



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

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

LEGISLATION AND REGULATION COMMITTEE REPORT

Pending Regulations

NO ACTION

Board Approved – Pending Administrative Approval.

On October 25, 2005 the board approved CCR 1727.1 to exclude the posting of pharmacist intern addresses on the Internet. This proposed regulation is currently undergoing administration review. It is anticipated that this regulation will be effective in early summer 2006.

Board Approved – Noticed.

On February 24, 2006 the board noticed the repeal 16 CCR section 1717(e) and to add 16 CCR section 1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions. The 45-day comment period on the regulation ended on April 10, 2006. Public comment received is incorporated into the board packet for the hearing on the regulation.

On March 3, 2006 the board noticed amending 16 CCR section 1793.7 and adding 1793.8, to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes. The 45-day comment period on the regulation will end on April 17, 2006. Public comment received is incorporated into the board packet for the hearing on the regulation.

Board Approved - Awaiting Notice.

Board omnibus regulation provisions for 2006 (technical changes)

- 16 CCR § 1706.2 - Abandonment of Application Files.
- 16 CCR § 1775.4 - Contested Citations.
- 16 CCR § 1709.1 - Designation of Pharmacist in Charge.
- 16 CCR § 1780 -Minimum Standards for Wholesalers.
- 16 CCR § 1780.1 - Minimum Standards for Veterinary Food-Animal Drug Retailers.
- 16 CCR § 1781 - Exemption Certificate.
- 16 CCR § 1786 (repeal) – Exemptions.

Repeal CCR 1717.2, Notice of Electronic Prescription Files. The purpose for repealing the regulation is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this

barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the Initial Statement of Reasons and Notice documents so action can be taken at the July 2006 board meeting.

Amend CCR 1760, Disciplinary Guidelines. This rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. The Guidelines will be ready for public notice and the formal start of the rulemaking process at the July or October board meeting.

Add CCR 1784, Self-Assessment of a Wholesaler by the Designated Representative-In-Charge. Staff has completed its internal review of the assessment form. It will be publicly noticed and brought to the board for action at the board's April 2006 meeting.

ACTION

Awaiting Board Review and Action.

The California Building Standards Commission (CBSC) has asked the board to review and update pharmacy building standards in the building code, in preparation of the CBSC adoption of the 2006 International Building Code and 2006 International Fire Code, the 2005 National Electrical Code, and 2006 Uniform Mechanical Code and Uniform Plumbing Code, in CCR, Title 24. The CBSC anticipates adopting the new standards in early 2008.

Staff reviewed and updated the relevant building code sections. The proposed changes to the code are attached. The board needs to review the proposed changes, and if acceptable, vote to allow the CBSC to move forward with the code revisions.

Attached is a copy of the specific language this regulation.

Awaiting

Board Review

[AMINISTRATIVE PROVISIONS]

PART 2, VOLUME 1, CALIFORNIA BUILDING CODE

SECTION 106
DEPARTMENT OF CONSUMER AFFAIRS (CA)

CA – Department of Consumer Affairs.

106.4 Board of Pharmacy.

Application – Pharmacies.

Enforcing Agency – State of local agency specified by applicable provisions of law.

Authority Cited – Business and Professions Code Section ~~4008~~, ~~4005~~

Reference – Business and Professions Code Sections ~~4008 and 4084~~ 4005, 4127.7 and 4102.

PART 4, CALIFORNIA MECHANICAL CODE

108.0 Powers and Duties of the Authority Having Jurisdiction

108.1 General. The Authority Having Jurisdiction is . . .

108.1.1.4 [For CA] CA – Department of Consumer Affairs

CA; Board of Pharmacy.

Application – Pharmacies.

Enforcing Agency – Agency-State or local agency specified by applicable provisions of law.

Authority Cited – B&PC §~~4008~~ ~~4005~~

References – B&PC §~~4008 and 4084~~ 4005, 4127.7 and 4102 .

PART 5, CALIFORNIA PLUMBING CODE

Adopt the following articles for Chapter 1 of the 2003 UPC:

(UPC standards adopted by CA are applicable to occupancies regulated by Consumer Affairs in California.)

