California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Jan E. Perez (916) 445-5014

LEGISLATION & REGULATION COMMITTEE

July 13, 2005
Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814
9:30 a.m. – 12 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 48 hours prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may be attending and may comment on the committee's agenda.

A. Call to Order **9:30 a.m.**

B. Regulation Update.

C. Consideration of Proposed Initiatives of Interest to the Board of Pharmacy.

D. Consideration of Bills of Interest to the Board of Pharmacy.

E. Comments from the Public on Items Not on the Agenda.

Adjournment **12:00 p.m.**

Committee materials will be available on the board's website by July 8, 2005.

Item B

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: July 13, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Regulation Update

Regulation Update

Rulemaking Activity

Staff published a 15-day notice on February 2, 2005 to make minor change to the omnibus group of regulations approved by the board at the January 2005 board meeting. That notice period ended on February 22, 2005. There were no changes or comments to made to this language.

The rulemaking package was submitted for administrative review in April; the regulations should be in place by late summer.

Pending Regulations

At the October 2004 Board meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devises to dispense refill medication when the patient has "opt-in" to use this system. This regulation is awaiting notice.

An informational hearing regarding the posting of intern pharmacist addresses on the Board's web site will be held at the Board meeting in San Diego on July 20, 2005.

Item C

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: July 13, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Initiative Update

On November 8, 2005 California will hold a special election. Eight initiatives have qualified for the November ballot; among them are two relating to prescription drug discount programs. A brief summary of each discount initiatives is listed below with the full text of the initiative provided as attachments one and two respectively.

1129. (SA05RF0065)
Prescription Drugs. Discounts. Initiative Statute.
Proponent: Ashlee N. Brown (916) 442-7757

Establishes discount prescription drug program, overseen by the Department of Health Services. Enables certain low - and moderate - income California residents to purchase prescription drugs at reduced prices. Imposes $15 application fee, renewable annually. Requires Department's prompt determination of residents' eligibility, based on listed qualifications. Authorizes Department to contract with pharmacies to sell prescription drugs at agreed-upon discounts negotiated in advance, and to negotiate rebate agreements with drug manufacturers. Permits outreach programs to increase public awareness. Creates state fund for deposit of rebate payments from drug manufacturers. Allows program to be terminated under specified conditions. Summary of estimate by Legislative Analyst and Director of Finance of fiscal impact on state and local governments: One-time and ongoing state costs, potentially in the millions to low tens of millions of dollars annually, for administration and outreach activities to implement the new drug discount program. A significant share of these costs would probably be borne by the state General Fund. A largely one-time state cost, potentially in the low tens of millions of dollars, to cover the funding gap between the time when drug rebates are collected by the state and when the state pays funds to pharmacies for drug discounts provided to consumers. Any such costs not covered through advance rebate payments from drug manufacturers would be borne by the state General Fund. Unknown savings on state and county health program costs due to the availability of drug discounts. (Attachment 1)

1106. (SA05RF0037)
Prescription Drug Discounts. State-Negotiated Rebates. Initiative Statute.
Proponent: Anthony Wright (916) 442-2308

Provides for prescription drug discounts to Californians who qualify based on income-related standards, to be funded through rebates from participating drug manufacturers negotiated by California Department of Health Services. Rebates must be deposited in State Treasury fund,

used only to reimburse pharmacies for discounts and to offset administration costs. At least 95% of rebates must go to fund discounts. Prohibits new Medi-Cal contracts with manufacturers not providing the Medicaid best price to this program, except for drugs without therapeutic equivalent. Establishes oversight board. Makes prescription drug profiteering, as defined, unlawful. Summary of estimate by Legislative Analyst and Director of Finance of fiscal impact on state and local governments: One-time and ongoing state costs, potentially in the millions to low tens of millions of dollars annually, for administration and outreach activities for a new drug discount program. A significant share of these costs would probably be borne by the state General Fund. A largely one-time state cost, potentially in the low tens of millions of dollars, to cover the funding gap between the time when drug rebates are collected by the state and when the state pays funds to pharmacies for drug discounts provided to consumers. Any such costs not covered through advance rebate payments from drug makers would be borne by the state General Fund. Unknown costs and savings as a result of provisions linking drug prices for the new drug discount program to Medi-Cal prices, including the potential effect on the state's receipt of supplemental rebates; unknown savings on state and county health program costs due to the availability of drug discounts; and unknown costs and offsetting revenues from the anti-profiteering provisions. (Attachment 2)

Attachment 1

SA2005RF0065

ASHLEE N. BROWN

February 4, 2005

RECEIVED
FEB - 4 2005
INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Ms. Tricia Knight
Initiative Coordinator
Office of the Attorney General
State of California
PO Box 994255
Sacramento, CA 94244-25550

Re: Request for Title and Summary for Proposed Initiative

Dear Ms. Knight:

Pursuant to Article II, Section 10(d) of the California Constitution, I am submitting the attached proposed statewide ballot measure to your office and request that you prepare a title and summary of the measure as provided by law. Included with this submission is the required proponent affidavit signed by the proponent of this measure pursuant to section 9608 of the California Elections Code. I have also included a check to cover the $200 filing fee.

Thank you for your time and attention to this important matter. If you require additional information or have any questions, please feel free to contact me at (916) 442-7757.

Very truly yours,

Ashlee N. Brown

Enclosure

SA2005RF0065

INITIATIVE MEASURE TO BE SUBMITTED DIRECTLY TO VOTERS

SECTION 1. FINDINGS AND DECLARATION OF PURPOSE

The People of the State of California do hereby find and declare that:

(a) Prescription drugs are an integral part to managing acute and chronic illness improving quality of life; and

(b) Prescription drugs are a convenient, cost-effective alternative to more costly medical interventions; and

(c) Increasing the affordability and access of prescription medicines will significantly improve healthcare quality and lower overall healthcare costs.

SECTION 2. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

Division 112 (commencing with Section130600) is added to the Health and Safety Code, to read as follows:

DIVISION 112. CALIFORNIA STATE PHARMACYASSISTANCE PROGRAM (CAL RX)

Chapter 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) "Manufacturers rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(j) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third–party payer program.

(k) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

(l) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

(m) "Third–party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third–party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi–Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third–party payer.

(B) The Medi–Cal program.

(C) The children's health insurance program.

(D) The disability medical assistance program.

(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third–party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi–Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third–party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third–party vendor. A pharmacy, physician office, clinic, or third–party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) The department or third–party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third–party vendor to enroll applicants in Cal Rx.

(f) During normal hours, the department or third–party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third–party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department or third–party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

130607. (a) The department or third–party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

> (2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.
>
> (3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department or third–party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.

(c) The department or third–party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third–party vendor.

(d) The department or third–party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third–party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third–party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third–party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third–party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.

(b) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(e) The department or third–party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(f) Drug rebate contracts negotiated by the third–party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.

(g) The third–party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third–party vendor.

130619. (a) The department or third–party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third–party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

130624. The department may terminate Cal Rx if the department makes any one of the following determinations:

(a) That there are insufficient discounts to participants to make Cal Rx viable.

(b) That there are an insufficient number of applicants for Cal Rx.

(c) That the department is unable to find a responsible third–party vendor to administer Cal Rx.

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division

in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SECTION 3: GENERAL PROVISIONS

(a) Conflicting Measures.

(1) This measure is intended to be comprehensive. It is the intent of the People that in the event that this measure and another initiative measure or measures relating to the same subject shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed to be in conflict with this measure. In the event that this measure shall receive a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and all provisions of the other measure or measures shall be null and void.

(2) If this measure is approved by voters but superseded by law by any other conflicting ballot measure approved by the voters at the same election, and the conflicting ballot measure is later held invalid, this measure shall be self-executing and given full force of law.

(b) Severability: The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(c) Amendment: The provisions of this Act may be amended by a statute that is passed by a vote of two-thirds of the membership of each house of the Legislature and signed by the Governor. All amendments to this Act shall be to further the Act and shall be consistent with its purposes.

SA2005RF0037

January 18, 2005

RECEIVED
JAN 18 2005
INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

VIA MESSENGER

Office of the Attorney General
1300 "I" Street
Sacramento, CA 95814

Attn: Tricia Knight
Re: *Cheaper Prescription Drugs for California Act (Ca Rx Plus)*

Dear Ms. Knight:

Pursuant to Elections Code section 9002, we request that the Attorney General prepare a title and summary of a measure entitled the "Cheaper Prescription Drugs for California Act" (Cal Rx Plus)." The text of the measure, a check for $200.00, the address at which we are registered to vote and the signed statement certifying that we will not willfully allow initiative signatures to be used for purposes other than qualification of the measure are enclosed.

Please direct all correspondence and inquiries regarding this measure to:

Anthony E. Wright
1127 11th St., #234
Sacramento, CA 95814
Phone: (916) 442-2308
FAX: (916) 497-0921

Sincerely,

Anthony Wright

Attachment 2

SA2005RF0037

CHEAPER PRESCRIPTION DRUGS FOR CALIFORNIA ACT (Cal Rx Plus)

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CHEAPER PRESCRIPTION DRUGS FOR CALIFORNIA ACT (Cal Rx Plus)

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the Cheaper Prescription Drugs for California Program or Cal Rx Plus.

130501. The Cheaper Prescription Drugs for California Program, or Cal Rx Plus, is established to reduce prescription drug prices and to improve the quality of health care for residents of the State. The program is administered by the Department of Health Services to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for Californians.

S. 130502. The People of California find that affordability is critical in providing access to prescription drugs for California residents. This program is enacted by the People to enable the State to take steps to make prescription drugs more affordable for qualified California residents, thereby increasing the overall health of California residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified California residents under this program.

130503. Cal Rx Plus shall be available to Californians facing high prescription drug costs to provide lower prescription drug prices. To the extent permitted by federal law, Cal Rx Plus shall also be available to small businesses and other entities as defined that provide health coverage for Californians.

130504. For purposes of this division, the following definitions apply:
(a) "Department" means the State Department of Health Services.
(b) "Fund" means the Cal Rx Plus Program Fund.
(c) "Program" means the Cheaper Prescription Drugs for California Program or Cal Rx Plus.
(d) (1) "Qualified Californian" means a resident of California whose total unreimbursed medical expenses equal 5 percent or more of family income.
(2) "Qualified Californian" also means an individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.
(3) "Qualified Californian" also means a resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines and who shall not

have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program.
(4) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.
(e) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

Chapter 2. Prescription Drug Discounts

130510. (a) The amount a Cal Rx Plus participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.
(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.
(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130511. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through Cal Rx Plus.
(b) Consistent with federal law, the department shall seek to contract for drug rebates that result in a net price comparable to or lower than the Medicaid best price for drugs covered by the program. The department shall also seek to contract a net price comparable to or lower than the price for prescription drugs provided to the Federal Government.
(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.
(d) No less than 95 percent of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.
(e) (1) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.
(2) Any drug manufacturer may participate in the program.

130512. (a) Subject to this section, the department may not enter into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer will not provide Cal Rx Plus a rate comparable to or lower than the medicaid best price. This provision shall not apply to a drug for which there is no therapeutic equivalent.
(b) To the extent permitted by federal law, the department may require prior authorization in the Medi-Cal program for any drug of a manufacturer that fails to agree to a price comparable to or lower than the Medi-Cal best price for prescription drugs purchased under this division. (c) If a contract with a manufacturer is precluded under (a) or if prior authorization is required for a drug pursuant to this section, in no event

shall a Medi-Cal beneficiary be denied the continued use of a drug that is part of a prescribed therapy until that drug is no longer prescribed for that beneficiary's therapy. The Department of Health Services shall approve or deny requests for prior authorization necessitated by this section as required by state or federal law.

(d) This section shall be implemented consistent with federal law.

130513. The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130514. (a) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under (1) dispensed to a participant.

(4) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(5) Require the manufacturer to provide, upon the request of the department, documentation to validate the rebate.

(6) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx Plus. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a participant's health information.

(b) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(c) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after the effective date of the act that added this subdivision.

(d) Interest pursuant to subdivision (k) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment.

130515. (a) The department shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx Plus.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130516. (a) The department shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of this division.

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in federal law.

(b) The department shall pay a participating pharmacy the discount provided to participants pursuant to this division by a date that is not later than two weeks after the claim is received.

(c) The department shall develop a mechanism for Cal Rx Plus participants to report problems or complaints regarding Cal Rx Plus.

