Agenda Item B

Approved Regulations

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

To: Legislation and Regulation Committee

From: Staff

Subject: Approved Regulation

The Office of Administrative Law recently approved a board rulemaking file.

Repeal of 16 CCR 1717.2 Notice of Electronic Prescription Files
The repeal of Section 1717.2 of the California Code of Regulations removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy. This regulation change will go into effect March 26, 2007

A copy of the exact language are provided.

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.~~

Agenda Item C

Board Adopted Regulations Pending Administration Review

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Adopted Regulations - Pending Administration Review

There are currently three regulations undergoing Administration Review.

Adoption of 16 CCR 1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge

The adoption of Section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This rulemaking was submitted to the Department on December 28, 2006 and was forwarded to the Office of Administrative Law on February 16, 2007.

Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation. This rulemaking was submitted to the Department on February 16, 2007.

Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation.

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time. This rulemaking was submitted to the Department on February 16, 2007.

Copies of the exact language are provided.

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 17M-26 (rev. 8/14/2006) 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.

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

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B & P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

☐ sole owner ☐ partnership ☐ corporation ☐ LLC

☐ non- licensed owner ☐ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Daily_____Sat_____ Sun_____ 24 Hours ☐

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH#_____Exp. Date _____

2. _____ DR#/RPH#_____Exp. Date _____

3. _____ DR#/RPH#_____Exp. Date _____

4. _____ DR#/RPH#_____Exp. Date _____

5. _____ DR#/RPH#_____Exp. Date _____

6. _____ DR#/RPH#_____Exp. Date _____

7. _____ DR#/RPH#_____Exp. Date _____

8. _____ DR#/RPH#_____Exp. Date _____

9. _____ DR#/RPH#_____Exp. Date _____

10_____ DR#/RPH#_____Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes	No	N/A	
☐	☐	☐	Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B & P 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**
☐	☐	☐	Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note:: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B & P 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

Premises, fixtures and equipment:

Yes	No	N/A	
☐	☐	☐	Are clean and orderly
☐	☐	☐	Are well ventilated
☐	☐	☐	Are free from rodents and insects
☐	☐	☐	Are adequately lit
☐	☐	☐	Have plumbing in good repair
☐	☐	☐	Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])
☐	☐	☐	Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B & P 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes	No	N/A	
☐	☐	☐	The owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory. (B & P 4081[b])
☐	☐	☐	Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B & P 4160[d])
☐	☐	☐	The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P 4305.5[a])
☐	☐	☐	The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.
☐	☐	☐	The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B & P 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes	No	N/A	
☐	☐	☐	If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B & P 4100, 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes	No	N/A	
☐	☐	☐	Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B & P 4163[b], 4169)

Yes No N/A

☐ ☐ ☐ If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B & P 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ Is all drug stock open for inspection during regular business hours? (B & P 4081[a])

☐ ☐ ☐ Are all drugs you order maintained in a secure manner at your licensed wholesale premises?. You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B & P 4167)

☐ ☐ ☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B & P 4342[a])

Yes No N/A

☐ ☐ ☐ Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

☐ ☐ ☐ When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (B & P 4059.5[a] [b][d], B & P 4169)

_____

_____

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes	No	N/A	
☐	☐	☐	Are drugs only furnished by your business to an authorized person? (B & P 4163[a]) Note: An authorized person can be a business or natural person.
			Does your business only receive drugs from a pharmacy if:
☐	☐	☐	the pharmacy originally purchased the drugs from you?
☐	☐	☐	your business is a "reverse distributor"?
☐	☐	☐	the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B & P 4126.5[a])
			Are all drugs that are purchased from another business or are sold, traded or transferred by your business:
☐	☐	☐	completed with a business licensed with this board as a wholesaler or pharmacy?
☐	☐	☐	free of adulteration as defined by the CA Health & Safety Code section 111250?
☐	☐	☐	free of misbranding as defined by CA Health & Safety Code section 111335?
☐	☐	☐	beyond their use date (expired drugs)? (B & P 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

Yes	No	N/A	
			If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:
☐	☐	☐	comply with all CA pharmacy laws related to the distribution of drugs?
☐	☐	☐	comply with the pharmacy law of the receiving state within the United States?
☐	☐	☐	comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?
☐	☐	☐	comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?
☐	☐	☐	comply with all applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B & P 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2007, an electronic pedigree must accompany all drugs (B & P 4163), even those for which your business is an authorized distributor.

☐ ☐ ☐ If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P 4380)

☐ ☐ ☐ Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B & P 4341, B & P 651, CCR 1766)

☐ ☐ ☐ Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B & P 650)

_____

_____

Yes No N/A

☐ ☐ ☐ Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B & P 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

Yes No N/A

☐ ☐ ☐ Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B & P 4166[a])

List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B & P 4059.5[a])

☐ ☐ ☐ Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B & P 4059[d])

☐ ☐ ☐ All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B & P 4059.5[c])

☐ ☐ ☐ If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B & P 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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11. Controlled Substances

Yes No N/A

☐ ☐ ☐ Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

Yes	No	N/A	
☐	☐	☐	Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])
☐	☐	☐	Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
☐	☐	☐	Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])
☐	☐	☐	Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])
☐	☐	☐	Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.07)

List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes	No	N/A	
☐	☐	☐	Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
☐	☐	☐	If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
☐	☐	☐	Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
☐	☐	☐	If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
☐	☐	☐	If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes	No	N/A	
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances.(CFR 1301.74[f])
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[f])
☐	☐	☐	Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)
☐	☐	☐	When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.09 [b])
☐	☐	☐	If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.11)
☐	☐	☐	When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.05[b])
☐	☐	☐	For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.09[e])
☐	☐	☐	Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances?
☐	☐	☐	Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.12)
☐	☐	☐	Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the

making? (B & P 4081, CCR 1718, CFR 1305.09[d], 1305.13[a] [b], and H & S 11252, 11253, 1304.03)

Yes	No	N/A	
☐	☐	☐	Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
☐	☐	☐	Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

Does your business always comply with the following requirements:

Yes	No	N/A	
☐	☐	☐	Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
☐	☐	☐	Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)
☐	☐	☐	Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])
☐	☐	☐	Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes	No	N/A	
☐	☐	☐	Receipt of drugs?
☐	☐	☐	Security of drugs?
☐	☐	☐	Storage of drugs? (including maintaining records to document proper storage)
☐	☐	☐	Inventory of drugs? (including correcting inaccuracies in inventories)
☐	☐	☐	Distributing drugs?
☐	☐	☐	Identifying, recording and reporting theft or losses?
☐	☐	☐	Correcting errors?
			Physically quarantining and separating:
☐	☐	☐	returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
☐	☐	☐	drugs that have been partially used?
☐	☐	☐	drugs where the outer or secondary seals on the container have been broken?

