2005

Watch Bills

AMENDED IN SENATE JUNE 15, 2005

AMENDED IN SENATE JUNE 6, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 26, 2005

AMENDED IN ASSEMBLY APRIL 12, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 651

Introduced by Assembly Members ~~Levine and Berg~~ *Berg and Levine*
(Coauthors: Assembly Members Bass, Canciamilla, Chu, Dymally, Goldberg, Koretz, Laird, Leno, and Wolk)
(Coauthors: Senators Kuehl, Lowenthal, and Romero)

February 17, 2005

An act to add Chapter 3.95 (commencing with Section 7195) to Part 1 of Division 7 of the Health and Safety Code, relating to death.

LEGISLATIVE COUNSEL'S DIGEST

AB 651, as amended, ~~Levine~~ *Berg*. California Compassionate Choices Act.

Existing law authorizes an adult to give an individual health care instruction and to appoint an attorney to make health care decisions for that individual in the event of his or her incapacity pursuant to a power of attorney for health care.

This bill would enact the California Compassionate Choices Act, which would authorize an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for

medication for the purpose of ending his or her life in a humane and dignified manner. The bill would establish procedures for making these requests.

This bill would further provide that no provision in a contract, will, or other agreement, or in a health care service plan contract, policy of disability insurance, or health benefit plan contract, shall be valid to the extent it would affect whether a person may make or rescind a request for medication for the purpose of ending his or her life in a humane and dignified manner. The bill would prohibit the sale, procurement, or issuance of any life, health, or accident insurance or annuity policy, or the rate charged for any policy, from being conditioned upon or affected by the request. The bill would require that nothing in its provisions be construed to authorize ending a patient's life by lethal injection, mercy killing, or active euthanasia, and would provide that action taken in accordance with the act shall not constitute suicide or homicide.

This bill would provide immunity from civil or criminal liability or professional disciplinary action for participating in good faith compliance with the act. The bill would provide that no health care provider is under any duty to participate in providing to a qualified patient medication to end that patient's life and would authorize a general acute care hospital to prohibit a licensed physician from carrying out a patient's request under this act on the premises of the hospital if the hospital has notified the licensed physician of its policy regarding this act.

This bill would require the State Department of Health Services to adopt regulations regarding the collection of information to determine the use of and compliance with the act, and would require the department to annually review a sample of certain records and make a statistical report of the information collected.

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. Chapter 3.95 (commencing with Section 7195)
2 is added to Part 1 of Division 7 of the Health and Safety Code, to
3 read:

Chapter 3.95. California Compassionate Choices Act

Article 1. General Provisions

7195. (a) The Legislature believes that dying patients should have choices throughout the continuum of palliative care and that much must be done to improve access to hospice care and pain management. Hospice and effective palliative care successfully assist many thousands of terminally ill patients to die with dignity and without pain, and the Legislature hopes that all patients considering the procedures available under this chapter will properly consider other options, including hospice care and effective pain management. The Legislature finds that medical studies have shown that between 5 and 10 percent of dying patients experience severe pain and suffering that cannot be palliated by the best hospice or comfort care. The Legislature finds that in response to the Death with Dignity Act in the State of Oregon, that the referrals to hospice increased significantly. In addition, doctors significantly increased the use of morphine and other strong pain medications, thus improving the end-of-life care for more dying patients.

(b) (1) It is the intent of the Legislature that the personal and autonomous choice of dying patients regarding the time and manner of their death provided under this chapter be viewed as but one of several end-of-life options for dying patients.

(2) It is the intent of the Legislature that this chapter be strictly construed and not expanded in any manner. The restrictions and safeguards in the provisions of this chapter are based on the intent of the Legislature to balance the personal and autonomous choice of dying patients regarding the time and manner of their death and the Legislature's goal of providing safeguards to ensure that there are not instances of a coerced, unwanted, or early death by a vulnerable dying patient.

(3) The Legislature finds and declares that historically persons with disabilities have been subject to discrimination in the provision of medical care and have been treated by some as though their lives were less valuable or worthy of maintenance than those without disabilities. The Legislature finds that this discriminatory conduct is both illegal and reprehensible.

(4) It is the intent of the Legislature that a disability or age alone are not reason for a patient to be a qualified patient as defined in subdivision (*l*) of Section 7195.1. Any disabled individual or elderly person, and any physician who is the attending physician to these individuals, must strictly comply with all of the provisions of this chapter. Strict and rigorous attention must be evidenced in distinguishing chronic conditions, which are not eligible conditions under this chapter, and terminal illnesses, which are eligible, as described in this chapter.

