AMENDED IN SENATE MAY 18, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 7, 2005

SENATE BILL No. 644

Introduced by Senator Ortiz
(Coauthors: Senators Kuehl and Romero)
(Coauthors: Assembly Members Frommer, Jones, and Laird)

February 22, 2005

An act to add Section 733 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 644, as amended, Ortiz. Dispensing prescription drugs and devices.

Existing law makes certain actions by a health care professional unprofessional conduct subject to disciplinary action by the licensing board regulating the health care professional.

This bill would include within those provisions, a requirement that a health care licentiate 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. The bill would authorize the licentiate to decline to dispense the prescription or order on that basis only if the licentiate notified his or her employer of the objection and it can be reasonably accommodated. The bill would require the licentiate's employer in those circumstances to establish protocols to ensure a patient's timely access to the prescribed drug or device.

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

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

SECTION 1. It is the intent of the Legislature that health care professionals dispense prescription drugs and devices in a timely way or provide appropriate referrals for patients to obtain the necessary prescription drugs and devices, despite the health care professional's objection to dispensing the drugs or devices on ethical, moral, or religious grounds.

SEC. 2 Section 733 is added to the Business and Professions Code, to read:

733. *(a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary action by his or her licensing agency.*

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

~~(a)~~

(1) Based *solely* on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law~~ or is contraindicated for the patient~~, *or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.*

~~(b) The pharmacy does not have the prescription drug or device in its~~

(2) The prescription drug or device is not in stock. If an order or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

~~(1)~~

(A) Immediately notify the patient and arrange for the drug or device to be delivered to th~~e pharmacy~~ *site* or directly to the patient in a timely~~ way~~ *manner.*

~~(2)~~

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is~~ within a reasonable distance from the pharmacy that is transferring the prescription or order~~ *near enough to the site from which the*

prescription or order is transferred, to ensure the patient has timely access to the drug or device.

~~(3)~~

(C) Return the prescription to the patient and refer the patient ~~to a pharmacy known to stock the prescription drug or device that is within a reasonable distance from the referring pharmacy~~ . *The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site* to ensure that the patient has timely access to the drug or device.

~~(e)~~

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this ~~subdivision~~ *section,* "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to ~~subdivision(1)~~ *subdivision (e)* of Section 12940 of the Government Code.

~~(d)~~

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

~~(e)~~

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 644 **VERSION: AMENDED MAY 18, 2005**

AUTHOR: ORTIZ **SPONSOR: PLANNED PARENTHOOD**

RECOMMENDED POSITION:

SUBJECT: DISPENSING PRESCRIPTION DRUG AND DEVICES

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)

This Bill:

1) States that no licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary action by his or her licensing agency.

2) Requires a licentiate to dispense drugs and devices pursuant to a lawful order or prescription unless one of the following circumstances exists:

a. Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

b. The prescription drug or device is not in stock. If an order or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

i. Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

ii. Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device and that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

iii. Return the prescription to the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

c. The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, if:

i. The licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects; and

ii. The licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection by establishing protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order.

3) States that the section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

4) Defines "reasonable accommodation" and "undue hardship" in accordance with the Government Code.

(B&P 733 Added)

Comment:

1) Author's Intent. The sponsor intent is to establish in law a duty to fill lawful prescriptions while balancing a licensees right to ethical, moral or religious objections with a patient's right to basic health care.

2) In the News. The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

3) Enforcement. Enforcement of SB 644 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacists' refusal to dispense EC. Consequently, if SB 644 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

4) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

5) Related Legislation. AB 21 (Levine 2005) Pharmacists: Practice Requirements, 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 has notified his or her employer in writing. The bill would make a violation of its provisions unprofessional conduct, subject to disciplinary action by the board. AB 21 failed passage when it was heard in the Senate Committee on Health on June 22, 2005 by a vote of 4-4 and was granted reconsideration.

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) Substantive Amendments since the April 27th Board Meeting. The addition of the provision that violating the provisions of the chapter would constitute unprofessional conduct.

8) Support / Opposition.

Support: Planned Parenthood Affiliates of California (sponsor)
NARAL Pro-Choice California (sponsor)
American Association of University Women (sponsor)
California Family Health Council (sponsor)
American Civil Liberties Union
American College of Obstetricians and Gynecologists
California Academy of Family Physicians
California Association for Nurse Practitioners
California Commission on the Status of Women
California Medical Association
California National Organization for Women
California Nurses Association
California Nurse Midwife Association
California Pharmacists Association
California State Board of Pharmacy
City of West Hollywood
National Association of Social Workers
National Organization for Women, Oakland East Bay Chapter

Opposition: California Catholic Conference
California Family Alliance
California Nurses for Ethical Standards
California ProLife Council, Inc
Capitol Resource Institute

9) History.

2005

June 21	From committee: Do pass, but first be re-referred to Com. On HEALTH. (Ayes 8. Noes 2.) Re-referred to Com. on HEALTH
June 9	To Coms. on B. & P. and HEALTH
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 26. Noes 13. Page 1190.) To Assembly.
May 25	Read second time. To third reading.
May 24	From committee: Do pass. (Ayes 8. Noes 5. Page 1147.)
May 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
May 16	Set for hearing May 23.
May 4	Read second time. Amended. Re-referred to Com. on APPR.

May 3	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 847.)
Apr. 26	From committee: Do pass, but first be re-referred to Com. On HEALTH. (Ayes 4. Noes 3. Page 770.) Re-referred to Com. On HEALTH
Apr. 13	Set for hearing April 25.
Apr. 12	Reset for hearing April 27 in HEALTH pending receipt.
Apr. 11	Set for hearing April 20 in HEALTH pending receipt.
Apr. 7	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 17	Set for hearing April 11.
Mar. 3	To Coms. on B., P. & E.D. and HEALTH
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 644

As Amended: May 18, 2005

ASSEMBLY COMMITTEE ON HEALTH

Wilma Chan, Chair

SENATE VOTE : 26-13

SUBJECT : Dispensing prescription drugs and devices.

SUMMARY : Requires a licentiate of the Board of Pharmacy (Board), as specified, to dispense drugs and devices pursuant to a lawful order or prescription unless specified circumstances exist. Specifically, this bill :

1)States that it is the intent of the Legislature that health care professionals dispense prescription drugs and devices in a timely way or provide appropriate referrals for patients to obtain the necessary prescription drugs and devices, despite the health care professional's objection to dispensing the drugs or devices on ethical, moral, or religious grounds.

2)Requires a licentiate Board, as specified, to dispense drugs and devices pursuant to a lawful order or prescription unless, based solely on the professional training and judgment of the licentiate, it would be contrary to law or the licentiate determines that the drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

3)Prohibits a licentiate from obstructing a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. Specifies that a violation of this bill constitutes unprofessional conduct by the licentiate and subjects the licentiate to disciplinary action by the Board of Pharmacy.

4)Provides that a licentiate does not have to dispense a prescription drug or device as defined if it is not in stock, but requires the licentiate to:

a) Immediately notify the patient and arrange for the drug or device to be delivered to the pharmacy or to the patient in a timely manner;

b) Promptly transfer the prescription to another pharmacy known to stock the drug or device and that is near enough to ensure that the patient has timely access; or,

c) Return the prescription to the patient and refer the patient to a pharmacy for which the licentiate has made a reasonable effort to ascertain that the drug or device is in stock and that is near enough to the referring pharmacy to ensure timely access.

5)Requires a licentiate, if he or she refuses on ethical, moral, or religious grounds to dispense a drug or devise pursuant to an order or prescription, to inform his or her employer in advance and in writing of the drug or class of drugs to which he or she objects.

6)Permits the licentiate's employer to provide reasonable accommodation, as defined, to the licentiate's refusal to dispense by establishing protocols that ensure that the patient has timely access to the prescribed drug or device as long as such protocols would not create an undue hardship.

7)Defines the terms "reasonable accommodation" and "undue hardship" as having the same meaning as those relating to unlawful employment practices and requirements of employers to provide reasonable accommodation of an employee's religious beliefs and observances, as long as they do not create undue hardship on the conduct or operation of its business.

8)Defines "prescription drug or device" as those drugs or devices defined as a "dangerous drug" or "dangerous device" and those drugs identified as those for purposes of EC drug therapy.

9)Applies the provisions of this bill to over-the-counter EC drug therapy as defined in current law.

10)Imposes no duty on a licentiate to dispense a prescription drug or device without payment for the drug or device, including payment directly by the patient, through a third party payer, or payment of any required copayment by the patient.

EXISTING LAW provides for the licensure and regulation of pharmacists by the Board and prohibits, except as specified, a person other than a pharmacist from dispensing a dangerous drug, as defined, pursuant to a prescription.

FISCAL EFFECT : According to the Senate Appropriations Committee analysis, costs of $100,000 in special funds per year for enforcement. The Pharmacy Board identifies a possible minor fiscal impact to the Board if it opts to pursue disciplinary action against pharmacists who refuse to fill a prescription without following the protocols provided by this bill.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, pharmacists provide an essential service to consumers who rely on their expertise to access medically necessary prescription medications and supplies. There is, however, no legal duty on a pharmacist to dispense medications and other prescription items to an individual with a lawful prescription. Existing law simply authorizes persons with particular training and competency to dispense prescription drugs. As a consequence, a pharmacist can legally refuse to fill a legal prescription at his or her discretion. There have been a number of reports in the past year or so that retail pharmacists are refusing to fill lawful prescriptions, particularly prescriptions for contraception, including Emergency Contraception (EC), based on individual pharmacists religious beliefs. While there is no intent in this bill to override the religious beliefs of individuals, the purpose of the bill is to ensure that consumers are not abandoned by pharmacists and pharmacies, and will have timely access to necessary medications even where an individual pharmacist will not dispense the drug requested.

2)REPORTS OF REFUSALS TO FILL PRESCRIPTIONS . There have been numerous news stories throughout the United States describing incidents where pharmacists have refused to dispense oral contraceptives and other types of birth control based on moral grounds or religious beliefs. A March 28, 2005 Washington Post article reported that it is not known how often that refusals are occurring, but there have been cases in California, Washington, Georgia, Illinois, Louisiana, Massachusetts, Texas, New Hampshire, Ohio, and North Carolina. The article stated that Wisconsin is one of at least 11 states considering "conscience clause" laws that would protect pharmacists' right to decline to fill a prescription and that four states already have laws that permit pharmacists to refuse to fill prescriptions that violate their beliefs. At least four other states are considering laws that would explicitly require pharmacists to fill all prescriptions. Some large pharmacy chains, including Walgreens, Wal-Mart and CVS, have instituted policies to balance pharmacists' and customers' rights by ensuring another pharmacist is on duty to fill the prescription or contacting another pharmacy willing to fill the prescription in the case that a pharmacist objects to filling it.

3)COMPLAINTS TO THE BOARD OF PHARMACY . Current law, through regulations, requires a pharmacist who declines to furnish EC based on a "conscience clause" to refer the patient to another EC provider. The law is silent on pharmacists' ability to object on religious, ethical, or moral grounds for any other drug. The Board has a system in place to receive and

investigate complaints, but received none regarding refusals to fill EC prescriptions in 2004.

4)RELATED LEGISLATION . AB 21 (Levine) is similar to this bill and would require a pharmacist to dispense a prescription except in specified circumstances, and permit 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. AB 21 failed passage when it was heard in the Senate Committee on Health on June 22, 2005 by a vote of 4-4 and was granted reconsideration.

5)PREVIOUS LEGISLATION . SB 490 (Alpert), Chapter 651, Statutes of 2003, permits a licensed pharmacist to initiate EC drug therapy in accordance with a standardized procedure approved by the Board and the Medical Board of California. It also requires a pharmacist, prior to furnishing EC, to complete a training program of at least one hour of approved continuing education on EC drug therapy.

6)SUPPORT . NARAL Pro-Choice California, the California Association for Nurse Practitioners, and the California Nurse Midwives Association write this bill will make sure that all individuals have access to their prescription medication in a timely manner, while respecting the rights of pharmacists. The American Association of University Women (AAUW) write that they support the right of an individual to object on ethical, moral or religious grounds to performing an act that is in conflict with the person's beliefs. However, AAUW also believes that pharmacies have a responsibility to ensure that patients receive needed medications in a timely and respectful manner. The American Civil Liberties Union supports the careful balance struck by this bill that would protect the rights of patients and health care licentiates. The American College of Obstetricians and Gynecologists believe that this bill respects a pharmacist's right to exercise their conscience while ensuring patients have timely access to essential, prescribed medications. The California Pharmacists Association states that it is appropriate to codify a practice of "dispense or refer" that is correct and enforceable, which this bill accomplishes.

7)OPPOSITION . The California Family Alliance states that this bill does not contain the necessary safeguard to protect pharmacists with sincerely held religious beliefs and that under the accommodation requirement of this bill, a pharmacist employer does not need to allow the pharmacist the right of conscience where there is an "undue hardship" on the employer. The California Catholic Conference contends that conscience objections would have to yield to the need to dispense the drugs due to an "undue hardship" on the employer or other

entity, which would thereby render the conscience clause inoperative upon someone's complaint. California ProLife Council writes that this bill does not make it clear whether or not a pharmacist would be able to refuse the dispensing of abortive drugs. The Capitol Resource Institute states that if this bill were to pass, California would be the first state to compel pharmacists to violate their moral and religious convictions and distribute contraceptives and abortifacients. California Nurses for Ethical Standards writes that this bill makes it more difficult for pharmacists to abide their consciences.