Yes No N/A

☐ ☐ ☐ drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

☐ ☐ ☐ drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

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13. Training

Yes No N/A

☐ ☐ ☐ Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B & P 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B & P 4059[d])

☐ ☐ ☐ Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the

prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B & P 4059[b])

☐ ☐ ☐ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B & P 4081[a], 4105[c], 4081, 4332, 4059.5[a])

☐ ☐ ☐ Are all purchase and sales records retained in a readily retrievable form? (B & P 4105[a])

☐ ☐ ☐ Is a current accurate inventory maintained for all dangerous drugs? (B & P 4081, 4332, 1718)

☐ ☐ ☐ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B & P 4105[b])

☐ ☐ ☐ Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

Yes No N/A

☐ ☐ ☐ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

☐ ☐ ☐ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B & P 4162[a][4]):

_____

_____

Yes No N/A

☐ ☐ ☐ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B & P 4083)

☐ ☐ ☐ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B & P 4315[e])

☐ ☐ ☐ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B & P 4101[b], 4305.5[c].

☐ ☐ ☐ The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B & P 4305.5[a])

Yes	No	N/A	
☐	☐	☐	The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
☐	☐	☐	The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])
☐	☐	☐	Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
☐	☐	☐	The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B & P 4201[i], CCR 1709[b])
☐	☐	☐	When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B & P 4164[a])
☐	☐	☐	Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must: 1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities 2. identify purchases of any dangerous drugs at preferential or contract prices 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B & P 4164[b])
☐	☐	☐	I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B & P 4201[g])
☐	☐	☐	The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
☐	☐	☐	If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B & P 4107, CFR 1305.11[a], B & P 4059.5[e])

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

Legal References

All references to California Business & Professions Code (B & P) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws http://www.dhs.ca.gov/fdb/PDF/Sherman%202006.PDF

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (http://www.deadiversion.usdoj.gov/21cfr/index.html).

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
http://www.mbc.ca.gov

Dental Board of California
1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
http://www.ombc.ca.gov

Physician Assistant Committee
1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
http://www.physicianassistant.ca.gov

Board of Podiatric Medicine
1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960
(Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
Registration: (888) 304-3251 or
(415) 436-7900
Theft Reports or Diversion: (415) 436-7854

DEA - Sacramento
4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100
or (916) 480-7250

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000
or (909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (408) 291-7620
or (408) 291-2631

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

Board of Pharmacy
Specific Language

Amend Section 1706.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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.
(e) An applicant for a pharmacist intern license who fails to complete all application requirements within one year 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code.

Board of Pharmacy
Specific Language

Amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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 by submitting a written request at least 2 days in advance of the scheduled office conference.
(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 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.

Note: Authority cited: Sections 129.5, 148 and 4005, Business and Professions Code. Reference: Sections 125.9, 148, 684, 4067, 4127.4 and Business and Professions Code and Section 56.36 of the Civil Code.

Agenda Item D

Board Approved Regulation Currently Noticed – Action Recommended at April 2007 Board Meeting

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Currently Noticed – Action Recommended at the April 2007 Board Meeting.

The following pending regulation was noticed on February 23, 2007.

Proposed Amendment to 16 CCR 1707.2 – Notice to Consumers

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 457, Statutes of 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to amend the "Notice to Consumer" 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.

A copy of the Notice, exact language and Initial Statement of Reasons is provided as well as the single comment received.

The comment period for this proposal is over April 9, 2007. To date the board has received comments from John Cronin, PharmD., J.D. in response to this notice, but no hearing has been requested.

A copy of Dr. Cronin's letter and comments is provided. Dr. Cronin states that the proposed language included in CCR 1707.2 restores requirements that opponents to AB 2583 worked to eliminate and as such the proposed regulation does not meet the language or intent of AB 2583, specifically the requirement that the require a separate notice for posting the additional "Notice to Consumer."

At the January 2007, board meeting, the board voted to create a second poster to contain the additional the provisions in AB 2583 (Chapter 487, Statutes of 2006) as the additional information could not fit on the current poster.

Dr. Cronin also states that the proposed language does adequately emphasize the other exceptions upon which a pharmacist may refuse to dispense a medication not does it adequately reflect the prohibition against obstructing a patient in obtaining a legally prescribed medication. Specifically Dr. Cronin provides two key provisions define these conditions - - that a pharmacist can legally decline to fill a prescription is based "soley on the pharmacist's professional training and judgment." and that a

legitimate reason to decline to fill a prescription is that the product is out of stock.

The board's language does speak specifically to the other scenarios when a pharmacist can refuse to dispense a medication, however the draft language provided by Dr. Cronin may be clearer.

Dr. Cronin also states that the proposed language implies that a pharmacist that declines to fill a prescription is required to assist in getting the prescription filled by another pharmacy and that this requirement is not part of the legislative change. Rather, a pharmacist is required to assist or refer the patient to another pharmacy if the pharmacy does not have the drug in stock, and in that situation the pharmacy can return the prescription and make a "reasonable effort" to refer the patient to a pharmacy that stocks the product. However, when a pharmacist declines to fill a prescription on ethical, moral or religious grounds, the pharmacy is required to have protocols in place to ensure the patient has timely access to the product.

Staff generally agrees with Dr. Cronin's statement that the pharmacy must have protocol's in place and is not required to refer the patient to another pharmacy.

Dr. Cronin provided alternative language, a copy of which is provided.

Board staff has reviewed Dr. Cronin's language and it appears to also comply with the requirements detailed in AB 2583 (Chapter 487, Statutes 2006). Should the committee recommend, and the board vote to amend the proposed language, an additional 15-day comment period will be required to allow interested parties to comment on the proposed changes, following the April Board Meeting.

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 April 9, 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 March 25, 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 shall 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 is 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 the "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

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 medicines and devices legally prescribed to or ordered for you after proper payment, unless providing them to you:</u>
>
> 1. <u>is against the law or</u>
> 2. <u>will cause a harmful interaction with drugs prescribed to you or</u>
> 3. <u>will affect your health in a negative way</u>
>
> <u>This pharmacy may refuse to fill a prescription for ethical, moral or religious reasons, but is required to help you get the prescription filled by another</u>

pharmacy. Ask about our procedure to help you get a drug or device 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.

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 is 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.

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March 22, 2007

Anne Sodergren
California State Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento CA 95834
via e-mail

re: Comments on Proposed Regulation: Notice to Consumers

Dear Ms. Sodergren:

Attached please find my comments on the proposed regulation to amend Section 1707.2 of the California Code of Regulations relating to the new requirements for the Notice to Consumer. I am submitting these comments on behalf of myself and my pharmacy business.

I am not requesting a hearing on this regulation. I have noticed that this regulation is on the agenda for the Legislation and Regulation Committee meeting on April 3. I will be attending that meeting and will be happy to discuss these comments with the Committee at that time.

Sincerely,

John Cronin, Pharm.D.,J.D.

