California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Dazé, Board Member
Robert Graul, Board Member
Ken Schell, PharmD, Board Member

REGULATION REPORT

1. BOARD ADOPTED REGULATIONS – PENDING ADMINISTRATIVE REVIEW

The following pending regulations were adopted by the board at the July 2007 Board meeting.

a. Proposed Amendment to 16 CCR 1707.2 – Notice to Consumer

FOR INFORMATION:

CCR 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122. Assembly Bill 2583 (Chapter 487, Statutes of 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to amend the "Notice to Consumers" to include a statement that describes a patient's right to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication is required.

The revised Notice, exact language and Initial Statement of Reasons is provided in **Attachment 1**

This rulemaking file was sent to the Office of Administrative Law (OAL) on September 18, 2007. The OAL has six weeks to act on the file.

b. Proposed Amendment to 16 CCR 1749 – Fee Schedule

FOR INFORMATION:

CCR 1749 established specific application and renewal fees for licensees according to the range set forth in Business and Professions Code. At the April 2007 Board Meeting, the board voted to approve a recommendation from the board's Organizational Development Committee to increase all board fees to their statutory maximum amounts.

This proposal will raise board fees to their statutory maximum as provided for the referenced Business and Professions Code sections. This proposal is necessary to ensure sufficient revenue to maintain current board operations.

For more than four years the board's expenses have exceeded the board's revenues. Repayment of a 2001 $6 million loan to the General Fund has allowed the board to maintain its operating expenses without increasing fees. However, a review of the Fund Condition for future years reveals that a fee increase must be sought now to continue board operations without a deficit. Without a fee increase, the board's fund condition will be reduced to a little over a one-month reserve by the end of fiscal year 2008-09 and will be in a deficit by three and one half months by the end of fiscal year 2009-10.

The Notice, exact language and Initial Statement of Reasons is provided in **Attachment 2.**

The rulemaking was submitted to the Office of Administrative Law on October 9, 2007.

c. Section 100 Changes

FOR INFORMATION:

The Board of Pharmacy submitted the following Section 100 regulation package to the Office of Administrative Law. The proposed amendments are listed below. These changes are without regulatory effect because they merely conform to statutory changes already in effect as well as to remove an outdated regulation.

Proposed Amendment to CCR §1707. Waiver Requirements for Off-Site Storage of Records - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

16 CCR § 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge. - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Amendment to CCR § 1715 – Self Assessment Forms - The self-assessment forms, which is incorporated by reference in the regulation, is a compilation of laws. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the forms last revision date.

Proposed Amendment to CCR §1717. Pharmacy Practice – This section currently makes reference to section 1306.26 of the Code of Federal Regulations. This reference is incorrect and needs to be changed to the appropriate CFR section, 1306.25.

16 CCR §1780.1 and §1781 – Replace the term "Exemptee" with "Designated Representative"- In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Repeal of 16 CCR §1786 – Return of Exemption Certificates - This section is outdated and needs to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law, which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

Proposed Amendment to CCR §1787. Authorization to Distribute Dialysis Drugs and Devices - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Amendment to CCR §1790. Assembling and Packaging - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Amendment to CCR § 1793.8. – Pharmacy Technicians in Hospitals - This section currently references Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

A copy of the exact language is provided in **Attachment 3.** Unfortunately because of the scope of the changes contained in the Self-Assessment forms, board staff withdrew this rulemaking to further substantiate each change being made in the form at the request of the OAL. The concern from OAL was that the board could be creating legal requirements within the form and wanted specific history references. Board staff is working on completing these historical summaries on legal citations and anticipates resubmitting this rulemaking in late October 2007.

d. Board Approved Regulations Awaiting Conformance with California Building Standards Rulemaking Process

FOR INFORMATION:

At the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. Thereafter, the Building Standards Commission advised the board of a new process to submit items into the California Building Code. These changes were submitted to the Buildings Standards Commission in compliance with their rulemaking procedures.