REGISTERED SUPPORT / OPPOSITION :

Support

Planned Parenthood Affiliates of California (sponsor)
NARAL Pro-Choice California (sponsor)
American Association of University Women (sponsor)
California Family Health Council (sponsor)
American Civil Liberties Union
American College of Obstetricians and Gynecologists
California Academy of Family Physicians
California Association for Nurse Practitioners
California Commission on the Status of Women
California Medical Association
California National Organization for Women
California Nurses Association
California Nurse Midwife Association
California Pharmacists Association
California State Board of Pharmacy
City of West Hollywood
National Association of Social Workers
National Organization for Women, Oakland East Bay Chapter

Opposition

California Catholic Conference
California Family Alliance
California Nurses for Ethical Standards
California ProLife Council, Inc
Capitol Resource Institute

Analysis Prepared by : Melanie Moreno / HEALTH / (916) 319-2097

Attachment 6

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 9, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 283

Introduced by Assembly Member Koretz
(Coauthor: Assembly Member Maze)
(Coauthors: Senators Alquist and Margett)

February 9, 2005

An act to add Section 11100.01 to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 283, as amended, Koretz. Ephedrine and pseudoephedrine: retail sale.

(1) Under existing law, a retailer who makes an over-the-counter retail sale of ephedrine or 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, punishable as specified.

This bill would provide that the dispensing, sale, or distribution at retail of any compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine shall be subject to specified additional requirements. The retailer would be required to store and display the product in a locked cabinet or as specified and the transaction would be required to be made by a retailer or employee of a retailer who meets specified requirements. A violation of any of

these provisions would be a misdemeanor, punishable as specified, except that (1) a retail clerk who fails to comply with these provisions would not be subject to any civil, criminal, or other penalty, unless the clerk is a willful participant in an ongoing criminal conspiracy to violate these provisions; and (2) a retailer whose employee sells pseudoephedrine or ephedrine in violation of these provisions would not be ~~liable~~ *guilty of a crime or subject to a civil penalty under the bill's provisions,* if the retailer complies with the storage and display requirements and can document that an employee training program was conducted to train employees on compliance with these provisions. *The bill would provide, however, that its provisions shall not alter or affect any cause of action or remedy otherwise available to a consumer under the law.* By creating new crimes, this bill would impose a state-mandated local program upon local governments.

(2) 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 11100.01 is added to the Health and
2 Safety Code, to read:
3 11100.01. (a) In addition to any requirement specified in
4 Section 11100, the dispensing, sale, or distribution at retail of any
5 compound, mixture, preparation, or product that contains any
6 detectable quantity of ephedrine, pseudoephedrine, or any
7 derivative of ephedrine or pseudoephedrine, or any detectable
8 quantity of any salt, optical isomer, or salt of an optical isomer of
9 ephedrine, pseudoephedrine, or any derivative of ephedrine or
10 pseudoephedrine, shall be subject to the following requirements:
11 (1) Any product specified in subdivision (a) shall be stored or
12 displayed by a retailer in a locked cabinet or in such a manner
13 that the product is accessible to the public only with the
14 assistance of the retailer or employee of the retailer. The retailer

or employee of the retailer shall at all times act to prevent the theft or diversion of the product.

(2) The dispensing, sale, or distribution at retail of any product specified in subdivision (a) shall be made only by a retailer or employee of a retailer who is trained in the legal requirements set forth in this section and who shall at all times act to prevent the theft or diversion of the product.

(b) This section shall not apply to any product specified in subdivision (a) in liquid, liquid capsule, or dissolvable strip form in which ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine is the active ingredient.

(c) (1) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that exempt a substance from the application of subdivision (a) if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

(2) The Department of Justice shall, upon satisfactory application by the manufacturer of a drug product to the department, exempt any product the department determines to have been formulated in such a way as to effectively prevent the conversion of any active ingredient in the product into methamphetamine or any other controlled substance.

(d) Except as provided in subdivision (e), any person who violates this section shall be punished as follows:

(1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section or Section 11100 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.

(e) Notwithstanding subdivision (d), liability for a violation of this section shall not be imposed in the following cases:

(1) A retail clerk who fails to comply with the provisions of subdivision (a) shall not be guilty of a crime pursuant to subdivision (d), shall not be subject to any civil penalty, and shall not be subject to any disciplinary action

or discharge by his or her employer, except if the retail clerk is a willful participant in an ongoing criminal conspiracy to violate this section.

(2) A retailer whose employee sells pseudoephedrine or ephedrine in violation of this section shall not be ~~liable~~ *guilty of a crime pursuant to subdivision (d) and shall not be subject to any civil penalty under this subdivision,* if the retailer complies with paragraph (1) of subdivision (a) and can document that an employee training program was conducted to train employees on compliance with this section.

(3) Nothing in this subdivision shall alter or affect any cause of action or remedy otherwise available to a consumer under the law.

(f) It is the intent of the Legislature that this section and Section 11100 shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing pseudoephedrine.

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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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 283 **VERSION: MAY 26, 2005**

AUTHOR: KORETZ **SPONSOR: KORETZ**

RECOMMENDED POSITION: NO POSITION

SUBJECT: EPHEDRINE AND PSEUDOEPHEDRINE: RETAIL SALE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Requires that the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, of or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, shall be subject to the following requirements:

   a. The products be stored or displayed by a retailer in a locked cabinet or locked area in such a manner that the product is accessible to the public only with the assistance of the retailer or employee of the retailer. The retailer or the employee of a retailer shall act to prevent the theft or diversion of the products.

   b. The sale of products shall be made only by a retailer or employee of a retailer who is trained in the legal requirements set forth in this section and who shall at all times act to prevent the theft or diversion of the products.

2) Sets the following penalties for any person who violate the measure:
   a. A first violation of the measure would be a misdemeanor.
   b. Subsequent violations and convictions would 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.

3) Specifies that a retail clerk who fails to comply with this law will not be guilty of a crime, or subject to civil penalties, or disciplinary action or discharge by his or her employer, except if the retail clerk is a willful participant in an ongoing criminal conspiracy to violate this section.

4) Specifies that a retailer whose employee sells pseudoephedrine or ephedrine in violation of this section shall not be guilty of a crime if the retailer has complied with the provision of the measure.

5) Allows the Department of Justice (DOJ) to adopt rules and regulations that exempt a drug product if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

6) This measure would not apply to any product in liquid, liquid capsule, or dissolvable strip form in which ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine is not the only active ingredient.

(H&S 11100.01 Added)

Comment:

1) Author's Intent. The author's intent is to reduce the proliferation of methamphetamine (meth) user labs by limiting the availability of ephedrine and pseudoephedrine; an ingredient used in making meth. (A user lab is a small-scale meth production lab that supplies one to a few meth users.)

The author's district includes the City of West Hollywood, where meth has become the party drug of choice the in the gay male community. Author's staff states that a person taking meth is three times as more likely then someone not taking the drug to test positive for HIV.

2) DOJ Tracks Distribution of Ephedrine and Pseudoephedrine Products. The DOJ permits wholesale distributors of all precursor chemicals for meth production, including ephedrine and pseudoephedrine. Under the conditions of a permit a wholesaler must report to the DOJ, all sales and transactions of product, including sales to drug stores. The DOJ reviews the data it receives from these reports, and if anomalies are found, such as a spike in quantity sold, the DOJ will initiate an investigation to determine the cause and source of the anomaly.

3) Retail Chains' Voluntary Efforts. In an effort to combat illegal methamphetamine production, the following major drug retailers have voluntarily agreed to move all single ingredient pseudoephedrine products behind the pharmacy counter: Albertsons, CVS, Longs Drugs, Kmart, Rite Aid, Shopko, Target, Walgreens, and Wal-mart. Additionally, the National Association of Chain Drug Stores, which represents more than 36,000 pharmacies, supports federal legislation (S 103) to reduce access to pseudoephedrine products, including requiring the sale of pseudoephedrine products behind the pharmacy counter by a licensed pharmacist or pharmacy personnel.

4) Based on Oklahoma Law. AB 283 is based on Oklahoma HB 2176 (2004) which went into effect in April 2004. Law enforcement in Oklahoma hope that other states will enact similar provisions.

5) State Legislation. SB 152 (Speier 2005) Pseudoephedrine is similar to AB 283 in its attempt to restrict the sale of pseudoephedrine for illegal uses. SB 152 would require 1) the product be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1. SB 152 is in the Senate B&P Committee and is a two-year bill.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

6) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

7) History.

2005	
June 27	In committee: Set first hearing. Failed passage. Reconsideration granted.
June 9	Referred to Coms. on B., P. & E D. and PUB. S.
June 1	In Senate. Read first time. To Com. on RLS. for assignment.
May 31	Read third time, passed, and to Senate. (Ayes 72. Noes 6. Page 1851.)
May 26	Read third time, amended, and returned to third reading.
May 23	Read second time. To third reading.
May 19	From committee: Do pass. (Ayes 15. Noes 3.) (May 18).
May 11	In committee: Hearing postponed by committee.
May 10	Re-referred to Com. on APPR.
May 9	From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
May 3	Re-referred to Com. on APPR.
May 2	Read second time and amended.
Apr. 28	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 5. Noes 0.) (April 26).
Apr. 19	In committee: Hearing postponed by committee.
Apr. 14	Re-referred to Com. on PUB. S.
Apr. 13	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
Mar. 14	Referred to Com. on PUB. S.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

AB 283

As Amended: May 26, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair

Bill No: Author:Koretz
Fiscal: Yes

SUBJECT: Ephedrine and pseudoephedrine: retail sale.

SUMMARY: Requires a retailer to store any compound, mixture, preparation, or product that contains any detectable quantity of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine, or any detectable quantity of salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine in a locked cabinet, or in such a manner that the product is accessible only with the assistance of the retailer or an employee of the retailer. This bill is similar to SB 152 (Speier), as it was proposed to be amended in this Committee, which was defeated.

Existing law: Uniform Controlled Substances Act:

1)Defines "retail distributor" as a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of pseudoephedrine products, are limited exclusively to the sale of pseudoephedrine products for personal use both in the number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

2)Requires retailer distributors and pharmacists that sell, transfer, or otherwise furnish pseudoephedrine to any person or entity in this state to submit a report of all those transactions to the Department of Justice (DOJ), as specified.

3)Exempts retailer distributors and pharmacists from reporting to DOJ, if pseudoephdrine is lawfully sold, transferred, or furnished over-the-counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act, and as long as the individual transaction does not involve more than three packages or nine grams of pseudoephdrine.

4)Makes it a misdemeanor for any retail distributor to sell in a single transaction more that three packages of a product that he or she knows to contain pseudoephdrine, or knowingly sell more than nine grams of pseudoephdrine, other than pediatric liquids as defined, and provides that a retail distributor may be imprisoned for no more than one year or be fined up to ten thousand dollars ($10,000) for a subsequent violation.

5)Defines "pediatric liquids" as a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure and provides that in no instance should the dosage units exceed 15 milligrams of pseudoephedrine per 5 millimeters of liquid product, unless for children under 2 years of age when the dosage unit should not exceed 2 milliliters nor one fluid ounce for total package content.

6)Makes it a felony for any person who, with intent to manufacture methamphetamine, possesses pseudoephedrine.

7)Requires the DOJ to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances, and for those practitioners to provide information to DOJ, as specified.

8)Requires CURES to operate under existing provisions of law to safeguard the privacy and confidentiality of patients and requires that data obtained from CURES only be provided to appropriate state, local and federal persons as specified and not to be disclosed, sold, or transferred to any third party.

9)Provides that DOJ may release to a licensed health care practitioner or a pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, but that the information released shall be considered as medical information subject to provisions of the state's Confidentiality of Medical Information Act.

Existing law, the Stop Tobacco Access to Kids Enforcement Act:

1)Prohibits a retailer of tobacco products from selling, offering for sale, or displaying for sale, any tobacco product or tobacco paraphernalia by self-service display.

2)Defines "self-service display" as an open display of tobacco products or tobacco paraphernalia in a manner that is accessible to the general public without the assistance of the retailer or employee of the retailer.

3)Subjects a retailer to civil penalties as specified for selling tobacco products or paraphernalia by self-service display.

This bill:

1)Requires a retailer to store or display products containing any detectable amount of ephedrine or pseudoephedrine, or any derivative of ephedrine or pseudoephedrine, or any detectable quantity of salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine in a locked cabinet or in such a manner that the product is accessible to the public only with the assistance of the retailer or an employee of the retailer.

2)Requires the retailer and employees of the retailer to at all times act to prevent the theft or diversion of any of the above listed products.

3)Requires any retailer or employee of a retailer who dispenses, sells, or distributes any of these products to be trained in the legal requirements set forth in this bill.

4)Exempts ephedrine or pseudoephedrine products in liquid, liquid capsule, or dissolvable strip from the above three requirements.

5)Allows DOJ to adopt rules and regulations to exempt any product from these requirements if DOJ finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

6)Requires DOJ to exempt, upon the application of a manufacturer of a drug product, any product DOJ determines to have been formulated in such a way as to effectively prevent the conversion of any active ingredient in the product into methamphetamine or any other controlled substance.

7)Provides that a violation of the provisions of this bill is a misdemeanor, and provides that a retailer or

employee of a retailer may be imprisoned for no more than one year or be fined up to ten thousand dollars ($10,000) for a subsequent violation.

8)Prohibits a violation from being imposed in the following cases:

a) A retail clerk shall not be guilty, not be subject to any civil penalty, or not be subject to any disciplinary action or discharge by the employer, except if the clerk is a willful participant in an ongoing criminal conspiracy to violate the law.

b) A retailer, whose employee violates this law, shall not be guilty of a crime and not be subject to a civil penalty if the retailer complies with the storage and employee training requirements.

9)Stipulates that nothing in this bill shall alter or affect any cause of action or remedy otherwise available to a consumer under the law and that it is the Legislature's intent that this bill and Section 11100 of the Health and Safety Code shall preempt all local ordinances or regulations governing the sale by a retailer of over-the-counter products containing pseudoephedrine.

FISCAL EFFECT: According to the analysis of the Assembly

Appropriations Committee, dated May 18, 2005, would include minor nonreimbursable local costs for enforcement, permissive costs to DOJ for regulations and review of exemptions, and unknown costs to private retailers.

COMMENTS:

1. Purpose and Need for the Measure. According to the Author, AB 283 will curb crystal methamphetamine production and use in California through purchase controls on the tablet form of pseudoephedrine, a key ingredient in methamphetamine production. The costs of crystal methamphetamine production and use in California are staggering. A recent Los Angeles Times article called crystal methamphetamine "as addictive as crack, more powerful than ecstasy, and cheaper than cocaine." Despite considerable state spending and legal limits on key ingredient sales and distribution, methamphetamine use continues to increase.