Comments on Proposed Regulation

Section 1707.2 Notice to Consumers

Submitted by John Cronin, Pharm.D., J.D.
Fredrickson, Mazeika & Grant and CWL Pharmacies, Inc.

The Board of Pharmacy proposes this regulatory change to meet the requirements of AB2583 (Chapter 487, Statutes of 2006) to incorporate a statement that describes a patient's rights to obtain prescribed medication into the existing Notice to Consumers required in B&P Code section 4122. The Board does not intend to hold a hearing on this regulation and these comments do not request a hearing. They are offered as changes to the proposed regulation language to better reflect the language and intent of AB2583 and B&P Code Section 733.

The Notice and Initial Statement of Reasons correctly reflect the language and intent of AB2583 that the new information be added to the existing Notice to Consumers. However, the proposed regulation language makes the new information a requirement for a new, and separate, notice that pharmacies are required to post.

When AB2583 was originally introduced, the author proposed that this information be provided in the form of a separate notice with separate posting requirements. The opponents of the bill objected to the burden and expense of this requirement. Eventually a compromise was reached in which the information would be incorporated into the existing Notice to Consumers – alleviating the objections raised to the legislation. The Board's proposed language now restores the requirement that opponents to AB2583 worked to eliminate. As such, the Board's regulation language does not meet either the language or the intent of AB2583. Our proposed approach and amendments deal with this problem.

The information that is required to be added is contained in B&P Code section 733, which was the subject of an intense legislative effort in 2005. The specific provisions contained in Sec. 733 create for pharmacists a duty to dispense unless one of the delineated exceptions applies. The exceptions go well beyond a pharmacist who has ethical, moral or religious objections to filling a prescription. In fact, pharmacists refuse to fill far more prescriptions based on the other exceptions than they do for ethical, moral or religious reasons.

The proposed language does not place adequately emphasis on these other exceptions. Nor does it adequate reflect the prohibition against obstructing a patient in obtaining a legally prescribed medication. Of particular concern is the lack of language addressing two key provisions in Sec. 733: 1) that a determination that the pharmacist can legally decline to fill a prescription is based "solely on the [pharmacist's] professional training and judgment;" and 2) that a legitimate reason to decline to fill a prescription is that the product is out of stock.

Finally, the proposed language implies that a pharmacist that declines to fill a prescription is "required to help you get the prescription filled by another pharmacy." This is not correct. There is no requirement to assist the patient in finding an alternative pharmacy if the pharmacist declines to fill the prescription based on their professional judgment. In that instance, the pharmacist is only prohibited from obstructing the patient from getting the prescription filled elsewhere, provided the prescription is legally prescribed. The pharmacist is required to assist or refer the patient to another pharmacy if the pharmacy does not have the drug in stock, and in that situation the pharmacy can return the prescription and make a "reasonable effort" to refer the patient to a pharmacy that stocks the product. When a pharmacist declines to fill a prescription

on ethical, moral or religious grounds, the pharmacy is required to have protocols in place to ensure the patient has timely access to the product, but this does not mean the pharmacist or pharmacy is "required to help" the patient get the prescription filled.

Alternative to the Board's proposal:

The regulation language should be changed to incorporate the content contained in subsection (g) into subsection (f) to make clear that there is a single Notice to Consumers that contains all the required information. The current Notice to Consumers is provided by the Board in a poster size format. The poster is current printed in "portrait" orientation. The additional information can easily be added as a separate part of the poster if the poster is printed with two sections in "landscape" orientation. If needed, the size of the Notice could be increased to preserve the current font size and spacing.

The content of the poster should be changed to properly reflect the provisions of Sec. 733. A suggested revision:

Know your rights under California law concerning medicine and devices prescribed for you.

You have the right to receive medicines and devices legally prescribed for you unless:

1. The medicine or device is not in stock at this pharmacy.
2. The pharmacist, based solely on his or her training and professional judgment, determines filling the prescription would:
    - Violate the law;
    - Cause a harmful drug interaction; or,
    - Have a harmful effect on your health.

The pharmacist may also decline to fill your prescription for ethical, moral or religious reasons. The pharmacy may decline to fill your prescription if it is not covered by your insurance or if you are unable or unwilling to pay for the medicine or any co-payment you owe.

If the pharmacist declines or is unable to fill your prescription for any reason, you are entitled to have the prescription returned to you or transferred to another pharmacy. This pharmacy may be able to assist you in finding a pharmacy that will fill your prescription. You should ask pharmacy staff for help if you need it.

Agenda Item E

Board Approved Regulations Awaiting Notice

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

The board previously approved four Section 100 changes. (A Section 100 change is used when a regulation requires changes that are technical rather than substantive.) These proposals are pending.

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

Proposed Amendment to 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.
Copies of the Notice, language and Initial Statement of Reasons are provided. 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 leave 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 1715 – Self Assessment Forms

This self-assessment form is incorporated by reference. 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 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.

Board of Pharmacy
Specific Language

CCR 1709.1 Designation of Pharmacist-in-Charge

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

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.

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

CCR 1780. Minimum Standards for Wholesalers.

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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~~ 2005, 28th ~~22nd~~ 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~~ 2005, 28th ~~22nd~~ 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.

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

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

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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.

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.

CCR 1781. Exemption Certificate

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

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.

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

CCR 1786. Exemptions.

Repeal Section 1786 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~(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.~~

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

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

(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~~ 3/07) entitled "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev ~~1/05~~ 3/07) 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.

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.

CCR 1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

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

(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.

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

The board previously approved two regulations that are awaiting notice. In both regulations a form will be incorporated by reference, both of which are undergoing revision.

Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines
In addition to the Section 100 changes listed above, 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 additional recommendations for changes that will be presented to the board at the June 2007 Enforcement Committee Meeting. No action will be taken on this proposal pending the outcome of the July 2007 board meeting.

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

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.

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 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 veterinary food-animal drug retailer 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 veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-?? (rev. ??/??/2007) entitled "Veterinary Food-Animal Drug Retailer of 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 premises for three years after it is completed.
(e) The veterinary food-animal drug retailer 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 4196 Business and Professions Code.

Agenda Item F

Board Approved Regulation – Awaiting Conformance with the California Building Commission Standards Rulemaking Process

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Conformance with California Building Standards Rulemaking Process

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. This summer, the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. Staff will pursue these changes in the new format this year to secure adoption of these standards into the building code.

Agenda Item G

Board Approved Regulation – Proposed Language to be Developed

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulation – Proposed Language to be Developed

Process and Criteria to Approve Accreditation Agencies for Pharmacies

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.

Language will be developed in concert with staff counsel.

Agenda Item H1

Proposed Legislation
Board Sponsored

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

To: Legislation and Regulation Committee

From: Staff

Subject: Proposed Legislation for 2007:

Omnibus Provisions

All of the following provisions should be omnibus provisions for 2007. Copies of the exact language follow.