7195.1. For purposes of this chapter the following definitions shall apply:

(a) "Adult" means an individual who is 18 years of age or older.

(b) "Attending physician" means the physician who has primary responsibility for the care of the patient and for treatment of the patient's terminal disease.

(c) "Capable" means that in the opinion of the patient's attending physician or consulting physician, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available. Incapable means that the patient does not have the mental capacity to make and understand decisions about his or her medical care.

(d) "Consulting physician" means a physician, other than the attending physician, who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's disease.

(e) "Counseling" means a consultation between a state licensed psychiatrist or psychologist and a patient for the purpose of determining whether the patient is suffering from a psychiatric or psychological disorder, or depression causing impaired judgment.

(f) "Health care provider" means a person licensed, certified, or otherwise authorized or permitted by the law of this state to administer health care in the ordinary course of business or practice of a profession, and includes a licensed health care facility.

(g) *(1)* "Health care facility" means any health facility described in Section 1250.

(2) "Hospice" means a comprehensive, interdisciplinary program of medical and socially supportive care delivered to patients with a terminal disease in order to palliate their symptoms and pain since the patient's condition is no longer amenable to curative therapies and for whom the primary therapeutic goal is comfort and dignity at the end of life.

(h) "Informed decision" means a decision, made by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is not based on coercion by the patient's next of kin or any other third parties, is based on an appreciation of the relevant facts, and is made after being fully informed by the attending physician of all of the following:

(1) His or her medical diagnosis.

(2) His or her prognosis.

(3) The potential risk associated with taking the medication to be prescribed.

(4) The probable result of taking the medication to be prescribed.

(5) The feasible alternatives, as provided in paragraph (5) of subdivision (b) of Section 7196, including, but not limited to, comfort care, hospice care, and pain control.

(i) "Medically confirmed" means the medical opinion of the attending physician has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.

(j) "Patient" means a person who is under the care of a physician.

(k) "Physician" means a doctor of medicine or osteopathy licensed to practice medicine by the Medical Board of California.

(*l*) "Qualified patient" means a capable adult who is a resident of California and has satisfied the requirements of this chapter in order to obtain a prescription for medication to end his or her life in a humane and dignified manner.

(m) "Resident" means a person who has lived in a principal place of residence in the State of California for six months or more.

(n) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months.

7195.3. An adult who is capable, is a resident of California, has been determined by the attending physician and a consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to obtain life-ending medication to his or her attending physician shall, in addition to the other requirements of this chapter, make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with this chapter in order to be eligible for qualification under this chapter.

7195.5. (a) A valid written request for medication under this chapter shall be in substantially the form prescribed by Section 7199, signed and dated by the patient and witnessed by at least two individuals who, in the presence of the patient, attest that to the best of their knowledge and belief the patient is capable, acting voluntarily, and is not being coerced to sign the request.

(b) ~~One~~ *Both* of the witnesses shall be a person who is not any of the following:

(1) A relative of the patient by blood, marriage, or adoption.

(2) A person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death under any will or by operation of law.

(3) An owner, operator, or employee of a health care facility where the qualified patient is receiving medical treatment or is a resident.

(c) The patient's attending physician at the time the request is signed shall not be a witness.

Article 2. Safeguards

7196. Upon being voluntarily informed by a qualified patient that the patient wishes to receive medication for the purpose of ending his or her life in a humane and dignified manner in accordance with this chapter, the attending physician shall do all of the following:

(a) Make the initial determination of whether a patient has a terminal disease, is capable, and has made the request voluntarily.

(b) Inform the patient of all of the following:

(1) His or her medical diagnosis.

(2) His or her prognosis.

(3) The potential risks associated with taking the medication to be prescribed.

(4) The probable result of taking the medication to be prescribed.

(5) The feasible alternatives, including, but not limited to, comfort care, hospice care, and pain control. This disclosure must be provided in writing to the patient, and shall include, but not be limited to, contact information about locally based providers of comfort and hospice care.

(c) Refer the patient to a consulting physician for medical confirmation of the diagnosis, and for a determination that the patient is capable and acting voluntarily.

(d) Refer the patient for counseling if appropriate pursuant to Section 7196.2.

(e) Request that the patient notify next of kin.