2. Background. The following information has been extracted from the comments and background material

supplied by the Author.

a) Super Labs and User Labs. Super labs are sites producing 10 pounds of methamphetamine or more in a single batch and are typically run by Mexican drug trafficking organizations. It is believed that a large percentage of methamphetamine sold in California originates from super labs both here and in Mexico. These larger operations are typically located in secluded rural locations.

Methamphetamine user labs are smaller and typically are not run by organized crime. They are difficult to find and easy to move. Methamphetamine addicts in need of a cheap source for their next fix can obtain a recipe from the internet and build a small methamphetamine lab in the trunk of a car, their bath tub, or any place out of public view. These user labs are dangerous fire and chemical hazards and pose a serious threat to public safety.

b) Pseudoephedrine: Key Ingredient in User Lab Methamphetamine Production. The key ingredient for user lab methamphetamine production is the tablet form of ephedrine/pseudoephedrine-containing products. Current California law limits ephedrine or pseudoephedrine purchases to nine grams or three packages per transaction. Therefore, methamphetamine users, in a process they call "smurfing," travel from store to store purchasing or shop lifting these products. Law enforcement commonly reports that maps found during methamphetamine lab busts are marked with the locations of retail outlets selling such products.

c) Methamphetamine Labs Are Accidents Waiting to Happen. Methamphetamine production requires the use of toxic solvents and when the products are cooked a flammable gas heavier than air is produced which drifts and collects at ground level. There is a considerable danger of fires and explosions. Any spark such as a neighbor's drop of a cigarette or the discharge of a police firearm can ignite an explosion that causes harm to life and property. The "off-gas" can also burn lungs and cause long-term respiratory disabilities.

d) Methamphetamine Fueling HIV Infections. Methamphetamine use is a problem in many communities, but it is spread among middle-class gay men and is taking a high priced and deadly toll. Called crystal, tina, crank, and speed, methamphetamine is believed to

be fueling new HIV infections.

Health surveys in Los Angeles and San Francisco have found that roughly a third of the people newly diagnosed with HIV report using methamphetamine. A recent Centers for Disease Control and Prevention study of San Francisco data documented that using methamphetamine and Viagra together leads to a significant increase in unsafe sex. Another study by San Francisco's Stop AIDS Project found that 20 percent of gay and bisexual men in that city have used methamphetamine in the last 6 months. Taken together, these studies are pointing to a growing problem of methamphetamine use leading to HIV infection among men who have sex with men.

e) User Labs Impact Children. User labs found in residential areas create fire, health, and environmental dangers to the people living nearby.

Children living and playing in buildings with methamphetamine labs inhale toxic gas that collects at floor level where adults may not detect its presence. Children also may suffer other exposure risks such as chemical burns or sticks from discarded needles. In 2003, there were 379 documented cases of California children impacted by methamphetamine labs located in their homes and neighborhoods. With thousands of undetected labs in existence, the full impact on kids and nearby residents is unknown.

f) Environmental Concerns. For every one pound of crystal methamphetamine produced, roughly seven pounds of toxic waste is generated. Methamphetamine cookers suffering from symptomatic paranoia often feel an extreme urgency to dispose of all evidence of the lab. Toxic solvents and byproducts are dumped down drains, onto the ground, and into streams, lakes, and rivers. Buckets, coolers, and other contaminated equipment are discarded in any place where lab cooks will not be detected. Methamphetamine lab clean ups are expensive. Contaminated surfaces often cannot be cleaned and must be removed. Toxic solvent byproducts are dumped in drains damage pipes, and when dumped on the ground these solvents contaminate ground water and waterways and can kill aquatic plants and animals. Property owners may bear costs easily exceeding $50,000 per site for everything from carpet and plumbing replacement to contaminated soil removal.

g) AB 283 Locks Up Pseudoephedrine. In January,

Illinois implemented a new law that requires retailers to lock up the tablet form of pseudoephedrine. This law aims to reduce the shoplifting of this product by methamphetamine cookers and to prevent the accidental sale of the product by retailers to those who would use the product for the illegal manufacture of crystal methamphetamine. AB 283 in its amended form would require the training of retail employees who are specially designated to handle pseudoephedrine tablet transactions. Like Illinois law, the purpose is to help retailers understand what products may be purchased by methamphetamine cookers and to help them report suspicious pseudoephedrine purchasers to police.

h) Restrictions to Access Will Limit Methamphetamine Production. Crystal methamphetamine users often develop feelings of paranoia that make simple tasks difficult. In Oklahoma, where a new law locked up pseudoephedrine products and required an I.D. check, law enforcement officials say the greatest deterrent effect in their new law is methamphetamine-induced paranoia; users find it impossible to go to the counter, ask for the pseudoephedrine product, show I.D., and have their identification information recorded. AB 283 will require everyone, including paranoid methamphetamine cookers, to ask a specially trained employee for the product. Irrational fear will deter many of these methamphetamine users from even trying to purchase the product.

i) Pseudoephedrine Tablets Sold on the Internet. Most internet websites require purchasers to give their name, shipping address, and credit card information. Lots of methamphetamine cookers are too paranoid to make that transaction. States with tight controls on pseudoephedrine product sales like Oklahoma and Oregon have seen dramatic reductions in methamphetamine lab busts. Their controls would not be effective if the internet was truly a common source of pseudoephedrine for methamphetamine labs.

j) PSE Tablets Are Instant Methamphetamine. Making methamphetamine from pseudoephedrine tablets is so easy that anyone who can measure is able to manufacture the illegal drug. Pseudoephedrine tablets are literally "instant" methamphetamine; just follow the directions on the internet.

It is true that liquid cold medicines exempted from the lock up provision of this bill can be used to make

crystal methamphetamine. However, it is far more difficult than just measuring a few ingredients.

3. Example of Recent Laws and Regulations of Other States. The Georgia Legislature passed House Bill 216, which requires that all single-entity pseudoephedrine products be placed behind a counter or other barrier so that such products are not accessible by the public but only by a retail store employee or agent. The bill placed a sales restriction on all pseudoephedrine products to three packages (or nine grams), except pediatric products, and it pre-empts local ordinances. Last year the Illinois legislature passed a bill allowing retailers options in reducing consumer access to pseudoephedrine products. The law does the following: (a) limits pseudoephedrine sales to a two-package limit; (b) requires an employee of the retailer to access this product; (c) requires the product to be kept behind the counter or in a locked case; (d) requires purchaser to sign a log and show photo ID; and, (e) requires mandatory employee training. The Oregon Board of Pharmacy recently adopted a "temporary rule" which was modeled after the Oklahoma law except that there is no requirement for the logging of each sale, no specific limitation over a 30-day period and the product is to be kept behind the counter.

4. Briefing Report Conducted by the Bureau of Narcotic Enforcement (BNE) of the DOJ: "Pseudoephedrine OTCs and Methamphetamine Related Issues." According to BNE's briefing report, methamphetamine and the illicit clandestine laboratories that produce it pose significant public health and safety problems in California. The social, economic, and environmental costs of methamphetamine use and production are extremely high. A large percentage of the methamphetamine consumed in the U.S. is produced right here in California. BNE indicates that California law enforcement has worked closely with the Legislature to attempt to regulate many of the chemical precursors used to produce methamphetamine. Currently, however, the most commonly used ingredient is not adequately regulated. Over the past ten years, pseudoephedrine/ ephedrine has become the predominate chemical used in the production of methamphetamine. Over-the-counter pseudoephedrine-containing products are a common component used in household methamphetamine production. Last year, in at least 28% of all lab seizures in California, over-the-counter pseudoephedrine containing products were found and noted to be attributable to methamphetamine production. Although the sale of

pseudoephedrine is restricted to three packages (or nine grams) at any one time, per purchaser, it does not prevent methamphetamine users from "smurfing" the products. The BNE reviewed several states which enacted laws where controls were in place to regulate the sale of over-the-counter pseudoephedrine products and reached the conclusion that these new requirements have dramatically decreased the number of methamphetamine labs in those jurisdictions. The DOJ strongly recommended in its paper that the Legislature enact similar legislation to address the rampant clandestine methamphetamine lab problem in California.

5. "Oppose Unless Amended" Issues.

a) Exemption of gel cap and liquid type pseudoephedrine products.

Pfizer Inc. is opposed to this measure unless it is amended to include these types of pseudoephedrine products. They argue that tests conducted by law enforcement demonstrate conclusively that pseudoephedrine can be extracted from the gel cap and liquid type products by the same, commonly used criminal methods used to convert single ingredient pseudoephedrine products. In fact, they argue that law enforcement agencies have found liquid-filled capsules had some of the highest conversion rates of all products tested, and if these types of products continue to be sold over-the-counter, it is predictable these products will be used by criminals to make methamphetamine.

Pfizer also provided a letter from the Drug Enforcement Administration (DEA) of the U.S. Department of Justice regarding the use of tablets and liquid and gel-cap pseudoephedrine products. According to DEA, although gel-caps and liquids are not yet commonly found in methamphetamine labs, the chemists at DEA have run extractions on liquid and gel-cap pseudoephedrine products and found that the precursor material is readily extractable. Just recently, a lab utilizing liquids and gel-caps was seized in Oregon. While it appears that it is not yet common knowledge among lab operators that you can use these liquid or gel-cap products to make methamphetamine, this is most likely due to the notion that lab operators are creatures of habit. They follow the recipe provided or the advice of other cooks. Most of these recipes refer to tablets so this may explain why they have not seriously sought liquids or gel-caps.

DEA further indicates that their chemical control efforts have been a game of cat and mouse with clandestine lab operators. A succession of federal laws has been necessary to eliminate loopholes in the control scheme. Consequently, whenever the law has exempted a type of product or material, the traffickers have adjusted their manufacturing procedure and attempted to circumvent DEA regulations by opting for the uncontrolled source of precursor material. DEA provides as an example the exemption provided for blister pack tablets of pseudoephedrine from the reporting and recordkeeping requirements of the Controlled Substances Act. Despite warnings from DEA that utilization of blister packs would increase clandestine labs, Congress granted this exemption. Since that time, clandestine laboratory operators have increasingly exploited pseudoephedrine blister packs.

The Author states, that while there is no dispute that liquid pseudoephedrine can be used in the manufacture of meth, officials at the DOJ state that the use of liquid forms is extremely rare today and not likely to increase dramatically, at least in the short term. For one, DOJ officials note that a rise in the use of liquid pseudoephedrine has not taken place in Oklahoma or Oregon, where liquid forms were excluded from pseudoephedrine restriction laws. Second, DOJ officials state that the large volume of liquid pseudoephedrine product needed to make meth renders it unwieldy to meth cooks. The Author maintains that putting strong restrictions on solid and single-ingredient forms of pseudoephedrine and allowing the sale of liquid pseudoephedrine under less restricted conditions, targets the problem at hand while ensuring consumer access to cold medicines. The Author states that If law enforcement finds in the future that the use of liquid pseudoephedrine has risen significantly, the Legislature always has the discretion to further restrict their sales.

b) Exemptions for time-release products.
Schering-Plough, the producer of Claritin, is opposed unless this bill is amended to exempt time-release medications from the locked cabinet and retail clerk requirement, so that these medications could continue to be sold over the counter without any additional controls. Schering-Plough also contends that time-release capsules are not the primary source for making methamphetamine and that the costs of requiring these controls are not justified. At a minimum, Schering-Plough requests that there be a delay in the

implementation of this bill to enable companies to reformulate their products with a substitute for pseudoephedrine. The delay is necessary because the new products would have to go through the entire federal approval system under the Food and Drug Administration.

6. Similar Legislation This Session. SB 152 (Speier) would have required as of June 1, 2006, that a pharmacist and retail distributor, as defined, store pseudoephedrine in a locked area, required the purchaser to provide valid identification prior to purchase, and required staff of the retail distributor to be trained in identification of pseudoephedrine products and in the usage of pseudoephedrine to make methamphetamine. As of January 1, 2008, it also would have required that an electronic system be set up by a pharmacy and retail distributor to track the sale of pseudoephedrine and assure that no more than three packages or no more than 9 grams are sold within a 30-day period to a single purchaser. However, as proposed to be amended by the Author, the requirement for setting up an electronic system to track purchases would have been eliminated. Even with those amendments, SB 152 was defeated in this Committee.

7. Department of Justice (DOJ) is Neutral. DOJ is currently neutral on this bill after suggesting some amendments that have been adopted by the Author. The Department believes that this measure is definitely a step in the right direction to discourage the purchase of ephedrine/pseudoephedrine products for the purposes of manufacturing methamphetamine. However, it may not go far enough to address the entire problem. Future legislation will probably be necessary to completely respond to this situation.

8. Policy Concern. A potential concern has been raised by staff of the Public Safety Committee and DOJ in that the exemption from violation of this act by a retail clerk may be too broad. As previously noted, a retail clerk is exempt from being convicted of a crime, having to pay a civil penalty, or being disciplined or discharged, except if the retail clerk is a willful participant in an ongoing criminal conspiracy to violate the law. This would protect the retail clerk even if he or she knows that the purchaser will use the drug to make methamphetamine. In addition, this bill could effectively lower penalties for conspiracies to manufacture methamphetamine or other illegal acts by making a conspiracy to sell or provide ephedrine or pseudoephedrine in violation of a crime defined by this

bill as a misdemeanor. This bill has also been referred to the Public Safety Committee where this concern will be addressed.

