



California State Board of Pharmacy

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

LEGISLATION AND REGULATION COMMITTEE

Regulation Report

FOR ACTION

Action Item 1 – Adopt regulation adding Section 1746 to Title 16 of the California Code of Regulations.

Discussion: This section will codify the statewide protocol for pharmacists dispensing emergency Contraception. (See Attachment 1)

Action Item 2 – Adopt changes to Section 1751 et seq. of Title 16 of the California Code of Regulations.

Discussion: The noticed changes remove provisions that were determined to be building standards and are not permitted to be adopted by the board. If these changes are approved, the file will be resubmitted to OAL and staff anticipates approval at that time. (See Attachment 2)

NO ACTION

Regulation Update

Rulemaking Activity

The listing below provides an update as to the status of pending board regulations. At this time, the only regulation awaiting notice is an update to the pharmacy self assessment forms. All other regulation items have either been noticed and are awaiting board action or have been submitted for administrative approval.

Pending Regulations

Section 1709.1 - Pharmacist-in-Charge at Two Locations

Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.
Status: Pending Administration Review

Section 1710 – Hospital Central Fill

Summary: This regulation will permit central refill operations for hospitals.
Status: Pending Administration Review

Section 1711 – Patient Notification

Summary: This regulation will clarify patient notification requirements in the event there is a medication error.
Status: Pending Administration Review

Section 1717.1 – Common Electronic Files

Summary: This regulation requires pharmacies using common electronic files to adopt policies ensuring patient confidentiality.

Status: Pending Administration Review

Section 1717.4 – Authentication of Prescriptions

Summary: This regulation will require pharmacists to ensure the authenticity of prescriptions.

Status: Pending Administration Review

Section 1720 – Pharmacist License Process

Summary: This regulation will require pharmacists to pay the licensing fee in a shorter time frame and require applicants to take the examination within one year of applying.

Status: Pending Administration Review

Section 1721 – Pharmacist Exam

Summary: This regulation will increase the penalties for cheating on the pharmacist licensure examination.

Status: Pending Administration Review

Section 1724 – Passing Score

Summary: This regulation will revise the methodology of determining the passing score on the pharmacist licensure examination to comply with changes made by Senate Bill 361.

Status: Pending Administration Review

Section 1746 – Emergency Contraception

Summary: This regulation will codify the statewide protocol for pharmacists to dispense emergency contraception that was approved by the board and the Medical Board of California earlier this year.

Status: Awaiting adoption.

Sections 1749 & 1793 et seq. – Pharmacy Technicians

Summary: This regulation conforms and clarifies regulations relating to pharmacy technicians to reflect changes made by Senate Bill 361.

Status: Pending Administration Review

Section 1751 – Sterile Compounding

Summary: This regulation will establish guidelines for the compounding of sterile drug products.

Status: Awaiting board action on 15-Day notice.

Section 1793.3 – “Clerk-Typist” Ratio

Summary: This regulation will eliminate the clerk/typist ratio.

Status: Pending Administration Review

Awaiting Notice

Section 1715 – Pharmacy Self Assessment

Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.

Status: Informational Hearing Required

Attachment 1

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TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on July 12, 2004.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on June 28, 2004.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 4005 of the Business and Professions Code and to implement, interpret or make specific Section 4052 of the Business and Professions Code the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4052 of the Business and Professions Code permits a pharmacist to furnish emergency contraception pursuant to a statewide protocol approved by the Board of Pharmacy and the Medical Board of California.

This notice proposed to add Section 1746 as follows:

1. Require a pharmacist dispensing emergency contraception based on the authority granted by Section 4052(a)(8)(ii) to comply with the protocol specified in this section.
2. Establishes the statewide protocol for furnishing emergency contraception. This protocol specifies the procedures to be followed and products to be furnished to patients requesting emergency contraception.

The Board of Pharmacy has proposed to this section to implement a statewide protocol as specified by Senate Bill 490 (Chapter 651, Statutes of 2003).

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The Board of Pharmacy made this determination because the proposed regulation would provide pharmacies with greater flexibility in providing emergency contraception products to consumers.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Paul Riches
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	Paul_Riches@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4005
Fax No.:	(916) 327-6308
E-Mail Address:	Virginia_Herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

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Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Emergency Contraception

Sections Affected: 1746

Specific Purpose of the Proposed Changes:

The Board of Pharmacy has proposed to add Section 1746 to implement the statewide protocol for pharmacist furnishing of emergency contraception established by Senate Bill 490 (Chapter 651, Statutes of 2003).

Factual Basis/Rationale

Senate Bill 490 (Chapter 651, Statutes of 2003) amended Section 4052 of the Business and Professions Code to permit a pharmacist with specified training to furnish emergency contraception to a patient without a prescription based on a statewide protocol approved by the Board of Pharmacy and the Medical Board of California. Existing law permits such furnishing by a pharmacist with specified training based on a protocol established between the pharmacist and a prescriber. The Board of Pharmacy has proposed this regulation to implement this provision and create an enforceable protocol for pharmacists.