2. BOARD APPROVED REGULATIONS – AWAITING PUBLIC NOTICE

a. Proposed Addition to CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

FOR INFORMATION:

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal

requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed at the September 2007 Enforcement Committee meeting with a recommendation that the board approve the regulation proposal at the October 2007 Board Meeting.

A copy of the draft language and form is included in the Enforcement Committee portion of this board packet.

b. Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines

FOR INFORMATION:

The board also approved amendment to 16 CCR 1760 – Disciplinary Guidelines.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff has suggested a number of amendments to the Disciplinary Guidelines that were last revised in 2001. Upon completion, this rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law.

Staff made recommendations for changes that were presented to the board at the June 2007 Enforcement Committee. The revised were Disciplinary Guidelines reviewed at the September 2007 Enforcement Committee meeting with a recommendation that the board approve the regulation proposal at the October 2007 Board Meeting.

A copy of the draft language and guidelines is included in the Enforcement Committee portion of this board packet.

c. Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material

FOR INFORMATION:

CCR 1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the April 2007 Legislation and Regulation Committee meeting the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material. At the June 2007 committee meeting, Dr. Schell offered to facilitate a taskforce to review the USP Standards Reference Material.

d. Proposed Regulation 16 CCR 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

FOR INFORMATION:

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal

A copy of the language is provided in **Attachment 4.**

Attachment 1

16 CCR 1707.2 – Notice to Consumer

- Notice
- Exact Language
- Initial Statement of Reasons

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 2, 2007.

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 18, 2007.

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, and make specific reference sections 733 and 4122, 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

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

California Code of Regulations Section 1707.2 currently requires that every pharmacy prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122.

Assembly Bill 2583 (Chapter 487, Statutes 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to add to the "Notice to Consumers", a statement that describes a patient's rights to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication are required.

Section 1707.2 of the California Code of Regulations will be amended to include the additional language now required.

The board will develop and distribute a new "Notice to Consumers" poster.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: $18,000

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. The Board will develop, reproduce and distribute this revised Notice to Consumer within existing Board funding.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business. This proposal expands the information contained on the existing "Notice to Consumer" posting and requires that pharmacies post the revised poster(s). The board will develop and reproduce the poster at no additional cost to pharmacies.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would 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 proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

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 may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

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

All the information upon which the proposed regulation is 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:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

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

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Notice to Consumers

Sections Affected: Amend 1707.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes amending Section 1707.2 of the California Code of Regulations to reflect statutory changes enacted by Assembly Bill 2583 (Chapter 487, Statutes of 2006).

Discussion: Assembly Bill 2583 (Chapter 487, Statutes 2006) amended Sections 733 and 4122 of the Business and Professions Code to require the board to add to the "Notice to Consumers" poster a statement that describes a patient's rights to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication are required.

Section 1707.2 of the California Code of Regulations will be amended to include the additional language now required.

Factual Basis/Rationale

This proposal will make CCR section 1707.2 consistent with the requirements detailed in Business and Professions Code sections 733 and 4122.

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 hearing 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.

Title 16. Board of Pharmacy
Proposed Language

Amend Section 1707.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1707.2 (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action

required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:

> "NOTICE TO CONSUMERS"
> At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.
>
> Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.
>
> Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.
>
> Before taking any prescription medicine, talk to your pharmacist; be sure you know:
>
> What is the name of the medicine and what does it do?
> How and when do I take it – and for how long? What if I miss a dose?
> What are the possible side effects and what should I do if they occur?
> Will the new medicine work safely with other medicines and herbal supplements I am taking?
> What foods, drinks or activities should I avoid while taking this medicine?
>
> Ask your pharmacist if you have additional questions.

<u>(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:</u>

> <u>Know your rights under California law concerning medicine and devices prescribed to you.</u>
>
> <u>You have the right to receive medicine and devices legally prescribed to you, unless:</u>
> <u>1. The medicine or device is not in stock in the pharmacy,</u>
> <u>2. The pharmacist, based upon his or her professional judgment determines providing the item:</u>
>
> - <u>is against the law,</u>
> - <u>could cause a harmful drug interaction, or</u>
> - <u>could have a harmful effect on your health</u>

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

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

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

Any questions? Ask the pharmacist!