NOTE : Double-referral to Public Safety Committee

SUPPORT AND OPPOSITION:

Support:
American Federation of State, County, and Municipal Employees (AFSCME)
Being Alive South Bay
California Grocers Association
California Retailers Association
California State Sheriff's Association
California STD Controllers Association
Gay and Lesbian Social Services
Gray Panthers
Honorable Henry Waxman, U.S. Representative, 30th District, California
Internet Sexuality Information Services, Inc.
Los Angeles County Sheriff's Department
Pharmacists Planning Service, Inc.
Rite Aid
San Bernardino County, Office of the Sheriff
San Francisco AIDS Foundation
San Francisco City and County
Solano County Board of Supervisors
Stop AIDS Project
Transgender Law Center

Neutral:
Department of Justice (DOJ)

Opposition:
Pfizer Inc (Oppose unless amended)
Schering-Plough (Oppose unless amended)

Consultant:George Cate

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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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 152 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: SPEIER **SPONSOR: SPEIER**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PSEUDOEPHEDRINE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Deletes B&P 405.1 provisions of the previous versions of the bill and replaces them with new H&S 11100.02 provisions.

2) Adds H&S 11100.02 Section 1 and states Section 1 will become operative on June 1, 2006, and will remain in effect only until January 1, 2008; Section 2 would become operative January 1, 2008.

Section 1

a. Requires a pharmacist and a retail distributor to store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine [product] in a locked area.

b. Prohibits a pharmacy and a retail distributor from selling a product 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. Requires staff members of a retail distributor to receive training in the following areas before they are permitted to sell product:

   i. Identification of pseudoephedrine products.

   ii. Usage of pseudoephedrine in manufacturing methamphetamine.

d. Makes a first violation of the provisions of the bill a misdemeanor and subsequent violations punishable by imprisonment in a county jail not exceeding one year, a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

e. Exempts the following products from the provisions of the bill: 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; a pediatric liquid.

3) Adds H&S 11100.02 Section 2 and states Section 2 shall become operative on January 1, 2008.

4) Repeats the requirements in Section 1 and adds the following requirements:

a. Requires a pharmacist and a retail distributor, to record the following information prior selling a product:

i. The date of purchase.

ii. The name and address of the purchaser.

iii. The number of the identification presented by the purchaser.

iv. The name and amount of the product that is purchased.

b. Requires a pharmacy and retail distributor to maintain the record for at least three years from the product's date of purchase in an electronic format approved by the AG.

c. Restricts the sale of product to no more than three packages or more than nine grams of the product within any 30-day period to a single purchaser.

d. Requires a pharmacist and a retail distributor to develop a system that notifies the pharmacist or retail distributor when a purchaser's limit has been reached.

(H&S 11100.02 Added)

Comment:

1) Author's Intent. The author is seeking to limit the supply of pseudoephedrine available for illegal methamphetamine (meth) production, while making the product reasonably accessible for legitimate use.

2) Enforcement. The April 18th version of the bill takes the provisions of the bill out of the Pharmacy Law and places them in the H&S Code. Consequently, the board would not be responsible for enforcing the measure.

3) Retail Chains' Voluntary Efforts. In an effort to combat illegal methamphetamine production, the following major drug retailers have voluntarily agreed to move all single ingredient pseudoephedrine products behind the pharmacy counter: Albertsons, CVS, Longs Drugs, Kmart, Rite Aid, Shopko, Target, Walgreens, and Wal-mart. Additionally, the National Association of Chain Drug Stores, which represents more than 36,000 pharmacies, supports federal legislation (S 103) to reduce access to pseudoephedrine products, including requiring the sale of pseudoephedrine products behind the pharmacy counter by a licensed pharmacist or pharmacy personnel.

4) State Legislation. AB 283 (Koretz), Pseudoephedrine: retail sale, is similar to SB 152 in its attempt to restrict the sale of pseudoephedrine for illegal uses. AB 283 would limit access to ephedrine and pseudoephedrine products by requiring 1) the products to be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the DOJ. AB 283 would place these provisions in H&S 11100.01.

AB 283 failed passage when it was heard in the Senate Business, Professions and Economic Development Committee on June 27, 2005; the measure has been granted reconsideration.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

5) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

6) History.

2005

May 2	Reconsideration granted.
Apr. 25	Set, final hearing. Failed passage in committee. (Ayes 3. Noes 3. Page 768.)
Apr. 18	From committee with author's amendments. Read second time.Amended. Re-referred to committee.
Apr. 11	Set, second hearing. Hearing canceled at the request of author. Set for hearing April 25.
Apr. 4	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 18.
Mar. 23	Set for hearing April 11.
Feb. 24	To Com. on B., P. & E.D.
Feb. 8	From print. May be acted upon on or after March 10.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 152

As Amended: April 18, 2005

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Liz Figueroa, Chair
Fiscal: Yes

SUBJECT: Pseudoephedrine.

SUMMARY: As of June 1, 2006, requires a pharmacist and retail distributor, as defined, to store pseudoephedrine in a locked area, requires the purchaser to provide valid identification prior to purchase, and requires staff of the retail distributor to be trained in identification of pseudoephedrine products and in the usage of pseudoephedrine to make methamphetamine. As of January 1, 2008, also requires that an electronic system be set up by a pharmacy and retail distributor to track the sale of pseudoephedrine and assure that no more than three packages or no more than 9 grams are sold within a 30-day period to a single purchaser.

Existing law, the Pharmacy Act provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy (Board) and provides that it shall be unprofessional conduct for a pharmacist to violate any provisions of the law governing pharmacy.

Existing law, the Uniform Controlled Substances Act:

1)Defines "retail distributor" as a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of pseudoephedrine products, are limited exclusively to the sale of pseudoephedrine products for personal use both in the number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

2)Requires retailer distributors and pharmacists that sell, transfer, or otherwise furnish pseudoephedrine to any person or entity in this state to submit a report of all those transactions to the Department of Justice (DOJ), as specified.

3)Exempts retailer distributors and pharmacists from reporting to DOJ, if pseudoephdrine is lawfully sold,

transferred, or furnished over-the-counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act, and as long as the individual transaction does not involve more than three packages or nine grams of pseudoephdrine.

4)Makes it a misdemeanor for any retail distributor to sell in a single transaction more that three packages of a product that he or she knows to contain pseudoephdrine, or knowingly sell more than nine grams of pseudoephdrine, other than pediatric liquids as defined, and provides that a retail distributor may be imprisoned for no more than one year or be fined up to ten thousand dollars ($10,000) for a subsequent violation.

5)Defines "pediatric liquids" as a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure and provides that in no instance should the dosage units exceed 15 milligrams of pseudoephedrine per five millimeters of liquid product, unless for children under two years of age when the dosage unit should not exceed two milliliters nor one fluid ounce for total package content.

6)Makes it a felony for any person who, with intent to manufacture methamphetamine, possesses pseudoephedrine.

7)Requires the DOJ to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances, and for those practitioners to provide information to DOJ, as specified.

8)Requires CURES to operate under existing provisions of law to safeguard the privacy and confidentiality of patients and requires that data obtained from CURES only be provided to appropriate state, local and federal persons as specified and not to be disclosed, sold, or transferred to any third party.

9)Provides that DOJ may release to a licensed health care practitioner or a pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, but that the information released shall be considered as medical information subject to provisions of the state's Confidentiality of Medical Information Act.

Existing law, the Stop Tobacco Access to Kids Enforcement Act:

1)Prohibits a retailer of tobacco products from selling, offering for sale, or displaying for sale, any tobacco product or tobacco paraphernalia by self-service display.

2)Defines "self-service display" as an open display of tobacco products or tobacco paraphernalia in a manner that is accessible to the general public without the assistance of the retailer or employee of the retailer.

3)Subjects a retailer to civil penalties as specified for selling tobacco products or paraphernalia by self-service display.

This bill, effective June 1, 2006:

1)Requires a pharmacist and a retail distributor to store products containing any amount of pseudoephedrine or salts, isomers, or salts of isomers of pseudoephedrine (pseudoephedrine) in a locked area.

2)Exempts pseudoephedrine type products that are a compound, mixture, or preparation of pseudoephedrine in a liquid, liquid capsule, or gel capsule form when pseudoephedrine is not the only active ingredient, and exempts pediatric liquid as defined.

3)Defines "gel capsule" as any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerin, polyethylene glycol, propylene glycol, and other liquid substances, and regardless of the product manufacturer's labeling, specifies that a gelatin covered solid is not a gel capsule.

4)Requires a purchaser or pseudoephedrine to present a valid, current identification that contains a photo that was issued by a governmental agency.

5)Specifies that no staff member of a retail distributor may sell pseudoephedrine unless the staff member has received training in both the identification of pseudoephedrine products and usage of pseudoephedrine in the manufacturing of methamphetamine.

6)Provides that a violation of the provisions of this bill is a misdemeanor, and provides that a retail distributor or pharmacist may be imprisoned for no more than one year or be fined up to ten thousand dollars ($10,000) for a subsequent violation.

This bill, in addition to above provisions effective June 1, 2006, would require the following after January 1, 2008:

1)Requires a pharmacist or retail distributor, before selling pseudoephedrine, to record the date of purchase, the name and address of the purchaser, the number of the identification presented, and the name and amount of the product purchased.

2)Requires a pharmacist or retail distributor to maintain the above information for at least three years from the product's date of purchase in an electronic format approved by the Office of the Attorney General (AG).

3)Prohibits a pharmacist or retail distributor from selling more than three packages or more than nine grams of pseudoephedrine within any 30-day period to a single purchaser.

4)Requires the pharmacist and a retail distributor to develop a system that notifies the pharmacist or retail distributor that the above limitation has been reached.

FISCAL EFFECT: Unknown. This bill is keyed "fiscal" by

COMMENTS:

1. Purpose and Need for the Measure. The Author is the sponsor of this measure. According to the Author, methamphetamine (meth) is one of the most addictive and damaging drugs on the street today, and according to the federal Drug Enforcement Agency, it is the "primary drug threat in California." The meth problem in this state is two-fold in that California is known for large-scale production and exportation to other states, but also wrestles with the consequences of small laboratory operations that supply meth users locally.

The Author explains that pseudoephedrine, a chemical cousin of ephedrine used in nasal decongestants such as Sudafed and Claritin-D, can be used as the main ingredient in methamphetamine. Though state law already limits the supply of methamphetamine to 3 packages or 9 grams per transaction (about 360 pills) in recognition of its potential for abuse, "smurfing operations," in which criminals return to one or more stores multiple times to buy packages of pseudoephedrine pills, effectively skirt the restrictions.

As stated by the state Bureau of Narcotics Enforcement

(BNE), "Lab operators acting alone, with co-conspirators, or with groups of up to five or six people will go to different checkout registers in a store with their three packages, then leave the store (to go to another store of the same chain or a different store), or simply take the pills to their vehicle and return back inside to purchase three more packages. Some have stolen extra packages while only paying for a few. This behavior is known as smurfing."

California is known as the "source country" of the nation's methamphetamine problem, the Author states. It is estimated that 80% of the meth supply in the U.S. comes from this state. The majority of this supply comes from "super labs" producing more than 10 pounds of meth per batch and relying on large quantities of precursor chemicals such as pseudoephedrine. According to conversations the Author's staff has had with law enforcement in the DOJ and elsewhere, super lab operators usually import their precursor chemicals from other countries, primarily Canada.

Smaller operations, sometimes known as "tweaker labs," make enough meth for local sale and use Many of these labs rely on supplies of precursors from over-the-counter medications. The DOJ reports that over-the-counter products were found at almost one third of all labs seized in the state last year. This bill, because it would restrict the supply of over-the-counter pseudoephedrine to illicit users, would primarily target these smaller labs.

According to the Author, small meth labs have a big negative impact on the health and safety of Californians - both adults and children. Aside from the damage these small labs do by increasing the supply of meth, the labs themselves are highly dangerous. It is reported that 15% of meth labs are discovered when they burst into flame or explode. In 2003, 344 meth labs had children present, where they were exposed to harmful chemicals, infection through needles, injury or death from explosions, and general neglect and abuse. Labs alone cost the state millions of dollars per year. The Department of Toxic Substances Control spent upwards of $2 million last year simply to remove the immediate evidence, chemicals, apparatus, and limited site contamination. According to the DOJ, although the number of laboratory seizures has declined over the past few years, the number of operating clandestine labs has not actually declined. The BNE attributes the decline in seized labs to a drop in staffing and budget since 2001. For example, the program in the BNE that handles

lab seizures has reportedly lost 60% of its personnel.

As argued by the Author, this bill would put a choke hold on small clandestine meth labs in California. It is based on an Oklahoma law (HB 2176) that was signed April 6, 2004 and went into full effect June 6, 2004. Figures provided by Oklahoma's Bureau of Narcotics show that in 2003, before the law passed, the meth lab seizure rate was 103 per month. After April 2004, when the law passed, Oklahoma averaged only 52 per month, putting the state on pace for a total drop of 609 lab seizures. Officials in the Oklahoma Bureau of Narcotics state that their lab seizure resources have not diminished, so the decline in labs seized cannot be explained by a staffing reduction as it can in California. (It should be noted that the Oklahoma law only allows pseudoephedrine products to be sold by a pharmacist.)

Officials in the Oklahoma Bureau of Narcotics and in the Oklahoma Pharmacists Association confirm that the impact of the new law on consumers' access to OTC cold medicines and on pharmacists' workload has been minimal. Indeed, the Author indicates that polling of consumers in another state that recently passed restrictions on pseudoephedrine sales, Iowa, confirm that the general public supports such an approach. The University of Northern Iowa surveyed consumers in that state and found that:

76% said having to ask a pharmacist or clerk for pseudoephedrine products would be of little or no inconvenience to them. 79% strongly or moderately support the idea.

82% said having to show a photo-ID for such products would be of little or no inconvenience to them. 79% strongly or moderately support the idea.

The Author points out that measures like this bill have been introduced in Legislatures throughout the nation. On the federal level, Senator Feinstein has introduced S. 103, the Combat Meth Act of 2005, which also closely tracks this bill.