**CHAPTER 1
ADMINISTRATION
MATRIX ADOPTION TABLE**

Adopting Agency	CA	COMMENTS
Repeal entire 2000 UPC Chapter 1 and Adopt entire 2003 UPC Chapter without amendments		
Repeal entire 2000 UPC Chapter 1 and Adopt Entire 2003 UPC Chapter as amended ^{1, 2, 3} (amended sections listed below)		
Adopt Only those sections of the 2003 UPC which are listed below and/or Adopt Only those California promulgated sections ^{1, 2, 3} listed below	X	

¹ New Amendments are shown underlined with “CA”

² Existing amendments of the 2001 California Plumbing Code being repealed are shown stricken with “CA”

³ Existing amendments being continued from the 2001 CPC into the 2004 CPC are shown italicized with “CA”

<u>101.1.1</u>	CA	X	
<u>101.2.2</u>	CA	X	
<u>101.4.0</u>	CA	X	
101.4.1.4.1	CA	X	
<u>101.4.4</u>	CA	X	
<u>101.4.4.1</u>	CA	X	
<u>101.4.4.2</u>	CA	X	
<u>101.6</u>	CA	X	
<u>101.7</u>	CA	X	
<u>101.8</u>	CA	X	
<u>101.9</u>	CA	X	
<u>101.10.1</u>	CA	X	
<u>101.10.2</u>	CA	X	
<u>101.11</u>	CA	X	
<u>101.11.4</u>	CA	X	
<u>101.11.4.1</u>	CA	X	
<u>101.11.4.2</u>	CA	X	
<u>101.11.4.3</u>	CA	X	
<u>101.11.4.4</u>	CA	X	
<u>101.11.4.5</u>	CA	X	
<u>101.11.4.6</u>	CA	X	
<u>101.11.4.7</u>	CA	X	

¹ New Amendments are shown underlined with "CA"

² Existing amendments of the 2001 California Plumbing Code being repealed are shown stricken with "CA"

³ Existing amendments being continued from the 2001 CPC into the 2004 CPC are shown italicized with "CA"

Amendments for chapter 1 are as follows:

101.0 Title, Scope and General

101.1 Title ...

101.1.1 [For CA] This document shall be known as the "California Plumbing Code." The provisions contained in the California Plumbing Code of the (compiled) California Building Standards Code as defined in Section 18910, Health and Safety Code, may be cited as such and are referred to hereafter as "these regulations", "these plumbing standards", or "this code".

101.2 Purpose ...

101.2.2 [For CA] To provide minimum standards to safeguard life or limb, health, property and public welfare, and protect against hazards that may arise from the use of plumbing piping and systems by regulating and controlling the design, construction, installation, quality of materials, location and operation of plumbing piping systems within the State of California.

101.3 Plans Required ...

101.4 Scope

101.4.0 [For CA] Application. The provisions of this code shall apply to the construction, alteration, moving, demolition, repair and use of all plumbing, gas, or drainage piping and systems of water heating or treatment equipment in or on any building or structure or outdoors on any premises or property.

101.4.1.4 Conflict Between Codes. When the requirements within ...

~~**101.4.1.4.1 [For CA] Conflicts Between Codes.** When the requirements of this code conflict with the requirements of the California Mechanical Code, Title 24, Part 4, the California Mechanical Code shall prevail.~~

Notation

Authority: B & PC §4008

Reference(s): B & PC §§4008 and 4081

101.4.2 ...

101.4.3 ...

101.4.4 [For CA] Effective Date. One hundred and eighty days after the date of publication, or as otherwise noted herein.

101.4.4.1 [For CA] The applicable subsection of Health and Safety Code Section 18938 is repeated here for clarity and reads as follows:

Section 18938 (b) The building standards contained in the Uniform Fire Code of the International Conference of Building Officials and the Western Fire Chiefs Association, Inc., the Uniform Building Code of the International Conference of Building Officials, Appendix Chapter 1 of the Uniform Code for Building Conservation of the International Conference of Building Officials, the Uniform Plumbing Code of the International Association of Plumbing and Mechanical Officials, the National Electrical Code of the National Fire Protection Association, and Uniform Mechanical Code of the International Conference of Building Officials, and the International Association of Plumbing and Mechanical Officials, as referenced in the California Building Standards Code, shall apply to all occupancies throughout the state and shall become effective 180 days after publication in the California Building Standards Code by the California Building Standards Commission or at a later date after publication established by the commission.

101.4.4.2 [For CA] The provisions of the model code which are adopted in this code are applicable to all occupancy groups and uses regulated by this code. The amendments to the model code are applicable only to those occupancies or uses which the State agency adopting the amendments is authorized to regulate as listed in Section 101.11.

101.6 [For CA] Non-Building Regulations. Requirements contained in the U.P.C., or in any other referenced standard, code, or document which are not building standards are defined in Section 18909, Health & Safety Code, shall not be construed as part of the provisions of this code.

101.7 [For CA] Order of Precedence. Where, in any specific case, different sections of this code specify different materials, methods of construction or other requirements, the most restrictive shall govern. When there is a conflict between a general and a specific requirement, the specific requirement shall apply.

101.8 [For CA] Format. This part fundamentally adopts the UMC by reference on a chapter-by-chapter basis. Such adoption is reflected in the adoption table of each chapter of this part. When the adoption table of a chapter of this part makes no reference to a specific chapter of the UMC, such chapter of the UMC is not adopted as a portion of this code.