(f) Inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15-day waiting period described in Section 7196.5.

(g) Verify, immediately prior to writing the prescription for medication under this chapter, that the patient is making an informed decision.

(h) Fulfill the medical record documentation requirements of Section 7196.8.

(i) Ensure that all appropriate steps are carried out in accordance with this chapter prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner.

7196.1. Before a patient is qualified under this chapter, a consulting physician shall examine the patient and his or her relevant medical records and shall, in writing, confirm, the attending physician's diagnosis and that the patient is suffering from a terminal disease and verify that the patient is capable, is acting voluntarily, and has made an informed decision.

7196.2. If, in the opinion of the attending physician or the consulting physician, a patient may be suffering from a psychiatric or psychological disorder that impairs judgment or from depression or medication that impairs judgment, *or the patient is not a hospice patient,* the attending physician or consulting physician shall require the patient to undergo

counseling as specified in subdivision (e) of Section 7195.1. In this case, no medication to end the patient's life in a humane and dignified manner shall be prescribed unless the patient first undergoes the requisite *consultation or* counseling and until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder that impairs judgment, or from impaired judgment caused by depression or medication.

7196.3. No person shall receive a prescription for medication to end his or her life in a humane and dignified manner unless he or she has made an informed decision as defined in subdivision (h) of Section 7195. Immediately prior to writing a prescription for medication in accordance with this chapter, the attending physician shall verify that the patient is making an informed decision.

7196.4. The attending physician shall ask the patient to notify the patient's next of kin of his or her request for medication pursuant to this chapter. A patient who declines or is unable to notify next of kin shall not have his or her request denied for that reason.

7196.5. In order to receive a prescription for medication to end his or her life in a humane and dignified manner, a qualified patient shall have made an oral request and a written request, and reiterate the oral request to his or her attending physician no less than 15 days after making the initial oral request. At the time the qualified patient makes his or her second oral request, the attending physician shall offer the patient an opportunity to rescind the request.

7196.6. A patient may rescind his or her request at any time and in any manner without regard to his or her mental state. No prescription for medication under this chapter may be written without the attending physician offering the qualified patient an opportunity to rescind the request.

7196.7. No less than 15 days shall elapse between the patient's initial oral request and the writing of a prescription under this chapter. No less than 48 hours shall elapse between the patient's written request and the writing of a prescription under this chapter.

7196.8. The following shall be documented or filed in the patient's medical record:

(a) All oral requests by a patient for medication to end his or her life in a humane and dignified manner.

(b) All written requests by a patient for medication to end his or her life in a humane and dignified manner.

(c) The attending physician's diagnosis and prognosis, and his or her determination that the patient is capable, acting voluntarily, and has made an informed decision.

(d) The consulting physician's diagnosis and prognosis, and his or her verification that the patient is capable, acting voluntarily, and has made an informed decision.

(e) A report of the outcome and determinations made during counseling, if performed.

(f) The attending physician's offer to the patient to rescind his or her request at the time of the patient's second oral request pursuant to Section 7196.5.

(g) The attending physician's discussion with the patient of feasible alternatives, including, but not limited to, hospice care, comfort care, and pain control.

(h) A note by the attending physician indicating that all the requirements of this chapter have been met and indicating the steps taken to carry out the request, including a notation of the medication prescribed.

7196.9. Only requests made by California residents under this chapter shall be granted.

7197.1. (a) The department shall adopt regulations regarding requirements for the collection of information to determine the use of and compliance with this chapter. The information collected shall not be a public record and shall not be made available for inspection by the public.

(b) The department shall generate and make available to the public an annual statistical report of information collected pursuant to subdivision (a).

(c) The department shall annually review a sample of records maintained pursuant to this chapter.

7197.3. (a) No provision in a contract, will, or other agreement, whether written or oral, to the extent the provision would affect whether a person may make or rescind a request for medication to end his or her life in a humane and dignified manner, shall be valid.

(b) No obligation owing under any contract in existence on or before January 1, 2006, shall be conditioned or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner.

(c) No health care service plan contract, as defined in subdivision (r) of Section 1345, shall be conditioned upon or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner. Any such contract provision shall be invalid.

(d) No provision of a policy of disability insurance or a health benefit plan contract that provides coverage for hospital, medical, or surgical expenses pursuant to Part 2 (commencing with Section 10110) of Division 2 of the Insurance Code shall be conditioned upon or affected by the making or rescinding of a request by a person to end his or her life in a humane and dignified manner. Any such policy provision shall be invalid.