1. Example of Recent Laws and Regulations of Other States. Although this bill is modeled after the Oklahoma law, there are two other states which recently enacted laws to deal with the sale of pseudoephedrine. The Georgia Legislature passed House Bill 216, which requires that all single-entity pseudoephedrine products be placed behind a counter or other barrier so that such products

are not accessible by the public but only by a retail store employee or agent. The bill placed a sales restriction on all pseudoephedrine products to three packages (or nine grams), except pediatric products, and it pre-empts local ordinances. Last year the Illinois legislature passed a bill allowing retailers options in reducing consumer access to pseudoephedrine products. The law does the following: (a) limits pseudoephedrine sales to two-package limit; (b) requires an employee of the retailer to access this product; (c) requires the product to be kept behind the counter or in a locked case; (d) requires purchaser to sign a log and show photo ID; and, (e) requires mandatory employee training. The Oregon Board of Pharmacy recently adopted a "temporary rule" which was modeled after the Oklahoma law except that there is no requirement for the logging of each sale, no specific limitation over a 30-day period and the product is to be kept behind the counter.

2. Briefing Report Conducted by the Bureau of Narcotic Enforcement (BNE) of the DOJ: "Pseudoephedrine OTCs and Methamphetamine Related Issues." According to BNE's briefing report, meth and the illicit clandestine laboratories that produce it pose significant public health and safety problems in California. The social, economic, and environmental costs of meth use and production are extremely high. A large percentage of the meth consumed in the U.S. is produced right here in California. BNE indicates that California law enforcement has worked closely with the Legislature to attempt to regulate many of the chemical precursors used to produce meth. Currently, however, the most commonly used ingredient is not adequately regulated. Over the past ten years, pseudoephedrine/ ephedrine has become the predominate chemical used in the production of meth. Over-the-counter pseudoephedrine-containing products are a common component used in household meth production. Last year, in at least 28% of all lab seizures in California, over-the-counter pseudoephedrine containing products were found and noted to be attributable to meth production. Although the sale of pseudoephedrine is restricted to three packages (or nine grams) at any one time, per purchaser, it does not prevent meth users from "smurfing" the products. The BNE reviewed several states which enacted laws where controls were in place to regulate the sale of over-the-counter pseudoephedrine products and reached the conclusion that these new requirements have dramatically decreased the number of meth labs in those jurisdictions. The DOJ strongly recommended in its

paper that the Legislature enact similar legislation to address the rampant clandestine meth lab problem in California.

3. "Oppose Unless Amended" Issues and Recent Amendments to Attempt to Address Some of These Concerns.

a) Keeping pseudoephedrine products in a locked area rather than behind a pharmacy counter. The California Retailers Association (CRA), the National Association of Drug Stores (NADS), Rite Aid , and the California Pharmacist Association were opposed to the initial requirement in the bill that pseudoephedrine products be kept behind the pharmacy counter. The Author amended the bill recently to address these concerns and now requires that pseudoephedrine be kept in a locked area only. As initially argued by CRA and others, most pharmacies are not open 24 hours and the need for pseudoephedrine type medications present themselves any time of day. Also, many people in need of this product may go to stores which do not have pharmacies, and finally there is a severe shortage of pharmacists and pharmacy technicians to do the work of compounding, dispensing, and counseling patients regarding prescription drugs. To add the dispensing of pseudoephedrine products to the list of the required activities for pharmacists and pharmacy technicians would further burden the workload on them.

b) Employee training regarding the sale of pseudoephedrine. CRA and others agreed with the requirement for employee training if pseudoephedrine products were to be kept in a locked area. The retailers indicated they will train employees who will be retrieving pseudoephedrine products from a locked area regarding methamphetamine abuse and precursor diversion and believe this training will allow employees to be alert to suspicious behavior and will serve as a deterrent to those who would use pseudoephedrine products for illegal purposes.

c) Electronic system to track the sale of pseudoephedrine within a
30-day period. CRA and others agreed that they would offer the cooperation of their Information Technology departments to work with the DOJ in developing a real-time electronic data collection system for the sale of pseudoephedrine products at point of sale. However, since such an electronic data collection system does not currently exist, CRA proposed that

this requirement be phased in, allowing time for the system to be established. They indicate that such electronic data collection will be forwarded to the appropriate law enforcement agency, allowing law enforcement to monitor pseudoephedrine purchases.

The Author's recent amendments provides for this phased in approach. The requirement for establishing an electronic system does not become effective until July 1, 2008. However, there is still concern by the retailers and others about attempting to track the sale of pseudoephedrine within the 30-day period and how they can assure that the pharmacist or retail person is always able to track when a customer may exceed the purchase of three packages or more than nine grams within a 30-day period.

d) Exemption of gel cap and liquid type pseudoephedrine products.

Pfizer Inc. is opposed to this measure unless it is amended to include these types of pseudoephedrine products. They argue that tests conducted by law enforcement demonstrate conclusively that pseudoephedrine can be extracted from the gel cap and liquid type products by the same, commonly used criminal methods used to convert single ingredient pseudoephedrine products. In fact, they argue that law enforcement agencies have found liquid-filled capsules had some of the highest conversion rates of all products tested, and if these types of products continue to be sold over-the-counter, it is predictable these products will be used by criminals to make methamphetamine.

Pfizer also provided a letter from the Drug Enforcement Administration (DEA) of the U.S. Department of Justice regarding the use of tablets and liquid and gel-cap pseudoephedrine products. According to DEA, although gel-caps and liquids are not yet commonly found in methamphetamine labs, the chemists at DEA have run extractions on liquid and gel-cap pseudoephedrine products and found that the precursor material is readily extractable. Just recently, a lab utilizing liquids and gel-caps was seized in Oregon. While it appears that it is not yet common knowledge among lab operators that you can use these liquid or gel-cap products to make methamphetamine, this is most likely due to the notion that lab operators are creatures of habit. They follow the recipe provided or the advice of other cooks. Most of these recipes refer to tablets so this may explain why they have not

seriously sought liquids or gel-caps.

DEA further indicates that their chemical control efforts have been a game of cat and mouse with clandestine lab operators. A succession of federal laws has been necessary to eliminate loopholes in the control scheme. Consequently, whenever the law has exempted a type of product or material, the traffickers have adjusted their manufacturing procedure and attempted to circumvent DEA regulations by opting for the uncontrolled source of precursor material. DEA provides as an example the exemption provided for blister pack tablets of pseudoephedrine from the reporting and recordkeeping requirements of the Controlled Substances Act. Despite warnings from DEA that utilization of blister packs would increase clandestine labs, Congress granted this exemption. Since that time, clandestine laboratory operators have increasingly exploited pseudoephedrine blister packs.

The Author states that while there is no dispute that liquid pseudoephedrine can be used in the manufacture of meth, officials at the DOJ state that the use of liquid forms is extremely rare today and not likely to increase dramatically, at least in the short term. For one, DOJ officials note that a rise in the use of liquid pseudoephedrine has not taken place in Oklahoma or Oregon, where liquid forms were excluded from pseudoephedrine restriction laws. Second, DOJ officials state that the large volume of liquid pseudoephedrine product needed to make meth renders it unwieldy to meth cooks. The Author maintains that putting strong restrictions on solid and single-ingredient forms of pseudoephedrine and allowing the sale of liquid pseudoephedrine under less restricted conditions, targets the problem at hand while ensuring consumer access to cold medicines. The Author states that If law enforcement finds in the future that the use of liquid pseudoephedrine has risen significantly, the Legislature always has the discretion to further restrict their sales.

4. Attorney General's Office (AG) is in Support if Amended. The AG had originally expressed several concerns with the bill but after recent amendments has only one concern which they would like addressed. They indicate that the measure does not address over-the-counter compounds that possess alternative compounds similar to the pharmaceutical affect to pseudoephedrine. The following compounds could also be used to manufacture methamphetamine: ephedrine, norpseudoephedrine,

N-methylephedrine, ethylephedrine, N-methylpseudoephedrine,

N-ethylpseudoephedrine, phenylpropanolamine, chloroephedrine, chloropseudoephedrine, or their salts, optical isomers, or salts of optical isomers. The Attorney General believes that these other compounds should also be addressed by this measure, especially any ephedrine type products.

5. Arguments in Opposition. Although the California Grocers Association (CGA) has registered opposition to this measure with the Committee, some of the recent amendments may address some of their concerns. They had indicated opposition to requiring that single-ingredient pseudoephedrine products be sold only via a pharmacy and argued that this would place retailers who did not have an in-store pharmacy at a competitive disadvantage with those that do, and it would place consumers at a disadvantage for they would need to search for a pharmacy or find one that fits their hours of shopping. They did however support the product being locked-up behind the counter and only available through a sales-assistant, much like they have for tobacco products. The CGA also objected to having to "log" the sale of single-ingredient products and argued that the technology is not readily available to place all these purchases onto a single database and that it would be a logistical nightmare to administer. They also argued that logs would contain private customer information and should not be available to law enforcement unless they have a valid subpoena. They recommended that a more reasonable approach is to require all retailers that sell these products to register or obtain a license with the State Board of Pharmacy and provide aggregate sales and volume data to the Board for tracking and inspection.

6. Similar Legislation This Session. AB 283 (Koretz) is similar to this bill. This bill: (a) Provides that the dispensing, sale, or distribution at retail of any compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine or any derivative of ephedrine or pseudoephedrine shall be stored or displayed by a retailer in a locked cabinet or locked area in such a manner that the product is accessible to the public only with the assistance of the retailer or employee of the retailer, and the retailer or employee shall at all times act to prevent the theft or diversion of the product. (b) Requires that only an employee of a retailer trained in the legal requirements set forth shall be able to sell the specified products

and shall at all times act to prevent the unlawful sharing of information that is collected to identify the purchaser and the name and amount of product purchased. This information collected shall only be provided to state, local, or federal persons or a public agency with respect to a disciplinary, civil, or criminal action related to a violation as specified or to the unlawful manufacture of meth or any other controlled substance. (c) Exempts products as specified that are in liquid, liquid capsule or dissolvable strip form. (d) Provides that the DOJ may adopt rules and regulations to exempt certain products as specified if it finds that the substance is not used in the unlawful manufacture of meth or any other controlled substance.

(e) Provides for the same penalties as in SB 152, but provides that a retail clerk who fails to obtain the information as specified shall not be subject to any disciplinary action or discharge by his or her employer.

AB 283 was heard in the Assembly Public Safety Committee on April 19, 2005 and failed passage.

7. Policy Concern: Consumer Medical Privacy. The bill requires that a pharmacist and a retail distributor shall record specified information regarding the purchaser and the name and amount of the product described in an electronic format that is approved by the Attorney General, and that they shall develop a system that notifies the pharmacist or retail distributor that the amount of three packages (or more than 9 grams) within a 30-day period has been exceeded. This information shall be maintained for at least three years.

AB 283 (Koretz) provides at least in part for certain protections regarding information collected regarding the purchaser of the product (see above). Currently, under the CURES program used for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances, it requires CURES to operate under existing provisions of law to safeguard the privacy and confidentiality of patients and requires that data obtained from CURES only be provided to appropriate state, local and federal persons as specified and not to be disclosed, sold, or transferred to any third party. It also provides that DOJ may release to a licensed health care practitioner or a pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, but that that information release shall be considered as medical information

and shall at all times act to prevent the unlawful sharing of information that is collected to identify the purchaser and the name and amount of product purchased. This information collected shall only be provided to state, local, or federal persons or a public agency with respect to a disciplinary, civil, or criminal action related to a violation as specified or to the unlawful manufacture of meth or any other controlled substance. (c) Exempts products as specified that are in liquid, liquid capsule or dissolvable strip form. (d) Provides that the DOJ may adopt rules and regulations to exempt certain products as specified if it finds that the substance is not used in the unlawful manufacture of meth or any other controlled substance.

(e) Provides for the same penalties as in SB 152, but provides that a retail clerk who fails to obtain the information as specified shall not be subject to any disciplinary action or discharge by his or her employer.

AB 283 was heard in the Assembly Public Safety Committee on April 19, 2005 and failed passage.

7. Policy Concern: Consumer Medical Privacy. The bill requires that a pharmacist and a retail distributor shall record specified information regarding the purchaser and the name and amount of the product described in an electronic format that is approved by the Attorney General, and that they shall develop a system that notifies the pharmacist or retail distributor that the amount of three packages (or more than 9 grams) within a 30-day period has been exceeded. This information shall be maintained for at least three years.

AB 283 (Koretz) provides at least in part for certain protections regarding information collected regarding the purchaser of the product (see above). Currently, under the CURES program used for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances, it requires CURES to operate under existing provisions of law to safeguard the privacy and confidentiality of patients and requires that data obtained from CURES only be provided to appropriate state, local and federal persons as specified and not to be disclosed, sold, or transferred to any third party. It also provides that DOJ may release to a licensed health care practitioner or a pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, but that that information release shall be considered as medical information

subject to provisions of the state's Confidentiality of Medical Information Act.

The issue of consumer medical privacy was also brought up in the Assembly Public Safety Committee analysis for AB 283, dated April 13, 2005. The analysis raised concerns that by requiring the retailers to collect personal medication information and then report that information to DOJ without restricting DOJ's ability to use this information might mandate an unwarranted disclosure of a constitutionally protected privacy interest to law enforcement authorities. AB 283, as argued in the analysis, potentially provides the DOJ greater access to information on people who purchase pseudoephedrine products than prescription Schedule II and III controlled substances, even though the Legislature has determined that Schedule II and III controlled substances are subject to greater abuse. Medications that contain pseudoephedrine are common products that people use every day for legitimate purposes; should government breach a person's privacy to monitor these consumers?

The Committee may want to consider if consumers, who will have to provide personal identification information as well as the type and the amount of product they purchase by January 1, 2008, should receive privacy protections similar to those provided under the CURES program if it is the intent of the Author to have this information shared with DOJ.

SUPPORT AND OPPOSITION:

Support:
Gray Panthers
Pharmacists Planning Service, Inc.
Los Angeles County Police Chiefs' Association
CA State Sheriffs' Association

Support if Amended:
Attorney General's Office, Department of Justice
Oppose Unless Amended:
California Retailers Association
National Association of Chain Drug Stores
Pfizer Inc.
Rite Aid

Opposition:
California Grocers Association

Consultant:Bill Gage

Attachment 7

AMENDED IN ASSEMBLY MARCH 30, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 446

Introduced by Assembly Member Negrete McLeod
(Principal coauthor: Senator Figueroa)

February 15, 2005

~~An act to amend Section 922 of the Business and Professions Code, relating to medicine.~~ *An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.*

LEGISLATIVE COUNSEL'S DIGEST

AB 446, as amended, Negrete McLeod. ~~Physicians and surgeons~~*Licensees: settlement agreements.*

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct is not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity acting on behalf of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program.