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

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**Board of Pharmacy
Emergency Contraception
Add Section 1746**

§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).

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

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

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.

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 medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

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.

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

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

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.

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

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.

Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

<u>Dedicated Emergency Contraception</u>				
<u>Brand</u>	<u>Manufacturer</u>	<u>Tablets per Dose</u>	<u>Ethinyl Estradiol per Dose (mg)</u>	<u>Levonorgestrel per Dose (mg)**</u>
<u>One Dose Regimen</u>				
<u>Plan B</u>	<u>Women's Capital Corporation</u>	<u>2 tablets</u>	<u>0</u>	<u>1.5</u>
<u>Two Dose Regimens</u>				
<u>Plan B</u>	<u>Women's Capital Corporation</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>0.75</u>
<u>Preven</u>	<u>Gynetics</u>	<u>2 tablets per dose</u>	<u>100</u>	<u>0.50</u>
<u>Oral Contraceptive Pills</u>				
<u>Brand</u>	<u>Manufacturer</u>	<u>Tablets per Dose (two doses 12 hours apart *)</u>	<u>Ethinyl Estradiol per Dose (mg)</u>	<u>Levonorgestrel per Dose (mg)*</u>
<u>Levora</u>	<u>Watson</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ovral</u>	<u>Wyeth</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ogestrel</u>	<u>Watson</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Nordette</u>	<u>Wyeth</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Tri-Levlen</u>	<u>Berlex</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Allesse</u>	<u>Wyeth</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>Duramed</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>Wyeth</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Levlen</u>	<u>Berlex</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>

<u>Trivora</u>	<u>Watson</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Levlite</u>	<u>Berlex</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Lo/Ovral</u>	<u>Wyeth</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Low-Ogestrel</u>	<u>Watson</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ovrette</u>	<u>Wyeth</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

Anti-nausea Treatment Options for use with Emergency Contraception

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

NOTE:

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

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Attachment 2

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California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

May 25, 2004

TO: ALL INTERESTED PARTIES

RE: PROPOSED ADDITION OF TITLE 16, SECTION 1751 ET SEQ., STERILE COMPOUNDING

In response to comments received from the Office of Administrative Law and the Building Standards Commission, the board is proposing to amend text of the proposed regulation regarding sterile injectable compounding standards. Changes to the final text of the regulation that was disapproved by the Office of Administrative Law are indicated in the accompanying text with ***bold italics*** denoting additions and double ~~strikeout~~ denoting deletions. These modifications are needed to eliminate the inclusion of building standards which cannot be adopted by the board.

The board will vote on these changes at its July 21-22, 2004 meeting.

The board is required to make available the proposed language for at least 15 days. Written comments regarding the latest proposed amendments must be sent to the board postmarked no later than June 11, 2004.

Written comments should be sent to the board at:

Board of Pharmacy
Attn: Paul Riches
400 R Street, Suite 4070
Sacramento, CA 95814

Comments may also be emailed to Paul_Riches@dca.ca.gov, or faxed to (916) 327-6308. Comments received by email or fax must contain the name and address of the commenter.

Attachment

Board of Pharmacy
Proposed Revisions to Title 16 CCR 1751 et seq.
May 25, 2004

*- Revisions noted with additions in *bold italics* and deletions noted in ~~double-strikeout~~

Article 7. Sterile Injectable Compounding

Amend Section 1751. Sterile Injectable Compounding Area. ~~for Parenteral Solutions.~~

(a) The pharmacy shall have a designated area for the preparation of sterile injectable products ~~for dispensing~~ which shall meet the following standards:

(a) (1) Clean Room and Work Station Requirements, shall be in accordance with Section ~~490A.3.1 2-714(g)(1)~~ of Title 24, Part 2, Chapter 4A of the California Code of Regulations Administrative Code.

(b) (2) Walls, ceilings and floors shall ~~have cleanable, nonporous surfaces and be constructed~~ be in accordance with Section ~~490A.3 2-714(g)(2)~~ of Title 24, Part 2, Chapter 4A of the California Code of Regulations Administrative Code.

(c) (3) Be ventilated in a manner in accordance with Section ~~505.12 4-1105(d)~~ of Title 24, Part 4, Chapter 5 of the California Code of Regulations Administrative Code.

(d) (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, United States General Services Administration, as amended May 30, 1976 (available from the U.S. General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, D.C. 20407). Certification records must be retained for at least 3 years.

(e) (5) The pharmacy shall be arranged in accordance with Section ~~490A.3 2-714(g)(3)~~ of Title 24, Part 2, Chapter 4A of the California Code of Regulations Administrative Code. Items related to the compounding of sterile injectable products ~~parenteral solutions~~ within the compounding area ~~may not be stored in corrugated cardboard boxes~~ and shall be stored in such a way as to maintain the integrity of an aseptic environment.