Chapter 3. Cal Rx Plus Application, Enrollment and Outreach

130520. (a) The department shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx Plus. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Specify that the application and annual reapplication fee due upon submission of the applicable form is ten dollars ($10).

(c) In assessing the income requirement for Cal Rx Plus eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx Plus, through a Web site or call center staffed by trained operators approved by the department. A pharmacy, physician office, clinic or non-profit community organization completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx Plus, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a participant.

(e) The department shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, non-profit community organization or through the third-party vendor to enroll applicants in Cal Rx Plus.

(f) During normal hours, the department shall make a determination of eligibility within four hours of receipt by Cal Rx Plus of a completed application. The department shall mail the participant an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a participant identification number for eligible applicants to the pharmacy for immediate access to Cal Rx Plus.
(h) A Cal Rx Plus participant who has been determined to be eligible shall be enrolled for 12 months or until the participant notifies the department of a desire to end enrollment.
(i) The department shall notify a participant 30 days prior to the termination of enrollment. A Cal Rx Plus participant shall remain enrolled until the participant notifies the department that the participant no longer meets the enrollment criteria.

130521. (a) The department shall conduct an outreach program to inform California residents of their opportunity to participate in the Cheaper Prescription Drugs for California Program. The department shall coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. No outreach material shall contain the name or likeness of a drug.
(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx Plus. The name of the organization sponsoring the material pursuant to subdivision (b) shall in no way appear on the material but shall be reported to the public and the Legislature as otherwise provided by law.

130522. (a) A drug dispensed pursuant to prescription, including a drug dispensed without charge to the consumer, must be accompanied by Cal Rx Plus participation information in a manner approved by the department and as permitted by law.

(b) The information shall include advice to consult a health care provider or pharmacist about access to drugs at lower prices.

(c)The requirements of this section may be met by the distribution of a separate writing that is approved by or produced and distributed by the department.

Chapter 4. Pharmaceutical Manufacturer Patient Assistance Programs

130530. (a) The department shall execute agreements with drug manufacturer and other private patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.
(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer or other private patient assistance program.
(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.
(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the

applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(e) The Cal Rx Plus card issued pursuant to this division shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.

Chapter 5. Employer-Paid Health Insurance Prescription Drug Discounts

S. 130540. The department may establish a prescription drug purchasing program to assist small businesses, small employer purchasing pools, Taft-Hartley trust funds and other entities that purchase health coverage for employees of those employers and their dependents.

S. 130541. No employer or other entity that purchases coverage for employees and dependents shall be eligible to participate unless the employer pays more than 50% of the cost of health coverage for their employees and their dependents.

S.130542. The department shall seek to obtain the department shall seek to contract for drug rebates that result in a net price comparable to the Cal Rx Plus program.

S. 130543. (a) The amount a participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

S.150544. The department shall work with employers, the California Chamber of Commerce, and other associations of employers as well as the California Labor Federation AFL-CIO and consumer organizations to develop and implement this chapter.

Chapter 6. Administration.

S. 130550. The Prescription Drug Advisory Board ("Board") is established to review access to and the pricing of prescription drugs for residents of the State, to advise the Secretary on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

(a) No board member shall have a financial interest in pharmaceutical companies or have worked for pharmaceutical companies or their agents or served within 5 years

before being appointed to the Board. No board member shall be employed for a pharmaceutical company for 5 years after serving on the board.
(b) The board shall consist of nine representatives of the public from the state at large. The Governor, the Senate President pro Tempore, and the Speaker of the Assembly shall each appoint three of these members. Legislative appointees shall serve staggered terms.
(c) (1) Of the three appointees by the Governor, one shall be a person over 65 enrolled in Medicare, one shall be from a school of pharmacy at the University of California, and one shall be an economist.
(2) Of the three appointees by the Speaker of the Assembly, one shall be a consumer or a representative of a recognized organization representing consumers eligible under this division, one shall be a retail pharmacist, and one shall be an employer or a representative a recognized organization representing employers eligible for Business Discount Drug Purchasing program.
(3) Of the three appointees by the Speaker Pro Tempore of the Senate, one shall be a labor trustee of a Taft-Hartley trust fund, one shall be a physician or nurse with expertise in drug benefits, and one shall be a member of the board of CalPERS.
(d) The term of office of board members shall be as follows:

(i) (1) A member appointed by the Governor shall serve for two years at the pleasure of the Governor, and may be reappointed for succeeding two-year periods, provided that the member may continue to serve beyond the two-year term until the Governor has acted and the appointee is authorized to sit and serve on the board.
(2) A member appointed by the Senate President pro Temp or the Speaker of the Assembly shall serve for four years, and may be reappointed for succeeding four-year periods, provided that the member may continue to serve beyond the four-year term until his or her appointing authority has acted and the appointee is authorized to sit and serve on the board. If the Senate President pro Temp or the Speaker of the Assembly has not acted within 60 days after the expiration of a member's term, the position shall become vacant until a person is appointed to a four-year term, calculated from the expiration date of the preceding term.
(ii) If a vacancy occurs prior to the expiration of the term for the vacated seat, the appointing authority shall appoint a member for the remainder of the unexpired term pursuant to this chapter.
(iii) On the effective date of the act, the Senate President pro Temp shall appoint three members to serve to two-year terms and the Speaker of the Assembly shall each appoint three members to serve four-year terms. All subsequent terms shall be for four years.

(d) Vacancies that occur shall be filled within 30 days after the occurrence of the vacancy, and shall be filled in the same manner in which the vacating member was selected or appointed.
(e) The Board members shall select one of their members to serve as chairperson and one of their members to serve as vice chairperson on an annual basis. The chairman shall have the authority to call meetings of the Prescription Drug Advisory Board.

130552. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130553. To implement and administer Cal Rx Plus, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. Drug rebate contracts negotiated by a third-party shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx Plus participants.

130554. (a) The department shall deposit all payments the department receives pursuant to this division into the Cal Rx Plus Program Fund, which is hereby established in the State Treasury.
(b) The fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to this division and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund. The fund shall also contain any interest accrued on moneys in the fund.

130555. (a) (1) The director may adopt regulations as are necessary for the initial implementation of this division. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the department is hereby exempted from the requirement that it describe specific facts showing the need for immediate action.

(b) As an alternative to the adoption of regulations pursuant to subdivision (a), and notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this article, in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action, provided that no such bulletin or other similar instructions shall remain in effect after July 31, 2007. It is the intent that regulations adopted pursuant to subdivision (b) shall be in place on or before July 31, 2007.

Chapter 7. Enforcement.

S. 130570. The Attorney General, upon the Attorney General's own initiative or upon petition of the department or of 50 or more residents of the State, shall investigate suspected violations of this division.

S. 130571. The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served

in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside.

S.130572. A court of competent jurisdiction may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

S.130574. If the Attorney General fails to act within 180 days to investigate suspected violations of this division, any person acting for the interests of itself, its members or the general public may seek to obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount of up to $100,000 or three times the amount of the damages, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

Division 112.5. Profiteering in prescription drugs

S. 130600 Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs. A manufacturer or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:
(a) Exacts or demands an unconscionable price;
(b) Exacts or demands prices or terms that lead to any unjust or unreasonable profit;
(c) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or
(d) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

S. 130601. Each violation of this division is a civil violation for which the Attorney General or any person acting for the interests of itself, its members or the general public may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount of $100,000 or three times the amount of the damages, whichever is greater, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

Section 2. This act shall be broadly construed and applied in order to fully promote its underlying purposes. If any provision of this initiative conflicts directly or indirectly with any other provisions of law, or any other statute previously enacted by the Legislature, it is the intent of the voters that such provisions shall be null and void to the extent that they are inconsistent with this initiative and are hereby repealed.

(b) No provision of this Act may be amended by the legislature except to further the purposes of that provision by a statute passed in each house by roll call vote entered in the journal, two-third of the membership concurring, or by a statute that becomes effective only when approved by the electorate. No amendment by the legislature shall be deemed to further the purposes of this Act unless it furthers the purpose of the specific provision of this Act that is being amended. In any judicial action with respect to any legislative amendment, the court shall exercise its independent judgment as to whether or not the amendment satisfies the requirements of this subsection.

(c) If any provision of this act or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect other provisions or applications of the act that can be given effect in the absence of the invalid provision or application. To this end, the provisions of this act are severable.

Item D

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: July 13, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legislation Update

Legislation

At the April 27, 2005 board meeting the board took positions on twelve bills and directed staff to watch the remainder of the bills on the list. In the intervening two months many of the bills the board has been tracking have been amended and the Legislation and Regulation Committee is now asked to review the board's positions those bill and make recommendations to the full board.

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

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

FOR ACTION

Item 1 – AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs
Board Sponsored Bill
Board's Position: Support
Version of Bill: 3/29/05
Current Version: 5/26/05

Summary: The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard.

A copy of the bill and committee analysis are in Attachment 1.

Item 2 – SB 1111 (B&P Committee) Omnibus Bill
Board's Position: Support
Version of Bill: Introduced
Current Version: 5/11/05

Summary: This is a committee omnibus bill that includes eight changes the board is proposing for the Business and Professions Code. These change are:

1. Rules of Professional Conduct: B&P 4005 & 4206
2. Recast and Revision: Requirements For Designated Representatives: B&P 4053
3. Technical Updates to Licensing Provisions: B&P 4127.5, 4205 & 4400
4. Continuing Education Requirements: B&P 4231 & 4232
5. Pharmacist Recovery Program: B&P 4360-4373
6. Pharmacy Technician Program: B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202
7. Letter of Admonishment: B&P 4315
8. Impairment or Theft by Licensed Individuals: B&P 4104

These changes cover are being proposed to clean up previous legislation, update the law or respond to state and national trends in regulating pharmacies and pharmacists. All the proposals are non-controversial. They have been reviewed and discussed at least twice during a public meeting of the board, and have been approved by the board for sponsorship.

A copy of the bill and committee analysis are in Attachment 2.

Item 3 – AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Nonresident Wholesaler License Surety Bond
Board Position: Support
Version of Bill: 4/19/0505
Current Version: 4/19/05

Summary: Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. This bill would instead require a single $100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 3.

Item 4 – SB 734 (Torlakson) Controlled Substances
Board's Position: Oppose Unless Amend
Version of Bill: 4/18/05
Current Version: 4/18/05

Summary: The bill is sponsored the Department of Justice. The author's intent is to make clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement.

Amendment: Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 4.

Item 5 – Right to Refuse to Fill a Prescription

AB 21 (Levine) Pharmacists: Practice Requirements
Note: This is a 2-year bill.
Board's Position: No Position
Version of Bill: 4/13/05
Current Version: 6/15/05

Summary: This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of those provisions unprofessional conduct and would also make harassment, as specified, of a patient by a pharmacist unprofessional conduct , subject to disciplinary action by the board. (B&P 4069)

SB 644 (Ortiz) Dispensing Prescription Drugs And Devices
Board's Position: Support
Version of Bill: 4/7/05
Current Version: 5/18/05

Summary: The bill would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. (B& P 733)

A copy of the bill, the board's analysis, and committee analysis are are Attachment 5.

Item 6 – Pseudoephedrine

AB 283 (Koretz) Pseudoephedrine: Retail Sale
Board's Position: No Position
Version of Bill: 4/13/05
Current Version: 5/26/05

Summary: The bill would limit access to ephedrine and pseudoephedrine products by requiring a retailer to place the products in a locked cabinet, and that The retailer or employee of the retailer shall at all times act to prevent the theft or diversion of the products. AB 283 would place these provisions in H&SC 11100.01.

SB 152 (Speier) Pseudoephedrine
Note: This is a 2-year bill
Board's Position: Oppose SB 152
Version of Bill: 4/18/05
Current Version: 4/18/05

Summary: The bill would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1.

A copy of the bill and the board's analysis are in Attachment 6.

Item 7 – AB 446 (NEGRETE MCLEOD) Settlement Agreements (Gag Clauses)
Note: The board supported similar legislation, AB 320, in 2003.
Board's Position: Support
Version of Bill: 3/30/05
Current Version: 3/30/05

Summary: This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator.

A copy of the bill and the board's analysis are in Attachment 7.

Item 8- SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services
Board's Position: Support
Version of Bill: 3/29/05
Current Version: 3/29/05

Summary: Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes.

A copy of the bill and the board's analysis are in Attachment 8.

Item 9 – AB 896 (Matthews) Clinical laboratories
Note: This is a 2-year bill.
Board's Position: Support
Version of Bill: Introduced
Current Version: Introduced

Summary: This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

A copy of the bill and the board's analysis are in Attachment 9.

