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

LEGISLATION AND REGULATION COMMITTEE REPORT

Legislation Report

The Legislature reconvened on January 4, 2006 for the 2006 Legislative Session. As of January 20, 2006 only two bills have been introduced that are of interest to the board, AJR 40 (Chan) Medicare Prescription Drugs, and AB 132 (Chapter 2, Statures of 2006) Medicare Part D. The Legislation and Regulation Committee (committee) will review these bills at its January 26, 2006 meeting and any committee recommendations will be provided to you at the board meeting. Copies of these bills are attached.

Currently, there are fourteen carryover bills from the 2005 Legislative Session; eight bills have board positions and six bills are on the board's watch list.

The Legislature has until January 31st to pass AB 72, AB 657, SB 19, and SB 152 out of their house of origin, otherwise these bills are considered dead for the remainder of the session. These bills are flagged with a double asterisk.

Also attached is a copy of the Legislative calendar for 2006.

2006 Introduced Bills

AJR 40 (Chan) Medicare Prescription Drugs **FOR ACTION**
Board Position:
Status: **Introduced on January 19, 2006**
Summary: Legislation has been introduced in the Congress, H.R. 3861, "The Medicare Informed Choice Act of 2005", that extends the deadline for enrollment in Medicare Part D until December 31, 2006, permits Medicare beneficiaries to change plans once in 2006 if they have made a poor selection, and protects those with retiree health benefits who may not be aware that purchasing Medicare drug coverage could cost them their retiree benefits. This bill would resolve the California State Assembly and the Senate that the Legislature of the State of California memorializes the Congress and the President of the United States to enact H.R. 3861 to protect our nation's disabled and senior citizens who are Medicare beneficiaries.

AB 132 (Chapter 2, Statutes of 2006) Medi-Cal: Rx Drug Benefit NO ACTION

Summary: This bill requires the Department of Health Services, beginning on January 12, 2006, and concluding 15 calendar days later, to provide drug benefits, when any of specified conditions exists, to a Medicare-eligible person who is also eligible for Medi-Cal prescription drug benefits and who is not able to obtain drug benefits from his or her prescription drug plan under the Medicare program. The bill allows the Governor to extend coverage for these drug benefits from the close of the initial 15-day period for up to an additional 15-calendar-day period. The bill appropriates $150,000,000 from the General Fund for the purposes of the bill. This bill declares that it is to take effect immediately as an urgency statute.

Board Approved Provisions for 2006 Omnibus Bill **NO ACTION**

At the Board's meeting in October 2005, the board approved a proposed statutory change to B&P section 4127.1 to allow the issuance of a temporary pharmacy permit for a change in ownership to pharmacies that compound injectable sterile drug products. A copy of the approved language is attached.

This proposed statutory change will be submit, along with any board approved provisions from section E(2)(g) on today's agenda, to the Senate Business, Professions and Economic Development Committee for inclusion into the Committees 2006 Omnibus bill.

2005 Introduced Bills

Pending Implementation **NO ACTION**

SCR 49 (Chapter 123, 2005)
The measure requires the Legislature to 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 requires the panel to convene by October 1, 2005 and to submit a preliminary report by March 1, 2006 to the Senate Committee on Health and a final report by June 1, 2006.

To date, the Medications Errors Panel has not been formed. The Senate Rules Committee is in the process of accepting applications for the panel and Senate Rules staff anticipates the panel forming by the end of January 2006. Given the late start the panel it is unlikely to meet the deadlines for the reports called for in the legislation and will likely establish new due dates once the panel meets.

Board member Powers has been nominated by Senator Speier as a public member of the committee.

Status of Bills with a Board Position **FOR ACTION**

Copies of these bills along with a full board analysis are attached.

AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs Board-Sponsored Bill
Board Position: **Support**
Status: **Senate floor, inactive file**

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.

Note: In August, Department of Health Services (DHS) took an oppose position on the May 26, 2005 version of the bill. The board is working to resolve the opposition.

AB 21 (Levine) Pharmacists: Practice Requirements
Board Position: **Oppose**
Status: **Senate Health Committee**

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)

Note: SB 644 (Chapter417, Statutes of 2005) was a related bill that stalled AB 21 in the Senate.

AB 225 (Negrete McLeod) Electronic Prescription Information
Board Position: **Support if Amended**
Status: **Senate Business, Professions And Economic Development Committee**

Summary: This bill would modify B&P section 650 to allow 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.

****AB 657 (Karnette) Pharmacies: Prescription Containers: Labels**
Board Position: **Support**
Status: **Senate Business, Professions And Economic Development Committee**

Summary: This bill would revise the prescription labeling requirements 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.

AB 896 (Matthews) Clinical Laboratories
Board Position: **Support**
Status: **Assembly Business and Professions Committee**
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.

****SB 152 (Speier) Pseudoephedrine**
Board Position: **Oppose**
Status: Senate Business, Professions And Economic Development Committee
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. Senate Bill 152 would place these provisions in B&P 4051.1.

SB 401 (Ortiz) Medical information: Pharmacies: Marketing
Board Position: **Oppose Unless Amended**
Status: **Assembly Health Committee**
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.
Amendments: 1) Provide a means for consumers to opt out of receiving advertisements with their prescriptions. 2) Require advertisements to be marked with the entity paying for the advertisement.

SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services
Board Position: **Support**
Status: Assembly **Health Committee**
Summary: This bill would permit 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.

Status of 2005 Bills of Interest

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of CA Drug Safety
Status: **Senate Health Committee**

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.

****AB 72 (Frommer) Prescription Drugs: Clinical Trials**
Status: **Senate Health Committee**

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.

AB 74 (Gordon) California Rx Prescription Drug Hotline
Status: **Senate Health Committee**

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
Status: **Senate Health Committee**

Summary: This bill would establish a prescription drug discount program for low-income state residents.
Note: AB 75 is similar to Proposition 79, which was rejected by voters in November 2006.

