

Agenda Item B

*Consideration of Bills of Interest
to the Board of Pharmacy*

Memorandum

To: Legislation & Regulation Committee

Date: April 14, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legislation Update

Board Sponsored Legislation

AB 595 (Negrete McLeod) Pharmacy: compounding of prescription drugs.

Status: Senate Floor.

This bill is sponsored by the board to establish standards for pharmacies that compound and to provide direction for regulations that will follow later this year. The board approved this legislative proposal at its January 2005 meeting.

AB 2408 (Negrete McLeod) Pharmacists, pharmacies, and nonresident pharmacies.

This bill is sponsored by the board and would update the definition of a pharmacy, nonresident pharmacy, and the professional practice of pharmacy. The board approved draft legislation at its February 2006 meeting.

Status: Status: Assembly Business and Professions Committee - Hearing April 17, 2006.

Omnibus Bill (Senate Business and Professions and Economic Development Committee). Note: This bill is not in print.

The board approved the following proposals for the omnibus legislation at prior board meeting:

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

B&P 4162 Wholesalers Surety Bond Requirements.

B&P 4104 Licensed Employee, Theft, Impairment: Pharmacy Procedures.

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device.

B&P 4160 Wholesaler License.

B&P 4180-4182 and 4190-4192 Nonprofit or Free Clinics.

B&P 4127.1 Injectable Sterile Drug Products.

B&P 4073 Substitution of Generic Drug, Check off Box on Electronic Prescriptions.

Board Sunset Extension Bill (Figueroa). Note: This bill is not in print.

This bill will extend the board's sunset date two years, from 2008 to 2010. The board's sunset report to the Legislature will be due September 2008.

Bills of Interest

AB 2583 (Nation) Dispensing prescription drugs and devices: refusal to dispense.

Status: Assembly Health Committee - Hearing April 18, 2006.

AB 2743 (Matthews) Pharmacists: ancillary personnel.

Status: Assembly Business and Professions Committee.

AB 2986 (Mullin) Controlled substances: prescription requirements.

Status: Assembly Public Safety Committee - Hearing April 18, 2006.

SB 1366 (Aanestad) Controlled substances.

Status: Assembly Public Safety Committee - Hearing April 25, 2006.

2006 Watch Bills

AB 1908 (Karnette) Medi-Cal: pharmacy reimbursement.

Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2057 (Cogdill) Controlled substances.

Status: Assembly Appropriations Committee.

AB 2198 (Houston) Health care: controlled substances and dangerous drugs.

Status: Assembly Business and Professions Committee – Hearing April 17, 2006.

AB 2308 (Plescia) Ambulatory surgical centers: licensure.

Status: Assembly Health Committee - Hearing April 18, 2006.

AB 2373 (Plescia) Automated drug delivery system.

Status: Assembly Health - Hearing April 18, 2006.

AB 2730 (Nation) Medi-Cal: contract drug list: advertising.

Status: Assembly Health Committee - Hearing April 18, 2006.

AB 2856 (Hancock) Informed consent: prescription medication off-label use.

Status: Assembly Health Committee - Hearing April 18, 2006.

AB 2877 (Frommer) Prescription drugs: importation: procurement.

Status: Assembly Health Committee - Hearing April 18, 2006.

AB 2911 (Nunez) California Discount Prescription Drug Program.

Status: Assembly Health Committee - Hearing April 25, 2006.

AJR 40 (Chan) Medicare Prescription Drugs.

Status: Assembly Floor.

AJR 49 (Nation) Direct-To-Consumer Prescription Drug Advertisements

Status: Assembly Health Committee - Hearing May 2, 2006.

SB 1305 (Figueroa) The Medical Waste Management Act.

Status: Senate Environmental Quality Committee – Hearing April 17, 2006.

SB 1430 (Alquist) The Local Pandemic and Emergency Health Preparedness Act of 2006.

Status: Senate Floor.

SB 1683 (Scott) Pharmaceutical information: clinical trial data.

Status: Senate Health Committee – Hearing April 19, 2006.

2005 Watch Bills

AB 651 (Berg) California Compassionate Choices Act.

Status: Senate Rules Committee.

AB 21 (Levine) Pharmacists: contraceptive devices.

Status: Senate Health Committee - Hearing Cancelled.

AB 71 (Chan) Pharmaceuticals: adverse drug reactions: Office of Ca. Drug Safety Watch.

Status: Senate Health Committee - Hearing Cancelled.

AB 75 (Frommer) Pharmaceutical assistance program.

Status: Senate Health Committee - Hearing Cancelled.

AB 225 (Negrete McLeod) Electronic prescription information.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 283 (Koretz) Pseudoephedrine: retail sale.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 657 (Karnette) Pharmacies: prescription containers.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

SB 380 (Alquist) Drugs: adverse event reporting.

Status: Assembly Floor, failed passage. Reconsideration granted.

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.

Assembly Health Committee - Failed passage in committee. Reconsideration granted.