- **Section 4084**
  To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
- **Sections 4162 and 4162.5**
  Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.
- **Sections 4314 and 4315**
  Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.
- **Sections 4160(f) – 4161(k)**
  Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.
- **Section 4208**
  Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

Board of Pharmacy
2007 Omnibus Bill Proposed Language

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device

Amend Section 4084 of the Business and Professions Code, to read:

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.
(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
(f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

B&P 4162 & 4162.5 Wholesaler License Surety Bond Requirements

Amend Sections 4162 and 4162.5 of the Business and Professions Code to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board 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 purposes 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 wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).
(3) A person to whom an approved new drug application 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 wholesaler, shall not be required to post a surety bond as provided in paragraph (1).
(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one

hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or 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 remain in effect only until January 1, ~~2011~~ 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

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 or a biologics license application 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 or biologics license 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~~ 2015, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to

this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

B&P 4160 Wholesaler License Required

Amend Section 4160 & 4161 of the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler~~. A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(g) This section shall become operative on January 1, 2006.

4161 a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.~~ A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

B&P 4208 Intern Pharmacist License

Amend Section 4208 of the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.
(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.
(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.
(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.
(c) An intern pharmacist shall notify the board within 30 days of any change of address.
(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) Persons who have not completed experience requirements necessary to be eligible for the licensure examination may have their intern license extended for a period of up to two years at the discretion of the board if able to demonstrate their inability to exercise the privileges of the intern license during the initial license period.

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

To: Legislation and Regulation Committee

From: Staff

Subject: **Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)**

The above legislation changes the reporting requirement for CURES, expands reporting to include Schedule IV controlled substances and adds elements that must be entered into CURES (e.g., the patient phone number and number of refills). Specifically, C-IIs, IIIs, and IVs now must be submitted weekly to Atlantic Associates. The board will monitor compliance with this requirement during 2007 inspections and is encouraging pharmacies to work with their software vendors to ensure compliance ASAP.

However, staff recommended a specific amendment to mandate a January 1, 2008, "drop dead date" for aggressive enforcement, as well as a requirement for prescribers to use of the new security prescription forms that contain the new data fields, also by January 1, 2008 (essentially by making the current security forms obsolete).

This proposal was made as an effort to assist industry with the implementation requirements mandated in AB 2986. There has been no expressed interest from the pharmacy industry so it is unclear if this proposal is still needed.

A draft of the proposed revisions is included.

Board of Pharmacy
Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)

CURES REPORTING

SECTION 1. Section 11162.1 of the Health and Safety Code is amended to read:
11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:
(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
(3) A chemical void protection that prevents alteration by chemical washing.
(4) A feature printed in thermo-chromic ink.
(5) An area of opaque writing so that the writing disappears if the prescription is lightened.
(6) A description of the security features included on each prescription form.
(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:
1–24
25–49
50–74
75–100
101–150
151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, <u>telephone number</u>, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.
(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
(11) The date ~~of origin of~~ the prescription <u>was written for the patient by the prescriber.</u>
(12) A check box indicating the prescriber's order not to substitute.
(13) An identifying number assigned to the approved security printer by the Department of Justice.
(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.
(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).
(2) Forms ordered pursuant to this subdivision shall have <u>preprinted on the form:</u>

(A) ~~t~~The name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber ~~and~~
(B) ~~t~~The name, address, category of licensure, and license number of the licensed health care facility, the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons. ~~preprinted on the form.~~
(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, telephone number, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and be maintained in the health facility for three years.
(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
~~(d) This section shall become operative on July 1, 2004.~~

SEC. 2. Section 11164 of the Health and Safety Code is amended to read:
11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the patient's name ~~of the ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription ~~is a~~ is being filled initially or as ~~first-time request or~~ a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:
11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.
(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.
(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy shall provide the following information to the

Department of Justice on a weekly basis each Monday for the preceeding week (Monday through Sunday), and in a format specified by the Department of Justice:
(1) Full name~~,~~ and address~~, and the telephone number~~ of the ~~ultimate user~~ patient or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ~~ultimate user~~ patient.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered.
(8) Whether the drug was dispensed or as the original of a prescription or as a refill ~~of a prescription or as a first-time request~~.
(9) Date ~~of origin of~~ the prescription was written or ordered for the patient.
(10) Date of dispensing of the prescription.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:
11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual patient under his or her care based on data contained in CURES.
(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual patient based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the ~~individual~~ patient.
(c) The history of controlled substances dispensed to ~~an individual~~ a patient based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 5. Section 11190 of the Health and Safety Code is amended to read:
11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, and the telephone number of the patient ~~ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Number of refills ordered.
(G) Whether the drug was dispensed as a refill of a prescription or as ~~a first-time~~ the original of a prescription request.
(H) Date ~~of origin of~~ the prescription was written or ordered for the patient by the prescriber.
(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.
(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user.
~~(d) This section shall become operative on January 1, 2005.~~
(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.
(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Agenda Item H2

Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction for Committee Consideration

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

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Staff identified the following introduced legislation as it could impact the practice of pharmacy or the board's jurisdiction. Included with the bill analysis for each of these proposals is a copy of the language. The committee should review each proposal and determine if a recommended position should be voted upon at the April Board Meeting.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 110 **VERSION: As introduced January 5, 2007**

AUTHOR: LAIRD **SPONSOR: Drug Policy Alliance Network**
San Francisco Aids Foundation

RECOMMENDED POSITION: Watch

SUBJECT: Drug paraphernalia: clean needle and syringe exchange projects

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EXISTING LAW:

1. Permits a needle exchange program (NEP) in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

2. Requires a city and county, or a county, or a city with or without a health department that authorizes a NEP, to authorize the exchange of clean hypodermic needles and syringes, as part of a network of comprehensive services, including treatment services.

3. Prohibits providers participating in an authorized NEP from being subject to criminal prosecution for possession of needles or syringes during participation in a NEP.

4. Requires local government, local public health officials, and law enforcement to be given the opportunity to comment on syringe exchange programs on an annual basis. Requires the public to be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of syringe exchange programs are addressed and mitigated. Requires the health officer of the participating jurisdiction to present annually at an open meeting of the board of supervisors or city council a report detailing the status of NEPs including, but not limited to, relevant statistics on blood-borne infections associated with needle sharing

activity. Requires law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public to be afforded ample opportunity to comment at this annual meeting, as specified.

THIS BILL:

1. Makes a number of findings and declarations related to the continuing spread of acquired immune deficiency syndrome (AIDS) and blood-borne hepatitis, the relationship between injection drug use and HIV/AIDS and hepatitis, the reduction in the transmission of HIV and hepatitis resulting from NEPs, and the need for NEPs to purchase adequate supplies of sterile hypodermic needles in order to further reduce HIV and hepatitis transmission.

