or video screen, the statement, repeated in all available languages, shall be made available on a cardstock flyer or handout kept within reach of consumers at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Such flyer/handout shall be at least 8 inches by 11 inches, on at least 8 point cardstock, which may be laminated. At least one copy of the flyer/handout shall be available at all hours that the pharmacy is open.

# **ATTACHMENT 2**

# Attachment 2

*Possible Text to Amend*

*16 CCR § 1793.5*

*re:*

*Pharmacy Technician Application*

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

**To Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

§ 1793.5. Pharmacy Technician Application.

The application for a pharmacy technician license (Form 17A-5 (Rev. 9/94 [OAL Insert Effective Date])) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for registration as a pharmacy technician shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in Section 1749, subdivision (c).

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

# **ATTACHMENT 3**

# Attachment 3

*Recently Approved Regulations*

*16 CCR § 1702*

*Effective December 7, 2010*

*Fingerprint Submissions for  
Pharmacists*

**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:

Section 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 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 the actual cost of compliance with subdivision (a).

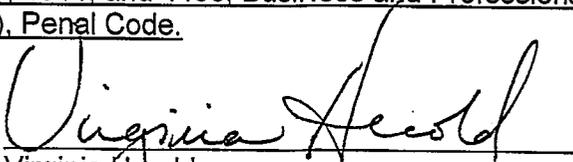
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(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 \$500 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, 4311, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

  
Virginia Herold  
Executive Officer  
Board of Pharmacy

State of California  
Office of Administrative Law

RECEIVED BY CALIF  
BOARD OF PHARMACY

2010 JUN -9 PM 4: 37

In re:  
Board of Pharmacy

NOTICE OF APPROVAL OF REGULATORY  
ACTION

Regulatory Action:

Government Code Section 11349.3

Title 16, California Code of Regulations

OAL File No. 2010-0430-03 S

Adopt sections: 1702

Amend sections:

Repeal sections:

This rulemaking adopts Title 16 section 1702 to establish the requirement that all pharmacist applicants for renewal who have not previously submitted fingerprints to the FBI or for whom an electronic record does not exist with DOJ to complete a state and federal level criminal offender record information search prior to license renewal. This new section also provides that a revoked license may not be reinstated until fingerprints are submitted and a criminal record search is conducted through DOJ.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 12/7/2010.

Date: 6/7/2010

  
Peggy J. Gibson  
Staff Counsel

For: SUSAN LAPSLEY  
Director

Original: Patricia Harris  
Copy: Anne Sodergren  
Carolyn Klein

# **ATTACHMENT 4**

# Attachment 4

## *Regulations Undergoing Administrative Review*

*Adopted Text  
16 CCR § 1721 and § 1723.1*

*Dishonest Conduct During a  
Pharmacist's Licensure Examination;  
Confidentiality*

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

**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 ~~card~~ 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.

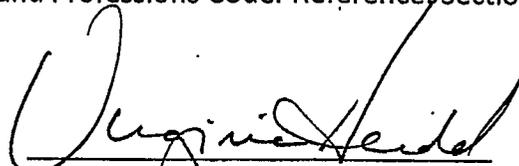
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

**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  
Board of Pharmacy

# **ATTACHMENT 5**

# Attachment 5

*Regulations Undergoing  
Administrative Review*

*Adopted Text  
16 CCR § 1707.5*

*Patient-Centered Prescription Drug  
Container Labels*

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

**Specific Language to Add Section 1707.5.**

Add Section 1707.5. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels on Medication Containers.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label

that comprises at least 50 percent of the label. Each item shall be printed

in at least a 10-point sans serif typeface or, if requested by the consumer,

at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use.

(D) Purpose or condition, if entered onto the prescription by the prescriber.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of

information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 [insert appropriate dosage form] at bedtime
- (B) Take 2 [insert appropriate dosage form] at bedtime
- (C) Take 3 [insert appropriate dosage form] at bedtime
- (D) Take 1 [insert appropriate dosage form] in the morning
- (E) Take 2 [insert appropriate dosage form] in the morning
- (F) Take 3 [insert appropriate dosage form] in the morning
- (G) Take 1 [insert appropriate dosage form] in the morning, and  
Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and  
Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and  
Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert  
appropriate dosage form] at noon, and 1 [insert appropriate dosage  
form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert  
appropriate dosage form] at noon, and 2 [insert appropriate dosage  
form] in the evening

- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take [insert appropriate dosage form] at a time. Wait at least [ ] hours before taking again. Do not take more than [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(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.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

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Virginia Herold  
Executive Officer  
Board of Pharmacy