Authority cited: Sections 4005 and 4122 Business and Professions Code. Reference: Sections 733, 4005 and 4122 Business and Professions Code.

Attachment 2

16 CCR 1749 – Fee Schedule

- Notice
- 15-Day Notice Language
- Initial Statement of Reasons

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 2, 2007.

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 18, 2007.

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, and make specific reference sections 122, 163.5, 4127.5, and 4400 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

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy and the administration of Chapter 9, Division 2.

Business and Professions Code section 122 allows the board to charge a fee for the processing and issuance of a duplicate copy of any certification of licensure or other form evidencing licensure or renewal of licensure.

Business and Professions Code section 163.5 establishes the criteria to determine the delinquency fee for any licensee within the Department of Consumer Affairs.

Business and Professions Code section 4127.5 establishes the minimum and maximum fee for the issuance on nongovernmental license or renewal of a license to compound sterile drug products.

Business and Professions Code section 4400 establishes the statutory minimum and maximum fee schedule for application, renewal and other fees for additional board applicants and licensees.
California Code of Regulations section 1749 establishes the fee schedule for application, renewal and other fees for board licensees and applicants.

This proposal would raise board fees to their statutory maximum as provided for in the

above referenced Business and Professions Code sections. This proposal is necessary to ensure sufficient resources to maintain current board operations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: Estimated to increase board revenues for FY 07/08 by approximately $795,000 and an increase to ongoing annual revenue by approximately $1.5 million. The board does not anticipate any effect on federal funding.

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 increase a business renewal $75 to $100/annually per business license. In addition a business seeking licensure with the board would also experience a $75 - $100 increase in the application fee, per site.

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 has made an initial determination that a pharmacist renewing his or her license would be subject to an additional $45 biennially and designated representatives would be subject to an additional $40 annually to renew a license.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would have a minimal effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would 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 proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the address indicated under "Contact Person."

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 may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

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

All the information upon which the proposed regulation is 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:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

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

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Fee Schedule

Sections Affected: Amend 1749

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1749 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is allow the board to raise fees to the statutory maximums specified in the relevant Business and Professions Code section.

Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy and the administration of Chapter 9, Division 2.

Business and Professions Code section 122 allows the board to charge a fee for the processing and issuance of a duplicate copy of any certification of licensure or other form evidencing licensure or renewal of licensure.

Business and Professions Code section 163.5 establishes the criteria to determine the delinquency fee for any licensee within the Department of Consumer Affairs.

Business and Professions Code section 4127.5 establishes the minimum and maximum fee for the issuance on nongovernmental license or renewal of a license to compound sterile drug products.

Business and Professions Code section 4400 establishes the statutory minimum and maximum fee schedule for application, renewal and other fees for additional board applicants and licensees.

California Code of Regulations section 1749 establishes the fee schedule for application, renewal and other fees for board licensees and applicants.

With the exception of a four-year period between 1995 and 1999 board applicants and licensees have not experienced a fee increase since 1988 when fees were raised pursuant to legislation (Chapter 657, Statutes of 1987). A review of the Consumer Price Index reveals that the cost of consumer goods has risen steadily since 1988, (approximately 73%); however, except as stated above, board fees have remained unchanged.

For more than four years the board's expenses have exceeded board's revenues. Repayment of a 2001 $6 million loan to the General Fund has allowed the board to maintain its operating expenses. A review of the anticipated Fund Condition for the board reveals that a fee increase must be sought to continue board operations. It is estimated that absent a fee increase, the board's fund condition will be reduced to a little over a one-month reserve by the end of fiscal year 2008-09 and will be in a deficit by three and one half months by the end of fiscal year 2009-10.