2. Permits a public entity that receives General Fund money from Department of Public Health (formerly DHS) for HIV prevention and education to use that money to support NEPs that are authorized by the public entity, as specified.

3. Permits the money to be used for, but not be limited to, the purchase of sterile hypodermic needles and syringes.

4. Requires funds allocated for the purchase of sterile hypodermic needles and syringes to be based upon epidemiological data as reported by the health jurisdiction in its local HIV prevention plan submitted to DPH.

5. Requires local health officers in jurisdictions with NEPs to include information on the use of public funds for NEPs in their annual report detailing the status of the project to the board of supervisors or city council.

AUTHOR'S INTENT

According to the author, the U.S. government prohibits the use of federal funds to support the purchase of sterile hypodermic needles and syringes by Needle Exchange Programs (NEPs) and to date the state has not permitted the use of its funds for the purchase of sterile hypodermic needles and syringes. The ability of NEPs to purchase an adequate supply of sterile hypodermic needles and syringes is essential to California's ability to further reduce the transmission of HIV and other blood-borne diseases and relieve the public cost for the care and treatment of those diseases.

The use of state General Fund to purchase clean needle and syringes for NEPs is not unprecedented. Eleven states currently expend these funds for this purpose (Connecticut, Hawaii, Massachusetts, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin). This bill would substantially aid local efforts to reduce the rate of HIV transmission through injection drug use in California by authorizing the use of state funds for the purchase of clean hypodermic needles and syringes. Any funds that would be expended for clean needles and syringes come from existing appropriations for state HIV prevention funds. Accordingly, this bill does not increase funding and will, in effect, make counties prioritize how they will expend prevention funds. One of these choices may be to purchase needles and syringes, which could result in significant savings for state funded health programs.

PRIOR HISTORY/RELATED BILLS

AB 547 (Berg and Richman) Chapter 692, Statutes 2005 - authorized clean NEPs in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county; the city council, the mayor, and the local health officer of a city with a health department; or, the city council and the mayor of a city without a health department. No board position

AB 1597 (Laird) of 2005 contained provisions substantially similar to this bill - Governor Schwarzenegger vetoed AB 1597, stating "authorizing the use of state funds to purchase syringes, without appropriate local controls, including mechanisms for input from local law enforcement, and protections against the use of state funds to supplant private or local resources is not prudent." No board position

AB 2076 (Laird) of 2006 contained provisions substantially similar to this bill - held on the Assembly Floor after passing both houses of the Legislature. No board position.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

SUPPORT AND OPPOSITION:

Support: AIDS Project Los Angeles
America Federation of State, County and Municipal Employees, AFL-CIO
California Hospital Association

California Opioid Maintenance Providers
California State Association of Counties
City of Moreno Valley
Drug Policy Alliance Network
Friends Committee on Legislation
Lamda Letters Project
San Francisco AIDS Foundation
Santa Clara County Board of Supervisors
Southern California HIV Advocacy Coalition

Oppose: California Narcotic Officers' Association

HISTORY:

2007
Mar. 7 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 12. Noes 5.) (March 6).
Feb. 1 Referred to Com. on HEALTH.
Jan. 6 From printer. May be heard in committee February 5.
Jan. 5 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 249 **VERSION: As introduced February 1, 2007**

AUTHOR: Eng **SPONSOR: Author**

RECOMMENDED POSITION: Support

SUBJECT: Licensees: healing arts: settlement agreements

EXISTING LAW:

1. Prohibits a physician or surgeon from including a provision in a civil settlement that prohibits the other party from contacting or cooperating with the Medical Board.
2. Prohibits a physician or surgeon from including a provision in a settlement for a civil action that requires the other party from filing a complaint with the Medical Board.
3. Prohibits a physician or surgeon from including a provision in a settlement that requires the other party to withdraw a complaint from the Medical Board.
4. Declares that such provisions is void as against public policy.
5. Specifies that a physician or surgeon who violates the section is subject to disciplinary action.

THIS BILL WOULD:

1. Expand the above prohibitions to apply to all licensees and entities or persons acting as an authorized agent of a licensee licensed under Division 2 of the Business and Professions Code.

AUTHOR'S INTENT

This bill is intended to close a loophole in current law that allows a healthcare professional licensed by DCA to prohibit a consumer who settles a civil suit from also filing a complaint or cooperating with the licensee's regulator. This bill is modeled on an existing statute that prohibits physicians and surgeons from including such clauses in civil settlements arising from his or her practice.

According to the author, "The state has created regulatory agencies to license healthcare professionals in order to protect patients, but those same healthcare practitioners can use gag clauses in malpractice settlements to prevent the licensing agency from finding out about their abuses. That makes absolutely no sense. Licensed healthcare professionals should not be able to misuse the civil justice system to conceal evidence of misconduct from their regulators."

PRIOR HISTORY/RELATED BILLS

AB 320 (Correa) of 2004 would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed. The governor's message is as follows: "I am returning Assembly Bill 320 without my signature as it further erodes the ability to do business in California by creating more uncertainty regarding litigation and litigation costs.

This bill prohibits all businesses and professions licensed under the Department of Consumer Affairs (DCA) from inserting gag clauses in civil suits settled with customers.

When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties. Often settlements are reached when the cost of settlement is less than the cost of defense even if a party believes they have not erred, it often makes economic sense to settle.

Under this bill a party who agrees to a civil settlement, could still file a complaint with a regulatory agency subjecting the licensee to double jeopardy. Even after the resolution of a civil suit, this bill could still require a licensee to a second adjudication before a regulatory body.

The policy implications of this bill does not further the goal of making California more business friendly, therefore, I cannot support this bill. The board had a support position on this bill."

AB 446 (Negrete McLeod) of 2005, would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed by the governor with the following message - - "I vetoed a similar bill last year because of the negative effect it would have had on the California economy. This bill further erodes the ability to do business in California by creating more uncertainty regarding litigation by prohibiting any licensee or professional overseen by the Department of Consumer Affairs from including in a civil settlement agreement a

provision that prohibits the other party from contacting or filing a complaint with the regulatory agency. When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties." The board had a support position on this bill.