7197.5. The sale, procurement, or issuance of any life, health, or accident insurance or annuity policy or the rate charged for any policy shall not be conditioned upon or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner. A qualified patient's act of ingesting medication to end his or her life in a humane and dignified manner in accordance with this chapter shall not have an effect upon a life, health, or accident insurance or annuity policy.

7197.7. Nothing in this chapter shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing, or active euthanasia. The patient must self-administer the medication provided under this chapter. Actions taken in accordance with this chapter shall not, for any purpose, constitute suicide, assisted suicide, mercy killing, or homicide, under the law.

Article 3. Immunities and Liabilities

7198. Except as provided in Section 7198.5:

(a) Notwithstanding any other provision of law, no person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with this chapter. This includes being present when a qualified

patient takes the prescribed medication to end his or her life in a humane and dignified manner.

(b) No professional organization or association, or heath care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating or refusing to participate in good faith compliance with this chapter.

(c) No request by a patient for or provision by an attending physician of medication in good faith compliance with this chapter shall constitute neglect for any purpose of law or provide the sole basis for the appointment of a guardian or conservator.

(d) No health care provider shall be under any duty, whether by contract, by statute, or by any other legal requirement to participate in the provision to a qualified patient of medication to end his or her life in a humane and dignified manner. If a health care provider is unable or unwilling to carry out a patient's request under this chapter, and the patient transfers his or her care to a new health care provider, the prior health care provider shall transfer, upon request, a copy of the patient's relevant medical records to the new health care provider.

(e) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250, may prohibit a licensed physician from carrying out a patient's request under this chapter on the premises of the hospital if the hospital has notified the licensed physician of its policy regarding this chapter.

7198.5. (a) Nothing in this chapter limits civil or criminal liability resulting from other negligent conduct or intentional misconduct by any person.

(b) The penalties in this chapter do not preclude criminal penalties applicable under other law for conduct that is inconsistent with this chapter.

Article 4. Severability

7198.9. Any section of this chapter that is held invalid as to any person or circumstance shall not affect the application of any other section of this chapter that can be given full effect without the invalid section or portion thereof.

Article 5. Form of the Request

7199. A request for a medication as authorized by this chapter shall be in substantially the following form:

REQUEST FOR MEDICATION
TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER

I, ____, am an adult of sound mind.

I am suffering from ____, which my attending physician has determined is a terminal disease which will, within reasonable medical judgment, likely lead to my death within six months, and which has been medically confirmed by a consulting physician.

I have been fully informed of my diagnosis, prognosis, the nature of the medication to be prescribed, and the potential associated risks, the expected result, and the feasible alternatives, including comfort care, hospice care, and pain control.

I request that my attending physician prescribe medication that will allow me to hasten the end of my life in a humane and dignified manner.

INITIAL ONE:

_____ I have informed my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

I understand that I have the right to rescind this request at any time.

I understand the full import of this request, and I expect to die when I take the medication to be prescribed.

I make this request voluntarily and without reservation, and I accept full moral responsibility for my actions.

Signed: _____

Dated: _____

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) Is personally known to us or has provided proof of identity;

(b) Signed this request in our presence;

(c) Appears to be of sound mind and not under duress, fraud, or undue influence;

(d) Is not a patient for whom either of us is the attending physician.

_____ Witness 1/Date

_____ Witness 2/Date

NOTE: One witness shall not be a relative (by blood, marriage, or adoption) of the person signing this request, shall not be entitled to any portion of the person's estate upon death, and shall not own, operate, or be employed at a health care facility where the person is a patient or resident.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 21 **VERSION: AMENDED JUNE 15, 2005**

AUTHOR: LEVINE **SPONSOR: LEVINE**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACISTS: PRACTICE REQUIREMENTS

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052(8))

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

4) Requires the board to take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. (B&P 4301)

This Bill:

1) Establishes the Women's Contraceptive and Pharmaceutical Freedom Act of 2005. (B&P 4069 Added)

2) States that it shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. (B&P 4316 Added)

3) Requires a violation of this section by a pharmacist to constitute unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board. (B&P 4069 Added)

4) Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:

a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

b. The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active

chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request.

   i. A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing of his or her objections.

   ii. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B&P 4069 Added)

5) Requires an employer, upon receipt of a pharmacist objections, to establish a policy and protocol to accommodate the patient's need for the drug. (B&P 4069 Added)

6) Does not permit an employer to withdraw an offer of employment or terminate employment based on the notification or change in the notification. (B&P 4069 Added)

Comment:

1) Author's Intent. The author's intent is to insure that pharmacists do not refuse to dispense EC to patients. Since enactment of SB 644 (Chapter417, Statutes of 2005), AB 21 has stalled in the Senate.