~~Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons. Under existing law, a physician and surgeon whose license has been expired for less than 5 years may be licensed under the Health Care Professional Disaster Response Act if he or she meets specified requirements.~~

~~This bill would also require that the licensee practiced medicine or podiatry for 20 or more years in this state, has reached retirement age under the Social Security Act, and customarily provides free services.~~

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

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

1 ~~SECTION 1. Section 922 of the Business and Professions~~
2 ~~Code is amended to read:~~
3 *SECTION 1. Section 143.5 is added to the Business and*
4 *Professions Code, to read:*
5 *143.5. (a) No licensee who is regulated by a board, bureau,*
6 *or program within the Department of Consumer Affairs, nor an*
7 *entity acting on behalf of a licensee, shall include or permit to be*
8 *included a provision in an agreement to settle a civil dispute,*
9 *whether the agreement is made before or after the*
10 *commencement of a civil action, that prohibits the other party in*
11 *that dispute from contacting, filing a complaint with, or*
12 *cooperating with the department, board, bureau, or program or*
13 *that requires the other party to withdraw a complaint from the*
14 *department, board, bureau, or program. A provision of that*
15 *nature is void as against public policy, and any licensee who*
16 *includes or permits to be included a provision of that nature in a*
17 *settlement agreement is subject to disciplinary action by the*
18 *board, bureau, or program.*
19 *(b) As used in this section, "board" shall have the same*
20 *meaning as defined in Section 22, and "licensee" means a*
21 *person that has been granted a license, as that term is defined in*
22 *Section 23.7.*
23 ~~922. (a) A physician and surgeon who satisfies the~~
24 ~~requirements of subdivision (d) but whose license has been~~
25 ~~expired for less than five years may be licensed under this~~
26 ~~chapter.~~

~~(b) To be licensed under this chapter, a physician and surgeon shall complete an application, on a form prescribed by the Medical Board of California, and submit it to the board, along with the following:~~

~~(1) Documentation that the applicant has completed the continuing education requirements described in Article 10 (commencing with Section 2190) of Chapter 5 for each renewal period during which the applicant was not licensed.~~

~~(2) A complete set of fingerprints as required by Sections 144 and 2082, together with the fee required for processing those fingerprints.~~

~~(c) An applicant shall not be required to pay any licensing, delinquency, or penalty fees for the issuance of a license under this chapter.~~

~~(d) A licensee who has practiced medicine or podiatry for 20 years or more in this state, has reached the age of retirement under the Social Security Act, and customarily provides his or her services free of charge to any person, organization, or agency may be licensed under subdivision (a). If charges are made, the charges shall be nominal, and the aggregate of the charges in any single calendar year shall not be in an amount that would make the licensee ineligible for full social security benefits.~~

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 446 **VERSION: AMENDED MARCH 30, 2005**

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

RECOMMENDED POSITION: SUPPORT

SUBJECT: LICENSEES: SETTLEMENT AGREEMENTS (GAG CLAUSES)

Existing Law:

Permits the board to take enforcement action against a licensee for unprofessional conduct or other violations of the Pharmacy Law.

This Bill:

1) Prohibits a licensee of a board, bureau or program within the Department of Consumer Affairs (DCA) or an entity acting on behalf of a licensee from including a provision in a civil settlement that prohibits the other party from contacting, filing a complaint with, or cooperating with the DCA, or a board, bureau, or program. (B&P 143.5 Added)

2) Prohibits a licensee of a board, bureau, or program within the DCA from including a provision in a settlement for a civil action that requires the other party to withdraw a complaint from the DCA, or a board, bureau, or program. (B&P 143.5 Added)

3) Declares that such provisions (i.e., "gag clauses") to be void as against public policy. (B&P 143.5 Added)

4) Specifies that a licensee who includes or permits a "gag clause" to be included in a settlement agreement is subject to disciplinary action by a board, bureau, or program. (B&P 143.5 Added)

Comment:

1) Author's Intent. According to the author, current law allows licensees to use regulatory gag clauses to keep their misconduct secret and avoid appropriate oversight to the detriment of the public. The full extent to which gag clauses are used by DCA licensees is unknown because they are, by definition, secret.

2) Gag Clauses. This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator. Such an agreement is known as a regulatory "gag clause." A regulatory gag clause requires a plaintiff to agree, as a condition of a malpractice or misconduct settlement with the licensee, to the inclusion of a provision prohibiting the plaintiff from contacting or cooperating with the defendant's regulator (or requiring the plaintiff to withdraw a pending complaint before that regulator.)

As an example, under current law, a physician who settles a malpractice complaint with an injured patient might require, as a condition of receiving the settlement payment, that the consumer not report the malpractice to the Medical Board of California (MBC) or otherwise speak regarding the case, even if the patient is contacted by DCA investigators or private attorneys who are looking into separate complaints against the physician.

3) Attorneys. This bill is modeled on an existing statute that prohibits attorneys from including such clauses in legal malpractice settlements, and is in line with a number of court decisions that describe a compelling public interest in voiding regulatory gag clauses so that the regulator can best protect the public from harm.

4) Previous Legislation. AB 644 is a copy of AB 320 (Correa 2003), which was enrolled and later vetoed by Governor Schwarzenegger. In his veto message the Governor states "under this bill a party who agrees to a civil settlement, could still file a complaint with a regulatory agency subjecting the licensee to double jeopardy. Even after the resolution of a civil suit, this bill could still require a licensee to a second adjudication before a regulatory body."

The board supported AB 320.

5) History.

2005

June 15	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 5. Noes 2.).
May 26	Withdrawn from committee. Re-referred to Com. on JUD.
May 19	Referred to Coms. on B., P. & E.D. and JUD.
May 5	In Senate. Read first time. To Com. on RLS. for assignment.
May 5	Read third time, passed, and to Senate. (Ayes 42. Noes 27. Page 1401.)
May 2	Read second time. To third reading.
Apr. 28	From committee: Do pass. (Ayes 13. Noes 5.) (April 27).
Apr. 20	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 0.) (April 19).
Mar. 31	Re-referred to Com. on B. & P.
Mar. 30	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Feb. 24	Referred to Com. on B. & P.
Feb. 16	From printer. May be heard in committee March 18.
Feb. 15	Read first time. To print.

7) Support and Opposition (for AB 320, 2003)

Support:

State Attorney General's Office
California Architects Board
California Medical Board
California Board of Accountancy
California Board of Optometry
California Board for Professional Engineers and Land Surveyors
Ca. State Board of Pharmacy
Dental Board of California
Board of Vocational Nursing and Psychiatric Technicians
AARP California
American Inst. of Architects Ca. Council
Center for Public Interest Law, University of San Diego Law School
CalPIRG
Citizens Commission on Human Rights
Congress of California Seniors
Consumer Attorneys of California
Consumers for Auto Reliability and Safety
Consumer Federation of California
Consumers Union
The Fund for Animals

Opposition:

Associated General Contractors of California (AGC)

California Building Industry Association (CBIA)
California Business Properties Association
Consulting Engineers and Land Surveyors of California (CELSOC)
Engineering Contractors' Association
California Fence Contractors' Association
Marin Builders' Exchange
California Chapter of the American Fence Contractors' Association

AB 446

As Amended March 30, 2005

SENATE JUDICIARY COMMITTEE

Senator Joseph L. Dunn, Chair
2005-2006 Regular Session

SUBJECT

Licensees: Ban on Regulatory "Gag Clauses" in Settlement Agreements

DESCRIPTION

This bill, which is virtually identical to AB 320 (Correa of 2004), would prohibit any licensee overseen by a board, bureau, or program within the Department of Consumer Affairs (DCA), or any entity acting on behalf of a licensee, from including in a civil settlement agreement any "gag clause" provision that prohibits the other party from contacting, filing a complaint with, pursuing a filed complaint, or cooperating with the regulatory body. This bill would deem a gag clause of that nature to be void as against public policy and would subject to disciplinary action any licensee who included or permitted that gag clause in a settlement agreement.

BACKGROUND

The DCA regulates numerous businesses, professions, and trades through its 40 boards, bureaus, programs, committees, and commissions. These entities are generally responsible for licensing, setting professional or trade standards, and enforcing those standards through disciplinary programs that investigate complaints of licensee misconduct, and, in appropriate cases, suspend, revoke, or restrict a licensee's privileges to protect the public. For example, the Medical Board is responsible for receiving and investigating complaints about physicians'

malpractice, the Contractors State Licensing Board oversees the licensing and discipline of the many classes of contractors in California, and the California Architects

Board regulates and oversees architects.

According to the Center for Public Interest Law (CPIL), based upon their 25 years of experience in observing the behavior of DCA licensing entities and their licensees, a "growing pervasive practice" is the use of gag clauses in settlement agreements that resolve a disgruntled consumer's civil action for damages against a negligent licensee. These gag clauses typically prevent the consumer from pursuing or maintaining a complaint with a DCA regulatory body. These clauses also typically prohibit a consumer from contacting or cooperating with a regulatory investigation. This bill, as was AB 320, is intended to prohibit such practices in future.

CHANGES TO EXISTING LAW

Existing law makes it a disciplinary offense for an attorney to agree or seek agreement to a gag clause that bars the reporting of professional misconduct or the terms settling a claim for professional misconduct to the professional's disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency, or to agree or seek agreement that the record of any civil action for professional misconduct shall be sealed from review by the disciplinary agency. This section applies to an attorney who is a party or who is acting as an attorney for a party. [Business and Professions Code Section 6090.5.]

Existing law provides for the licensing and regulation of various professions by various boards, bureaus, and programs under the DCA.

Existing law states that the highest priority for licensing boards, commissions, and bureaus, in performing their licensing, regulatory, and disciplinary functions, is the protection of the public.

This bill would prohibit any licensee overseen by a board, bureau, or program within the DCA, or entity acting on behalf of a licensee, from including in any agreement settling a civil action any "gag clause" provision that prohibits the other party from contacting, filing a complaint with, pursing a filed complaint, or cooperating

with the regulatory body. This provision would apply regardless of whether the agreement is made before or after commencement of a civil action.

This bill would deem a gag clause of that nature to be void as against public policy and would subject to disciplinary action any licensee who included or permitted that gag clause in a settlement agreement.

COMMENT

1. Need for the bill

The CPIL, which has long studied DCA occupational licensing agencies and their licensees, asserts that the growingly pervasive use of gag clauses is a practice that must be stopped. The CPIL argues that regulatory gag clauses in private settlement agreements cost regulatory agencies money and time (delay), and sometimes prevent them from taking disciplinary action against negligent licensees altogether when the consumer/victim's refusal or inability to cooperate in a regulatory action allows the statute of limitations to run, thus freeing the negligent licensee from any sanction by the regulatory body. CPIL is familiar with a number of these cases, including one in which a doctor required a gag clause in about 25 patients' cases, thus ensuring that none of them would complain to or cooperate with the Medical Board, and leaving him free to injure more people.

CPIL also notes that "as mandated by AB 269 (Correa, Chapter 107, Statutes of 2002), DCA occupational licensing agencies have a duty to protect the public from incompetent, dishonest, or impaired practitioners as their 'paramount' priority, yet they are deprived of information about their own licensees by their own licensees when they settle separate civil actions challenging their conduct or behavior in their capacity as a state licensee."

The author provides:

> In spite of court rulings that deem regulatory gag clauses invalid as against public policy, the use of regulatory gag clauses persists and appears to be increasing. They are often used to intimidate injured victims so they will refuse to cooperate with

investigations, thereby preventing regulatory licensing bodies from performing their basic function to protect consumers from unscrupulous and incompetent licensed professionals. Invalidating regulatory gag orders through the courts increases costs to taxpayers, delays the efforts of regulators to investigate wrongdoing by professional licensees, which allows more harm to consumers, and tarnishes the reputation of competent and reputable licensed professionals. California should not continue to turn a blind eye to repeat offenders who cheat or injure consumers and then hide their illegal acts from government investigators.

2. Statutory precedent for prohibiting regulatory gag clauses

The CPIL asserts that this bill is backed by similar precedent applicable to lawyers and their licensing and regulatory body - the State Bar of California. It states: "Business and Professions Code section 6090.5 prohibits a lawyer who is being sued for legal malpractice (and any lawyer representing that lawyer) from including in a settlement agreement any provision that (1) prohibits the plaintiff from reporting that lawyer to the State Bar, (2) requires the plaintiff to withdraw a complaint already filed with the State Bar, and/or (3) requires the plaintiff to agree to seal the settlement from the State Bar. Section 6090.5 - which has been in existence for almost 20 years - simply ensures that the State Bar learns of alleged misconduct by its licensees, and preserves its inherent discretion to investigate that allegation."
The Consumers for Auto Reliability and Safety (CARS), a supporter of this bill, cites as another precedent its sponsored law that bans an auto manufacturer's use of gag clauses in lemon law cases. AB 2410 (Shelley, Chapter 1063, Statutes of 1998) prohibits the imposition of gag agreements on auto lemon owners when their claim for a defective, non-repairable vehicle was resolved. Prior to that bill, auto manufacturers were increasingly requiring lemon owners to sign a gag agreement in order to receive a refund or replacement for their defective vehicles, thus making it easier for auto manufacturers to engage in "lemon laundering" and to stop consumers from communicating with the DMV.

3. Case law likewise supports ban on regulatory gag clauses; need for statute

The Attorney General's Office, also a supporter of the bill, writes:

> We have long maintained that such contracts and/or settlement provisions are void as against public policy. Case law supports this view. (See, Picton v. Anderson Union High School (1996) 50 Cal.App.4th 726 [non-disclosure agreement in teacher misconduct case held unenforceable and illegal as a matter of public policy]; Mary R. v. Division of Medical Quality of the Board of Medical Quality Assurance (1983) 149 Cal.App.3d 308 [gag orders stricken once the Medical Board has intervened and asserted its interest in fulfilling its statutory obligations to supervise and regulate the practice of medicine]; and Cariveau v. Halferty (2000) 83 Cal.App.4th 126 [a civil settlement agreement which prohibits customers of a securities agent from reporting misconduct to regulator is void as against public policy].)