****SB 19 (Ortiz) California Rx Program**
Status: **Senate Rules**

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.
Note: SB 19 is similar to Proposition 78, which was rejected by voters in November 2006.

SB 380 (Alquist) Drugs: Adverse Event Reporting
Status: **Assembly Floor – inactive file**

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.

**These bills must be passed out of their house of origin by January 31, 2006, otherwise the bills are consider dead for the 2006 session.

2006 Introduced Bills

Assembly Joint Resolution No. 40

Introduced by Assembly Members Chan and Berg

January 19, 2006

Assembly Joint Resolution No. 40—Relative to Medicare prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AJR 40, as introduced, Chan. Medicare prescription drugs.

This measure would memorialize the United States Congress and President to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005."

Fiscal committee: no.

1 WHEREAS, The United States Congress enacted the Medicare
2 Prescription Drug, Improvement, and Modernization Act (MMA)
3 in 2003; and
4 WHEREAS, The MMA promised a voluntary prescription
5 drug benefit, known as Medicare Part D, to all Medicare
6 beneficiaries; and
7 WHEREAS, At the insistence of Congress and the President of
8 the United States, Part D is administered by multiple private
9 insurance companies offering dozens of different plans in every
10 state; and
11 WHEREAS, In California alone, Medicare beneficiaries who
12 wish to enroll in Part D must choose from 47 different
13 stand-alone Medicare prescription drug plans and many more
14 Medicare Advantage plans; and

WHEREAS, On October 15, 2005, Medicare prescription drug plan sponsors began aggressively marketing their plans to seniors and persons with disabilities; and

WHEREAS, On November 15, 2005, Medicare beneficiaries throughout the country began enrolling in the new Medicare Part D prescription drug plans; and

WHEREAS, As of December 2005, only 1 million of the approximately 21 million Medicare beneficiaries throughout the country who are eligible for voluntary enrollment in Part D had enrolled; and

WHEREAS, In addition only a small percentage of the millions of low-income beneficiaries eligible for federal subsidies have enrolled in Part D; and

WHEREAS, Federal law currently requires the initial open enrollment period to end on May 15, 2006, after, which Medicare beneficiaries will be subject to substantial permanent financial penalties for "late enrollment"; and

WHEREAS, The structure of Part D and the need to choose from among dozens of plans are causing confusion and consternation among seniors; and

WHEREAS, There have not been enough independent counselors available to help guide seniors through the myriad options; and

WHEREAS, Seniors who currently have retiree health care coverage, including prescription drug coverage, are at risk of losing both their existing health and drug coverage if they inadvertently enroll in Medicare Part D; and

WHEREAS, The federal government should not penalize seniors for being confused, but should work to provide Medicare beneficiaries the time and opportunity to make the best choice about their prescription drug coverage; and

WHEREAS, Legislation has been introduced in the Congress, H.R. No. 3861, "The Medicare Informed Choice Act of 2005", that extends the deadline for enrollment in Medicare Part D until December 31, 2006, permits Medicare beneficiaries to change plans once in 2006 if they have made a poor selection, and protects those with retiree health benefits who may not be aware that purchasing Medicare drug coverage could cost them their retiree benefits; now, therefore, be it

1 *Resolved by the Assembly and the Senate of the State of*
2 *California, jointly,* That the Legislature of the State of California
3 memorializes the Congress and the President of the United States
4 to enact H.R. No. 3861, "The Medicare Informed Choice Act of
5 2005" to protect our nation's disabled and senior citizens who are
6 Medicare beneficiaries; and be it further
7 *Resolved,* That the Chief Clerk of the Assembly transmit
8 copies of this resolution to the President of the United States and
9 to all Member of the Congress of the United States.

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AMENDED IN SENATE JANUARY 17, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 132

Introduced by ~~Committee on Budget (Laird (Chair), Arambula, Bermudez, Chan, Coto, De La Torre, Dymally, Evans, Goldberg, Hancock, Montanez, Mullin, Nava, Parra, Pavley, and Wolk)~~*Assembly Member Nunez*

(Principal coauthor: Assembly Member McCarthy)

(Principal coauthors: Senators Ackerman and Perata)

(Coauthor: Assembly Member Chan)

(Coauthor: Senator Ortiz)

January 13, 2005

~~An act relating to the Budget Act of 2005.~~ *An act to amend Section 14133.23 of the Welfare and Institutions Code, relating to Medi-Cal, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

AB 132, as amended, ~~Committee on Budget~~ *Nunez.* ~~Budget Act of 2005.~~ *Medi-Cal: prescription drug benefit.*

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits, including, for certain beneficiaries, prescription drug benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid provisions.

Existing law provides for the federal Medicare program, which provides health care benefits, including prescription drug benefits, to persons 65 years of age and older and other specified persons. Under the Medicare program, prescription drug benefits are obtained

through enrollment in a prescription drug plan offered under the program. Existing law requires Medicare-eligible persons who are also eligible for Medi-Cal prescription drug benefits to obtain those benefits through a prescription drug plan under the Medicare program, except as specified.

This bill would require the department, beginning on January 12, 2006, and concluding 15 calendar days later, to provide drug benefits, when any of specified conditions exists, to a Medicare-eligible person who is also eligible for Medi-Cal prescription drug benefits and who is not able to obtain drug benefits from his or her prescription drug plan under the Medicare program. The bill would allow the Governor to extend coverage for these drug benefits from the close of the initial 15-day period for up to an additional 15-calendar-day period.

The bill would appropriate $150,000,000 from the General Fund for the purposes of the bill.

This bill would declare that it is to take effect immediately as an urgency statute.