AB 2260 (Negrete McLeod), Chapter 565, Statutes of 2006, prohibits physicians and surgeons licensed by the Medical Board from including a gag clause in a civil settlement agreement. The board did not take a position on this bill.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

SUPPORT AND OPPOSITION:

Support: California Nurses Association
Center for Public Interest Law

Opposition: None on file

HISTORY:

2007
Mar. 6 From committee: Do pass, and re-refer to Com. on JUD. Re-referred. Ayes 10. Noes 0.)
Feb. 20 Referred to Coms. on B. & P. and JUD.
Feb. 2 From printer. May be heard in committee March 4.
Feb. 1 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 501 **VERSION: As introduced February 20, 2007**

AUTHOR: Swanson **SPONSOR: Alameda County Board of Supervisors**

RECOMMENDED POSITION: None

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

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EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers
   a. Any container used for collection of solid waste, recyclable materials for greenwaste
   b. Any container used for the commercial collection of solid waste or recyclable materials from a business establishment
   c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home generated sharps waste shall be transported only in a sharps container, or other container approved by the enforcement agency as managed by one of the following:
   a. A household hazardous waste facility
   b. A "home generated sharps consolidation point"
   c. A medical waste generator's facility
   d. A facility though the use of an approved medical waster mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of self-inject prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the US Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Require every pharmaceutical company whose product is dispensed through a prefilled syringe, prefilled pen needle or other prefilled injection device shall provide each person in this state with a method to safely dispose of the device.
4. Require that if the person receives the device as part of a starter kit, the pharmaceutical company shall make available to the person, at no additional cost, either a postage pre-paid mail back sharps container or a coupon to obtain such a container or provide the person with a distribution point chosen by the pharmaceutical company.
5. Require the pharmaceutical company to make available, at no additional charge and through an annually renewable program, postage prepaid, mail back sharps containers to any person who uses the pharmaceutical company's product.
6. Define "coupon," "patient starter kit" and "sharps container."

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 –Prohibits, as of January 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home generated-sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT:

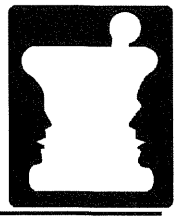
The board does not anticipate any substantial fiscal impact on its operations.

HISTORY:

2007
Feb. 21 From printer. May be heard in committee March 23.
Feb. 20 Read first time. To print.

Revised March 26, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 543 **VERSION: As introduced February 21, 2007**

AUTHOR: Plescia **SPONSOR: CA Ambulatory Surgery Assoc.**

RECOMMENDED POSITION:

SUBJECT: Ambulatory surgical centers: licensure

EXISTING LAW:

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale unless licensed by the board.

THIS BILL WOULD:

1. Change the name "surgical center" to "ambulatory surgical center."
2. Modify the licensing requirements for an ambulatory surgical center to include:
   - licensure by the DHS under 1204 of the Health and Safety Code
   - accreditation by an approved agency
   - or certification to participate in the Medicare Program.

   This license would allow the clinic to purchase drugs at wholesale for administration or dispensing.

AUTHOR'S INTENT

The sponsor states that this bill is intended to standardize the licensing requirements for ambulatory surgical clinics. Additional amendments to the existing language will also be made to ensure a consistent and comprehensive set of state-specific licensure requirements for ambulatory surgical centers as required by the DHS.

PRIOR HISTORY/RELATED BILLS

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in the se facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner."

The board had no position on this bill.

FISCAL IMPACT:

The sponsor believes that 400 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications as well as an additional 0.5 inspector to complete routine inspections and complaint investigations.

COMMENTS:

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However there is no requirement that an ambulatory surgical center must be licensed by the DHS to operate. The unintended consequence is that approximately 400 – 500 ambulatory surgical centers do not qualify for licensure as a clinic by the board, but would under this bill.

There are currently four approved accreditation agencies:

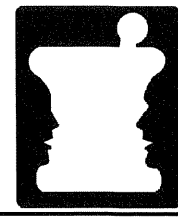
- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Joint Commission of Accreditation of Healthcare Organizations (JCAHO)
- The Institute for Medical Quality (IMQ)

HISTORY:

2007
Mar. 1 Referred to Com. on HEALTH.

Feb. 22 From printer. May be heard in committee March 24.
Feb. 21 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 851 **VERSION: AS INTRODUCED February 22, 2007**

AUTHOR: BROWNLEY **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: PRESCRIPTION DRUGS: INFORMATIONAL INSERT

EXISTING LAW:

1. Requires a pharmacist to inform a patient orally or in writing of the harmful side effects of a prescription drug if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug provided may impair a person's ability to drive a motor vehicle. Relevant drug classifications are detailed in CCR 1744.
2. States that the notification requirement does not apply to drugs furnished in conjunction with treatment or emergency services provided in a health facility.
3. States that a health facility must establish and implement a written policy to ensure each patient receives this information at the time of discharge to include:
    - use and storage of the medication(s)
    - precautions and relevant warnings
    - importance of compliance with the directions

THIS BILL WOULD:

1. Require a pharmacist to include a large print informational insert with any prescription drug that poses substantial risk to the person when taken in combination with alcohol or other medications, including over-the-counter medications.
2. Specify that the insert must warn the patient of the specific risk involved.
3. Specify that a pharmacist cannot satisfy this requirement by referencing an outside source of information, such as an internet Web site.

4. Continue to require that a pharmacist, verbally and in writing, notify a patient if the drug may impair a person's ability to drive a motor vehicle.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board.

SUPPORT AND OPPOSITION:

COMMENTS:

This bill would require pharmacists to provide written information for medicine that interacts with alcohol, other prescription medicines or over-the-counter medicines. This is an expansion of the current requirement. Pharmacies may provide such written information sheets now. There is no mention what the source the pharmacist must consult to provide this information, e.g. Facts and Comparisons, Physician's Desk Reference, etc.

Typically, software vendors provide much of this written information in a form where pharmacists can provide it to the patient at the time of dispensing.

HISTORY:

2007
Feb. 23 From printer. May be heard in committee March 25.
Feb. 22 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 865 **VERSION: As introduced February 22, 2007**

AUTHOR: Davis **SPONSOR: Author**

RECOMMENDED POSITION:

SUBJECT: State agencies, live customer service agents

EXISTING LAW:

1. Requires each state agency to establish a procedure to ensure that incoming calls on any public line will be answered within 10 rings during regular business hours.

THIS BILL WOULD:

1. Require each state agency to answer telephone calls on any public line by a live customer service agent within 10 rings during regular business hours.

AUTHOR'S INTENT:

This legislation is to address the general frustration some constituents experience trying to access a live agent to speak with. Illinois enacted a similar requirement in 2005. The primary difference however is that the Illinois law allows for the use of an automated answering service, but must allow for a "zero-out" option.

FISCAL IMPACT:

Should this bill be enacted, the board will need to pursue a part-time office assistant to help assist board receptionists during peak calling times, e.g., Mondays, during renewal cycles etc.

COMMENTS:

The board's main public number is currently automated with the use of a phone tree. Callers are advised at the beginning of the recorded

message of the option to zero-out to speak with a board receptionist. This proposal would require the board to eliminate the use of the phone tree resulting in additional staff resources to respond to incoming calls. Because of limitations with the current phone system, staff is not aware of an new incoming call when the line is already in use.

The author's office indicates that there may be room to negotiate a requirement similar to the Illinois legislation.