In Mary R., the court struck down a gag clause and sealed court records in a case where a physician had molested a minor, writing:

> The stipulated order of confidentiality is contrary to public policy, contrary to the ideal that full and impartial justice shall be secured in every matter and designed to secrete the evidence in the case from the very public agency charged with the responsibility of policing the medical profession. We believe it clearly improper to pervert public policy by shielding the doctor from governmental investigation designed to protect the public from misconduct within the medical profession similar to an agreement to conceal judicial
>
> proceedings and to obstruct justice.

The Attorney General also asserts that many serious cases of misconduct never see the light of day due to gag clauses in settlement agreements, thus exposing the unwary public to unnecessary dangers, and that [v]ictims of misconduct should not become accomplices in covering

up the misconduct perpetrated against them and as a consequence expose other consumers to negligent, incompetent, or unethical practitioners."
Despite consistent case authority, the CPIL, the Attorney General, and other proponents assert that a statutory ban on regulatory gag clauses is still vitally necessary to protect the public. As the Medical Board notes, a gag clause can be voided, but only through legal action, costing investigators additional time and expense even if a victim agrees to cooperate. And, that action could be taken only if the regulator finds out about the case from a third party. Proponents contend that an explicit statutory ban on the use of regulatory gag clauses will save the time and expense lost having to litigate gag clauses on a case-by-case basis, would allow for uniform application across the DCA's broad spectrum of licensees, also without the need for case-by-case litigation, and would better protect the public from bad actors.

4. Opposition from various contractors and response thereto

Opponents argue that parties to a settlement agreement should have some assurance that a dispute has been resolved in a satisfactory manner, when civil litigation is settled before trial, and that this bill would destroy that assurance. CELSOC (Consulting Engineers and Land Surveyors of CA) asserts that their members frequently settle civil matters when the cost of settlement is less than the cost of defense; it makes economic sense to settle. They state that the "gag clause" is an assurance that finality has been brought to the matter. However, they say this bill would enable a disgruntled client, who agreed to settle, to still file, out of spite, a complaint with a regulatory body over a dispute that has been resolved. CELSOC argues this unfairly subjects the licensee to a type of double jeopardy.

Finally, the contractor groups argue that since the real motivation for the bill is gag clauses in medical malpractice cases, the bill should be amended to exclude licensees of the Contractors State License Board.

The CPIL and other proponents strongly disagree with the opposition arguments. CPIL points out that the bill does not prohibit any party from settling at any time or in

any way; it simply prohibits the agreement from including a gag clause that serves to deprive the appropriate regulator of information about licensee misconduct and appropriately removes from civil settlement negotiations the issue of concealment from the regulator. CPIL also points out that contractors, engineers, and other construction trades are regulated because they can cause significant harm to consumers when they are incompetent or dishonest. Thus, as noted in the court decisions above, gag clauses that keep relevant information from the licensing body about a licensee's misconduct or negligence are contrary to public policy and the public interest.

The CPIL also strongly disagrees with exempting any group of licensees from the bill's application. It notes that every court that has entertained the issue has declared gag clauses void as against public policy, and that the Legislature would in fact be cutting back on that judicial precedent if it allows any exemption from the provisions of the bill. CPIL argues that the rule against regulatory gag clauses has been found to be good public policy in the cases of doctors, lawyers, teachers, investment advisors, and auto manufacturers, and asserts that it would be equally good public policy in cases involving contractors and engineers.

5. Governor's veto of AB 320 (Correa of 2004), virtually identical bill

The governor's veto message to AB 320 echoed the opponents' arguments regarding the need for assurance of finality in settlement agreements, the fact that cases may be settled for economic reasons, and that a regulatory body's investigation of a licensee who has settled a civil case is tantamount to double jeopardy.

The CPIL responds that the governor's veto message reflects:

> [a] misunderstanding of both the legal doctrine of "double jeopardy" (which is applicable only in the criminal arena, not in civil or administrative matters), and of the difference between the purposes of the civil tort system and the administrative discipline system. Civil courts entertain a

plaintiff's claim against a defendant who has allegedly caused injury to the plaintiff in order to determine whether the plaintiff is owed compensation. In contrast, the purpose of administrative agencies is to appropriately license and discipline certain trades and professions to prevent future harm to consumers by licensees who are incompetent or dishonest. If the harm that can be caused by incompetence or dishonesty is so serious as to justify the creation of a regulator to protect the public, then it makes no sense to deprive that regulator of information about misconduct committed by its own licensees in the course and scope of the licensed activity. If a consumer wants to file a complaint, a regulatory agency is entitled to learn of it. After that, it is the agency's call what to do about it - whether to close the case, investigate it, or take appropriate disciplinary action. AB 446 simply preserves the ability of agencies to learn of and the discretion of agencies to investigate complaints filed against repeat offenders who have and will continue to injure the public.

Support: CA Nurses Association; CA State Board of Pharmacy; CA Board of Accountancy; CA Public Interest Research Group (CALPIRG); Consumers Union; Center for Public Interest Law; Consumer Federation of CA; CA Architects Board; CA Alliance for Retired Americans; Consumers for Auto Reliability and Safety (CARS); Attorney General's Office; Wendy Conner; Maxwell Nealy, LLC; Jody Costello (Contractors from Hell.com)

Opposition: Engineering Contractor's Association; CA Fence Contractors' Association; Marin Builders' Exchange; Flasher/Barricade Association; CA Chapter of American Fence Contractors' Association; Consulting Engineers and Land Surveyors of CA

HISTORY

Source: Author

Related Pending Legislation: None Known

Prior Legislation: AB 320 (Correa of 2004), which was virtually identical to this bill was vetoed.

Prior Vote: Assembly Business and Professions (Ayes 7, Noes 0)
Assembly Appropriations (Ayes 13, Noes 5)
Assembly Floor (Ayes 42, Noes 27)

Attachment 8

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL No. 592

Introduced by Senator Aanestad

February 18, 2005

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as amended, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met. *The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.*

Because a failure to meet the training *and other* requirements in this bill 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. The Legislature finds and declares all of the*
2 *following:*
3 *(a) Pharmacists have emerged as critical members of a*
4 *medical team by providing services such as patient education,*
5 *drug therapy monitoring, and pharmacokinetic consultations.*
6 *Pharmacists often work side by side with physicians and nurses,*
7 *and participate in medical rounds. Pharmacists play an integral*
8 *role in ensuring a safe medication use process. Through*
9 *interpretation, evaluation, and clarification of orders,*
10 *pharmacists ensure the absence of drug allergies, interactions,*
11 *duplications, and the optimal selection of dose, dosage form,*
12 *frequency, route, and duration of therapy.*
13 *(b) There currently exists a shortage of pharmacists in the*
14 *state, and this shortage has the potential to cause harm to*
15 *patients because hospitals lack sufficient staffing to fully take*
16 *advantage of clinical pharmacy programs that have been shown*
17 *to reduce the number of medication errors in hospitals and*
18 *improve patient outcomes.*
19 *(c) Studies authorized by the California State Board of*
20 *Pharmacy, and conducted under the direction of the University*
21 *of California, San Francisco, at major California hospitals, have*
22 *established that certain nondiscretionary functions currently*
23 *performed by pharmacists in the hospital setting can safely be*
24 *performed by properly trained pharmacy technicians.*
25 *Specifically, allowing properly trained pharmacy technicians to*
26 *check certain tasks performed by other pharmacy technicians is*
27 *a safe and efficient use of staff, and frees pharmacists to provide*
28 *the more important and skilled clinical pharmacy services that*
29 *are critical to quality patient care and the reduction of*
30 *medication errors.*

(d) Pharmacists are substantially over-qualified for performing these nondiscretionary inpatient checking functions, and current rules that require pharmacists to perform these functions unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain nondiscretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

~~SECTION 1.~~

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

~~4128. Notwithstanding any other provision of this chapter or any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. A hospital implementing and operating a program pursuant to this section shall meet all of the following requirements:~~

~~(a) The hospital shall conduct a special training program for technicians who perform the checking function that provides the technicians with the same training that a pharmacist would be provided with under paragraph (1) of subdivision (b) of Section 4052.~~

~~(b) The hospital shall conduct a continuous quality improvement program.~~

~~(c) The hospital shall establish and maintain a program utilizing pharmacists to provide clinical services, as described in Section 4052.~~

~~(d) The hospital shall have a current, nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.~~

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts a special training program for technicians who perform the checking function that satisfies the requirements of subdivision (b).

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is requalified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The training program required by paragraph (1) of subdivision (a) shall include both didactic and practical

elements, and shall specify requirements to be completed prior to the technician commencing participation in the checking program.

(1) The didactic component of the training shall consist of at least four hours of education covering the following topics:

(A) Information required to be on the label of unit dose or extemporaneous packaging.

(B) Identification of expired or contaminated medications.

(C) The product characteristics that need to be checked for each drug dispensed from the pharmacy.

(D) Special packaging or handling requirements, including refrigeration for certain medications.

(E) Generic names for common name-brand medications.

(F) Recognition and identification of various dosage forms.

(G) Common medical abbreviations and symbols used in pharmacy.

(H) Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

(2) The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(c) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section.

(d) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(e) Data and records required by this section shall be retained in each participating hospital for at least three years.

(f) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(g) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be

limited to the holder of the pharmacy permit and the pharmacist in charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certification Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

~~SEC. 2.~~

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.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: AANESTEAD **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)

2) Requires hospitals implementing TCT to do the following:

a. Conduct ongoing training for technicians.
b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.
e. Be inspected by the Board of Pharmacy.
f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

a. The didactic component of the training shall consist of at least four hours of education covering the following topics:
   i. Information required to be on the label of unit dose or extemporaneous packaging.
   ii. Identification of expired or contaminated medications.
   iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.
   iv. Special packaging or handling requirements, including refrigeration for certain medications.
   v. Generic names for common name-brand medications.
   vi. Recognition and identification of various dosage forms.
   vii. Common medical abbreviations and symbols used in pharmacy.
   viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT. (B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1Added)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1 Added)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Union (labor), consequently the measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

3) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the January 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in 2006.

4) Amended on March 29, 2005. The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended onJuly 16, 2003.

5) History.

2005	
June 14	Set, first hearing. Failed passage in committee. Reconsideration granted.
May 26	To Com. on HEALTH.
May 9	In Assembly. Read first time. Held at Desk.
May 9	Read third time. Passed. (Ayes 23. Noes 8. Page 972.) To Assembly.
May 3	Read second time. To third reading.
May 2	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 21	Set for hearing May 2.
Apr. 18	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 625.) Re-referred to Com. on APPR.
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 592

As Amended: March 29, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair

SUBJECT : Acute care hospitals: inpatient pharmacy technician services.

SUMMARY : Allows a general acute care hospital to implement a program of allowing specially trained pharmacy technicians to check the work of other pharmacy technicians relating to the filling of floor and ward stock and unit dose distribution for patients whose orders have previously been reviewed by a licensed pharmacist (checking program), under specific requirements. Specifically, this bill :

1)Requires hospitals implementing the checking program to meet all of the following:

a) Conduct special training program for technicians who perform the checking function, as specified in #2) below;

b) Conduct quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. Prohibits a pharmacy technician from checking the work of other pharmacy technicians if his or her audited accuracy rate falls below 99.8%, until he or she is requalified, as specified;

c) Possess current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization;

d) Have the hospital pharmacy inspected by the Board of Pharmacy (Board); and,

e) Establish and maintain a program using pharmacists to provide clinical services, as specified in existing law.

2)Requires the training program specified in #1) a) to include didactic and practical elements, and specify requirements to be completed before the technician starts participating in the checking program.

3)Requires the didactic training to consist of at least four hours of education covering topics on label or packaging information, identification of expired or contaminated

medications, product characteristics, special packaging or handling requirements, generic names, dosage forms, medical abbreviations and symbols, and basic mathematical principles.

4)Requires the practical component of the training to consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures under the direct observation of the supervisor.

5)Allows the Board to establish other rules, through regulations, for hospitals utilizing the checking program.

6)Allows the Board to order a hospital to stop the checking program at any time a hospital fails to satisfy the Board that it is capable of meeting the requirements of the checking program.

7)Requires a hospital to retain data and records for at least three years.

8)Requires a licensed health care provider practicing within the scope of his or her license to administer to a patient medications placed in floor or ward stock or unit dose distribution systems.

9)Limits legal responsibility or liability for errors or omissions that occur as a result of a checking program to the holder of the pharmacy permit and the pharmacist in charge.

10)Requires a hospital to maintain, for inspection by the Board, a current list of all pharmacy technicians that have been qualified to perform checking functions.

11)Requires a pharmacy technician, to qualify under the checking program, to be currently certified by the Pharmacy Technician Certification Board and registered with the Board.

12)Makes findings and declarations regarding the workload of pharmacists and the need for pharmacy technicians to perform specific functions to ease the workload of pharmacists.

EXISTING LAW :

1)Requires pharmacy technicians to be certified by the Board. Allows a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

2)Requires a pharmacist on duty to be directly responsible for the conduct of a pharmacy technician. Requires any pharmacist

responsible for a pharmacy technician to be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view.

3)Requires an applicant for registration as a pharmacy technician to be issued a certificate of registration if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements:

a) Obtains an associate's degree in pharmacy technology;

b) Completes a course of training specified by the Board; or

c) Graduates from a school of pharmacy accredited by the American Council on Pharmaceutical Education or a school of pharmacy recognized by the board.