~~This bill would express the intent of the Legislature to enact statutory changes relating to the Budget Act of 2005.~~

Vote: ~~majority~~ *2/3*. Appropriation: ~~no~~ *yes*. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

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

1 *SECTION 1. Section 14133.23 of the Welfare and Institutions*
2 *Code is amended to read:*
3 14133.23. (a) To the extent that federal financial
4 participation is not available, the provision of drug benefits under
5 this chapter to full-benefit dual eligible beneficiaries who are
6 eligible for drug benefits under Part D of Title XVIII of the
7 Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or under
8 a Medicare Advantage-Prescription Drug plan (MA-PD plan)
9 under Part C of Title XVIII of the Social Security Act (42 U.S.C.
10 Sec. 1395w-21 et seq.), is eliminated, except as otherwise
11 provided under this section.
12 (b) (1) Notwithstanding any other provision of law, only drug
13 benefits for which federal financial participation is available shall
14 be provided under this chapter to a full-benefit dual eligible
15 beneficiary, except as otherwise provided under subdivision (c).

(2) As a benefit under this chapter, the department, subject to the approval of the Department of Finance and only to the extent that federal financial participation is available, may elect to provide a drug or drugs in a class of drugs not covered under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or under a MA-PD plan under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.) to full-benefit dual eligible beneficiaries.

(3) As a benefit under this chapter, and only to the extent that federal financial participation is available, the department shall provide a drug or drugs to full-benefit dual eligible beneficiaries who are otherwise eligible to receive the drug or drugs due to their entitlement under Title 42 United States Code, Chapter 7, Title XVIII, Part A or their enrollment under Title 42 United States Code, Chapter 7, Title XVIII, Part B.

(4) Except as provided under paragraph (3) and subdivision (c), nothing in this section shall be interpreted to require the department to provide any drug or drugs not covered under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or under a MA-PD plan under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.) if federal financial participation is not available.

(c) (1) The department shall review the drug formularies of prescription drug plans under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or MA-PD plans under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.) available to full-benefit dual eligible beneficiaries.

(2) The department shall develop a process that would allow the department to provide to a full-benefit dual eligible beneficiary, on an emergency basis only, coverage for a drug or drugs not included on the full-benefit dual eligible beneficiary's prescription drug plan's formulary or by prior authorization under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or MA-PD plans under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.) for which federal financial participation is not available.

(3) Only to the extent that the Legislature made a specific appropriation to fund the provision of emergency drug benefits for which federal financial participation is not available to

full-benefit dual eligible beneficiaries, the department shall provide, through the process described in paragraph (2), these emergency drug benefits to a full-benefit dual eligible beneficiary only when all of the following conditions are met:

(A) The drug is not available to the full-benefit dual eligible beneficiary under his or her plan's drug formulary or by prior authorization.

(B) The pharmacist provides or dispenses the drug as an emergency service.

(C) The quantity of the drug provided or dispensed in no greater than a 60-day supply.

(D) The pharmacist has not previously provided or dispensed nor has knowledge that another pharmacist has provided or dispensed the same drug for that full-benefit dual eligible beneficiary on or after January 1, 2006.

(E) The date of service is from January 1, 2006 through December 31, 2006, inclusive.

(4) The department may impose a pre- or post- service prepayment or postpayment review or audit, to review the medical necessity of emergency services provided to full-benefit dual eligible beneficiaries.

(d) The department shall seek approval of any amendments to the state plan necessary to implement this section as required by Title XIX of the Social Security Act (42 U.S.C. Sec. 1396 et seq.).

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret or make specific this section by means of all county letters, provider bulletins, or similar instructions. Thereafter, the department may adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(f) *(1) Notwithstanding any other provision of this section, and only to the extent that funds are appropriated for this purpose, the department shall provide on a time-limited basis, as described in paragraph (7), drug benefits to a full-benefit dual eligible beneficiary who is not able to obtain drug benefits from his or her Medicare Drug Plan only when one or more of the following conditions are met:*

(A) The pharmacy has submitted a claim for the provision of drug benefits to the full-benefit dual eligible beneficiary's Medicare Drug Plan and the claim has been denied payment for reasons other than processing errors or omissions made by the pharmacy, lack of medical necessity, or health or safety reasons.

(B) The pharmacy is unable to submit a claim for the provision of drug benefits solely due to the unavailability of complete or accurate Medicare Drug Plan enrollment information from the full-benefit dual eligible beneficiary's Medicare Drug Plan, the federal Centers for Medicare and Medicaid Services, or entities under contract with the Centers for Medicare and Medicaid Services to provide enrollment information.

(C) The Medicare Drug Plan provides information that the full-benefit dual eligible beneficiary's deductible or copayment amount is higher than the copayment amounts that are established by Medicare for full-benefit dual eligible beneficiaries.

(2) The director may impose a pre- or post-service prepayment or postpayment review or audit to determine whether a pharmacy has accurately and in good faith established the existence of any condition certified by the pharmacy pursuant to subparagraph (A), (B), or (C) of paragraph (1) in support of a submitted claim to the department.

(3) If the claim submitted by the pharmacy to the Medicare Drug Plan meets the circumstances described in subparagraph (C) of paragraph (1), the department shall pay the Medi-Cal rate less the Medicare Drug Plan reimbursement amount and the Medicare copayment amount.

(4) To obtain reimbursement from the department, a pharmacy must be an enrolled provider in the Medi-Cal program and certify on its claims under penalty of perjury that one of the conditions specified in paragraph (1) exists.

(5) The department shall seek reimbursement from the federal government of all funds spent to comply with the provisions of this subdivision.

(6) To the extent that the department reimburses a pharmacy for claims authorized under this subdivision, the director shall have the right to recover or recoup the full cost expended by the

state for that reimbursement from the full-benefit dual eligible beneficiary's Medicare Drug Plan.

(7) Reimbursement for claims authorized under this subdivision shall be limited to those drug benefits provided to a full-benefit dual eligible beneficiary beginning on January 12, 2006, and concluding 15 calendar days later. The Governor may, upon notice to the Joint Legislative Budget Committee, extend coverage for drug benefits provided to a full-benefit dual eligible beneficiary from the close of the initial 15-day period for up to an additional 15-calendar-day period.