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

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

4) Enforcement. Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. The June 15th amendments regarding unprofessional conduct and emotional distress may be difficult to enforce. If AB 21 is enacted the board anticipates that it will need to train its inspectors on the nuances of the law governing emotional distress.

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

SB 644 (Chapter417, Statutes of 2005) Dispensing Prescription Drugs And Devices, requires a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate.

6) Federal Legislation. In April 2005, Senator Boxer introduced S 778, the Pharmacy Consumer Protection Act of 2005. S778 would require a pharmacist to fill a legal prescription unless the prescribed item is not in the pharmacy's stock, in which case the pharmacy would order such item without unnecessary delay or, if the patient prefers, the pharmacy would transfer the prescription to a local pharmacy of the patient's choice or return the prescription to the patient, at the patient's request. S 778 would not prohibit a pharmacist from refusing to dispense a prescribed item, in accordance with standard pharmacy practice, if there is a valid medical concern that such prescribed item will cause problems due to therapeutic duplications, drug-disease contraindications, drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, or drug abuse or misuse. S 778 has been referred to the Senate Finance Committee.

7) Support & Opposition.

Support: American Academy of Pediatrics, California District
California Medical Association
NARAL Pro-Choice California (if amended)
National Association of Social Workers, California Chapter
Planned Parenthood Affiliates of California (in concept)

Oppose: California Association for Health Services at Home (unless amended)
California Family Alliance
California Pharmacists Association (unless amended)
California Retailers Association (unless amended)
California Right to Life Committee, Inc.
California Society of Health-System Pharmacists
Traditional Values Coalition

9) History.

2005

June 22	In committee: Set first hearing. Failed passage. Reconsideration granted.
June 15	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Coms. on HEALTH and B., P. & E.D.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 52. Noes 25. Page 2096.)
May 9	Read second time. To third reading.
May 5	From committee: Do pass. (Ayes 12. Noes 5.) (May 4).
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 2.) (April 26).
Apr. 14	Re-referred to Com. on B. & P.
Apr. 13	Read second time and amended.
Apr. 12	From committee: Amend, do pass as amended, and re-refer to Com. onB. & P. (Ayes 10. Noes 3.) (April 5).
Mar. 30	Re-referred to Com. on HEALTH.

Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004
Dec. 7 From printer. May be heard in committee January 6.
Dec. 6 Read first time. To print.

AMENDED IN SENATE JUNE 15, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 21

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

December 6, 2004

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of ~~its~~ *those* provisions unprofessional conduct *and would also make harassment, as specified,*

of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board.

Because the bill would specify ~~an~~ additional ~~requirement~~ *violations* under the Pharmacy Law, ~~a violation of~~ which would be *punishable as* a crime, it would impose a state-mandated local program.

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

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

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

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

1 *SECTION 1. This act shall be known and may be cited as the*
2 *Women's Contraceptive and Pharmaceutical Freedom Act of*
3 *2005.*
4 ~~SECTION 1.—~~
5 *SEC. 2.* Section 4069 is added to the Business and
6 Professions Code, to read:
7 4069. (a) Notwithstanding any other provision of law, a
8 pharmacist shall dispense a lawful prescription unless one of the
9 following circumstances exists:
10 (1) The pharmacist determines, based on his or her
11 professional training and judgment, that dispensing the
12 prescription is contrary to law or, after consulting with the
13 patient's prescriber, that it is contraindicated for the patient.
14 (2) The pharmacy does not have the prescribed trade or brand
15 name drug in stock. The pharmacist shall offer the patient
16 another drug product, if available, with the same active chemical
17 ingredients of the same strength, quantity, and dosage form and
18 of the same generic drug name, as determined by the United
19 States Adopted Names and accepted by the federal Food and
20 Drug Administration, as the prescribed drug product and follow
21 the procedure or protocol described in Section 4073.
22 (3) (A) The pharmacist elects to refuse on ethical, moral, or
23 religious grounds to dispense a drug pursuant to a lawful request.
24 A pharmacist may decline to dispense a drug on these grounds

only after notifying his or her employer in writing of his or her objections. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B) An employer shall, upon receipt of the notification described in subparagraph (A), establish a policy and protocol to accommodate the patient's ~~needs~~ *need* for the drug.