Item 10 – AB 657 (Karnette) Pharmacies: Prescription Containers: Labels
Board's Position: Oppose
Version of Bill: 4/13/05
Current Version: 6/21/05

Summary: Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription..

A copy of the bill and the board's analysis are in Attachment 10.

Item 11 – AB 225 (Negrete McLeod) Electronic Prescription Information
Board's Position: Support if Amended
Version of Bill: 4/7/05
Current Version: 4/7/05

Summary: This bill allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances.

Amendment: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient's choice.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 11.

Item 12 – AB 522 (Plescia) Automated drug delivery system
Board's Position: Support if Amended
Version of Bill: 3/29/05
Current Version: 6/23/05

Summary: This bill is intended to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

Amendment: Add the words "and dosage" to page 4, line 33 to read:

"After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

A copy of the bill, the board's analysis, and committee analysis are in Attachment 12.

Item 13 – SB 401 (Ortiz) Medical information: Pharmacies: Marketing
Board's Position: No Position
Version of Bill: 4/12/05
Current Version: 6/15/05

Summary: This bill would define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 13.

Item 14 – SCR 49 (Speier) Medication Errors Panel
This is a new bill introduced on June 15, 2005
Current Version: 6/30/05

Summary: This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

A copy of the bill and committee analysis are in Attachment 14.

Item 15 –Other Bills for Consideration

Note: The board did not take a position on the following bills, but would like staff to watch for amendments.

A copy of the bill, the board's analysis, and committee or floor analysis (if available) are in Attachment 15.

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of California Drug Safety

Summary: This bill would establish the Office of California Drug Safety Watch, which would require the construction of a public database of adverse prescription drug reactions.

SB 380 (Alquist) Drugs: Adverse Event Reporting

Summary: This bill would require a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

AB 72 (Frommer) Prescription Drugs: Clinical Trials

Note: This is a 2-year bill.

Summary: This bill would establish the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

SB 19 (Ortiz) California Rx Program

Summary: This bill is sponsored by the Governor and would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

AB 73 (Frommer) Prescription Drugs: Importation: Procurement

Summary: This bill would establish a state Web site to help patients purchase lower-cost prescription drugs from pharmacies in Canada, U.K., and Ireland.

AB 74 (Gordon) California Rx Prescription Drug Hotline

Summary: This bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs

AB 75 (Frommer) Pharmaceutical Assistance Program

Summary: This bill would establish a prescription drug discount program for low-income state residents

AB 76 (Frommer) Office of Pharmaceutical Purchasing

Summary: This bill would place the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

AB 78 (Pavley) Pharmacy Benefits Management

Summary: The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues.

SB 798 (Simitian) Prescription Drugs: Collection And Distribution Program

Summary: This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Attachment 1

AMENDED IN SENATE MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including "manufacturer."

This bill would delete the definition of manufacturer. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard. Because the bill would specify requirements for compounded drug products under the Pharmacy Law, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4019.5 is added to the Business and
2 Professions Code, to read:
3 4019.5. (a) "Compounding" means any of the following
4 activities occurring in a pharmacy pursuant to a prescription:
5 (1) Altering the dosage form or delivery system of a drug.
6 (2) Altering the strength of a drug.
7 (3) Combining components or active ingredients.
8 (4) Preparing a drug product from bulk chemicals.
9 (b) "Compounding" shall not include the reconstitution of a
10 drug pursuant to the manufacturer's direction for oral, rectal, or
11 topical administration.
12 ~~(c) This section shall not apply to over-the-counter drugs or~~
13 ~~nonprescription drugs.~~
14 SEC. 2. Section 4033 of the Business and Professions Code is
15 repealed.
16 SEC. 3. Section 4051 of the Business and Professions Code is
17 amended to read:
18 4051. (a) Except as otherwise provided in this chapter, it is
19 unlawful for any person to compound, furnish, sell, or dispense
20 any dangerous drug or dangerous device, or to dispense or
21 compound any prescription pursuant to Section 4040 of a
22 prescriber unless he or she is a pharmacist under this chapter.
23 (b) Notwithstanding any other law, a pharmacist may
24 authorize the initiation of a prescription, pursuant to Section
25 4052, and otherwise provide clinical advice or information or
26 patient consultation if all of the following conditions are met:
27 (1) The clinical advice or information or patient consultation is
28 provided to a health care professional or to a patient.
29 (2) The pharmacist has access to prescription, patient profile,
30 or other relevant medical information for purposes of patient and
31 clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~(g) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the
4 penalty for a crime or infraction, within the meaning of Section
5 17556 of the Government Code, or changes the definition of a
6 crime within the meaning of Section 6 of Article XIII B of the
7 California Constitution.

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AB 595

As Amended: May 26, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair
As Fiscal: Yes

SUBJECT: Pharmacy: compounding of prescription drugs.

SUMMARY: Defines compounding of prescription drugs and establishes standards for pharmacies that compound drug products for patients.

Existing law:

1)Provides for the licensing and regulation of pharmacists and pharmacies and the practice of pharmacy by the California State Board of Pharmacy (Board).

2)Defines "manufacturer" as a person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufacturers on the immediate premises where the drug or device is sold to the ultimate consumer.

3)Specifies that "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription provided that the drug is not prepared prior to receipt of the prescription.

4)Specifies that "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

5)Provides that it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription of a prescriber, as required, unless he or she is a pharmacist.

6)Requires that any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report the contractual arrangement to the Board within 30 days of commencing the

compounding.

7)Requires any pharmacy, in order to compound injectable sterile drug products, to obtain a license from the Board of Pharmacy to compound injectable sterile drug products and specifies other requirements as it pertains to compounding injectable drug products.

This bill:

1)Defines compounding as any of the following activities occurring in a pharmacy relating to a prescription:

a) Altering the dosage form, or delivery system of a drug;

b) Altering the strength of a drug;

c) Combining components of active ingredients; or,

d) Preparing a drug product from bulk chemicals.

2)Excludes from the definition of "compounding" the reconstruction of a drug pursuant to the manufacturer's direction of oral, rectal, or topical administration.

3)Requires that a compounded drug product be dispensed or furnished to a patient only pursuant to a prescription or where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

4)Allows a pharmacy to conduct anticipatory compounding of a drug product in limited quantity, as specified, and allows a pharmacy to base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

5)Allows a pharmacy to contract with another pharmacy to compound drug products on behalf of its patients.

6)Allows a pharmacist to do both of the following:

a) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, as long as the drug is not compounded before receipt of the prescription; and,

b) Repackage a drug previously dispensed to the patient at

the request of the patient or the patient's agent.

7)Deletes the definition of manufacturer and the requirement for a pharmacy that contracts to compound a drug for parenteral therapy to report the arrangement to the Board.

8)Makes other technical non-substantive changes.

FISCAL EFFECT: According to the analysis of the Assembly Appropriations Committee, dated April 27, 2005, minor and absorbable costs to the Board.

COMMENTS:

1.Purpose. According to the Board, the sponsor of this bill, over the last ten years there has been an increase in compounding drugs by pharmacies. This increase in compounding activity and potential harm to the public from improperly compounded drugs makes it necessary for the Board to establish standards for pharmacies that compound drugs.

The Author states that compounding is a practice that is centuries old. In the 1950s, with the rise in large drug manufacturers, the practice began to decline. However, the need for specialized drugs to treat ailments that do not affect the public at large, and are therefore not profitable for large-scale manufacturers to produce, caused a resurgence in compounding drugs by pharmacies. It is estimated that compounding may make up one percent of the prescriptions filled. This increase in compounding was accompanied by news reports of people dying from improperly compounded drugs. Since 1990 the Food and Drug Administration (FDA) is aware of 200 adverse drug events involving 71 compounded drugs. In 2001 alone, three deaths and thirteen hospitalizations occurred following injection of a compounded drug that was contaminated with bacteria.

2.Background.

a) Drug Compounding. According to background information provided by the Author, drug compounding involves the mixing, combining, or altering of ingredients to create a customized medication for an individual patient. Some of the products commonly compounded include lotions, ointments, creams, gels, suppositories, and intravenously administered fluids and medications. Some compounded drugs, like intravenously administered chemotherapy drugs, are sterile products that require special safeguards to prevent injury or death to patients receiving them. These safeguards include cleaner facilities, specific training for pharmacy

personnel, and testing of the compounded drug for sterility. According to the FDA, compounding occurs because there are drugs for certain conditions that are not made by manufacturers and even if a drug is mass-produced for a medical condition, patients might need a custom-made version for various reasons. However, compounding has its risks. Background information revealed that several compounding cases resulted in serious illness and deaths and raised concerns about oversight to ensure safety and quality of compounded drugs.

b) Compounding Oversight and Development of this Proposal. According to the Board, the FDA and Department of Health Services (DHS) consider compounding by a pharmacy to be drug manufacturing. The DHS licenses and the FDA registers licensees' businesses engaged in certain compounding activities. Under federal and state law, any manipulation of a drug product or component, which alters its original state including repackaging or relabeling, constitutes manufacturing, including what has been traditionally considered pharmacy compounding. However, federal and state drug laws, including California's Pharmacy Law, recognize compounding as a proper function of pharmacy practice and exempt pharmacies engaged in legitimate compounding from licensure or registration as manufacturers. The Board has jurisdiction over anyone who handles or prepares a dangerous drug, whether for sale, retail or otherwise in California. The FDA and DHS have authority over manufacturing, including compounding, even by those exempt from licensure and registration, but, in the exercise of their discretion, both the FDA and DHS have chosen to target pharmacy compounding that occurs outside the bounds of traditional pharmacy practice and leave the day-to-day regulation of traditional pharmacy practices to state boards of pharmacy.

In 1992, FDA issued a compliance policy guide that delineated FDA's enforcement policy on pharmacy compounding. That guide remained in effect until 1997, when Congress enacted the Food and Drug Administration Modernization Act of 1997. The new law clarified the status of pharmacy compounding under federal law. The FDA Modernization Act of 1997 defined the limits of legitimate compounding and included a section exempting drugs compounded on a customized basis for an individual patient from key portions of the Food Drug and Cosmetic Act (FDCA), if certain criteria were met. However, a 2002 decision by the U. S. Supreme Court found the section dealing with drug compounding contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescription for and advertising specific compounded drugs) and held the entire section of

law as invalid. In May 2002, the FDA issued a compliance guide on pharmacy compounding to represent its current position which indicated that the FDA will generally defer to state authorities in dealing with less significant violations of the FDCA, and expects to work cooperatively with the states in coordinating investigations, referrals, and follow-up actions. The practical effect of the FDA's compliance policy was to delegate to states the authority to regulate drug compounding when it is done to meet the unique needs of individual patients.

As a result of the many activities related to compounding especially at the federal level, DHS requested clarification from the Board on how it determines when pharmacy compounding falls outside of the scope of pharmacy practice. In response the Board formed a "Workgroup on Compounding" comprised of pharmacists and FDA and DHS representatives to develop drug compounding proposals and the provisions of this measure were developed over a one-year period in a series of meetings. One of the outcomes that the workshop hoped to achieve was to develop a list of factors (similar to the FDA compliance guide) that would be considered by Board inspectors that may suggest that a pharmacy that claims to be compounding may actually be engaged in manufacturing. It was the Board's position that it wanted to provide uniformity in compounding in California to better regulate the practice to enhance public protection. Also, by solidifying the role of compounding in pharmacy practice, it may diminish the likelihood that pharmacies compounding within their practice of pharmacy will be required to register as manufacturers.

The workshop developed this legislative proposal and at the same time drafted regulations to be promulgated once the legislation is passed. The regulations will further establish the requirements for general compounding by pharmacies. They will require a master formula record for all compounded drug products, and specify that the pharmacist who compounds the drug assures that the drug product retains its strength, quality and integrity until dispensed, and that it is prepared, labeled, stored and delivered according to specified requirements. The regulations will also establish record keeping and labeling requirements, quality assurance specifications for the compounding process and the compounded drug product, and the requirements for facilities and equipments. The regulations will also mandate that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia Compendia specifications, and require that the patient must be

informed that the drug product has been compounded and the pharmacy will be required to recall a drug product that is misbranded, adulterated, or has the potential for patient harm.

3. Previous Legislation. SB 293 (Torlakson), Chapter 827, Statutes of 2001, required the Board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy, required some pharmacies that compound these drug products to be specially licensed, and provided for inspection and investigations of compounding pharmacies. This 2001, legislation was the result of a case where contaminated drugs compounded in a pharmacy led to the deaths of three patients and the hospitalization of many others.