FISCAL EFFECT : Unknown. This bill was approved by the Senate Appropriations Committee pursuant to Senate Rule 28.8.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the California Society of Health System Pharmacists (CSHSP), the sponsor of this bill, California is currently experiencing a shortage of pharmacists. Allowing pharmacy technicians to perform tasks within their training, education, and registration would allow hospital-based pharmacies to provide more clinically based functions with physicians, nurses, and other health care providers. CSHSP points out this bill would significantly reduce medication related errors and greatly improve the quality of care processes for chronically ill patients receiving treatment in hospitals. CSHSP stresses that this bill is based upon a 2002 collaborative study between the University of California, San Francisco, School of Pharmacy, Long Beach Memorial Medical Center, and Cedars-Sinai Medical Center, in which the Board authorized an experimental program to evaluate and compare the accuracy between licensed pharmacists and registered pharmacy technicians

2)EXPERIMENTAL PROGRAM . According to background information provided by CSHSP, in 1997, Cedars-Sinai Medical Center (Cedars) and Long Beach Memorial Medical Center (Long Beach) petitioned the Board to grant a waiver of the California Code of Regulations prohibiting board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. When

filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. The pharmacist then verifies the filled cassette against the list to minimize the possibility of errors. Cedars and Long Beach wanted to conduct an experimental program under the direction of the University of California, San Francisco, School of Pharmacy, to compare the accuracy of unit dose medication cassettes checked by pharmacists with those of registered pharmacy technicians. In May 1998, the Board granted the waiver and the experimental program was known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The report on the experimental program was released in December 2002 and indicated that pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacists shortage. The pharmacists and technicians were all aware of the study but not when audits would be conducted. The report revealed that of the 39 pharmacy technician checkers, 161,740 doses were checked and an accuracy rate of over 99.8% was achieved. The program compared this to 29 pharmacists who checked 35,829 doses and achieved an accuracy rate of over 99.5%.

3)MEDICAL ERRORS. According to a 1999 report by the Institute of Medicine (IOM) entitled "To Err is Human," between 44,000 and 98,000 Americans die each year as a result of all types of medical errors. Medication errors, according to the report, include stocking patient-care units in hospitals with certain full-strength drugs. The report also stated that medication errors increase with complexity. Complexity in the medication system arises from several sources; including the extensive knowledge and information that are necessary to correctly prescribe a medication regimen for a particular patient; the intermingling of medications of varying hazard in the pharmacy, during transport, and on the patient care units; and the multiple tasks performed by nurses, of which medication preparation and administration are but a few. IOM also estimates that medication-related errors for hospitalized patients cost roughly 2.4 million extra hospital days and $9.3 billion in extra charges for longer stays and additional care per year.

4)WORKFORCE SHORTAGE . According to a study published in December, 2000, by the United States Department of Health and Human Services, "The Pharmacist Workforce: A Study of the

Supply and Demand for Pharmacists," the evidence clearly indicates the emergence over the past few years of a shortage of pharmacists. The study found that there has been an unprecedented demand for pharmacists and for pharmaceutical care services, and the factors causing the current shortage are of a nature not likely to abate in the near future without fundamental changes in pharmacy practice and education. Factors causing the shortage include a 44% increase in the number of retail prescriptions dispensed per year in the United States between 1992 and 1999, and a 32% increase in the number of prescriptions filled per pharmacist during the same time period. According to this study, the pharmacist supply in California was at 54 pharmacists per 100,000 population, well below the nationwide average of 68 per 100,000.

California ranks 49th in the nation in the proportion of registered nurses per 100,000 population. The Employment Development Department estimates that California needs 30,000 additional nurses in the next four years and by 2010, there will be a demand for 109,600 nurses. According to the California Board of Registered Nursing, there are 539 full time-equivalent registered nurses per 100,000 population.

5)OTHER STATES . According to the report on the experimental program, other states, including Washington, Kansas, and Minnesota, currently allow pharmacy technicians to check unit dose medication cassettes.

6)SUPPORT . The supporters point out that California hospitals are experiencing a severe shortage of pharmacists and this bill would allow pharmacists to perform more complex tasks in hospitals. They state that the tasks delegated to pharmacy technicians in this bill can be safely delegated as indicated by the experimental program at Cedars and Long Beach Hospitals. Cedars-Sinai Health System points out that in a hospital setting, the checking of doses in the pharmacy is performed prior to the medications being delivered to the inpatient units where the nurse again checks the medication to ensure it is correct before giving it to the patient.

7)OPPOSITION . According to the California Nurses Association (CNA), allowing pharmacy technicians to perform the work of pharmacists would put unreasonable and increased load on nurses who are already experiencing enormous pressures in acute care settings. In addition, CNA states this bill would put patients at an increased risk of medication errors. Other opponents believe pharmacists should continue to check the work of pharmacy technicians so that pharmacists do not lose control of pharmacy practices for which pharmacists are legally responsible and to insure that pharmacies are operated at the highest degree of integrity and efficiency.

8)POLICY QUESTIONS . Does the policy proposed in this bill have the potential to worsen medication errors in California hospitals? Will the policy proposed in this bill put more pressure on nurses? Has there been sufficient study of the issue in California to warrant this policy change? Does one nonrandomized study of 29 pharmacists and 39 technicians in two hospitals provide sufficient evidence to support a lower oversight standard in all California hospitals?

9)PRIOR LEGISLATION . SB 393 (Aanestad) introduced in 2003, is substantially similar to the provisions of this bill and would have authorized general acute care hospitals to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians under prescribed conditions and circumstances. This bill did not move out of the Senate.

10)REFERRAL REQUEST . Assembly Committee on Business and Professions requested to hear this bill. Should this bill pass out of this committee, it will be referred to the Assembly Committee on Business and Professions.

REGISTERED SUPPORT / OPPOSITION :

Support

California Society of Health System Pharmacists (sponsor)
Arroyo Grande Community Hospital
California Hospital Association
California Medical Association
California Pharmacists Association
California State Board of Pharmacy
Catholic Healthcare West
Cedars-Sinai Health System
Dominican Hospital
French Hospital Medical Center
Mark Twain St Joseph's Hospital
Mercy Medical Center Redding
Northridge Hospital Medical Center
San Gabriel Valley Medical Center
Scripps Health
Sierra Nevada Memorial Hospital
St. Joseph's Medical Center
Sutter Health

Opposition

California Labor Federation
California Nurses Association
United Food & Commercial Workers

Analysis Prepared by : Rosielyn Pulmano / HEALTH / (916) 319-2097

Attachment 9

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.

Attachment 10

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 MAY 9, 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)

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 last year. 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.

Attachment 11

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:

1 SECTION 1. Section 650 of the Business and Professions
2 Code is amended to read:
3 650. *(a)* Except as provided in Chapter 2.3 (commencing
4 with Section 1400) of Division 2 of the Health and Safety Code,
5 the offer, delivery, receipt, or acceptance by any person licensed
6 under this division or the Chiropractic Initiative Act of any
7 rebate, refund, commission, preference, patronage dividend,
8 discount, or other consideration, whether in the form of money or
9 otherwise, as compensation or inducement for referring patients,
10 clients, or customers to any person, irrespective of any
11 membership, proprietary interest or coownership in or with any
12 person to whom these patients, clients, or customers are referred
13 is unlawful.
14 ~~The~~
15 *(b) The* payment or receipt of consideration for services other
16 than the referral of patients which is based on a percentage of
17 gross revenue or similar type of contractual arrangement shall not
18 be unlawful if the consideration is commensurate with the value
19 of the services furnished or with the fair rental value of any
20 premises or equipment leased or provided by the recipient to the
21 payer.
22 ~~Except~~
23 *(c) Except* as provided in Chapter 2.3 (commencing with
24 Section 1400) of Division 2 of the Health and Safety Code and in
25 Sections 654.1 and 654.2, it shall not be unlawful for any person
26 licensed under this division to refer a person to any laboratory,
27 pharmacy, clinic (including entities exempt from licensure
28 pursuant to Section 1206 of the Health and Safety Code), or
29 health care facility solely because the licensee has a proprietary
30 interest or coownership in the laboratory, pharmacy, clinic, or
31 health care facility; provided, however, that the licensee's return
32 on investment for that proprietary interest or coownership shall
33 be based upon the amount of the capital investment or
34 proportional ownership of the licensee which ownership interest
35 is not based on the number or value of any patients referred. Any
36 referral excepted under this section shall be unlawful if the
37 prosecutor proves that there was no valid medical need for the
38 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.

AB 225

As Amended: April 7, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair

SUBJECT : Electronic prescription information.

SUMMARY : Allows the provision of 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), as specified. Specifically, this bill.

1)Allows the provision of nonmonetary remuneration, as specified, 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, as specified, become effective.

EXISTING LAW :

1)Makes it unlawful to offer, deliver, receive, or accept, by physicians and other specified licensed health care providers, any rebate, refund, commission, preference, 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 co-ownership in or with any person to whom these patients, clients or customers are referred.

2)Provides that a violation of # 1) above is a public offense where the first conviction is punishable 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 $50,000, or both by imprisonment and fine. Specifies that a second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of $50,000.

3)Includes as a health care facility, a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and others, as specified.

FISCAL EFFECT : None

COMMENTS :

1)PURPOSE OF THIS BILL . According to L.A. Care Health Plan, the sponsor of this bill, this measure would conform state law to federal law, encourage the use of E-health technology, and clarify that entities responsible for the administration of health care services can equip providers with hardware and software to promote electronic prescribing. The sponsor points out that in the 2003 Medicare Modernization Act (Medicare Act), Congress incorporated language mandating a safe harbor for certain E-health hardware used in conjunction with electronic prescribing. According to background information provided by the sponsor, the intent of the safe harbor was for electronic prescribing to serve as a vehicle to reduce medical errors and improve efficiencies in the health care system. However, the sponsor points out that California's anti-kickback statutes present a barrier because these statutes prohibit the giving and acceptance of any form of consideration by physicians.

2)BACKGROUND . According to the sponsor, studies by the Institute of Medicine and others have found that fragmented and inaccessible clinical information adversely affects the quality of health care and compromises patient safety. Recognizing this, health care providers are increasingly using health information technology, often referred to as E-health, to collect, store, retrieve, and transfer clinical, administrative and financial health information electronically. E-health services include the use of electronic medical records to ensure physicians' timely access to laboratory results, improved health data collection, and fewer potentially dangerous drug interactions resulting from electronic prescribing. However, information technology also has its weaknesses. A study by Eclipsys Corporation of Boca

Raton, Florida, of a computerized physician order entry (CPOE) system, which requires doctors to enter medication orders into computers installed throughout the Hospital of the University of Pennsylvania, revealed various problems. The potential or actual mistakes researchers found included incorrect doses prescribed for patients, patients failed to get medication in a timely manner because of computer-related problems and difficulty determining which patient was supposed to get a drug that had been prescribed.

3)PROMULGATION OF E-HEALTH SAFE HARBOR . The Medicare Act required the Secretary of the U.S. Department of Health and Human Services (HHS), in consultation with the U.S. Attorney General to promulgate regulations that provide for a safe harbor from criminal sanctions under both Section 1128 (B)(b)(1) and (2) of the Social Security Act (Act) and the anti-referral prohibition under Section 1877 of the Act with respect to the provision of nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription standards, as specified. Nonmonetary remuneration is defined to include hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this section and in the following cases:

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

b) In the case of a group practice, as defined, by the practice to prescribing health care professionals who are members of such practice; and,

c) In the case of a prescription drug plan sponsor or

Medical Advantage organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

4)FEDERAL ANTI-KICKBACK & ANTI-REFERRAL STATUTES . Section 1128(B)(b) of the Act, commonly referred to as the anti-kickback statute, makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by federal health care programs. The statute imposes liability to parties on both sides of an impermissible "kickback" transaction. Remuneration under the Act includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Violation of this statute constitutes a felony punishable by a maximum fine

of $25,000, imprisonment of up to five years, or both. Conviction will also lead to automatic exclusion from federal health care programs, including Medicare and Medicaid.

The Stark amendments to the Medicare Act are contained in Section 1877. These amendments prohibit physicians from referring Medicare and Medicaid patients for certain designated health services to any facility or entity with whom the referring physician or an immediate family member has any financial relationship, unless an exception set forth in statute or regulation is satisfied. Section 1877 is violated by the mere fact that a financial relationship exists. The intent of the referring physician is irrelevant.

5)CALIFORNIA ANTI-KICKBACK & ANTI-REFERRAL STATUTES . Business & Professions Code Section 650 prohibits the offer, delivery, receipt or acceptance of compensation to induce the referral of patients. A first conviction under this section is punishable 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 $50,000 or both imprisonment and fine.

Welfare and Institutions Code Section 14107.2 prohibits the solicitation or receipt of any remuneration, including kickbacks, in return for the referral of any individual to a person for furnishing any service or merchandise which is paid for by Medi-Cal. A first conviction of this law is punishable by imprisonment in the county jail for no longer than one year, or state prison, or by a fine not exceeding $10,000, or by both imprisonment and fine.

Federal and California anti-kickback and anti-referral statutes reflect the recognition that payments made or accepted in return for the referral of patients could result in actual or threatened patient harm, over utilization and increased health care costs.

6)POLICY CONCERN . The Medicare Act instructs the Secretary of HHS Agency, in consultation with the Attorney General, to promulgate regulations that would provide a safe harbor for federal anti-kickback and anti-referral statutes, as outlines in the Medicare Act. These regulations are not currently in place. The problem this bill seeks to address may be premature since the federal regulations are unknown.

7)SUPPORT . Supporters, including AARP, the California Association of Health Plans, and Health-e-LA Coalition, believe this bill is an important measure that would improve the quality and efficiency of the health care system.

8)RELATED LEGISLATION . AB 1672 (Nation & Richman) would require

health care facilities, health insurers and health care service plans to record all health care information, as defined, they obtain in an electronic record keeping system. This bill will be heard in the Assembly Health Committee on April 26, 2005.

REGISTERED 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, Southern California
Health-e-LA Coalition
Local Health Plans of California
Los Angeles County Medical Association
Rite-Aid
San Francisco Health Plan

Opposition

None on file

Analysis Prepared by : Rosielyn Pulmano / HEALTH / (916) 319-2097