(b) An employer shall not withdraw an offer of employment or terminate employment based on the notification or change in the notification, as described in subparagraph (A) of paragraph (3) of subdivision (a).

(c) A violation of this section by a pharmacist constitutes unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board.

SEC. 3. Section 4316 is added to the Business and Professions Code, to read:

4316. It shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.

~~SEC. 2.—~~

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 71 **VERSION: AMENDED JUNE 23, 2005**

AUTHOR: CHAN et. al. **SPONSOR: CHAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)

2) Requires the office to do all of the following:

   a. Establish a central repository of information about the safety and effectiveness of prescription drugs; the office would not collect information on drugs that are used primarily to treat mental illness.

   b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved. Requires that website to contain the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."

   c. Assure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available.

   d. Request units of the University of California and the California State University to provide assistance.

   e. Rely on systematically reviewed evidence-based research.

   f. Requires the office to select therapeutic classes of drugs to develop information on, that have 1) been recently published reports of safety concern; 2) been frequently advertised

directly to consumers; and 3) had recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(H&S 111657 Added)

3) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

4) Defines the following terms, evidence-based research and systematically reviewed.

(H&S 111657.1 Added)

5) Requires DHS to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state. (H&S 111657.2 Added)

6) Establishes the Drug Safety Watch Fund in the State Treasury. (H&S 111657.2 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

2) Necessity for Bill? The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project (ODERP), Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

3) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

4) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill that was introduced but not heard in its first committee.

6) History.

2005	
June 27	In committee: Set, first hearing. Hearing canceled at the request of author.
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 44. Noes 34. Page 2146.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
April 27	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 19	Re-referred to Com. on APPR.
Apr. 18	Read second time and amended.
Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (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.
Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Cohn, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television,~~ *that belong to classes of drugs for which there have been*

recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site~~,~~ *and* to request assistance from the University of California and California State University~~, and to rely on systematically reviewed evidence-based research~~.

This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.

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. The Legislature finds and declares all of the
2 following:
3 (a) Since 1997, when the United States Food and Drug
4 Administration (FDA) allowed drug manufacturers to advertise
5 directly to consumers, the amount spent on advertising has risen
6 dramatically.
7 (b) According to the United States General Accounting Office
8 (GAO) report, the pharmaceutical industry spent $2.7 billion in
9 2001 on direct-to-consumer advertising. A December 6, 2004,
10 New York Times report states that such spending has reached
11 $3.8 billion.
12 (c) According to the same GAO report, while overall spending
13 on drug promotion was less than spending on research and
14 development ($19.1 billion versus $30.3 billion), spending on
15 direct-to-consumer advertising is increasing at a faster rate than
16 overall drug promotion spending or spending on research and
17 development. Between 1997 and 2001, the increase in
18 direct-to-consumer advertising was 145 percent compared to a 59
19 percent increase for research and development.
20 (d) Although the FDA is responsible for postmarket
21 surveillance of prescription drugs, numerous concerns have been
22 raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Drugs that are frequently advertised to consumers present special safety concerns because direct-to-consumer advertising is likely to minimize potential side effects and safety concerns and because advertised drugs are likely to be highly utilized by Californians.

~~(h)~~

(i) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

~~(i)~~

(j) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

~~(j)~~

(k) Various nationally respected sources of clinical information are available as sources for a central respository of information about prescription drug safety and effectiveness.

~~(k)~~

(l) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are ~~frequently advertised on television.~~ *selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.*

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~

(b) In selecting therapeutic drugs about which to develop information, the office shall only include classes of drugs that have all of the following characteristics:

(1) Classes of drugs for which there have been recently published reports of safety concerns.

(2) Classes of drugs that have been frequently advertised directly to consumers.

(3) Classes of drugs for which there are recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(c) The office shall request the appropriate units of the University of California and the California State University to provide assistance in implementing this article.

(d) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

(e) The office shall rely on systemically reviewed evidence-based research.

(f) The process that the office uses to identify relevant research and standards of clinical evidence shall be transparent and publicly available.

