Agenda Item C

Regulation Update

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: April 14, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Regulation Update

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 will be incorporated into the board packet for the April 26, 2006 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 will be incorporated into the board packet for the April 26, 2006 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 competed 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.

Attached is a copy of the specific language for each proposed regulation awaiting notice.

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.

Board Approved

Awaiting Notice

Board omnibus regulation provisions for 2006 (technical changes)

Repeal 16 CCR Section 1786 - An Outdated Provision Related To Exemptees.

~~**CCR 1786. Exemptions.**~~

~~(a) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4054, leaves the employ of a supplier, said supplier shall immediately return the certificate of exemption to the board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4051, 4053 and 4054, Business and Professions Code.~~

Revise Section 1706.2 of the California Code of Regulations, to read:

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy~~,~~ wholesaler, out-of-state distributor, ~~or~~ clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4029, 4037, 4043, 4110, 4112, 4115, 4120, 4127.1, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

Revise Section 1775.4 of the California Code of Regulations, to read:

CCR 1775.4. (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)
(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code.
Reference: Sections 125.9 and 148, Business and Professions Code.

Revise Section 1709.1 of the California Code of Regulations, to read:

CCR 1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

Revise Section 1780 of the California Code of Regulations, to read:

CCR 1780. The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:
(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).
(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
(1) All facilities shall be equipped with an alarm system to detect entry after hours.
(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(3) The outside perimeter of the wholesaler premises shall be well-lighted.
(d) All materials must be examined upon receipt or before shipment.
(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of

prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

Revise Section 1780.1 and 1781 of the California Code of Regulations, to read:

CCR 1780.1. In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots

of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

g. Refilling A Veterinarian's Prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer
(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)
(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and

number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

1781. Exemption Certificate
A registered pharmacist, or a~~n~~ ~~exemptee~~ designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.

Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1717.2. Notice of Electronic Prescription Files.**~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~_____ _____~~
~~(date) (signature of patient)~~

~~_____~~
~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

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

Board of Pharmacy
Specific Language to Amend Section 1760

Amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/~~2001~~ 2006), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

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Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form M- (created 1/06) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

Awaiting

Board Review

Blank

[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 4081~~ 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 4081~~ 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"

101.1.1 *CA*	X	
101.2.2 *CA*	X	
101.4.0 *CA*	X	
~~*101.4.1.4.1*~~ ~~*CA*~~	~~X~~	
101.4.4 *CA*	X	
101.4.4.1 *CA*	X	
101.4.4.2 *CA*	X	
101.6 *CA*	X	
101.7 *CA*	X	
101.8 *CA*	X	
101.9 *CA*	X	
101.10.1 *CA*	X	
101.10.2 *CA*	X	
101.11 *CA*	X	
101.11.4 *CA*	X	
101.11.4.1 *CA*	X	
101.11.4.2 *CA*	X	
101.11.4.3 *CA*	X	
101.11.4.4 *CA*	X	
101.11.4.5 *CA*	X	
101.11.4.6 *CA*	X	
101.11.4.7 *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 §~~4081~~ 4005, 4127.7 and 4201

Notation
Authority: B & PC §~~4008~~ 4005
Reference(s): B & PC §§~~4008 and 4081~~ 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 4081~~ 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, se 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 Parenterial 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.

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[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

Agenda Item D

Consideration of request from MedImmune, Inc. to Amend B&P section 4162.5(a)(4) related to surety bond requirements

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: April 14, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: MedImmune Legislative Proposal Request

ACTION

On March 21, 2006 the board received a letter from Colleen Chawla, Government Affairs Manager for MedImmune, Inc.. MedImmune Inc. is requesting the board sponsor legislation for a technical amendment to B&P Section 4162.5(a)(4), Submission of Surety Bond for the Issuance or Renewal of Nonresident Wholesaler License; Exemption. Attached it the letter from MedImmune Inc. and proposed language.

MedImmune, Inc.

BOARD OF PHARMACY
2006 MAR 21 PM 2:39

March 17, 2006

Patricia Harris
Executive Officer
California Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Harris:

I am writing to respectfully request that the Board of Pharmacy consider including in its sponsored legislation pertaining to non-resident wholesalers a clarifying amendment to California statute relating to surety bond requirements for licensed manufacturers who are also licensed as nonresident wholesalers in California. I have attached proposed language for this amendment.

Currently, as noted in the October 2005 issue of *The Script*, "[l]icensed manufacturers who are licensed as wholesalers or nonresident wholesalers in California are exempt from [surety bond] requirements." Business & Professions Code Section 4162.5(a)(4) exempts from surety bond requirements a holder of an approved new drug application, which allows for the sale and marketing of a pharmaceutical product in the United States. Our understanding is that this exemption was meant to be applied in its broadest sense to include licensed manufacturers of any pharmaceutical products considered drugs or biologics. Please note, with respect to pharmaceutical products, the FDA uses terminology particular to drugs and biologics. Specifically, manufacturers of biological products may hold a *biologics license application*, which is the equivalent of a *new drug application* for biologic products.

The attached proposed language would clarify and remove any ambiguity that the exemption to the surety bond requirement for licensed manufacturers that are also licensed as nonresident wholesalers applies to manufacturers with approved new drug applications <u>and</u> approved biologics license applications.

I very much appreciate your consideration of this request. Please feel free to contact me at (510) 339-1693 if I can answer any questions or if you would like to discuss this further.

Sincerely,

Colleen Chawla
Government Affairs Manager

Enclosure

One MedImmune Way Gaithersburg, Maryland 20878 301-417-0770 Fax: 301-527-4200

MedImmune Legislative Proposal Request

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application <u>or a biologics license application</u> has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.