SUPPORT AND OPPOSITION:

Support: California State Board of Pharmacy (Sponsor)

Opposition: (None received as of June 15, 2005.)

Consultant: Bill Gage

Attachment 2

AMENDED IN SENATE MAY 11, 2005

SENATE BILL No. 1111

Introduced by Committee on Business, Professions and Economic Development (Senators Figueroa (Chair), Aanestad, Campbell, Florez, Morrow, Murray, and Simitian)

March 30, 2005

An act to amend Sections 2053.6, 2230, 2234.1, 2741, ~~2760.1,~~ 3735, 3739, 4005, 4038, 4053, 4104, 4114, 4115, 4115.5, 4127.5, 4202, 4205, 4231, 4232, 4315, 4360, 4364, 4365, 4366, 4369, 4371, 4372, 4373, 4400, and 4850 of, to add Sections 3779 and 4023.5 to, to repeal Sections 3735.3, 3736, 3775.2, 3775.3, 4206, 4363, 4367, 4368, and 4370 of, and to repeal and add Sections 4361 and 4362 of, the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1111, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the regulation of various professions, including physicians and surgeons, nurses, respiratory care practitioners, and pharmacists.

This bill would revise and recast certain provisions regulating these professions. The bill would require the Division of Medical Quality to organize itself as 2 panels of 7 members. The bill would require an applicant for a license to practice respiratory care to successfully pass the national respiratory therapist examination. The bill would require a pharmacy to have written policies and procedures for detecting chemical, mental, or physical impairment among licensed individuals employed by or with the pharmacy. The bill would require a pharmacy to report certain information to the California State Board of

Pharmacy for the protection of the public. The bill would require the board to operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competence may be impaired due to abuse of alcohol, drug use, or mental illness. The bill would establish requirements for this program and require the board to contract with one or more qualified contractors to administer the program. Because the bill would increase fees under the Pharmacy Law that would be deposited into the Pharmacy Board Contingent Fund which is continuously appropriated, the bill would make an appropriation.

Because a violation of the bill with respect to pharmacists would be a crime, it would impose a state-mandated local program

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 2053.6 of the Business and Professions
2 Code is amended to read:
3 2053.6. (a) A person who provides services pursuant to
4 Section 2053.5 that are not unlawful under Section 2051 or 2052
5 shall, prior to providing those services, do the following:
6 (1) Disclose to the client in a written statement using plain
7 language the following information:
8 (A) That he or she is not a licensed physician.
9 (B) That the treatment is alternative or complementary to
10 healing arts services licensed by the state.
11 (C) That the services to be provided are not licensed by the
12 state.
13 (D) The nature of the services to be provided.
14 (E) The theory of treatment upon which the services are based.
15 (F) His or her educational, training, experience, and other
16 qualifications regarding the services to be provided.

(2) Obtain a written acknowledgement from the client stating that he or she has been provided with the information described in paragraph (1). The client shall be provided with a copy of the written acknowledgement, which shall be maintained by the person providing the service for three years.

(b) The information required by subdivision (a) shall be provided in a language that the client understands.

(c) Nothing in this section or in Section 2053.5 shall be construed to do the following:

(1) Affect the scope of practice of licensed physicians and surgeons.

(2) Limit the right of any person to seek relief for negligence or any other civil remedy against a person providing services subject to the requirements of this section.

SEC. 2. Section 2230 of the Business and Professions Code is amended to read:

2230. (a) All proceedings against a licensee for unprofessional conduct, or against an applicant for licensure for unprofessional conduct or cause, shall be conducted in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) except as provided in this chapter, and shall be prosecuted by the Senior Assistant Attorney General of the Health Quality Enforcement Section.

(b) For the purpose of exercising its disciplinary authority against a physician and surgeon pursuant to this chapter and the Administrative Procedure Act, the Division of Medical Quality shall organize itself as two panels of seven members. Two members of each panel shall be public members. For purposes of this article, "agency itself," as used in the Administrative Procedure Act, means a panel of the division as described in this subdivision. The decision or order of a panel imposing any disciplinary action pursuant to this chapter and the Administrative Procedure Act shall be final.

SEC. 3. Section 2234.1 of the Business and Professions Code is amended to read:

2234.1. (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered

to a patient is alternative or complementary medicine if that treatment or advice meets all of the following requirements:

(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine he or she practices.

(3) It does not cause a delay in or discourage traditional diagnosis of a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine" means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

SEC. 4. Section 2741 of the Business and Professions Code is amended to read:

2741. An application for reexamination shall be accompanied by the fees prescribed by this chapter.

~~SEC. 5. Section 2760.1 of the Business and Professions Code is amended to read:~~

~~2760.1. (a) A registered nurse whose license has been revoked, or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including reduction or termination of probation, after a period not less than the following minimum periods has elapsed from the effective date of the decision ordering that disciplinary action, or if the order of the board or any portion of it is stayed by the board itself or by the superior court, from the date the disciplinary action is actually implemented in its entirety:~~

~~(1) Except as otherwise provided in this section, at least two years for reinstatement of a license that was revoked, except that the board may, in its sole discretion, specify in its order a lesser period of time provided that the period shall be not less than one year.~~

~~(2) At least two years for early termination of a probation period of three years or more.~~

~~(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.~~

~~(b) The board shall give notice to the Attorney General of the filing of the petition. The petitioner and the Attorney General shall be given timely notice by letter of the time and place of the hearing on the petition, and an opportunity to present both oral and documentary evidence and argument to the board. The petitioner shall at all times have the burden of proof to establish by clear and convincing evidence that he or she is entitled to the relief sought in the petition.~~

~~(c) The hearing may be continued from time to time as the board deems appropriate.~~

~~(d) The board itself shall hear the petition and the administrative law judge shall prepare a written decision setting forth the reasons supporting the decision.~~

~~(e) The board may grant or deny the petition, or may impose any terms and conditions that it reasonably deems appropriate as a condition of reinstatement or reduction of penalty.~~

~~(f) The petitioner shall provide a current set of fingerprints accompanied by the necessary fingerprinting fee.~~

~~(g) No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole, or subject to an order of registration pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.~~

~~(h) Except in those cases where the petitioner has been disciplined for violation of Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.~~

~~SEC. 6.~~

SEC. 5. Section 3735 of the Business and Professions Code is amended to read:

3735. Except as otherwise provided in this chapter, no applicant shall receive a license under this chapter without first successfully passing the national respiratory therapist examination conducted by those persons, and in the manner and under the rules and regulations, as the board may prescribe.

~~SEC. 7.~~

SEC. 6. Section 3735.3 of the Business and Professions Code is repealed.

~~SEC. 8.~~

SEC. 7. Section 3736 of the Business and Professions Code is repealed.

~~SEC. 9.~~

SEC. 8. Section 3739 of the Business and Professions Code is amended to read:

3739. (a) (1) Except as otherwise provided in this section, every person who has filed an application for licensure with the board may, between the dates specified by the board, perform as a respiratory care practitioner applicant under the direct supervision of a respiratory care practitioner licensed in this state provided he or she has met education requirements for licensure as may be certified by his or her respiratory care program, and if ever attempted, has passed the national respiratory therapist examination.

(2) During this period the applicant shall identify himself or herself only as a "respiratory care practitioner applicant."

(3) If for any reason the license is not issued, all privileges under this subdivision shall automatically cease on the date specified by the board.

(b) If an applicant fails the national respiratory therapist examination, all privileges under this section shall automatically cease on the date specified by the board.

(c) No applicant for a respiratory care practitioner license shall be authorized to perform as a respiratory care practitioner applicant if cause exists to deny the license.

(d) "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area.

~~SEC. 10.~~

SEC. 9. Section 3775.2 of the Business and Professions Code is repealed.

~~SEC. 11.~~

SEC. 10. Section 3775.3 of the Business and Professions Code is repealed.

~~SEC. 12.~~

SEC. 11. Section 3779 is added to the Business and Professions Code, to read:

3779. For purposes of license verification, a person may rely upon a printout from the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

~~SEC. 13.~~

SEC. 12. Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

~~SEC. 14.~~

SEC. 13. Section 4023.5 is added to the Business and Professions Code, to read:

4023.5. For the purposes of this chapter "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

~~SEC. 15.~~

SEC. 14. Section 4038 of the Business and Professions Code is amended to read:

4038. (a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.

~~SEC. 16.~~

SEC. 15. Section 4053 of the Business and Professions Code, as added by Section 7 of Chapter 857 of the Statutes of 2004, is amended to read:

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78–410).

~~SEC. 17.~~

SEC. 16. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for detecting chemical, mental, or physical impairment, as well

as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(7) Any information supporting a reasonable suspicion that a licensed individual is chemically, mentally, or physically impaired to the extent it affects his or her ability to practice.

(8) Any information supporting a reasonable suspicion that a licensed individual has engaged in theft, diversion, or self-use of dangerous drugs.

(d) Anyone participating in good faith in the making of a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

~~SEC. 18.~~

SEC. 17. Section 4114 of the Business and Professions Code is amended to read:

4114. (a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the direct supervision

and control of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

~~SEC. 19.~~

SEC. 18. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may 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 paragraph.

(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a

pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

~~SEC. 20.~~

SEC. 19. Section 4115.5 of the Business and Professions Code is amended to read:

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

~~SEC. 21.~~

SEC. 20. Section 4127.5 of the Business and Professions Code is amended to read:

4127.5. The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

~~SEC. 22.~~

SEC. 21. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a General Education Development equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

~~SEC. 23.~~

SEC. 22. Section 4205 of the Business and Professions Code is amended to read:

4205. (a) A license issued pursuant to Section 4110, 4120, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use.

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of Article 9 (commencing with Section 4140) of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

~~SEC. 24.~~

SEC. 23. Section 4206 of the Business and Professions Code is repealed.

~~SEC. 25.~~

SEC. 24. Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704.

~~SEC. 26.~~

SEC. 25. Section 4232 of the Business and Professions Code is amended to read:

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

~~SEC. 27.~~

SEC. 26. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, 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, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

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

~~SEC. 28.~~

SEC. 27. Section 4360 of the Business and Professions Code is amended to read:

4360. The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

~~SEC. 29.~~

SEC. 28. Section 4361 of the Business and Professions Code is repealed.

~~SEC. 30.~~

SEC. 29. Section 4361 is added to the Business and Professions Code, to read:

4361. (a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

~~SEC. 31.~~

SEC. 30. Section 4362 of the Business and Professions Code is repealed.

~~SEC. 32.~~

SEC. 31. Section 4362 is added to the Business and Professions Code, to read:

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on the pharmacists or intern pharmacists entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

~~SEC. 33.~~

SEC. 32. Section 4363 of the Business and Professions Code is repealed.

~~SEC. 34.~~

SEC. 33. Section 4364 of the Business and Professions Code is amended to read:

4364. (a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

~~SEC. 35.~~

SEC. 34. Section 4365 of the Business and Professions Code is amended to read:

4365. The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

~~SEC. 36.~~

SEC. 35. Section 4366 of the Business and Professions Code is amended to read:

4366. The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

~~SEC. 37.~~

SEC. 36. Section 4367 of the Business and Professions Code is repealed.

~~SEC. 38.~~

SEC. 37. Section 4368 of the Business and Professions Code is repealed.

~~SEC. 39.~~

SEC. 38. Section 4369 of the Business and Professions Code is amended to read:

4369. (a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

~~SEC. 40.~~

SEC. 39. Section 4370 of the Business and Professions Code is repealed.

~~SEC. 41.~~

SEC. 40. Section 4371 of the Business and Professions Code is amended to read:

4371. The board shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the pharmacists recovery program.

~~SEC. 42.~~

SEC. 41. Section 4372 of the Business and Professions Code is amended to read:

4372. All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery , subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and

records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

~~SEC. 43.~~

SEC. 42. Section 4373 of the Business and Professions Code is amended to read:

4373. No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

~~SEC. 44.~~

SEC. 43. Section 4400 of the Business and Professions Code, as added by Section 50 of Chapter 857 of the Statutes of 2004, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053 shall be one hundred eighty-five dollars ($185) and may be increased to two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund seventy-five dollars ($75) of the fee.

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred dollars ($100) of the fee.

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars ($150).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(m) The board may waive or refund the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(r) The board shall charge a fee for the processing and issuance of a license to a pharmacy technician and a separate fee for the biennial renewal of the license. The license fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

~~SEC. 45.~~

SEC. 44. Section 4850 of the Business and Professions Code is amended to read:

4850. Every person holding a license under this chapter shall conspicuously display the license in his or her principal place of business.