(8) Any drug benefits made available to full-benefit dual eligible beneficiaries under the authority of this subdivision shall be limited to the funds appropriated by the Legislature to the department for this purpose. These drug benefits shall not be deemed to be an entitlement.

(g) (1) For the purposes of this section, a "full-benefit dual eligible beneficiary" means an individual who meets both of the following criteria:

~~(1)~~

(A) The beneficiary is eligible or would be eligible for coverage for the month for covered Part D drugs under a prescription drug plan under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or under a MA-PD plan under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.).

~~(2)~~

(B) Notwithstanding any other provision of this section, the beneficiary is determined eligible for full scope services, including drug benefits, for which federal financial participation is available.

~~(g)~~

(2) For the purposes of this section, "Medicare Drug Plan" means a prescription drug plan under Part D of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-101 et seq.) or under a MA-PD plan under Part C of Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395w-21 et seq.)

(h) Subdivisions (a) and (b) and paragraph (3) of subdivision (c) shall become operative on January 1, 2006.

SEC. 2. There is hereby appropriated from the General Fund the following sums:

(a) The sum of one hundred twenty-seven million five hundred thousand dollars ($127,500,000) to the State Department of Health Services to implement subdivision (f) of Section 14133.23 of the Welfare and Institutions Code, as contained in Section 1 of this act. On June 30, 2007, the remaining balance of the appropriation made under this subdivision shall be reverted back to the General Fund.

(b) The sum of twenty-two million five hundred thousand dollars ($22,500,000) for expenditure for the 2005–06 fiscal year in augmentation of, and for the purposes provided in, Item 9840-001-0001 of Section 2.00 of the Budget Act of 2005 (Chapter 38, Statutes of 2005).

SEC. 3. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that Medi-Cal beneficiaries receive prescription drug benefits without delay or extra cost, it is necessary that this act take effect immediately.

~~SECTION 1. It is the intent of the Legislature to enact statutory changes relating to the Budget Act of 2005.~~

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Board Approved Provisions for 2006 Omnibus Bill

Article 7.5 – Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.
(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.
(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.
(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.
(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:
(1) The sterile powder was obtained from a manufacturer.
(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.
(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.
(g) The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be established by the board at an amount not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

2005 Introduced Bills

Senate Concurrent Resolution No. 49

RESOLUTION CHAPTER 123

Senate Concurrent Resolution No. 49—Relative to medication errors.

[Filed with Secretary of State September 14, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, Speier. Medication errors panel.

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 Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

WHEREAS, Numerous studies establish that medication errors cause injury and death to patients and consumers; and

WHEREAS, The Institute of Medicine estimates the cost for treatment of drug-related morbidity and mortality may run nearly $77 billion a year nationally; and

WHEREAS, Research demonstrates that most injuries resulting from medication errors are not the fault of any individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug Administration has approved 122 chemical compounds since 2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans;

patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmacy, a representative of the California Pharmacists Association, a representative of the California Association of Health Plans, a representative of the Pharmaceutical Research and Manufacturers of America, a member of the California Medical Association, a member or representative of the Assembly Democratic Caucus, a member or representative of the Assembly Republican Caucus, and a consumer representative; and be it further

Resolved, That the Senate Committee on Rules shall designate the chair and appoint to the panel a representative of the California Retailers Association Chain Drug Committee, a member of the California Society of Hospital Pharmacists, a representative of the Generic Pharmaceutical Association, a representative of a public health organization, a member of the California Nurses Association, a representative of AARP, a representative of the Consumer Health Care Products Association, a member or representative of the Senate Democratic Caucus, and a member or representative of the Senate Republican Caucus; and be it further

Resolved, That the members of the panel shall not receive compensation, but shall be reimbursed from private sources for necessary travel expenses for the purpose of attending meetings of the panel, including any public meetings that the panel schedules, and the panel shall be funded by private sources; and be it further

Resolved, That the panel shall submit to the Senate Committee on Health and the Assembly Committee on Health a preliminary report of its conclusions and recommendations by March 1, 2006, and a final report of its conclusions and recommendations no later than June 1, 2006; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the author for appropriate distribution.

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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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SENATE RULES COMMITTEE
Office of Senate Floor Analyses
1020 N Street, Suite 524
(916) 445-6614 Fax: (916)
327-4478

AB 595

THIRD READING

Bill No: AB 595
Author: Negrete McLeod (D)
Amended: 5/26/05 in Senate
Vote: 21

SENATE. BUS., PROF. AND ECON. DEV COMMITTEE : 5-0, 6/20/05
AYES: Figueroa, Campbell, Florez, Murray, Simitian
NO VOTE RECORDED: Aanestad, Morrow

SENATE APPROPRIATIONS COMMITTEE : Senate Rule 28.8

ASSEMBLY FLOOR : 73-0, 5/05/05 (Passed on Consent) - See last page for vote

SUBJECT : Pharmacy: compounding of prescription drugs

SOURCE : California State Board of Pharmacy

DIGEST : This bill defines compounding of prescription drugs and establishes standards for pharmacies that compound drug products for the patients.

ANALYSIS :

Existing Law

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

CONTINUED

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.

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.

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.

Background

Drug Compounding . 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.

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.

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.