HISTORY:

2007

Mar. 1	Referred to Com. on HEALTH.
Feb. 22	From printer. May be heard in committee March 24.
Feb. 21	Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1025 **VERSION: As introduced February 22, 2007**

AUTHOR: Bass **SPONSOR:**

RECOMMENDED POSITION:

SUBJECT: Professions and vocations: denial of licensure

EXISTING LAW:

1. Allows the board to deny a license on the grounds that an applicant has done any of the following:
   - Been convicted of a crime including a plead or verdict of guilty or a conviction following a plead of nolo contendere
   - Done any act involving dishonesty, fraud, deceit with the intent to substantially benefit himself or another, or substantially injure another
   - Done any act which if done by a licentiate of the business or profession in question would be grounds for suspension or revocation of a license
2. Prohibits the board from denying a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certification of rehabilitation or that he or she has been convicted of misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation as developed by the board
3. Allows the board to deny a license on the grounds that the applicant knowingly makes a false statement of fact required to be relevant in the application
4. Specifies the procedures the board must comply with to deny an application for licensure
5. Authorizes the board to suspend or revoke a license on the grounds that the licensee has been convicted of a crime if the crime is substantially related to the duties of the license
6. Details the board's requirement to notify the licensee of the revocation or suspension

THIS BILL WOULD:

1. Prohibit the board from denying an application based on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code (which means the court can dismiss the accusations or information against the defendant under certain circumstances.)
2. Prohibits the board from denying a license based on an arrest more than one year old if no disposition is reported.
3. Requires the board to include with a notice of denial a copy of the criminal record relied upon in making the denial determination.
4. Prohibit the board from suspending or revoking a license based on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code.
5. Requires the board to send a copy of the criminal history record relied upon in making the determination to suspend or revoke the license to the ex-licensee.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board as criminal history records are already obtained as part of the investigation process.

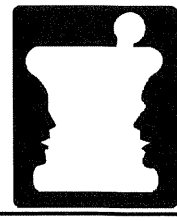
COMMENTS:

Currently the board initiates disciplinary actions and may revoke, suspend or deny a license based on a conviction that is set aside if the conviction is substantially related to the license currently held, or being sought. However, the board does not provide a copy of the arrest report or criminal history record, although these documents may be referred to in the legal pleadings used to deny or revoke a license.

HISTORY:

Mar. 12	Referred to Com. on B. & P.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 22	Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1276 **VERSION: As introduced February 23, 2007**

AUTHOR: Karnette **SPONSOR: California Senior Legislature**

RECOMMENDED POSITION:

SUBJECT: Pharmacies: prescription labels: intended use

EXISTING LAW:

1. Details the labeling requirements for a prescription container to include, among other things, the condition for which the drug was prescribed, if it is requested by the patient.
2. Prohibits a pharmacist from dispensing a prescription medicine except in a container that meets the requirements of state and federal law.

THIS BILL WOULD:

1. Revise the labeling requirement to replace the condition for which the drug is prescribed with the intended purpose of the drug.
2. Require the authorized prescriber to ask a patient, or a patient's authorized representative whether to indicate the intended purpose of the prescription on the prescription label.
3. Exempt veterinarians from this new requirement.
4. Update references to recodified sections of pharmacy law.

AUTHOR'S INTENT

According to the California Senior Legislature, the sponsor of this bill, current law does not require the purpose of the medication to be written on the container and most patients are unaware of their right to make such a request to their doctor or pharmacist. Including the purpose for the prescription drug on the label will reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of the drug. It will also prevent patients from taking the wrong drug if they are not certain about the specific purpose of the medication. If someone is taking multiple medications, and there is no information

about the purpose of the drugs on the container, there is a potential for error and this bill is intended to eliminate or greatly reduce the risk of taking the wrong medication. The Veteran's Administration pharmacy in Sepulveda, California currently requires their physicians to include the purpose of the medication on all prescriptions.

PRIOR HISTORY/RELATED BILLS

AB 657 (Karnette) of 2005 – The bill died in the Senate. The board had a support position.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

COMMENTS:

This proposal appears to address the intent of a recommendation in the Medication Errors Panel Report, which requires that the intended use of the medication be included on all prescriptions.

HISTORY:

2007
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1399 **VERSION: As introduced February 23, 2007**

AUTHOR: Richardson **SPONSOR: National Federation for the Blind**

RECOMMENDED POSITION: Support If Amended

SUBJECT: Pharmacies: prescription labels: assistive technology device

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EXISTING LAW:

1. Details the labeling requirements for a prescription container.

THIS BILL WOULD:

1. Revise the labeling requirement to require, upon the request of a customer who is blind or visually impaired, a prescription label that is readable by an assistive technology device for such individuals. All Pharmacies would be required to comply with this section.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact.

COMMENTS:

The federal government has been looking at the issue since 2001. In 2005, the FDA submitted a report to the Senate Finance committee on this topic. We were unable to obtain a copy of this report.

We support the intent of this proposal because we agree that the label exists to assist patients with information on how to take their medication safely. However, we are concerned about the mandate that all pharmacies acquire necessary equipment to accommodate the various devices consumers may use.

Staff identified at least three such devices that are available to assist blind or visually impaired individuals.

The Talking RX Prescription Accessory is a reusable digital recorder that attaches to the bottom of the most common sized prescription vials and allows for the recording of necessary medical and prescription information. This product retails for about $40.00.

The Aloud Audio Labeling System produced an audio version of a printed prescription label, which is then attached to the medication container. The consumer then uses an Aloud Player unit to replay the information recorded by the pharmacist.

The ScripTalk System works by the pharmacy software printing an auxiliary smart label using a dedicated, small-footprint printer. This smart label stores in the prescription information on the label. The consumer can hear the information by using a ScripTalk Reader.

HISTORY:

2007
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1587 **VERSION: As introduced February 23, 2007**

AUTHOR: De La Torre **SPONSOR: Author**

RECOMMENDED POSITION:

SUBJECT: Personal information: pharmacy.

EXISTING LAW:

1. Defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product of service.
2. Details exemptions to the definition to include:
   - Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration
   - Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network.
   - Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about, among other things, treatment options. Such communications may result in direct or indirect remuneration if the individual receiving the communication is notified of such, in a typeface no smaller that 14-point font.

THIS BILL WOULD:

1. Also exempt a written communication or message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, if all of the following apply:
   - The communication does not involve the sale or transfer of individually identifiable patient information
   - The communication assists the pharmacist or pharmacy personnel in the transmittal of use information regarding a prescription drug dispensed to the patient
   - The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease

or health condition for which the drug is dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient.

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type.
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for.

AUTHOR'S INTENT

This bill is intended to clarify the existing statute and would exempt drug information from the definition of "marketing communications."

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board.