~~SEC. 46.~~

SEC. 45. 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

1 crime within the meaning of Section 6 of Article XIII B of the
2 California Constitution.

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SB 1111

As Amended: May 11, 2005

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Gloria Negrete McLeod, Chair
SB 1111 (Committee on Business and Professions)

SUBJECT : Professions and vocations.

SUMMARY : Makes several non-controversial, minor, non-substantive or technical changes to various miscellaneous provisions pertaining to regulatory boards of the Department of Consumer Affairs (DCA). Specifically, this bill :

1)Makes the following changes pertaining to the Medical Board of California (MBC):

a) Specifies that the MBC's Division of Medical Quality shall be comprised of two panels of seven members (to reflect the change in composition already made by previous legislation).

b) Makes updating and clarifying changes.

2)Makes the following changes pertaining to the Board of Registered Nursing (BRN): Deletes the 3-month limitation on how often an applicant may be reexamined.

3)Makes the following changes pertaining to the Board of Pharmacy (BOP):

a) Streamlines the pharmacist licensure procedure, removing the outdated rules of professional conduct.

b) Recasts and revises the requirements for designated representatives, the non-pharmacists who oversee the operations of drug wholesalers.

c) Makes several technical updates to pharmacy licensing provisions.

d) Establishes 30 hours of continuing education (CE) for license renewal; specifies that a pharmacist who fails to provide proof within 60 days of license renewal of CE completion will be issued an inactive license and barred from practicing pharmacy; and changes the requirement for the CE exemption from two years after graduation to the first renewal of a pharmacist license.

e) Changes the term "pharmaceutical education" to "pharmacy education."

f) Deletes the provision that would keep the identity of a licensee who voluntarily enters the pharmacist recovery program confidential from BOP and adds a provision that would prohibit BOP from taking enforcement action against a self-referred licensee based on his or her entry into the program or any information obtained from a licensee while participating in the program.

g) Deletes the provision that allows unlicensed personnel to act as pharmacy technicians for one year if they work in one the following departments: Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services, or the Department of Veterans Affairs; makes technical amendments to the pharmacy technician program; and standardizes the level of supervision of a pharmacist over designated pharmacy staff to "direct supervision and control."

h) Deletes the requirement that a copy of a pharmacist's letter of admonishment be kept on the pharmacy's premises.

i) Requires pharmacies to notify BOP within 30 days of a pharmacist who engages in theft, diversion, or self use of dangerous drugs. Additionally, requires pharmacies to hand over evidence against pharmacists engaged in these activities.

4)Makes the following changes pertaining to the Respiratory Care Board (RCB):

a) Repeals unnecessary or outdated language and identifies the national examination required for licensure.

b) Repeals the authority for RCB to charge fees to CE providers.

c) Repeals the requirement for RCB to report fee increases.

d) Provides that printouts of license verifications via RCB's website may be relied upon.

5)Makes the following change pertaining to the Veterinary Medical Board (VMB): Clarifies that a licensee must display his or her license - not a copy - at the principal place of business.

EXISTING LAW:

1)Provides for the licensing and regulation of physicians by MBC.

2)Provides for the licensing and regulation of registered nurses by BRN.

3)Provides for the licensing and regulation of pharmacists by BOP.

4)Provides for the licensing and regulation of respiratory care therapists by RCB.

5)Provides for the licensing and regulation of veterinarians by VMB.

FISCAL EFFECT : Unknown

COMMENTS :

Purpose of this bill . This bill is one of three "committee bills" authored by the Senate Business and Professions Committee that are intended to consolidate a number of non-controversial provisions related to various regulatory programs governed by the Business and Professions Code, and generally located within DCA. Consolidating the provisions in one bill is designed to relieve the various licensing boards from the necessity and burden of having separate measures for a number of non-controversial revisions.

Many of the provisions make minor, technical and updating changes, while other provisions are substantive changes which are intended to improve the ability of the various licensing programs to efficiently and effectively administer their respective licensing laws.

Continuing Education . B&P Code Sections 4231 and 4232 establish BOP's authority to require continuing education as a condition for renewal of a pharmacist license. BOP has identified four technical and non-substantive amendments that would clarify CE requirements to licenses. The first amendment would establish CE requirements of at 30 hours, which is currently the amount required in regulations.

The second would modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license. This change would effectively exempt both recent graduates from California schools and pharmacists coming from outside of California who have recently taken the North American Pharmacy License Exam and the California Jurisprudence

Exam, from the CE requirement.

The third would establish that a pharmacist who fails to provide proof of completed CE within 60 days as part of a license renewal would be issued an inactive license and be prohibited from practicing until proof of the completed CE is presented to BOP. (A pharmacist cannot practice with an inactive license.) Clarification of the law is needed because some pharmacists pay their licensing renewal fees but do not provide proof of CE. Currently these licenses are in limbo; the renewal has not been completed because they have not submitted proof of CE, but BOP has the fee.

The fourth would be to change the term "pharmaceutical education" to "pharmacy education" in Section 4232, to reflect current terminology.

Pharmacist Recovery Program . B&P Code Sections 4360-4373 establish the Pharmacist Recovery Program. Most of the proposed changes to the program are minor, technical revisions to more closely conform the statute to the current operation of the program. However, some of the changes offer substantive changes to the existing program. The following summarizes the changes offered in each section:

Section 4360 adds a directive to operate the program and clarifies that BOP may allow intern pharmacists to participate in the program; Section 4361 eliminates unnecessary definitions; and Section 4362 recasts the provisions specifying who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of, or in addition to, disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects the current operation of the program.

The substantial change made is that licensees who enter the program voluntarily will not have their identities withheld from BOP. Current law indicates that such "self-referrals" are confidential and BOP is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign a disclosure agreement upon entering the program that permits the program to release their identity to BOP. This statutory change would conform to existing practice by the program.

Letter of Admonishment . SB 361 (Figueroa), Chapter 539, Statutes of 2003, added Section 4315 to the Business and Professional Code. B&P Code Section 4351 authorizes the executive officer to issue a letter of admonishment for a violation of Pharmacy Law and requires that a licensee receiving

a letter keep a copy of the letter in the pharmacy that he or she works in for three years. This requirement is problematic for licensees who do not work regularly in the same pharmacy or in a pharmacy at all. BOP recommends deleting the requirement that a copy of a letter of admonishment be kept in a pharmacy.

Impairment or Theft by Licensed Individuals . B&P Code Section 4101 establishes policies and procedures regarding theft, diversion, and self use of dangerous drugs by a pharmacist. This provision will add new requirements that pharmacies: 1) have procedures to detect chemical, mental or physical impairments, as well as theft or self-use drugs by pharmacy employees; and 2) pharmacies report to BOP within 30 days specified acts involving theft, diversion, or self-use of drugs, mental or physical impairment of employees. The goal is to prevent individuals from merely resigning or being fired and going to work in another pharmacy when the problems continue many times unbeknownst to the new owner, thus placing the public at risk. BOP would like to strengthen its ability to collect information on pharmacists who have engaged in these activities. BOP proposes that pharmacies be required to notify BOP and handover evidence if a pharmacist is in violation of the law. The proposal includes a provision that would give immunity from any liability to a person, who in good faith makes a report to BOP.

REGISTERED SUPPORT / OPPOSITION :

Support

California State Board of Pharmacy

Opposition

None on file.

Analysis Prepared by : Ross Warren / B. & P. / (916) 319-3301

Attachment 3

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section ~~4161~~ *4162.5* of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as amended, Negrete McLeod. Drug wholesalers and manufacturers: ~~licensure exemption.~~ *nonresident wholesaler license surety bond.*

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. *Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California.*

This bill would ~~exempt from this licensure requirement certain transactions between affiliated or related wholesalers, as defined~~ *instead require a single $100,000 surety bond, or an equivalent means*

of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 4161 of the Business and Professions~~
2 ~~Code, as added by Chapter 887 of the Statutes of 2004, is~~
3 ~~amended to read:~~
4 *SECTION 1. Section 4162.5 of the Business and Professions*
5 *Code is amended to read:*
6 4162.5. (a) (1) An applicant for the issuance or renewal of a
7 nonresident wholesaler license shall submit a surety bond of one
8 hundred thousand dollars ($100,000)~~ for each site to be licensed~~,
9 or other equivalent means of security acceptable to the board,
10 such as an irrevocable letter of credit, or a deposit in a trust
11 account or financial institution, payable to the Pharmacy Board
12 Contingent Fund. The purpose of the surety bond is to secure
13 payment of any administrative fine imposed by the board and any
14 cost recovery ordered pursuant to Section 125.3.
15 (2) For purpose of paragraph (1), the board may accept a
16 surety bond less than one hundred thousand dollars ($100,000) if
17 the annual gross receipts of the previous tax year for the
18 nonresident wholesaler is ten million dollars ($10,000,000) or
19 less in which the surety bond shall be twenty-five thousand
20 dollars ($25,000).
21 (3) For applicants who satisfy paragraph (2), the board may
22 require a bond up to one hundred thousand dollars ($100,000) for
23 any nonresident wholesaler who has been disciplined by any state
24 or federal agency or has been issued an administrative fine
25 pursuant to this chapter.
26 (b) The board may make a claim against the bond if the
27 licensee fails to pay a fine within 30 days of the issuance of the
28 fine or when the costs become final.
29 (c) A single surety bond or other equivalent means of security
30 acceptable to the board shall satisfy the requirement of
31 subdivision (a) for all licensed sites under common control as
32 defined in Section 4126.5.

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

~~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.~~

~~(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.~~

~~(m) The licensure requirements of this section shall not apply to a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For purposes of this subdivision, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.~~

~~(n) This section shall become operative January 1, 2006.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 497 **VERSION: AMENDED APRIL 19, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: NEGRETE MCLEOD**

RECOMMENDED POSITION:

SUBJECT: DRUG WHOLESALERS AND MANUFACTURERS: LICENSURE EXEMPTION

Existing Law:

Requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. (This requirement will be operative January 1, 2006, to January 1, 2011.) (B&P 4162.5)

This Bill:

Revises the nonresident wholesaler license requirement to require an applicant to submit only one surety bond of $100,000, or an equivalent means of security, regardless of how many individual sites are licensed. (B&P 4162.5 Amended)

Comment:

1) Author's Intent. The author's intent is to provide clean up language for the wholesaler license requirement in last year's board sponsored AB 2628.

2) Amended April 19, 2005. The April 19, 2005 amendment was made at the request of the board. The previous versions of AB 497 would have exempted from the licensing requirements of B&P 4161, a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices into this state solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160.

3) Legislative History. In 2004 the board sponsored SB 1307 (Chapter 857, Statutes of 2004) Wholesalers and Manufacturers of Dangerous Drugs and Devices, and AB 2682 (Chapter 887, Statutes of 2004) Pharmacy: Out-of-State Wholesalers.

4) Support/ Opposition.

Support: Amerisource Bergen Corporation (Sponsor)
California State Board of Pharmacy
Cardinal Health
McKesson Corporation

Opposition: None on file.

5) History.

2005

June 20	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 0.).
June 13	In committee: Hearing postponed by committee.
May 26	Referred to Com. on B., P. & E.D.
May 16	In Senate. Read first time. To Com. on RLS. for assignment.
May 16	Read third time, passed, and to Senate. (Ayes 77. Noes 0. Page 1555.)
May 9	Read second time. To Consent Calendar.
May 5	From committee: Do pass. To Consent Calendar. (May 4).
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR. With recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (April 26).
Apr. 21	Re-referred to Com. on B. & P. by unanimous consent.
Apr. 20	Re-referred to Com. on HEALTH.
Apr. 19	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 12	In committee: Set, first hearing. Hearing canceled at the request of author.
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 3	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

AB 497

As Amended: April 19, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair
Fiscal: Yes

SUBJECT: Drug wholesalers and manufacturers: nonresident wholesaler license surety bond.

SUMMARY: Allows an applicant for a license as a nonresident wholesaler of pharmaceutical drugs to submit a single surety bond to cover each site to be licensed, rather than a surety bond to cover each individual site.

Existing law:

1)Provides for the licensing and regulation of pharmacies and pharmacists by the California State Board of Pharmacy (Board) in the Department of Consumer Affairs.

2)Requires a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale to be considered as a nonresident wholesaler and to be licensed by the Board prior to engaging in those activities.