FISCAL EFFECT : Appropriation: No Fiscal Com.: Yes Local: Yes

SUPPORT : (Verified 7/11/05)

State Board of Pharmacy (source)

ASSEMBLY FLOOR :
AYES: Aghazarian, Arambula, Baca, Bass, Benoit, Berg, Bermudez, Blakeslee, Bogh, Calderon, Canciamilla, Chan, Chavez, Chu, Cogdill, Cohn, Coto, Daucher, De La Torre, DeVore, Dymally, Emmerson, Evans, Frommer, Garcia, Goldberg, Hancock, Harman, Haynes, Shirley Horton,

Houston, Huff, Jones, Karnette, Keene, Klehs, Koretz, La Malfa, La Suer, Laird, Leno, Lieber, Liu, Matthews, McCarthy, Montanez, Mountjoy, Mullin, Nakanishi, Nation, Nava, Negrete McLeod, Niello, Oropeza, Parra, Pavley, Plescia, Richman, Ridley-Thomas, Ruskin, Saldana, Salinas, Spitzer, Strickland, Torrico, Tran, Umberg, Vargas, Villines, Walters, Wyland, Yee, Nunez
NO VOTE RECORDED: Gordon, Jerome Horton, Leslie, Levine, Maze, Sharon Runner, Wolk

JJA:cm 7/11/05 Senate Floor Analyses

SUPPORT/OPPOSITION: SEE ABOVE

**** END ****

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: OPPOSE

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. Since enactment of SB 644 (Chapter417, Statutes of 2005), AB 21 has stalled in the Senate.

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) Emotional Distress. AB 21 adds an emotional distress provision to pharmacy law. Emotional distress provisions are not uncommon in professions law such as those governing Marriage and Family Therapists, Licensed Vocational Nurses, and Licensed Clinical Social Workers, where a licensee has the power to misuse their position and inflict emotional distress on a patient. The practice of pharmacy differs from other professions where a pharmacist interacts with a wide range of patients and customers. Some of these patients are on medications that may alter their perception of reality and others may be addicted to some medications and seeking to get more medications illegally. It is up to a pharmacist to use his or her best professional judgment under the law to either dispense or refuse to dispense a medication. Some patients may misinterpret a pharmacist's use of their judgment as causing emotional distress. In this situation, under the provision in AB 21 the patient can file can a claim with the board claiming a pharmacist has misused their position. The board believes that it currently has the powers it needs to take enforcement action against a pharmacist that misuses their position and the addition of an emotional distress provision to pharmacy law is unnecessary.

4) 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.

5) 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.

SB 644 (Chapter417, Statutes of 2005) Dispensing Prescription Drugs And Devices, requires 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.

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

9) 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.

AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 225

Introduced by Assembly Member Negrete McLeod

February 3, 2005

An act to amend Section 650 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 225, as amended, Negrete McLeod. Electronic prescription information.

Existing law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions.

This bill would, *upon the effective date of specified regulations adopted by the Secretary of the United States Department of Health and Human Services pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003,* exempt from these provisions ~~a licensed health care facility or licensed health care professional prescribing or dispensing medication~~ *specified entities* that ~~receives~~ *receive* nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, *under certain conditions.*

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

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

SECTION 1. Section 650 of the Business and Professions Code is amended to read:

650. *(a)* Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

~~The~~

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

~~Except~~

(c) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

~~Except~~

(d) (1) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful ~~for a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, as provided in Section 11164 of the Health and Safety Code. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.~~ *to provide 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 the following situations:*

(A) In the case of a hospital, by the hospital to members of its medical staff.

(B) In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice.

(C) In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

(2) The exceptions set forth in this subdivision are adopted to conform state law with the provisions of Section 1860D-4(e)(6) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) and are limited to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals (42 U.S.C. Sec. 1395w-101).

(3) The exceptions set forth in this subdivision shall not be operative until the regulations required to be adopted by the Secretary of the United States Department of Health and Human Services, pursuant to Section 1860D-4(e) of the Medicare

Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395W-104) are effective.

~~"Health~~

(e) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

~~A~~

(f) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, or by a fine not exceeding fifty thousand dollars ($50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars ($50,000).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 225 **VERSION: AMENDED APRIL 7, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: L.A. CARE HEALTH PLAN**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: ELECTRONIC PRESCRIPTION INFORMATION.

Existing Law:

1) The Federal Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("DIMA") establishing a "safe harbor" for certain health care providers and administrators to exchange "nonmonetary remuneration" under certain limitations to stimulate the use of e-prescribing.

2) State law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions (B&P 650)

This Bill:

1) 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 the following circumstances:

a. In the case of a hospital, by the hospital to members of its medical staff;

b. In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice; and,

c. In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

2) Limits the application of this bill to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals.

3) Makes this bill operative only when the regulations adopted by the Secretary of the U.S. Department of Health and Human Services become effective.

Comment:

1) Author's Intent. The author's intent is to conform state law to applicable federal provisions so the advances in e-prescribing can take place in California without violating existing state laws. The author believes AB 225 is an initial step towards expanded e-health, and improvements in the quality and efficiency of health care in California, in a fashion consistent with national policies and goals.

2) Consumer Gain? An argument can be made that getting hardware and software for e-prescriptions writing into the hands of prescribers will benefit consumers. Generally e-prescriptions have been thought of as a way to reduce prescription errors, but recent studies have shown that that while e-prescriptions have reduced errors, they are not error free. Consequently, increasing the number of health care professionals and pharmacies capable of writing and processing e-prescriptions should be in the consumers' interests.

AB 225 may have the unintended consequence of restricting consumer choice. Business and Professions Code section 4170 gives patients the option of obtaining a prescription for a pharmacy of their choice. If prescribers and pharmacies are given hardware and software to facilitate e-prescriptions, a health care professional that has the option of writing e-prescriptions may direct patients to specific pharmacies that have the ability to process these prescriptions with preprogrammed connections to specific pharmacies. These pharmacies may not be the ones a consumer would choose in the absence of the prescriber influence. Additionally, software compatibility (prescribers' and pharmacys') may restrict choice to specific pharmacies again limiting a patient's freedom of choice. Pharmacies that are equipped to process e-prescriptions are likely to see a financial gain if this measure is enacted.

Who stands to gain the most if AB 225 is enacted? Prescribers, consumers, or pharmacies?

