

## 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 orally or in writing relevant to the action proposed at a hearing to be held at 400 R Street, Sacramento California, at 1:30, on April 29, 2003. 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 April 7, 2003 or must be received by the Board of Pharmacy at the hearing. 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 Sections 4005 and 4127 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005 of said 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

The proposed regulations substantially revise and update existing board regulations relating to the compounding of sterile injectable drug products. The board is required to develop such standards by Senate Bill 293 (Chapter 827, Statutes of 2001) as the standard for licensure of sterile injectable compounding pharmacies. The proposed regulations establish standards for compounding sterile injectable drug products (including injectables) based on the board's rulemaking authority in Business and Professions Code 4005. Section 4005 states in pertinent part,

“The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the **protection of the public**. Included therein shall be the right to adopt rules and regulations as follows:...pertaining to the **practice of pharmacy**; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to **establishments wherein any drug or device is compounded**, prepared, furnished, or dispensed; **providing for standards of minimum equipment** for establishments licensed under this chapter...” (emphasis added)

The board has proposed these regulations to fulfill the requirements of Senate Bill 293. The proposed regulations were drafted to establish a minimum standard that is consistent with patient safety and good pharmacy practice. The proposed regulations preserve patient access to compounded sterile injectable drug products.

#### 1. Amend Section 1751

This proposal would revise and update existing law relating to the maintenance of the compounding environment for the compounding of sterile injectable drug products.

2. Adopt Section 1751.01

This proposal would specify facility and procedure requirements for pharmacies compounding sterile injectable drug products from one or more non-sterile ingredients.

3. Adopt Section 1751.02

This proposal would specify the written policies and procedures required for pharmacies compounding sterile injectable drug products.

4. Amend Section 1751.2

This proposal would revise and update the labeling requirements for sterile injectable drug products compounded in a pharmacy.

5. Amend Section 1751.3

This proposal would revise and update the record keeping requirements for sterile injectable drug products compounded in a pharmacy both for dispensing to directly to patients or compounded for future use.

6. Amend Section 1751.4

This proposal would revise and update the requirements for protective clothing worn when compounding sterile injectable drug products in a pharmacy.

7. Amend Section 1751.5

This proposal would revise and update the training requirements for the pharmacy staff compounding sterile injectable drug products and the patients receiving those products.

8. Amend Section 1751.6

This proposal would revise and update the requirements for disposing of waste material associated with the compounding of sterile injectable drug products.

9. Amend Section 1751.7

This proposal would revise and update the quality assurance requirements for pharmacies compounding sterile injectable drug products.

10. Repeal Section 1751.8

This proposal would repeal this section because its provisions have been incorporated in a prior section.

## 11. Amend Section 1751.9

This proposal would revise and update the reference materials required for pharmacies compounding sterile injectable drug products.

### FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: Potential costs vary based on the number of governmental pharmacies that perform sterile compounding activities, the existing facilities and equipment at those pharmacies, and the nature of the sterile compounding activities required at those pharmacies. Potential costs of approximately \$30,000 per sterile compounding pharmacy for facility upgrades may be incurred if the pharmacy elects to compound sterile injectable drug products from non-sterile ingredients.

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 of Pharmacy has made an initial determination that the adoption of this regulation may have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The following types of businesses would be affected:

- (A) Pharmacies
- (B) Hospitals

The following reporting, recordkeeping or other compliance requirements are projected to result from the proposed action:

- (A) Additional recordkeeping requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients.
- (B) Additional facility requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients.
- (C) Additional training and testing requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients.

The Board of Pharmacy has not considered proposed alternatives that would lessen any adverse economic impact on business and invites you to submit such proposals. Submissions may include the following considerations:

- (A) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
- (B) Consolidation or simplification of compliance and reporting requirements for businesses.
- (C) The use of performance standards rather than prescriptive standards.
- (D) Exemption or partial exemption from the regulatory requirements for businesses.

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 cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action and that are known to the Board of Pharmacy are those costs associated with additional training, testing and facility requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would affect small businesses.

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](http://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
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Website Access: Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).