3)Requires, as of January 1, 2006 and until January 1, 2011, an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or other equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California.

4)Specifies that a single surety bond or other equivalent means of security acceptable to the Board shall satisfy the above requirement for a bond for all licensed sites under common control, as defined.

5)Specifies that the purpose of the surety bond is to secure payment of any administrative fine imposed by the Board and any cost recovery that may be ordered pursuant to disciplinary action taken by the Board.

This bill provides that an applicant for a nonresident

wholesaler license would only have to submit a single $100,000 surety bond, or other equivalent means of security acceptable to the Board, instead of a bond or security for each site to be licensed.
FISCAL EFFECT: According to the Assembly Appropriations analysis dated May 4, 2005, there would be no state fiscal effect.

COMMENTS:

1. Purpose. This bill is sponsored by the AmerisourceBergen Corporation. According to the sponsor, this bill addresses a conflict in existing law that specifically requires a surety bond for each nonresident wholesaler's site, yet otherwise allows for a single surety bond for a multi-site nonresident wholesaler under the common control of a single entity, such as ownership by voting rights or contract. The sponsor indicates that this measure is a technical-clean up issue that remained from the passage of two bills from last year. The surety bond requirement imposed by those measures mistakenly applied the surety bond requirement to each licensed out-of-state wholesaler. The intent was to allow a national wholesale company with multiple licensed distribution centers to post a single bond to cover all of its licensed centers.

2. Previous Legislation. SB 1307 (Figueroa), Chapter 857, Statutes of 2004, changed the licensing requirements of pharmaceutical wholesalers by establishing bonding requirements, and required all prescription drugs to have a "pedigree," as defined, that tracks the ownership of drugs from the manufacturer to the ultimate ownership by the pharmacy. SB 1307 also gave the Board stronger enforcement tools for wholesaler violations of these new requirements. SB 2682 (Negrete McLeod), Chapter 887, Statutes of 2004, required out-of-state manufacturers and wholesalers of dangerous drugs and devices to comply with the same requirements as in-state wholesalers.

3. Arguments in Support. The California State Board of Pharmacy is in support of this measure and indicates that they consider this change as technical clean-up to SB 1307 and SB 2682. The surety bond requirement imposed by these measures mistakenly applied the surety bond requirement to each licensed out-of-state wholesaler, when the intent of those bills was to allow a national wholesale company with multiple licensed distribution centers to post a single bond to cover all of its licensed centers.

SUPPORT AND OPPOSITION:

Support:

AmerisourceBergen Corporation (Sponsor)
California State Board of Pharmacy
Cardinal Health
McKesson Corporation

Opposition: (None received as of June 15, 2005)

Consultant: Bill Gage

Attachment 4

SENATE BILL No. 734

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as introduced, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by

the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the board or department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the

forms to set forth specified information, as appropriate, with respect to practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and multiple prescribers.

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department.

(7) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11159.2 of the Health and Safety Code
2 is amended to read:
3 11159.2. (a) Notwithstanding any other provision of law, a
4 prescription for a ~~Schedule II~~ controlled substance for use by a
5 patient who has a terminal illness shall meet the following
6 requirements:
7 (1) Contain the information specified in subdivision (a) of
8 Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate prescription blanks or~~ controlled substance prescription forms in the practitioner's possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order*. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the

court. Any practitioner possessing prescription ~~blanks~~ *forms* in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender ~~all triplicate prescription blanks or~~ *controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using* controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the ~~Board of Pharmacy~~ *Department of Justice.*

(b) The ~~Board of Pharmacy~~ *department* may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The ~~applicant~~ *department* shall ~~also~~ provide *the applicant with the means and direction to provide* fingerprints *and related information*, in a manner specified by the ~~Board of Pharmacy~~ *department*, for the purpose of completing state ~~and~~, federal, *or foreign* criminal background checks.

(C) *Any applicant described in subdivision (b) shall submit* his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the *department establishes that the* applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision *(l)* of Section 11105 of

the Penal Code. Requests for federal level criminal offender record information *received by the department* pursuant to this section shall be forwarded to the Federal Bureau of Investigation *by the department.*

(D) The department shall assess against each applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits fingerprints and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) ~~Prior to approving a security printer application, the Board of Pharmacy shall submit a copy of the application to the Department of Justice; the Department of Justice may, within 30~~ *The department may, within 60* calendar days of receipt of the application from th~~e Board of Pharmacy~~ *applicant*, deny the security printer application.

(d) The~~ Board of Pharmacy or the Department of Justice~~ *department* may deny a security printer application on any of the following grounds:

(1) The applicant*, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms,* has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Board of Pharmacy or Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) The ~~Board of Pharmacy~~ *department* shall maintain a list of approved security printers and the ~~Board of Pharmacy~~ *department* shall make this information available to prescribers and other appropriate government agencies, including the ~~Department of Justice~~ *Board of Pharmacy*.

(f) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(g) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(h) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(i) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(j) (1) The ~~Board of Pharmacy or the Department of Justice~~ *department* may revoke its approval of a security printer for a

violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the ~~Board of Pharmacy or the Department of Justice~~ *department* revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

~~(k) Security printer applicants may appeal a denial or revocation by the Board of Pharmacy to the full board in a public meeting of the Board of Pharmacy.~~

SEC. 4. 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 ~~either (A)~~ contain a statement printed on the bottom of the prescription blank that the

~~"Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and 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) *(A)* The preprinted name, category of licensure, license number, ~~and~~ federal controlled substance registration number of the prescribing practitioner.

(B) The privileges of a practitioner to prescribe any of the following controlled substances shall be preprinted beside the prescriber's name and as designated in the prescriber's certificate issued by the federal Drug and Enforcement Agency:

(i) Schedule II narcotic.

(ii) Schedule II nonnarcotic.

(iii) Schedule III narcotic.

(iv) Schedule III nonnarcotic.

(v) Schedule IV.

(vi) Schedule V.

(10) A check box indicating the prescriber's order not to substitute.

(11) An identifying number assigned to the approved security printer by the Department of Justice.

(12) A physician assistant authorized by Section 3502.1 of the Business and Professions Code to issue a drug order may do so under his or her own name on prescription forms preprinted with the information required by Section 11162 that are in compliance with subdivision (d) of Section 3502.1 of the Business and Professions Code.

(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 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 the name, category of licensure, license number, and federal controlled substance registration number of the designated

prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) *(A) Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber.*

(B) Each designated prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by the prescriber's name.

(4) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

~~(4)~~

(5) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record 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; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 5. 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 and Schedule III 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 and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III 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, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III 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 or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the 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) Date of issue of the prescription.
(8) Date of dispensing of the prescription.
(9) Method of payment for prescription.
(e) This section shall become operative on January 1, 2005.

SEC. 6. 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 or Schedule III 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, 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) Date of dispensing of the prescription.
(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in ~~either hardcopy or electronic form~~ *a format set by the Department of Justice.*
(d) This section shall become operative on January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, 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.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 734 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: TORLAKSON **SPONSOR: DEPARTMENT OF JUSTICE**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: CONTROLLED SUBSTANCES

Existing Law:

1. Provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2)

2. Provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (H&S 11161)

3. Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the board; the board may approve security printer applications after the board has completed a state and federal criminal background check. (H&S 11161.5)

4. Provides that the board or the Department of Justice (DOJ) may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime. (H&S 11161.5)

5. Provides that prescription forms shall be printed with specified features. (H&S 11162.1)

6. Provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified. (H&S 11190)

This Bill:

This bill would make several changes to facilitate the operation of Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) and to allow for consistency with existing DOJ policy and practice and conformity with "best practices" model to prevent diversion of controlled substances. The bill would make the following changes:

1. Transfers responsibility from the board to DOJ to control the manner in which fingerprints are provided when conducting criminal background investigations of vendors applying to print security prescription forms.

   a. Allows DOJ to collect fees.

   b. Extends from 30 days to 60 days the period with which DOJ may deny an application.

c. Allows DOJ to retain fingerprint impressions for subsequent enforcement and arrest.

d. Allows DOJ to examine the books of security printers.

(H&S 11161.5 Amended)

2. Allows the terminally ill exemption (allowing a prescriber to use nonsecurity forms) for any controlled substance prescription. (Current law designates only C II drugs can be prescribed in this manner.) (H&S 11159.2 Amended)

3. Authorizes the Superior Court to order a prescriber not to order, obtain, or use any prescription forms during a pending criminal action. (H&S 11161 Amended)

4. Clarifies that DOJ is solely responsible for determining whether security printer applications are complete, for maintaining a list of approved security printers, and for revoking approval of security printers. (H&S 11161.5 Amended)

5. Clarifies how prescribers and physician assistants can state number of prescriptions included on form and otherwise comply with CURES program. (H&S 11162.1 Amended)

6. Requires approved security printers to print forms with a vendor identification code issued by the DOJ. (H&S 11162.1 Amended)

7. Requires the DOJ, when are available, to evaluate the viability of implementing real time reporting to CURES. (H&S 11165 Amended)

8. Requires direct dispensers of controlled substances to submit information to the DOJ in a format specified by the DOJ. (H&S 11190 Amended)

9. Makes other technical changes to allow for consistency with existing DOJ policy and practice.

Comment:

1) Author's Intent. The bill is sponsored the DOJ. The author's intent is to make technical and clean-up changes to facilitate the effective operation of the CURES and the program duties of the Bureau of Narcotics Enforcement. Additionally, this bill would make technical changes to be consistent with existing DOJ policy and practice and conform to their "best practices" model to prevent diversion of controlled substances.

2) Above and Beyond Current Requirements: Provisions in AB 734 go beyond transferring oversight of the security printer program from the board to DOJ. In many cases the new requirements seem excessive. New provisions would:

a. Expand DOJ authority to:

   i. Retain the figure prints of applicants.

   ii. Extend the time to review security printer applications from 30 to 60 days.

   iii. Deny an application for a security printer if an applicant is found to have been convicted of a crime or if the applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime.

   iv. Inspect a security printer's business, or examine books and records anytime during regular business hours.

b. Expand information required on prescription forms to include the identification number of security printer.

This bill expands and alters the components required on a security form. It expands the information pharmacies must submit to CURES.

The board submitted a modification to section 11165 to cap the board's funding to CURES at the amount approved by the Governor and the Legislature. This amendment needs to be included in the bill. (See attached.)

3) Proposed Amendment. Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

4) Previous Legislation. SB 151 (Burton, 2003, Chapter 406) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

5) Support / Opposition.

Support: Attorney General Bill Lockyer (sponsor)

Opposition: California Medical Association

6) History.

2005

June 30	Re-referred to Com. on HEALTH.
June 29	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 5. Noes 1.) Re-referred to Com. on APPR.
June 13	To Coms. on PUB. S. and HEALTH
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 25. Noes 9. Page 1174.) To Assembly.
Apr. 18	Set for hearing April 26.
Apr. 18	Read second time. Amended. Re-referred to Com. on PUB. S.
Apr. 14	From committee: Do pass as amended, but first amend, and re-refer to Com. on PUB. S. (Ayes 6. Noes 0.)
Apr. 6	Set for hearing April 13.
Apr. 4	Set, first hearing. Hearing canceled at the request of author.
Mar. 16	Set for hearing April 6.
Mar. 10	To Coms. on HEALTH and PUB. S.
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.

SB 734: Proposed Amendments to CURES Statutory Provisions for Budgetary Issues

SECTION 1. 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 and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate ~~funds~~ appropriations 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 and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Payment from any of the above special funds for costs that exceed budgeted amounts is contingent upon receiving appropriation augmentations sufficient to cover the full costs billed by the Department of Justice.

(b) The reporting of Schedule III 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, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III 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 or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the 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) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SB 734

As Amended: April 18, 2005

ASSEMBLY COMMITTEE ON PUBLIC SAFETY
Mark Leno, Chair

SB 734 (Torlakson) -

SUMMARY : Makes various technical and clarifying changes to the Controlled Substance Utilization Review and Evaluation System (CURES). Specifically, this bill :

1)Removes the reference to Schedule II controlled substances in Health and Safety Code Section 11159.2 to ensure that terminally ill patients can receive a prescription for illnesses, such as cancer or HIV, that contain not only Schedule II drugs but also compounds or combinations from all schedules, which can be written on the same prescription. This will ensure pharmacists will fill such prescriptions without disruption.

2)Authorizes the superior court to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action and requires the law enforcement agency obtaining such an order to notify the Department of Justice (DOJ).