3) Federal Legislation. U.S. Senators Frist and Clinton have introduced the "Health Technology to Enhance Quality Act of 2005." The Act would implement health information technology standards that would guide the design and operation of interoperable health information systems. The legislation would codify the Office of National Coordinator for Information Technology and establishs standards for the electronic exchange of health information. The measure would also establish a narrow statutory safe harbor from the federal "Stark" self-referral and Antikickback laws for standard compliant hardware, software and support services. The safe harbor would apply to physicians and other health care providers as long as these tools are used to exchange health information as part of a system designed to improve health care quality and safety, reduce medical errors, reduce health care costs, improve care coordination, simplify administrative processes, and promote transparency and competition. Lastly the measure would direct the Secretary of Health and Human Services to conduct a study of privacy laws and practices to determine how the variation among such state laws and practices may impact the electronic exchange of health information among states, between states and the federal government, and among private entities.

4) Amendment. The prescriber, prior to the electronic transmitting of a prescription, offers to transmit the prescription to a pharmacy of the patient's choice.

5) Support & Opposition.

Support:
L.A. Care Health Plan (sponsor)
AARP California
California Association of Health Plans
California Association of Physician Groups
California Medical Association
First 5 LA
Healthcare Information and Management Systems Society, So. Cal
Health-e-LA Coalition
Local Health Plans of California
Los Angeles County Medical Association
Rite-Aid
San Francisco Health Plan

Opposition: None on file.

6) History.

2005

June 14	In committee: Set, first hearing. Hearing canceled at the request of author.
June 7	In committee: Hearing postponed by committee.
May 5	Referred to Com. on B., P. & E.D.
Apr. 18	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 18	Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 980.)
Apr. 14	Read second time. To third reading.
Apr. 13	From committee: Do pass. (Ayes 14. Noes 0.) (April 12).
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 5	In committee: Set, first hearing. Hearing canceled at the request of author.
Feb. 15	Referred to Com. on HEALTH.
Feb. 4	From printer. May be heard in committee March 6.
Feb. 3	Read first time. To print.

AMENDED IN SENATE JUNE 21, 2005

AMENDED IN ASSEMBLY MAY 9, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 657

Introduced by Assembly Member Karnette
(Coauthor: Assembly Member Mountjoy)

February 17, 2005

An act to amend Section 4076 of, and to add Section 4079 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as amended, Karnette. Pharmacies: prescription containers: labels.

Existing law, the Pharmacy Law makes the California State Board of Pharmacy responsible for the regulation of the practice of pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose, as defined, of the drug, as set forth on the

prescription, and would require that the purpose be listed on the prescription.

The bill would, *except for veterinarians,* require a person who is authorized to write or issue a prescription to ask the patient or his or her authorized representative whether to indicate the intended purpose of the prescription on the prescription's label.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is 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. Section 4076 of the Business and Professions
2 Code is amended to read:
3 4076. (a) A pharmacist shall not dispense any prescription
4 except in a container that meets the requirements of state and
5 federal law and is correctly labeled with all of the following:
6 (1) Except where the prescriber or the certified nurse-midwife
7 who functions pursuant to a standardized procedure or protocol
8 described in Section 2746.51, the nurse practitioner who
9 functions pursuant to a standardized procedure described in
10 Section 2836.1, or protocol, the physician assistant who functions
11 pursuant to Section 3502.1, or the pharmacist who functions
12 pursuant to a policy, procedure, or protocol pursuant to either
13 subparagraph (D) of paragraph (4) of, or clause (iv) of
14 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
15 4052 orders otherwise, either the manufacturer's trade name of
16 the drug or the generic name and the name of the manufacturer.
17 Commonly used abbreviations may be used. Preparations
18 containing two or more active ingredients may be identified by
19 the manufacturer's trade name or the commonly used name or
20 the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The intended purpose of the drug or drugs, if indicated on the prescription. As used in this section, "purpose" means a concise description of the symptom or symptoms that the drug is, or drugs are, intended to treat.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. Section 4079 is added to the Business and Professions Code, to read:

4079. A person described in paragraph (2) of subdivision (a) of Section 4040 shall ask the patient or the patient's authorized representative, if the patient is either incapacitated or a minor who can not provide informed consent, whether to indicate the intended purpose of the prescription on the prescription's label. *This section does not apply to prescriptions dispensed by veterinarians.*

1 SEC. 3. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution
3 because the only costs that may be incurred by a local agency or
4 school district will be incurred because this act creates a new
5 crime or infraction, eliminates a crime or infraction, or changes
6 the penalty for a crime or infraction, within the meaning of
7 Section 17556 of the Government Code, or changes the
8 definition of a crime within the meaning of Section 6 of Article
9 XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 657 **VERSION: AMENDED JUNE 21, 2005**

AUTHOR: KARNETTE **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled. (B&P 4076(a))

If requested by the patient, a label may list the condition for which the drug was prescribed. (B&P 4076(a)(10))

This Bill:

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. (B&P 4076(a)(10) Amended)

The revised prescription labeling requirement would not apply to prescriptions dispensed by veterinarians. (B&P 4079 Amended)

Comment:

1) Author's Intent. The author intends to increase patient compliance and reduce confusion with prescribed drug therapy.

2) Confusion. Many prescription drugs have more than one use or purpose. A number of people, particularly seniors, have unexpired prescription drugs in their medicine cabinets, and do not know the intended use for the drug because it is omitted from the label. Many patients are unaware of their right to request that the prescription label contain information about the drug's purpose.

Including the purpose for the prescription drug on the prescription label may 1) reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of a prescription; 2) provide a check system between the doctor writing the prescription and the pharmacist filling the prescription; and 3) reduce medication error.

3) Other Legislation. A version of AB 288 (AB 2125 Levine 2004) was introduced in 2004. The author pulled the bill before its first committee hearing.

AB 288 (Mountjoy 2005) Pharmacies Prescription Containers Labels, a bill very similar to AB 657 has been introduced this session. AB 288 would require prescription labels to contain the

"condition" for which a drug is prescribed unless the patient receiving the drug request the information be omitted. Assemblyman Mounthjoy pulled AB 288 before it could be heard in its first committee hearing.