HISTORY:

2007
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 472 **VERSION: As introduced February 23, 2007**

AUTHOR: Richardson **SPONSOR:**

RECOMMENDED POSITION:

SUBJECT: Pharmacies: prescription labels: assistive technology device

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EXISTING LAW:

1. Details the labeling requirements for a prescription container.
2. Prohibits a pharmacist from dispensing a prescription that does not meet the labeling requirements

THIS BILL:

1. Makes findings about the cost of health care and prescription drugs
2. Makes findings about the number of medication errors and sites some causes for these errors.
3. States that it is the intent of the Legislature to adopt a standard format for the labeling of prescription drug containers dispensed in this state, to include a regulation for the font size of printed words, the placement of the information of the prescription as well as translated prescription drug labels for a patient whose primary language is not English.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

FISCAL IMPACT:

The board does not anticipate major any fiscal impact to the board.

COMMENTS:

This proposal appears to be in the drafting phase and could be one response initiated to address recommendations made in the Medication Error Panel Report.

HISTORY:

2007
Feb. 28 To Com. on RLS.
Feb. 22 From print. May be acted upon on or after March 24.
Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 615 **VERSION: As introduced February 22, 2007**

AUTHOR: Oropeza **SPONSOR: The Latino Coalition for a Health California**

RECOMMENDED POSITION:

SUBJECT: Pharmacy technicians: scholarship and loan repayment program.

EXISTING LAW:

1. Defines the requirements for licensure as a pharmacy technician.

THIS BILL WOULD:

1. Establish a scholarship and loan repayment program for pharmacy technicians.
2. Allow a licensed pharmacy technician to make a voluntary contribution of $10.00 to this account at the time of renewal.

AUTHOR'S INTENT

This bill is intended to provide a financial incentive to recruit more individuals to become pharmacy technicians to assist in medically underserved areas. US Bureau of Labor statistics detail a shortage of technicians from different cultural backgrounds.

FISCAL IMPACT:

The cost associated with the development and implementation of this fund could include modifications to existing cashiering programs, forms and procedures for deposits into separate funds. However, these costs would be covered by the board's prorata to the Department.

SUPPORT AND OPPOSITION:

COMMENTS:

This proposal is similar to one passed in 2002, which established a scholarship and loan repayment fund for pharmacists. To date, no funds have been distributed from this fund, as the minimum account balance of $200,000 annually has not yet been obtained. The board was coincidentally doing a newsletter article updating licensees about the status of this law and learned that to date, pharmacies and pharmacists have contributed approximately $38,000.

Current statutes detail the licensing requirements for technicians to include:

- Completion of a technician training program
- AA degree in pharmacy technology
- Satisfy requirements for RPH exam
- Certification by the Pharmacy Technician Certification Boards.

This proposal would only assist those applicants who qualify based on the training program or pharmacy technology.

The Licensing Committee recently discussed the qualification methods for pharmacy technicians and will be continuing their discussion about the possible enhancement/standardization of the minimum qualifications.

HISTORY:

2007
Mar. 15 Set for hearing April 11.
Mar. 13 Withdrawn from committee. Re-referred to Coms. on HEALTH and B. & P.
Mar. 8 To Coms. on B., P. & E.D. and HEALTH
Feb. 23 From print. May be acted upon on or after March 25.
Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 963 **VERSION: As introduced February 23, 2007**
AUTHOR: Ridley-Thomas **SPONSOR: BP& ED Committee**

RECOMMENDED POSITION:

SUBJECT: Regulatory boards: termination

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Continue to require all boards to submit a Sunset Review report no later than 22 months before each board is slated to shall become inoperative; the report must detail among other items, the board's purpose, enforcement priorities, fund condition and legislative efforts to improve its legislative mandate.
2. Remove the DCA as the successor should the board become inoperative or is repealed.

AUTHOR'S INTENT

According to the author's office, the intent of this legislation is to determine or redefine the sunset review process. It is anticipated that the bill language will be amended in mid-April, in advance of the policy committee meeting.

FISCAL IMPACT:

It is difficult to anticipate the fiscal impact of this legislation until the full scope of the changes are documented.

COMMENTS:

This legislation does not release the board from the Sunset Review process, whereby the board's report will be due to the Legislature no later than May 2008.. This bill is silent on what agency, if any, would succeed the board with all the powers, purpose, responsibilities and jurisdiction not otherwise repealed.

HISTORY:

2007

Mar. 15	To Com. on B., P. & E.D.
Feb. 26	Read first time.
Feb. 25	From print. May be acted upon on or after March 27.
Feb. 23	Introduced. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 966 **VERSION: As introduced February 23, 2007**

AUTHOR: Simitian and Kuehl **SPONSOR: Constituent**

RECOMMENDED POSITION:

SUBJECT: Pharmaceutical drug disposal

EXISTING LAW:

1. Existing law is silent on how a consumer should dispose of unused medication.

THIS BILL WOULD:

1. Make findings and declarations related to the presence of prescription and non prescription drugs in streams and the negative effects on fish and other aquatic species.
2. Discuss the potential impact this may have on human health.
3. Establish a program through which the public may return and ensure the safe and environmentally sound disposal of prescription drugs.
4. Define "consumer", "pharmaceutical drug", "retailer", and "sale."
5. Require on or after July 1, 2008, that every retailer shall have a system to accept pharmaceutical drugs for proper disposal.
6. Require the system to:
   - Be at no cost to the consumer if it is the type or brand which the retailer sold previously
   - Provide a notice to consumers that provides consumers access to obtain more information about opportunities and locations for no-cost pharmaceutical drug recycling
   - Provide information about the retailer's pharmaceutical drug return opportunities
7. Make it unlawful for a retailer to sell a pharmaceutical drug to a consumer unless the retailer is in compliance with these requirements.

8. States that any person who violates this section, if convicted, be subject to imprisonment and/or a fine of up to ($1,000.)

AUTHOR'S INTENT

This bill was introduced upon recommendation of a constituent. The language is modeled after a similar bill that defined a dry cell batter as a household waste and requires retailers to accept these back to ensure appropriate disposal.

The intent of this legislation is to classify over-the-counter and prescription drugs as household waste as well as to require pharmacy retailers to accept such returned household waste for proper disposal.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board.

COMMENTS:

We recognize the need for the intent of this legislation, but are concerned that the appropriate balance is not achievable given the language of the bill as introduced.

The author's office has been in contact with the board and appears willing to accept amendments that could potentially ease the burden on pharmacies, without compromising the intent of the legislation.

The board's Enforcement Committee recently heard concern from a representative of Omnicare who stated that the return of prescription drugs from patients in Long Term Care is problematic as no mechanism is in place to allow for this to occur. Absent any regulation, there is no safeguard to ensure that the returned medications will not be diverted.

HISTORY:

2007

Mar. 19	Set for hearing March 26.
Mar. 15	To Coms. on E.Q.; B.P. & E.D.; and RLS.
Feb. 26	Read first time.
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 23	Introduced. To Com. on RLS. for assignment. To print.