111657.1. For purposes of this article, the following terms have the following meanings:

~~(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.~~

(a) "Evidence-based research" means research that is based on clinical evidence, including therapeutic outcomes, and that uses a hierarchy of evidence to evaluate the reliability of the research. In well-conducted research, the hierarchy of evidence, from highest to lowest, is the system review of randomized clinical trials, individual randomized clinical trials, controlled trials, cohort studies, and case control studies.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence

increases the reliability of the results, and the transparency of the procedures.

~~(c) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period prior to the date the office begins compiling the drug safety and effectiveness information required by this article. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.~~

111657.2. (a) There is hereby imposed, pursuant to this section, a fee on manufacturers of drugs sold in the state.

(b) (1) The specific fee to be assessed on a drug manufacturer shall be established by the State Department of Health Services, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state.

(2) A fee shall not be assessed on a drug manufacturer that can demonstrate, as determined by the State Department of Health Services, that it does not manufacture drugs that have the characteristics described in subdivision (b) of Section 111657.

(c) The fee shall be assessed and collected annually by the State Board of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees collected shall be deposited in the Drug Safety Watch Fund, which is hereby established in the State Treasury. Moneys in the fund shall be expended, upon appropriation by the Legislature, for the purposes of this article, including the costs of the State Board of Equalization for collection and administration of fees. All interest earned on the moneys that have been deposited into the Drug Safety Watch Fund shall be retained in the fund.

(d) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this article. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this article. The department shall not spend more than it collects from the fees, and the earnings thereon, in implementing this article.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 75 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)

2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)

3. Establishes the criteria for a qualified resident as:

   a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - $38,280 for an individual and $77,400 for a family of four)

   b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)

4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)

5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)

6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater then Medi-Cal rebates. (H&S 130518 Added)

7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is now a two-year bill.

5) Support / Opposition.

Support: AIDS Healthcare Foundation
Alzheimer's Association
American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Federation of Labor
California Federation of Teachers
California Labor Federation
California Nurses Association
California Pharmacists Association
California Public Interest Research Group
Consumers Union
Health Access California
NAMI California (if amended)
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition: BIOCOM
California Chamber of Commerce
Department of Health Services (unless amended)
National Association of Chain Drug Stores (unless amended)
Mental Health Association of California
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Western Center on Law & Poverty
Wyeth Pharmaceuticals

6) History.

2005

June 28	In committee: Set, first hearing. Hearing canceled at the request of author.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 43. Noes 34. Page 2141.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 4.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
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 7. Noes 1.) (April 26).
Apr. 20	Re-referred to Com. on B. & P.
Apr. 19	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 75

Introduced by Assembly Members Frommer and Chan
(Principal coauthor: Assembly Member Baca)
(Coauthors: Assembly Members Bass, Berg, Cohn, Coto, De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs, Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas, Ruskin, Saldana, ~~and Salinas~~ *Salinas, and Torrico*)
(Coauthor: Senator Alquist)

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements

with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program, upon appropriation by the Legislature.

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. Division 112 (commencing with Section
2 130500) is added to the Health and Safety Code, to read:
3
4 DIVISION 112. CALIFORNIA RX PLUS STATE
5 PHARMACY ASSISTANCE PROGRAM
6
7 CHAPTER 1. GENERAL PROVISIONS
8
9 130500. (a) This division shall be known, and may be cited,
10 as the California Rx Plus State Pharmacy Assistance Program.
11 (b) For purposes of this division, the following definitions
12 apply:
13 (1) "Department" means the State Department of Health
14 Services.
15 (2) "Fund" means the California Rx Plus Program Fund.

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

(4) "Program" means the California Rx Plus State Pharmacy Assistance Program.

(5) (A) "Qualified resident" means a resident of California who has a *gross* family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of *gross* family income or whose total unreimbursed medical expenses equal 15 percent or more of *gross* family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

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

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, a person shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program, or any other program that uses federal funds to pay part or all of the cost of the person's outpatient prescription drugs.

(b) Notwithstanding subdivision (a), a person enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program. The application form shall include a requirement that the applicant or the

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

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

(c) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible shall be guilty of a misdemeanor.

(d) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible may be denied a drug discount card under this program for up to one year from the date of the denial of coverage by the department.