In addition, the board anticipates an increase in its operating expenses to allow for a recruitment and retention differential for pharmacy inspectors. This recruitment and retention differential, which was included in the Governor's budget, would authorize an additional $576,000/year to the board's budget. This has accelerated the need to increase fees by six months.

Underlying Data

Analysis of Fund Condition with current fees.
Analysis of Fund Condition with proposed fee increase effective January 1, 2008.
Estimated Workload and Revenue with current fees.
Estimated Workload and Revenue with proposed fee increase effective Jan 1, 2008.

Business Impact

The board does not believe that this regulation will have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

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

Consideration of Alternatives

The only alterative to this proposal is to keep fees at their current level. However as evidenced by the Analysis of Fund Condition, this would create a significant deficit for the board.

No reasonable alternative to repealing 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 repeal of the regulation.

Board of Pharmacy
Specific Language

Amend Section 1749 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749. Fee Schedule.
The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections ~~122,~~ 163.5, 4110, 4127.5, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:
(a) The fee for the issuance of a pharmacy license is ~~three hundred forty dollars ($340)~~ four hundred dollars ($400). The fee for the annual renewal of pharmacy license is ~~one hundred seventy-five dollars ($175)~~ two hundred fifty dollars ($250). The penalty for failure to renew is ~~eighty-seven dollars and fifty cents ($87.50)~~ one hundred and twenty five dollars ($125).
(b) The fee for the issuance of a temporary license is ~~one hundred seventy-five dollars ($175)~~ two hundred fifty dollars ($250).
(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25).
(d) The fee for application and examination as a pharmacist is ~~one hundred fifty-five dollars ($155)~~ one hundred eighty five dollars ($185).
(e) The fee for regrading an examination is ~~seventy-five dollars ($75)~~ eighty-five dollars ($85).
(f) The fee for the issuance of an original pharmacist license is ~~one hundred fifteen dollars ($115)~~ one hundred fifty dollars ($150).
(g) The fee for the biennial renewal of a pharmacist's license is ~~one hundred fifteen dollars ($115)~~ one hundred fifty dollars ($150). The penalty fee for failure to renew is ~~fifty-seven dollars and fifty cents ($57.50)~~ seventy-five dollars ($75).
(h) The fee for the issuance or renewal of a wholesaler's license is ~~five hundred fifty dollars ($550)~~ six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is ~~ninety dollars ($90)~~ one hundred twenty five dollars ($125). The penalty for failure to renew is ~~forty-five dollars ($45)~~ sixty-two dollars and fifty cents ($62.50).
(j) ~~The fees for a certificate of exemption designated representative under the provisions of sections 4053 or 4054 of the Business and Professions Code are as follows:~~
~~(1) For the application and investigation of the applicant, the fee is seventy-five dollars ($75) one hundred forty dollars.~~
The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($150)
~~(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). For the annual renewal of a certificate, the fee is one hundred fifty dollars ($150).~~ The penalty for failure to renew is ~~fifty-five dollars ($55)~~ seventy-five dollars ($75).

(k) The fee for the issuance or renewal of a license as ~~an out-of-state distributor~~ a nonresident wholesaler is ~~five hundred fifty dollars ($550)~~ six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for an intern pharmacist license is ~~sixty-five dollars ($65)~~ seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state is ~~ten dollars ($10)~~ ~~twenty-five dollars ($25)~~ twenty dollars ($20).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is ~~sixty dollars ($60)~~ one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is ~~three hundred forty dollars ($340)~~ four hundred dollars ($400). The fee for the annual renewal of clinic license is ~~one hundred seventy-five dollars ($175)~~ two hundred fifty dollars ($250). The penalty for failure to renew is ~~eighty-seven dollars and fifty cents ($87.50)~~ one hundred and twenty five dollars ($125).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).
(r) The fee for a veterinary food-animal drug retailer license is four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer is two hundred and fifty dollars ($250). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250)
(s) The fee for the issuance of a retired pharmacist license shall be thirty dollars ($30).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections ~~122,~~163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4196, 4200, 4400,4401 and 4403, Business and Professions Code.