4) History.

2005

June 27	In committee: Hearing postponed by committee.
June 21	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
June 14	In committee: Hearing postponed by committee.
June 2	Referred to Com. on B., P. & E.D.
May 19	In Senate. Read first time. To Com. on RLS. for assignment.
May 19	Read third time, passed, and to Senate. (Ayes 42. Noes 30. Page 1608.)
May 10	Read second time. To third reading.
May 9	Read second time and amended. Ordered returned to second reading.
May 5	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 4).
Apr. 27	In committee: Hearing postponed by committee.
Apr. 20	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 8. Noes 4.) (April 19).
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 7	Referred to Coms. on HEALTH and B. & P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

ASSEMBLY BILL No. 896

Introduced by Assembly Member Matthews

February 18, 2005

An act to amend Section 4052.1 of, and to add Section 1209.2 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 896, as introduced, Matthews. Clinical laboratories.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under that law, a pharmacist is authorized to perform skin puncture in the course of routine patient assessment procedures or specified clinical laboratory testing. Existing law providing for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services, requires that these functions be performed under the supervision of a laboratory director, as defined. Under existing law, a violation of the provisions regulating clinical laboratories and their personnel is a crime.

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.

Because a pharmacist acting in this capacity without satisfying the designated criteria would violate the provisions regulating clinical laboratories, and would be a crime, the bill 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 1209.2 is added to the Business and
2 Professions Code, to read:
3 1209.2. Notwithstanding any other provision of law, a
4 pharmacist may serve as a laboratory director, as described in
5 Section 1209, in a clinical laboratory that provides routine patient
6 assessment procedures, as defined in Section 4052.1, if both of
7 the following conditions are satisfied:
8 (a) The pharmacist has completed a training program on the
9 duties and responsibilities of a laboratory director for a clinical
10 laboratory performing tests classified as "waived" under CLIA.
11 (b) The clinical laboratory possesses a certificate of waiver
12 under CLIA.
13 SEC. 2. Section 4052.1 of the Business and Professions Code
14 is amended to read:
15 4052.1. *(a)* Notwithstanding Section 2038 or any other
16 provision of law, a pharmacist may perform skin puncture in the
17 course of performing routine patient assessment procedures or in
18 the course of performing any procedure authorized under Section
19 1206.5. For purposes of this section, "routine patient assessment
20 procedures" means *either of the following:* ~~(a) procedures~~
21 *(1) Procedures* that a patient could, with or without a
22 prescription, perform for himself or herself~~, or (b) clinical~~.
23 *(2) Clinical* laboratory tests that are classified as waived
24 pursuant to the federal Clinical Laboratory Improvement
25 Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations
26 adopted thereunder by the federal~~Health Care~~
27 ~~FinancingAdministration~~ *Centers for Medicare and Medicaid*
28 *Services*, as authorized by paragraph (11) of subdivision (a) of
29 Section 1206.5. ~~A~~
30 *(b) A* pharmacist performing these functions shall report the
31 results obtained from a test to the patient and any physician
32 designated by the patient. ~~Any~~

1 *(c) A* pharmacist who performs the service authorized by this
2 section shall not be in violation of Section 2052.
3 SEC. 3. No reimbursement is required by this act pursuant to
4 Section 6 of Article XIII B of the California Constitution because
5 the only costs that may be incurred by a local agency or school
6 district will be incurred because this act creates a new crime or
7 infraction, eliminates a crime or infraction, or changes the
8 penalty for a crime or infraction, within the meaning of Section
9 17556 of the Government Code, or changes the definition of a
10 crime within the meaning of Section 6 of Article XIII B of the
11 California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 896 **VERSION: INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: CPHA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: CLINICAL LABORATORIES

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

4) Defines "routine patient assessment procedures" as a procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived pursuant to CLIA. (B&P 4052.1)

This Bill:

1) Permits a pharmacist to serve as a laboratory director when:

a. The laboratory is only conducting laboratory tests that a pharmacist may perform under existing law.

b. The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

c. The clinical laboratory possesses a certificate of waiver under CLIA.

(B&P 1209.2 Added)

2) The tests that can be preformed are:

a. Procedures that a patient could, with or without a prescription, perform for himself or herself.

b. Clinical laboratory tests that are classified as waived under CLIA.

3) Requires the pharmacist performing laboratory tests to report the results to both the patient and any physician specified by the patient. (B&P 4052.1 Amended)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

The author has also introduced AB 1370 this session, which would accomplish the same goal as AB 896. After some reflection, the author has decided to drop AB 1370 and put efforts into AB 896.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available.

Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) Legislative History. AB 896 is similar to AB 1460 (Nation 2003), Laboratory Directors. The board supported this bill. AB 1460 died in its first committee hearing.

6) Related Legislation. AB 1370 (Matthews 2005), Clinical Laboratory Directors: Pharmacists, would amend B&P 1209, to redefine a laboratory director to include a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure. The author's office has stated that the author plans to drop this bill since it would accomplish the same thing as AB 896.

7) History.

2005	
Apr. 12	In committee: Hearing postponed by committee.
Mar. 29	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 7	Referred to Coms. on B. & P. and HEALTH
Feb. 20	From printer. May be heard in committee March 22.
Feb. 18	Read first time. To print.

AMENDED IN SENATE APRIL 18, 2005

SENATE BILL No. 152

Introduced by Senator Speier

February 7, 2005

~~An act to add Section 4051.1 to the Business and Professions Code, relating to pharmacy.~~ *An act to add, repeal, and add Section 11100.02 of the Health and Safety Code, relating to controlled substances.*

LEGISLATIVE COUNSEL'S DIGEST

SB 152, as amended, Speier. Pseudoephedrine.