3)Specifies that DOJ, and not the Board of Pharmacy, will control the manner in which fingerprints are provided.

4)Allows DOJ to collect a fee for processing criminal background checks when a vendor applies to become an approved security printer of prescription forms. Each applicant shall pay, at the time of filing an application for a permit, a fee determined by DOJ that will not exceed the application processing costs of DOJ.

5)Specifies and defines the security printer applicant class that must submit criminal background checks as any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms.

6)Authorizes DOJ to examine the books and records of any applicant or visit and inspect a certified security printer.

7)Directs security prescription form printers to submit a sample of their secure prescription forms to DOJ.

8)Requires an approved security printer to print their security prescription forms with a vendor identification code issued by DOJ.

9)Requires a check box by the name of each prescriber on a security prescription form to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

10)Allows a prescriber designated by a license health care facility, licensed clinic or other clinic exempt from licensure to order controlled substance prescription forms for use by prescribers when treating patients in that facility. This would also allow the licensed clinic or clinic exempt from licensure to avoid specified printing requirements that appear on the security prescription form.

11)Requires a designated prescriber to meet the requirements adding licensed clinic or clinic exempt from licensure pursuant to Health and Safety Code 1206 preprinted on the form.

12)Clarifies, by striking out text and allowing for a simple pre-printed statement on the bottom of prescription blanks that "prescription is void if the number of drugs is not noted."

13)Requires a prescriber who directly dispenses controlled substances to submit the information to DOJ in a format set by DOJ pursuant to regulation.

EXISTING LAW :

1)Establishes CURES for the electronic monitoring by DOJ of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these substances. (Health and Safety Code Section 11165.)

2)Requires that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (Health and Safety Code Section 11161.)

3)Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy. The Board of Pharmacy may approve security printer applications after the applicant has

provided specific information and fingerprints, in a manner specified by the Board. The required information is used for the purpose of completing state and federal criminal background checks. (Health and Safety Code Section 11161.5.)

4)Provides that the Board of Pharmacy or DOJ may deny a security printer application for specific reasons, including where the applicant has been convicted of a crime. (Health and Safety Code Section 11161.5.)

5)Provides that prescription forms shall be printed with specific features. (Health and Safety Code Section 11162.1.)

6)Provides that with respect to specific controlled substances, each dispensing pharmacy or prescriber shall provide specific information to DOJ. [Health and Safety Code Section 11165(d).]

7)Provides that a violation of the provisions relating to the prescription of controlled substances is an alternate misdemeanor/felony. (Health and Safety Code Section 11153.)

8)States a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (Health and Safety Code Section 11159.2.)

FISCAL EFFECT : Unknown

COMMENTS :

1)Author's Statement : According to the author, "This bill makes technical and clean up changes to the law governing the CURES program in order to facilitate the effective operation of CURES and the program duties of DOJ's Bureau of Narcotics Enforcement."

2)Senate Health Committee : The Senate Health Committee analysis of this bill contains the following background information, "Under existing federal and state laws, controlled substances are ranked according to their potential for abuse, accepted medical use, and safety under medical supervision. Schedule I substances (e.g., heroin and LSD) have high potential for abuse, no currently accepted medical use, and lack accepted safety for use. Schedule II drugs (e.g., morphine, codeine, Demerol, and Percodan) have a high potential for abuse and high potential for physical or psychological dependence if used improperly, but have accepted medical value in treating pain.

"Schedule III drugs (e.g., Vicodin, anabolic steroids, codeine

with aspirin or Tylenol), Schedule IV drugs (e.g., Darvon, Valium, Halcyon, and Xanax), and Schedule V drugs (over-the-counter cough medicines with codeine) generally have less potential for abuse than Schedule I or II drugs, have accepted medical use in treatment, and lower potential for physical or psychological dependence.

"The Bureau of Narcotic Enforcement within DOJ currently administers and enforces the multiple-copy prescription surveillance program and is responsible for all state-controlled substance enforcement activities.

"The CURES program was established in 1997 by AB 3042 (Takasugi) in response to recommendations of the Controlled Substance Prescription Advisory Council established by SCR 74 in 1992. The purpose of CURES was to provide for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances. CURES provides for the electronic transmission of Schedule II prescription data to DOJ at the time prescriptions are dispensed.

"CURES was established as a three-year pilot project, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies of the two systems. Subsequent legislation extended the sunset on the program to July 1, 2008. A report to the Legislature by DOJ and the Board of Pharmacy in 1999 recommended that CURES be made a permanent program.

"According to the sponsor, the Attorney General, this bill addresses needed technical and administrative changes to existing state law. DOJ sponsors these changes to assist in the permanent operation of CURES within the CURES program. The changes remove inconsistencies within SB 151 and provide that DOJ policy and practice will conform with the 'best practices' model to prevent diversion of controlled substances.

"SB151 brought forth significant changes to the CURES program. One of the major changes was the elimination of the 65-year-old triplicate prescription form. The form was replaced with a new secure, tamper-resistant prescription form for Schedules II through IV controlled substances. In addition, CURES was also authorized to collect Schedule III prescription information.

"This bill attempts to amend several sections of the Health and Safety Code as it relates to controlled substances, the facilitation of the ongoing operation of CURES, and continued efforts by law enforcement in preventing the diversion and abuse of prescription drugs."

3)Arguments in Support : According to the Office of the Attorney General, "This bill makes technical changes to facilitate the operation of CURES and to clarify the program duties of the Bureau of Narcotics Enforcement and Board of Pharmacy. . . . This bill would make several changes to conform with the 'best practices' model to prevent diversion of controlled substances. . . . In addition, this bill makes other technical changes to allow for consistency with existing DOJ policy and practice. . . . Finally, this bill will allow for prescriptions from all schedules of drugs to be included on the same prescription form, and will require direct dispensers of controlled substances to submit information to the DOJ in a format to be developed by the DOJ."

4)Arguments Regarding Still Existing Problems With CURES : According to the California Medical Association, "Amendments must be adopted that will allow residents, interns, and fellows who do not have the ability to provide all information required on the security prescription pads to continue to prescribe as allowed by law and their respective training programs. . . . Further, amendments must be adopted to address the filling of faxed prescriptions."

REGISTERED SUPPORT / OPPOSITION :

Support

Office of the Attorney General (Sponsor)
California Medical Association (Support if amended)

Opposition

California State Board of Pharmacy (Oppose unless amended)

Analysis Prepared by : Heather Hopkins / PUB. S. / (916) 319-3744

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Attachment 5

AMENDED IN SENATE JUNE 15, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 21

Introduced by Assembly Member Levine
(Coauthors: Assembly Members Berg, Chavez, Cohn, De La Torre, Evans, Goldberg, Jones, Koretz, Laird, Lieber, Montanez, Nava, and Ruskin)

December 6, 2004

An act to add ~~Section 4069~~ *Sections 4069 and 4316* to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 21, as amended, Levine. Pharmacists: ~~dispensing~~ *practice* requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of that law a crime *and subject to the assessment of a fine by the board*. Under existing law, a prescription may be lawfully dispensed only by a pharmacist, unless otherwise specified by the Pharmacy Law.

This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of ~~its~~ *those* provisions unprofessional conduct *and would also make harassment, as specified,*

of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board.

Because the bill would specify ~~an~~ additional ~~requirement~~ *violations* under the Pharmacy Law, ~~a violation of~~ which would be *punishable as* a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 *SECTION 1. This act shall be known and may be cited as the*
2 *Women's Contraceptive and Pharmaceutical Freedom Act of*
3 *2005.*
4 ~~SECTION 1.—~~
5 *SEC. 2.* Section 4069 is added to the Business and
6 Professions Code, to read:
7 4069. (a) Notwithstanding any other provision of law, a
8 pharmacist shall dispense a lawful prescription unless one of the
9 following circumstances exists:
10 (1) The pharmacist determines, based on his or her
11 professional training and judgment, that dispensing the
12 prescription is contrary to law or, after consulting with the
13 patient's prescriber, that it is contraindicated for the patient.
14 (2) The pharmacy does not have the prescribed trade or brand
15 name drug in stock. The pharmacist shall offer the patient
16 another drug product, if available, with the same active chemical
17 ingredients of the same strength, quantity, and dosage form and
18 of the same generic drug name, as determined by the United
19 States Adopted Names and accepted by the federal Food and
20 Drug Administration, as the prescribed drug product and follow
21 the procedure or protocol described in Section 4073.
22 (3) (A) The pharmacist elects to refuse on ethical, moral, or
23 religious grounds to dispense a drug pursuant to a lawful request.
24 A pharmacist may decline to dispense a drug on these grounds

only after notifying his or her employer in writing of his or her objections. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B) An employer shall, upon receipt of the notification described in subparagraph (A), establish a policy and protocol to accommodate the patient's ~~needs~~ *need* for the drug.

(b) An employer shall not withdraw an offer of employment or terminate employment based on the notification or change in the notification, as described in subparagraph (A) of paragraph (3) of subdivision (a).

(c) A violation of this section by a pharmacist constitutes unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board.

SEC. 3. Section 4316 is added to the Business and Professions Code, to read:

4316. It shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.

~~SEC. 2.—~~

SEC. 4. 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.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 21 **VERSION: AMENDED JUNE 15, 2005**

AUTHOR: LEVINE **SPONSOR: LEVINE**

RECOMMENDED POSITION:

SUBJECT: PHARMACISTS: PRACTICE REQUIREMENTS

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052(8))

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

4) Requires the board to take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. (B&P 4301)

This Bill:

1) Establishes the Women's Contraceptive and Pharmaceutical Freedom Act of 2005. (B&P 4069 Added)

2) States that it shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. (B&P 4316 Added)

3) Requires a violation of this section by a pharmacist to constitute unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board. (B&P 4069 Added)

4) Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:

a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

b. The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active

chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request.

   i. A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing of his or her objections.

   ii. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B&P 4069 Added)

5) Requires an employer, upon receipt of a pharmacist objections, to establish a policy and protocol to accommodate the patient's need for the drug. (B&P 4069 Added)

6) Does not permit an employer to withdraw an offer of employment or terminate employment based on the notification or change in the notification. (B&P 4069 Added)

Comment:

1) Author's Intent. The author's intent is to insure that pharmacists do not refuse to dispense EC to patients.

2) In the News. The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

3) Enforcement. Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. The June 15th amendments regarding unprofessional conduct and emotional distress may be difficult to enforce. If AB 21 is enacted the board anticipates that it will need to train its inspectors on the nuances of the law governing emotional distress.

4) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

5) Related Legislation. SB 644 (Ortiz 2005) Dispensing Prescription Drugs And Devices, would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. SB 644 is awaiting hearing in the Assembly Health Committee.

6) Federal Legislation. In April 2005, Senator Boxer introduced S 778, the Pharmacy Consumer Protection Act of 2005. S778 would require a pharmacist to fill a legal prescription unless the prescribed item is not in the pharmacy's stock, in which case the pharmacy would order such item without unnecessary delay or, if the patient prefers, the pharmacy would transfer the prescription to a local pharmacy of the patient's choice or return the prescription to the patient, at the patient's request. S 778 would not prohibit a pharmacist from refusing to

dispense a prescribed item, in accordance with standard pharmacy practice, if there is a valid medical concern that such prescribed item will cause problems due to therapeutic duplications, drug-disease contraindications, drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, or drug abuse or misuse. S 778 has been referred to the Senate Finance Committee.

7) Support & Opposition.

Support: American Academy of Pediatrics, California District
California Medical Association
NARAL Pro-Choice California (if amended)
National Association of Social Workers, California Chapter
Planned Parenthood Affiliates of California (in concept)

Oppose: California Association for Health Services at Home (unless amended)
California Family Alliance
California Pharmacists Association (unless amended)
California Retailers Association (unless amended)
California Right to Life Committee, Inc.
California Society of Health-System Pharmacists
Traditional Values Coalition

8) History.

2005

June 22 In committee: Set first hearing. Failed passage. Reconsideration granted.
June 15 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15 Referred to Coms. on HEALTH and B., P. & E.D.
June 6 In Senate. Read first time. To Com. on RLS. for assignment.
June 2 Read third time, passed, and to Senate. (Ayes 52. Noes 25. Page 2096.)
May 9 Read second time. To third reading.
May 5 From committee: Do pass. (Ayes 12. Noes 5.) (May 4).
Apr. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 2.) (April 26).
Apr. 14 Re-referred to Com. on B. & P.
Apr. 13 Read second time and amended.
Apr. 12 From committee: Amend, do pass as amended, and re-refer to Com. onB. & P. (Ayes 10. Noes 3.) (April 5).
Mar. 30 Re-referred to Com. on HEALTH.
Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004

Dec. 7 From printer. May be heard in committee January 6.
Dec. 6 Read first time. To print.