101.9 [For CA] Validity If any chapter, section, subsection, sentence, clause or phrase of this code is for any reason held to be unconstitutional, contrary to statute, exceeding the authority of the State as stipulated by statutes, or otherwise inoperative, such decision shall not effect the validity of the remaining portion of this code.

101.10 Standard Reference Documents

101.10.1 [For CA] The codes, standards and publications, adopted and set forth in this code, including other codes, standards and publications referred to therein, by title and date of publication., are hereby adopted as standard reference documents of this code.

101.10.2 [For CA] When this code does not specifically cover any subject relating to building design and construction, recognized fire-prevention engineering practices shall be employed. The National Fire Codes and the Fire Prevention Handbook of the National Fire Protection Association may be used as authoritative guides in determining recognized fire-prevention engineering practices.

101.11 [For CA] Application – Vesting authority. When adopted by a state agency, the provisions of this code shall be enforced by the appropriate Administrative Authority, but only to the extent of authority granted to that agency by the State Legislature.

Following is a list of the state agencies that adopt building standards, the specific scope of application of the agency responsible for enforcement, and the specific authority of each agency to adopt and enforce these provisions of building standards of this code, unless otherwise stated.

101.11.4 [For CA]

CA-Department of Consumer Affairs

101.11.4.1 CA; Board of Barber Examiners.

101.11.4.5 CA; Board of Pharmacy.

Application – Pharmacies.

Enforcing Agency – State or local agency specified by applicable provisions of law.

Authority Cited – B&PC §4008- 4005

References– B&PC §4084 4005, 4127.7 and 4201

Notation

Authority: B & PC §4008 4005

Reference(s): B & PC §§~~4008 and 4084~~ 4005, 4127.7 and 4102.

[TECHNICAL PROVISIONS]

PART 2, VOLUME 1, CALIFORNIA BUILDING CODE

304.2.2.4 [For CA] Pharmacies, veterinary facilities, barber colleges and shops, schools of cosmetology, cosmetological establishments, satellite classrooms and acupuncture offices. See Chapter 4A, Division 9.

SECTION 490A [FOR CA] – PHARMACIES

490A.1 Restrooms. A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

490A.2 Sink. All pharmacies shall be equipped with a sink within the pharmacy for pharmaceutical purposes. The sink shall be supplied with hot and cold running water.

490A.3 Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.
2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solution.

There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

- (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- (b) An ISO class 5 cleanroom.
- (c) A barrier isolator that provides an ISO class 5 environment for compounding.

NOTE: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

Notation

Authority: B & PC §4008 4005

Reference(s): B & PC §§~~4008 and 4084~~ 4005, 4127.7. and 4201

PART 4, CALIFORNIA MECHANICAL CODE

Adopt the following articles for Chapter 5 of the 2003 UMC:

(UMC standards adopted by CA are applicable to all occupancies regulated by Consumer Affairs in California.)

**CHAPTER 5
EXHAUST SYSTEMS
MATRIX ADOPTION TABLE**

Adopting Agency	CA	COMMENTS
Repeal entire 2000 UMC Chapter 5 and Adopt entire 2003 UMC Chapter without amendments		
Repeal entire 2000 UMC Chapter 5 and Adopt Entire 2003 UMC Chapter as amended ^{4, 5, 6} (amended sections listed below)		
Adopt Only those sections of the 2003 UMC which are listed below and/or Adopt Only those California promulgated sections ^{1, 2, 3} listed below	X	
505.12 CA	X	
505.12.1 CA	X	

505.12 Pharmacies – Compounding Area for Parenteral Solutions. [For CA – Board of Pharmacy]
The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. Be ventilated in a manner not interfering with laminar air flow.

NOTE: For additional pharmacy building standard requirements, see Chapter 4A, Section 490A, California Building Code.

505.12.1 Pharmacies – laminar flow biological safety cabinet. [For CA – Board of Pharmacy] In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.

505.12.2 Pharmacies Compounding Parenteral Solutions from One or More Nonsterile Ingredients.
Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

- (d) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- (e) An ISO class 5 cleanroom.
- (f) A barrier isolator that provides an ISO class 5 environment for compounding.

¹ New Amendments are shown underlined with "CA"

² Existing amendments of the 2001 California Mechanical Code being repealed are shown stricken with "CA"

³ Existing amendments being continued from the 2001 CMC into the 2004 CMC are shown italicized with "CA"

NOTE: For additional pharmacy building standard requirements, see Chapter 4A, Section 490A, California Building Code.

Notation

Authority: B & PC §~~4008~~ 4005

Reference(s): B & PC §§~~4008 and 4081~~ 4005, 4127.7 and 4102