Board Sponsored

Legislation

AMENDED IN SENATE MAY 26, 2005
AMENDED IN ASSEMBLY APRIL 18, 2005
AMENDED IN ASSEMBLY MARCH 29, 2005
CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

Statutory provisions establish procedures for making that reimbursement.

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

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

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

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

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

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

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

7 4123. (a) A compounded drug product shall only be
8 dispensed or furnished to a patient pursuant to a prescription
9 meeting the requirements of Section 4040.

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

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

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

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

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

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

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

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

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

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

O

AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 2408

Introduced by Assembly Member ~~Calderon~~ *Negrete McLeod*

February 23, 2006

~~An act to amend Section 10153.4 of, to amend, repeal, and add Sections 10156.6, 10156.7, and 10215 of, to add and repeal Section 10153.10 of, and to repeal Section 10154 of, the Business and Professions Code, relating to real estate salespersons. An act to amend Sections 4036, 4037, 4050, 4051, 4052, 4112, 4120, 4201, 4207, 4301, and 4306.5 of, to amend, renumber, and add Section 4052.1 of, to add Sections 4052.2 and 4052.3 to, and to repeal and add Section 4302 of, the Business and Professions Code, relating to pharmacies.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 2408, as amended, ~~Calderon~~ *Negrete McLeod*. ~~Real estate salespersons: conditional licensure. Pharmacies.~~

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacies by the Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime.

Existing law defines a pharmacist and a pharmacy, requires pharmacists and pharmacies to be licensed by the board, and authorizes a licensee to engage in certain activities. Existing law also sets forth activities that constitute unprofessional conduct for a pharmacist to engage in.

This bill would require a pharmacist to be a natural person, and would entitle a licensed pharmacist to practice pharmacy within or outside of a licensed pharmacy. The bill would revise the activities in

which a pharmacist may engage, including the adjustment of prescriptions and provisions of cognitive services, would revise the pharmacist's responsibilities and requirements with regard to certain activities, and would make certain additional acts or omissions unprofessional conduct. The bill would revise the definition of a pharmacy to include, among other things, all pharmacies in which the profession of pharmacy is practiced. The bill would list different types of pharmacies and would require a pharmacy or nonresident pharmacy to specify its type in its application for licensure and to update the board if that information changes. The bill would make it unlawful for an unlicensed person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other health care providers.

Existing law defines a nonresident pharmacy and requires a nonresident pharmacy to meet certain criteria, including registration with the board. Existing law prohibits an unregistered nonresident pharmacy from engaging in certain activities, including selling or distributing dangerous drugs or dangerous devices in this state through any person or media other than a licensed wholesaler. Existing law requires a nonresident pharmacy to disclose to the board the location, names, and titles of specified persons, including all pharmacists dispensing controlled substances, dangerous drugs, or dangerous devices to residents of California. Existing law authorizes the board to deny, revoke, or suspend a nonresident registration for failure to comply with specified requirements or for conduct that causes serious bodily or psychological injury to a California resident, in specified circumstances.

This bill would revise the definition of a nonresident pharmacy to require shipping, mailing, or delivering directly to patients in California, and to include a pharmacy located outside of the state that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. The bill would delete the requirement that a nonresident pharmacy must disclose the location, names, and titles of pharmacists, and the prohibition against a nonresident pharmacy selling or distributing dangerous drugs or devices in California through any person or media other than a licensed wholesaler. This bill would also delete the authorization for the board to deny, revoke, or suspend a nonresident registration for

failure to comply with specified requirements or for conduct causing serious bodily harm or psychological injury to a California resident, and would instead authorize the board to deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment, or take any other action against a nonresident pharmacy that it may take against a resident pharmacy. The bill would also authorize the board to report violations of laws or regulations by a nonresident pharmacy to its regulatory or licensing agency.

This bill would revise and recast related provisions of the Pharmacy Law.

Because this bill would create new requirements and prohibitions under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

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

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

~~Existing law, the Real Estate Law, provides for the licensure and regulation of real estate salespersons by the Department of Real Estate. Under that law, an applicant for licensure as a real estate salesperson is required to submit to the Real Estate Commissioner evidence of the successful completion of specified courses in real estate either prior to issuance of the license or within 18 months after its issuance.~~

~~This bill would, for persons who apply for licensure on or after January 1, 2007, delete the provisions from the Real Estate Law that allow an applicant to submit evidence of his or her completion of the real estate courses within 18 months after issuance of the license.~~

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

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

- 1 *SECTION 1. Section 4036 of the Business and Professions*
- 2 *Code is amended to read:*
- 3 *4036. "Pharmacist" means a natural person to whom a*
- 4 *license has been issued by the board, under Section 4200, except*

1 as specifically provided otherwise in this chapter. *The holder of*
2 *an unexpired and active pharmacist license issued by the board*
3 *is entitled to practice pharmacy as defined by this chapter, within*
4 *or outside of a licensed pharmacy as authorized by this chapter.*