Attachment 3

Section 100 Changes

Language

BOARD OF PHARMACY

Final Language

(1) Amend Section 1707 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707. Waiver Requirements for Off-Site Storage of Records.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining

the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or ~~exemptee~~ designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

(2) Amend Section 1709.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1709.1. Designation of Pharmacist-in-Charge.

(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.

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

(3) Amend Section 1715 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy'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 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(c) The components of this assessment shall be on Form 17M-13 (Rev ~~1/05~~ 6/07) entitled "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev ~~1/05~~ 6/07) entitled "Hospital Pharmacy Self-Assessment" which are 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 pharmacy for three years after it is performed.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4305, 4330, 4332 and 4333, Business and Professions Code.

(4) Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, ~~1306.26~~ 1306.25.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

NOTE: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

(5) Amend Section 1780.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

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.

(c~~.~~) Dangerous Drugs, legend drugs or extra label use drugs returned to a veterinary food-animal drug retailer from a client shall be treated as damaged or outdated prescription drugs and stored in the quarantine area specified in section 1780(e)(1). Returned drugs may not be returned to stock, or dispensed, distributed or resold.

(d~~.~~) ~~a~~ A pharmacist or person issued a permit under Business and Professions Code section 4053 (hereafter called a vet retailer ~~exemptee~~ designated representative) may dispense drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian. Only a pharmacist or the vet retailer ~~exemptee~~ designated representative may receive an oral order for a veterinary food-animal drug from the veterinarian. A written copy of the oral prescription shall be sent or electronically transmitted to the prescribing veterinarian within 72 hours.

(e~~.~~) ~~When a~~ 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 ~~Exemptees~~ 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.

NOTE: 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.

(6) Amend Section 1781 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. Exemption Certificate.

A registered pharmacist~~,~~ or ~~an exemptee~~ a 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.

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

(7) Section 1786 of Division 17 of Title 16 of the California Code of Regulations is repealed.

~~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.~~

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

(8) Amend Section 1787 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1787. Authorization to Distribute Dialysis Drugs and Devices.

(a) Only the following dangerous drugs and devices may be distributed directly to home dialysis patients in case or full shelf package lots:

(1) Dialysate

(2) Heparin 1000u/cc

(3) Sterile Sodium Chloride 0.9% for injection

(4) Needles

(5) Syringes

(6) Dialyzers, delivery systems and their accessory equipment necessary for chronic hemodialysis.

(b) The drugs and devices specified in 1787(a) may be distributed on the basis of a written or oral order received from a licensed prescriber. The prescriber or his or her authorized employee may transmit oral orders directly to a pharmacist or ~~exemptee~~ designated representative.

(c) Orders are refillable during a six-month interval as ordered by the prescriber. Records of such refills shall be retained by the supplier for three years.

NOTE: Authority cited: Sections 4005 and 4059, Business and Professions Code. Reference: Sections 4059, 4081 and 4332, Business and Profession Code.

(9) Amend Section 1790 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1790. Assembling and Packaging.

A record of shipment or expanded invoice shall be included in the patient's shipment, and shall include the name(s) of the drugs or devices, quantities,

manufacturer's name and lot number, date of shipment, and the name of the pharmacist or ~~exemptee~~ designated representative who supervised and was responsible for the distribution. Copies of the record shall also be distributed to the prescribing physician and retained by the supplier for three years.

NOTE: Authority cited: Sections 4005 and 4059, Business and Profession Code. Reference: Sections 4059, 4081 and 4332, Business and Professions Code.

(10) Amend Section 1793.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8. Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in ~~4052~~ 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

NOTE: Authority cited: Section 4005 and 4115, Business and Professions Code. Reference: Section 4005 and 4115 Business and Professions Code.

Attachment 4

16 CCR 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Language

1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
   (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
   (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
   (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
   (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
   (5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.