(f) (6) A sink ~~with hot and cold running water~~ shall be *included* in accordance in Section ~~490A.3.4 2-714(g)(4)~~ of Title 24, Part 2, Chapter 4A of the California Code of Regulations Administrative Code.

(g) (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

NOTE:

Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Add Section 1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

~~(a) On and after January 1, 2005 this subdivision shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients. The aseptic processing of such products shall occur in one of the following environments:~~

- ~~(1) A class 100 laminar airflow hood within a class 10,000 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.~~
- ~~(2) A class 100 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.~~
- ~~(3) A barrier isolator that provides a class 100 environment for compounding.~~
- ~~(b) No sterile injectable product shall be prepared if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.~~
- ~~(c) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.~~
- ~~(d) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.~~
- ~~(e) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~

NOTE:

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Add Section 1751.02. Policies and Procedures.

- (a) Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to:
- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.

(E) Personnel access and movement of materials into and near the controlled area.

(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).

(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.

(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.

(J) Sterilization.

(K) End-product evaluation and testing.

NOTE:

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

Amend Section 1751.2. Labeling Requirements.

In addition to existing labeling requirements, a pharmacy which compounds sterile parenteral injectable products shall include the following information on the labels for those products:

- a. Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- b. Name and concentrations of all ingredients contained in the sterile injectable parenteral product including primary solution.
- c. Instructions for storage and handling.
- d. All cytotoxic agents shall bear a special label which states “Chemotherapy-Dispose of Properly.”

NOTE:

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

Amend Section 1751.3. Recordkeeping Requirements.

~~Pharmacies which both compound parenteral solutions and dispense those solutions shall have on the premises or readily accessible a patient record for each patient being treated with parenteral therapy. In addition to existing recordkeeping requirements, the following records shall be maintained:~~

- ~~(a) Records of furnishing of all prescriptions and medical supplies;~~
- ~~(b) Information relevant to the patient's parenteral therapy shall include but not be limited to:
 - ~~(1) Patient's name, age, sex, address, and body weight.~~~~

- ~~(2) Primary diagnosis related to need for prescribed therapy; secondary diagnosis if available.~~
- ~~(3) Summary of most recent hospitalization and/or previous history.~~
- ~~(4) Medication history, including current diet/medication regimen and drug/food allergies.~~
- ~~(c) Progress notes documenting contact with the patient or physician relative to parenteral therapy.~~
- ~~(d) Laboratory data relevant to parenteral therapy.~~
- (a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.
 - (3) Certification of the sterile compounding environment.
 - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
 - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
 - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.

NOTE:

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

Amend Section 1751.4. ~~Protective Clothing Attire.~~

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

NOTE:

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

Amend Section 1751.5. Training of Staff, Patient, and Caregiver.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of ~~parenterals~~ sterile injectable products and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products ~~parenteral solutions~~ shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, ~~parenteral solutions~~ including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ~~insure~~ ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products ~~parenteral solutions~~.

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.

(I) Sterilization techniques.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

NOTE:

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

Amend Section 1751.6. Disposal of Waste Material.

Pharmacies ~~providing parenteral services~~ compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction. ~~The pharmacy shall ensure the return of such materials or shall communicate the proper destruction of such materials to the caregiver.~~

NOTE:

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

Amend Section 1751.7. Quality Assurance and Process Validation.

(a) There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

- ~~(a) (1)~~ Cleaning and sanitization of the parenteral medication preparation area.
- ~~(b) (2)~~ Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive.
- ~~(c)~~ ~~If manufacturing of parenteral products is performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of product from quarantine. This process must include testing for sterility and pyrogens.~~
- ~~(d) (3)~~ The storage of compounded sterile injectable parenteral products in the pharmacy and periodic documentation of refrigerator temperature.
- ~~(e) (4)~~ Steps to be taken in the event of a drug recall.
- ~~(f) (5)~~ Written justification of the chosen expiration dates for compounded sterile injectable parenteral products.

(b) Each individual involved in the preparation of sterile injectable products from one or more non-sterile ingredients must successfully complete a validation process on technique before being allowed to prepare sterile products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are to be used in the validation process. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

NOTE:

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

Repeal Section 1751.8. Policies and Procedures.

~~Written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products shall include, but not be limited to:~~

- ~~(a) Compounding and labeling of intravenous admixtures.~~
- ~~(b) Administration of intravenous therapy.~~
- ~~(c) Equipment and supplies.~~
- ~~(d) Training of staff, patient and caregiver.~~
- ~~(e) Procedures for handling cytotoxic agents.~~

- ~~(f) Quality assurance program.~~
- ~~(g) Recordkeeping requirements.~~

NOTE:

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

Amend Section 1751.9. Reference Materials.

There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

~~Such references shall include information on:~~

- ~~(a) The drugs and chemicals used in parenteral therapy services and~~
- ~~(b) All parenteral therapy, manufacturing, dispensing, distribution, and counseling services provided.~~

NOTE:

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

PATRICIA HARRIS
Executive Officer

DATE