AB 21

AS AMENDED: June 15, 2005

SENATE HEALTH

COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Business, Professions and Economic Development / 1
Appropriations

CONSULTANT:
Vazquez / ak

SUBJECT

Pharmacists: dispensing requirements

SUMMARY

This bill requires pharmacists to dispense a lawful prescription unless certain specified circumstances exist, including allowing a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug if the pharmacist satisfies certain conditions. The bill deems a violation of these provisions unprofessional conduct and harassment, as specified.

ABSTRACT

Existing law:

1. Provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy (Board) and provides that it shall be unprofessional conduct for a pharmacist to violate any provisions of law governing pharmacy.

2. Provides that it is unlawful, unless otherwise provided under law, for any person other than a pharmacist to dispense a prescription.

3. Defines "dispense" as the furnishing of drugs or devices by a pharmacist upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant, or pharmacist acting within the scope of his or her practice.

4.Defines "dispense" also as the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse
midwife, nurse practitioner, or physician assistant acting within the scope of his or her practice.

5.Defines "prescription" as an oral, written, or electronic transmission that includes specified information including the name of the patient, the name and quantity of the drug or device prescribed, the condition for which being prescribed if requested, and if in writing, the signature of the prescriber issuing the order; and provides also that a prescriber's drug order that meets specified requirements may be treated as a prescription by the dispensing pharmacist.

6.Provides for the furnishing of emergency contraception (EC) drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber, or developed and approved by the Board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities.

7.Provides under general provisions of the Business and Professions Code that it shall be unprofessional conduct for a health care provider to engage in repeated acts of excessive prescribing or administering of drugs or treatment, the commission of any act of sexual abuse, misconduct, or relations with a patient, or to engage in other unprofessional conduct as specified.

This bill:

1.States that this law shall be known and may be cited as the Women's Contraceptive and Pharmaceutical Freedom Act of 2005.

2.Requires a pharmacist to dispense a lawful prescription unless one of the following circumstances exists and that violation of this section by a pharmacist constitutes unprofessional conduct subject to disciplinary action by the Board:

a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient;

b. The pharmacy does not have the prescribed trade or brand name drug in stock, in which case requires the pharmacist to offer the patient another drug product, if available, with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as specified; or

c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to an order or prescription. Permits a pharmacist to decline to dispense a drug on these grounds only after notifying his or her employer in writing, upon acceptance of employment and immediately after any change to that decision, of the drug to which he or she objects.

3.States that it shall constitute unprofessional conduct for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress, and that for these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.

FISCAL IMPACT

According to the Assembly Appropriations Committee, there are minor absorbable special fund costs (Pharmacy Board Contingent Fund) to the Board of Pharmacy. The Board of Pharmacy is funded by licensing fees paid by pharmacists and deposited in the Pharmacy Board Contingent Fund.

BACKGROUND AND DISCUSSION

Purpose of the bill
According to the author, current law is silent to the question of whether a pharmacist can refuse to fill a prescription for non-medical reasons. The author states that there have been a growing number of cases around the country where pharmacists have refused to dispense drugs because of personal objections. The most common cases are with hormonal contraception, but some women have been refused a drug needed for a dilatation and curettage following a miscarriage. There are incidents of pharmacist refusal around the country and most states that have looked at this issue have adopted laws to protect the pharmacist's ability to refuse. It is the author's intent that this bill provide the access to necessary medication that should be the priority of pharmacists and pharmacies in

California.

Reports of refusals to fill prescriptions
There have been numerous news stories throughout the United States describing incidents where pharmacists have refused to dispense oral contraceptives and other types of birth control based on moral grounds or religious beliefs. A March 28, 2005 Washington Post article reported that it is not known how often that refusals are occurring, but there have been cases in California, Washington, Georgia, Illinois, Louisiana, Massachusetts, Texas, New Hampshire, Ohio, and North Carolina. The article stated that Wisconsin is one of at least 11 states considering "conscience clause" laws that would protect pharmacists' right to decline to fill a prescription and that four states already have laws that permit pharmacists to refuse to fill prescriptions that violate their beliefs. At least four other states are considering laws that would explicitly require pharmacists to fill all prescriptions. Some large pharmacy chains, including Walgreens, Wal-Mart and CVS, have instituted policies to balance pharmacists' and customers' rights by ensuring another pharmacist is on duty to fill the prescription or contacting another pharmacy willing to fill the prescription in the case that a pharmacist objects to filling it.

Complaints to the Board of Pharmacy
Current law, through regulations, requires a pharmacist who declines to furnish emergency contraception (EC) based on a "conscience clause" to refer the patient to another EC provider. The law is silent on pharmacists' ability to object on religious, ethical, or moral grounds for any other drug. The Board has a system in place to receive and investigate complaints, but received none regarding refusals to fill EC prescriptions in 2004.

Related legislation
SB 644 (Ortiz) would require a pharmacist to dispense a lawful prescription except in specified circumstances, including on ethical, moral, or religious grounds and permits the pharmacist to decline to dispense the prescription on that basis only if his or her employer is able to reasonably accommodate that objection. SB 644 will be heard before the Assembly Committee on Business and Professions on June 21, 2005.

Prior legislation
SB 490 (Alpert, Chapter 651, Statutes of 2003), permits a licensed pharmacist to initiate EC drug therapy in accordance with a standardized procedure approved by the Board and the Medical Board of California. It also

requires a pharmacist, prior to furnishing EC, to complete a training program of at least one hour of approved continuing education on EC drug therapy.

Arguments in support
The California District of the American Academy of Pediatrics (AAP-CA) supports this bill and states that in small towns where there is only one pharmacy and pharmacist, or it is cumbersome for a woman to access alternate pharmacies, it is imperative that she be able to obtain her needed prescription or drug. AAP-CA states that a pharmacist has a right to his or her own personal belief with respect to his or her choice of personal medical treatments, however, he or she should not be able to impose those beliefs on others by restricting the availability of legal drugs. The National Association of Social Workers, California Chapter states that this measure recognizes the need to establish clear regulation and that it will ensure that clients have access to all medications they are prescribed. Planned Parenthood Affiliates of California supports the bill in concept and supports the right of every individual to have access to his or her legal prescription. NARAL Pro-Choice California additionally writes with a support if amended position and states that it is committed to working with the author on unresolved issues expressed, such as ensuring that a protocol set forth by the pharmacy allows for timely access to necessary medication for the patient and reasonable disciplinary action and enforcement.

Arguments in opposition
The California Association for Health Services at Home (CAHSAH) representing home health agencies and hospice providers, as well as providers of private personal care services in the home, opposes the bill and objects to the bill's lack of acknowledgement of the professional judgment of the pharmacist, and because of this absence, CAHSAH states that it will negatively impact and eliminate pharmacists' discretion when a physician is unavailable or when issues arise that impact the patients' medical condition. CAHSAH states that this could have serious adverse consequences for patients, as home health agencies provide care around the clock and operate under systems that rely on a pharmacist's professional judgment to comply with the patient care directive and plan of treatment. CAHSAH additionally raises a concern that the bill will require pharmacists to dispense medications even if they don't accept the coverage of the prescription or possibly even if the patient can't pay for it.

The California Society of Health-System Pharmacists (CSHP)

writes in opposition to subjecting a pharmacist to unprofessional conduct for acts of undefined "emotional distress" and "extreme or outrageous conduct" that places the pharmacist in an overly broad vicariously liable situation. CSHP states that the California Board of Pharmacy already has the authority to take action against any pharmacist for the reasons suggested by AB 21. For example, unprofessional conduct includes, but is not limited to, gross immorality or any act involving moral turpitude, dishonesty, fraud, deceit or corruption, citing Business and Professions Section 4301. Furthermore, CSHP objects to the mandatory dispensing approach taken by AB 21 and states that it would prefer a more passive objection for the reasons enumerated in the bill.

The Capitol Resource Institute states that this bill would compel pharmacists to violate their moral and religious convictions and openly discriminates against the religious convictions and moral dictates of a pharmacist. The California Family Alliance opposes the bill on the basis of the referral provisions as pharmacists who cannot in good conscience dispense contraceptives or morning-after pills will find it just as objectionable to refer a patron to someone who does. The California Right to Life Committee, Inc. asserts that pharmacists are professionals and must continue their right to exercise their freedom of conscience during their hours of employment.

Oppose unless amended
The California Pharmacists Association (CPhA) and the California Retailers Association (CRA) write with "oppose unless amended" positions on AB 21 and state that the bill as currently drafted provides for sweeping reform of pharmacy practice and will remove the professional judgment of a pharmacist from patient care, which the organizations state currently provides a check and balance on medication errors, adverse drug reaction, and unnecessary prescriptions, and furthers optimal pharmaceutical care. The CPhA and CRA request the following amendments:

Clarification of the use of professional judgment by providers.

Removal of Section 4069 from the pharmacy practice act and insertion instead into the general provisions of the Business and Professions Code.

Inclusion of a provision of standards that ensure access to prescription products without imposing unrealistic burdens on providers.

Establishment of a respectful right of conscience clause for providers that also ensures that patients receive access to medications.

Clarification of coverage and payment issues that create unintended consequences.

Imposition of a penalty of unprofessional conduct for violation of its provisions.

Author's amendments
The author has offered the following two amendments to address some of the concerns raised by the opposition:

1. The intent of the following amendment is to address the concern raised around a pharmacist's ability to access a prescriber who may not be directly available:

   On page 2, line 13, after "prescriber" insert "or any other treating or supervising physician who is authorized by the patient's prescriber to treat the patient"

2. The intent of the following amendment is to address concerns raised around a "mandate to dispense" and how this might affect payment arrangements and requirements:

   On page 3, line 15, insert a new subdivision (d) to read: "This section imposes no duty on a pharmacist to dispense a lawful prescription without payment for the prescription, including payment directly by the patient or through a third party payer accepted by the licentiate or payment or any required copayment by the payment."

Additional questions for the Committee

1. Accuracy of title. The title on page 2, lines 1-2 currently calls this law the "Women's Contraceptive and Pharmaceutical Freedom Act of 2005." Given that the bill affects all drugs and not only contraception, should the title be revised to reflect this?

2. Duplication of generic substitution section. The bill currently provides for generic substitution if a drug is not in stock and restates the authority that exists in current law, Section 4073 of the Business and Professions Code. Does the author wish to consider removal of this duplicative language?

3. Pharmacists currently employed. The bill specifies that a pharmacist shall provide notification upon acceptance of employment and immediately after any change to that decision. It is implied that current pharmacist employees shall notify their employer if they decide that they will decline to dispense. Arguably, the bill needs clarification because it requires notification to be given upon acceptance of employment by new employees and it is unclear when current employees would need to provide this. What is the procedure for current employees and can this be reconciled to the requirement for the newly employed?

4. Employer requirement. The bill currently states that a violation by a pharmacist constitutes unprofessional conduct, but does not provide for consequences for an employer who does not accommodate a pharmacist's objections and a patient's need for the drug. Can a standard for employer accommodation be included in the bill to enable enforcement for this section of the bill?

5. Meaning and enforcement of harassment provisions. The bill states that it shall constitute unprofessional conduct for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress, and that for these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. What are the definitions of various terms used in this section, including "extreme or outrageous conduct" and "reckless indifference"? Is this enforceable and is the current complaint system adequate to ensure that this anti-harassment policy is meaningful?

6. Technical amendment . On page 2, line 24, the author may wish to consider adding after the word "drug" the language "or class of drugs" to allow for the notification and conscience clause to apply to more than individual drugs to facilitate the effectiveness of the bill.

PRIOR ACTIONS

Assembly Floor:	52 - 25	Pass
Assembly Appropriations:	12 - 5	Do Pass
Assembly B & P:	7 - 2	Do Pass

Assembly Health: 10 - 3 Do Pass as Amended

POSITIONS

Support: American Academy of Pediatrics, California District
California Medical Association
NARAL Pro-Choice California (if amended)
National Association of Social Workers,
California Chapter
Planned Parenthood Affiliates of California (in concept)

Oppose:California Association for Health Services at Home (unless amended)
California Family Alliance
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California Society of Health-System Pharmacists
Capitol Resource Institute
Traditional Values Coalition