(e) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

130507. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

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

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

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

(3) The total number of prescriptions or 30-day supplies, and total value, of each of the manufacturer's brand name drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (e) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. (a) The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall implement an outreach, education, and enrollment program with Health Insurance Counseling and Advocacy Program agencies, the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

(b) The department shall implement a plan to prevent the occurrence of fraud in the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the

specific drug or an average discount for a group of drugs or all drugs covered by the program.

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

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

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) The department shall seek to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medi-Cal rebate program pursuant to Section 14105.33 of the Welfare and Institutions Code.

(c) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

(d) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(e) All of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

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

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

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

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

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

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

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

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

(8) Require the manufacturer to calculate and pay interest on late or unpaid rebates. The department may, by regulation, establish the date upon which the interest payments by drug manufacturers shall begin to accrue as well as any other regulations it deems necessary for the implementation of this paragraph.

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

130519. (a) (1) The department may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division, to the extent the department determines *that* it is appropriate to do *so* in order to encourage manufacturer participation in the program, ~~and~~ to the extent permitted by federal law, and subject to any necessary federal approvals or waivers.

(2) In making a determination to require prior authorization in the Medi-Cal program pursuant to paragraph (1), the department shall ensure that there are as many single-source drugs within each therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. In no event shall a Medi-Cal beneficiary be denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary.

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

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with

pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Upon appropriation by the Legislature, moneys in the fund shall be used for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

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 225 **VERSION: AMENDED APRIL 7, 2005**

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

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: ELECTRONIC PRESCRIPTION INFORMATION.

Existing Law:

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

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

This Bill:

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

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

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

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

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

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

Comment:

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

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

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

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

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

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

5) Support & Opposition.

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

Opposition: None on file.

6) History.

2005

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

AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 225

Introduced by Assembly Member Negrete McLeod

February 3, 2005

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

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

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

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

~~The~~

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

~~Except~~

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

~~Except~~

(d) (1) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful ~~for a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, as provided in Section 11164 of the Health and Safety Code. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.~~ *to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) in the following situations:*

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

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

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

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

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

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

~~"Health~~

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

~~A~~

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 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	
July 11	In committee: Set, second hearing. Hearing canceled at the request of author.
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.

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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 657 **VERSION: AMENDED JUNE 21, 2005**

AUTHOR: KARNETTE **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

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

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

This Bill:

Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription. (B&P 4076(a)(10) Amended)

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

Comment:

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

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

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

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

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

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

4) History.

2006

Mar. 13	In committee: Hearing postponed by committee.

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.

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: SB 380 **VERSION: AMENDED JUNE 21, 2005**

AUTHOR: ALQUIST **SPONSOR: SENIOR CITIZENS, SO. CAL**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

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

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825 or any other provisions in law. (Penalties under H&S 111825 are imprisonment for not more than one year in the county jail or a fine of not more than $1,000, or both the imprisonment and fine.)

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA's MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

6) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

7) Support & Opposition.

Support: American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition: American College of Obstetricians and Gynecologists, Region IX
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

8) History.

2005

June 29	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0.) Re-referred to Com. on APPR.
June 21	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 15	From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 9. Noes 4.) Re-referred to Com. on B. & P.
June 7	Set, first hearing. Hearing canceled at the request of author.
May 26	To Coms. on HEALTH and B. & P.
May 2	In Assembly. Read first time. Held at Desk.
May 2	Read third time. Passed. (Ayes 23. Noes 13. Page 867.) To Assembly.
Apr. 28	Read second time. Amended. To third reading.
Apr. 27	From committee: Do pass as amended. (Ayes 9. Noes 2. Page 767.)
Apr. 18	Set for hearing April 25.
Apr. 11	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 7	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)
Mar. 14	Set for hearing March 30.
Feb. 24	To Com. on HEALTH.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.

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

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

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization,

1 disability, congenital anomaly, or required intervention to
2 prevent permanent impairment or damage.
3 (c) Any health professional or health facility that is required to
4 report an adverse drug event pursuant to this section shall do so
5 using the FDA 3500 Voluntary form developed by the federal
6 Food and Drug Administration for MedWatch.
7 111658. A licensed health professional or health facility that
8 violates any provision of this article shall not be subject to the
9 penalties and remedies outlined in Chapter 8 (commencing with
10 Section 111825) or any other provision of law. *Nothing in this*
11 *section affects otherwise existing duties, rights, or remedies*
12 *under the law.*

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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 Workers Union. 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 April 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 April 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 on July 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.

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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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