Under existing law, a retailer who makes an over-the-counter retail sale of pseudoephedrine is generally subject to a 3-package per transaction limitation or 9-gram per transaction limitation. Any violation of this requirement is a crime.

This bill would impose additional requirements on the sale by a pharmacist or retail distributor, as defined, of a product, except as specified, containing any amount of pseudoephedrine or its salts or isomers or the salts of isomers of pseudoephedrine. The bill would, effective June 1, 2006, require the purchaser of the product to present a government-issued photo identification and would require that a retail distributor's staff complete certain training before selling the product. The bill would add to these requirements, effective January 1, 2008, a provision that the pharmacist and retail distributor maintain a record of the sales of the product and limit sales to a single purchaser to 3 packages or 9 grams within a 30-day period.

Because the bill would make a violation of these provisions a crime, it would impose a state-mandated local program.

~~Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy. That law authorizes a pharmacist to furnish and~~

~~dispense prescription drugs. A knowing violation of the Pharmacy Law is a misdemeanor.~~

~~This bill would prohibit, subject to specified exceptions, the furnishing of a product containing pseudoephedrine by other than a pharmacist or pharmacy technician in a pharmacy. The bill would limit the amount of the product that a person could acquire in a 30-day period and would impose requirements on acquisition.~~

~~Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is 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. Section 4051.1 is added to the Business and~~
2 ~~Professions Code, to read:~~
3 *SECTION 1. Section 11100.02 is added to the Health and*
4 *Safety Code, to read:*
5 *11100.02. (a) A pharmacist and a retail distributor, as*
6 *defined in paragraph (5) of subdivision (h) of Section 11100,*
7 *shall store products containing any amount of pseudoephedrine*
8 *or the salts, isomers, or salts of isomers of pseudoephedrine in a*
9 *locked area.*
10 *(b) A pharmacy and a retail distributor shall not sell a product*
11 *described in subdivision (a) to a purchaser unless the purchaser*
12 *presents a valid, current identification that contains a photo of*
13 *himself or herself and that was issued by a governmental agency.*
14 *(c) No staff member of a retail distributor may sell a product*
15 *described in subdivision (a) unless the staff member has received*
16 *training in both of the following subjects:*
17 *(1) Identification of pseudoephedrine products.*
18 *(2) Usage of pseudoephedrine in manufacturing*
19 *methamphetamine.*

(d) This section shall not apply to either of the following:

(1) A compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. Regardless of the product manufacturer's labeling, a gelatin covered solid is not a gel capsule for purposes of this subdivision.

(2) A pediatric liquid, as defined in paragraph (4) of subdivision (h) of Section 11100.

(e) A first violation of this provision is a misdemeanor. A person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(f) This section shall become operative on June 1, 2006, and shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

SEC. 2. Section 11100.02 is added to the Health and Safety Code, to read:

11100.02. (a) A pharmacist and a retail distributor, as defined in paragraph (5) of subdivision (h) of Section 11100, shall store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine in a locked area.

(b) A pharmacy and a retail distributor shall not sell a product described in subdivision (a) to a purchaser unless the purchaser presents a valid, current identification that contains a photo of himself or herself and that was issued by a governmental agency.

(c) (1) Before selling a product described in subdivision (a) to a purchaser, the pharmacist or retail distributor shall record the following information:

(A) The date of purchase.

(B) The name and address of the purchaser.

(C) The number of the identification presented by the purchaser.

(D) The name and amount of the product, as described in subdivision(a), that was purchased.

(2) The pharmacy and retail distributor shall maintain the record described in paragraph (1) for at least three years from the product's date of purchase in an electronic format approved by the Attorney General.

(d) (1) A pharmacist or a retail distributor shall not sell more than three packages or more than nine grams of the product described in subdivision (a) within any 30-day period to a single purchaser.

(2) A pharmacist and a retail distributor shall develop a system that notifies the pharmacist or retail distributor that the limitation described in paragraph (1) has been reached.

(e) No staff member of a retail distributor may sell a product described in subdivision (a) unless the staff member has received training in both of the following subjects:

(1) Identification of pseudoephedrine products.

(2) Usage of pseudoephedrine in manufacturing methamphetamine.

(f) This section shall not apply to either of the following:

(1) A compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. Regardless of the product manufacturer's labeling, a gelatin covered solid is not a gel capsule for purposes of this subdivision.

(2) A pediatric liquid, as defined in paragraph (4) of subdivision (h) of Section 11100.

(g) A first violation of this provision is a misdemeanor. A person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) This section shall become operative on January 1, 2008.

SEC. 3. 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.

~~4051.1. (a) A product containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine shall be furnished only by a pharmacist or pharmacy technician in a pharmacy.~~

~~(b) Notwithstanding Section 11100 of the Health and Safety Code, no person shall purchase, receive, or otherwise acquire more than nine grams of the product described in subdivision (a) within any 30-day period. Before purchasing, receiving, or otherwise acquiring a product described in subdivision (a), a person shall produce a valid California driver's license or other valid identification containing a photograph of the person and showing his or her date of birth. The person shall sign a written document, as specified by the Attorney General, indicating the date of the purchase, receipt, or acquisition and the amount of the product involved in the transaction.~~

~~(c) The pharmacist shall store the product described in subdivision (a) in a locked area within the view of the pharmacist. The pharmacist and all persons with access to the locked storage area shall prevent the theft or diversion of the product.~~

~~(d) (1) This section shall not apply to a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. "Active ingredient" includes the matrix found in liquid capsules. Regardless of the product manufacturer's labeling, a gelatin-covered solid is a gel capsule for purposes of this subdivision.~~

~~(2) The exception in paragraph (1) shall not apply to a liquid preparation that is discovered in an illegal laboratory, that is associated with an illegal laboratory, or that is any form other~~

~~than one manufactured and sold by a manufacturer for medicinal purposes.~~

~~(c) This section does not apply to a substance furnished pursuant to a valid prescription.~~

~~SEC. 2. 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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