5 *SEC. 2. Section 4037 of the Business and Professions Code is*
6 *amended to read:*

7 4037. (a) "Pharmacy" means an area, place, or premises
8 licensed by the board in which the profession of pharmacy is
9 practiced ~~and where prescriptions are compounded.~~ Only a
10 "dispensing pharmacy," as defined in subdivision (b), may
11 possess, prepare, manufacture, derive, compound, repackage,
12 furnish, sell, or dispense controlled substances, dangerous drugs,
13 or dangerous devices. In all other respects, whenever the term
14 "pharmacy" is used in this chapter, it shall be deemed to refer to
15 all of the types of pharmacies listed in subdivision (b).
16 "Pharmacy"

17 (b) "Pharmacy" includes, but is not limited to, ~~any~~ all of the
18 following:

19 (1) A "dispensing pharmacy," which is any area, place, or
20 premises described in a license issued by the board wherein
21 controlled substances, dangerous drugs, or dangerous devices are
22 stored, possessed, prepared, manufactured, derived, compounded,
23 or repackaged, and from which the controlled substances,
24 dangerous drugs, or dangerous devices are furnished, sold, or
25 dispensed at retail.

26 ~~(b)~~

27 (2) A "prescription processing pharmacy," which is any area,
28 place, or premises described in a license issued by the board
29 wherein personnel licensed by the board engage in or supervise
30 drug order or prescription review by performing functions
31 including, but not limited to, data entry, drug utilization review,
32 patient or prescriber contact, patient profile review, and allergy
33 and drug-interaction review.

34 (3) An "advice/clinical center pharmacy," which is any area,
35 place, or premises described in a license issued by the board
36 wherein personnel licensed by the board provide cognitive
37 pharmacy services including, but not limited to, clinical advice
38 or information, telephonic or in-person patient consultation,
39 drug utilization review, and medication therapy management.

1 (c) "Pharmacy" shall not include any area in a facility licensed
2 by the State Department of Health Services where floor supplies,
3 ward supplies, operating room supplies, or emergency room
4 supplies of dangerous drugs or dangerous devices are stored or
5 possessed solely for treatment of patients registered for treatment
6 in the facility or for treatment of patients receiving emergency
7 care in the facility.

8 (d) "Pharmacy" shall not include a clinic licensed under
9 Section 4180 or Section 4190.

10 SEC. 3. Section 4050 of the Business and Professions Code is
11 amended to read:

12 4050. (a) In recognition of and consistent with the decisions
13 of the appellate courts of this state, the Legislature hereby
14 declares the practice of pharmacy to be a profession.

15 (b) Pharmacy practice is a dynamic patient-oriented health
16 service that applies a scientific body of knowledge to improve
17 and promote patient health by means of appropriate drug use,
18 drug-related therapy, and communication for clinical and
19 consultative purposes. *Pharmacy practice is continually evolving*
20 *to include more sophisticated and comprehensive patient care*
21 *activities.*

22 SEC. 4. Section 4051 of the Business and Professions Code is
23 amended to read:

24 4051. (a) *The holder of an unexpired and active pharmacist*
25 *license issued by the board is vested with the authority and*
26 *responsibility to perform the following functions inherent to*
27 *pharmacy practice:*

28 (1) *Interpreting, verifying, and implementing drug orders and*
29 *prescriptions.*

30 (2) *Dispensing pursuant to legitimate drug orders and*
31 *prescriptions.*

32 (3) *Ensuring proper drug storage, documentation, inventory,*
33 *labeling, and record-keeping.*

34 (4) *Maintaining accurate, complete, and confidential patient*
35 *profiles and records.*

36 (5) *Supervising pharmacy technicians and other ancillary*
37 *personnel in the pharmacy.*

38 (6) *Designing and implementing quality assurance procedures*
39 *and protocols.*

1 (7) *Compounding drug products pursuant to prescription and*
2 *for prescriber office use.*

3 (8) *Maintaining safe, secure, and sanitary conditions in*
4 *licensed premises.*

5 (9) *Performing cognitive services, including drug utilization*
6 *reviews and management, medication therapy reviews and*
7 *management, and patient counseling and consultation.*

8 (10) *Collaborating with prescribers and other health care*
9 *providers regarding patient care.*

10 (11) *Implementing standardized procedures and protocols*
11 *regarding patient care.*

12 (12) *Administering or furnishing drugs or biologicals, where*
13 *permitted by law.*

14 (13) *Initiating, adjusting, or implementing patient drug*
15 *regimens where permitted by law.*

16 (14) *Any other pharmacy functions authorized by this chapter.*

17 (b) Except as otherwise provided in this chapter, it is unlawful
18 for any person to manufacture, compound, furnish, sell, or
19 dispense any dangerous drug or dangerous device, or to dispense
20 or compound any prescription pursuant to Section 4040 of a
21 prescriber unless he or she is a pharmacist *licensed* under this
22 chapter.

23 (b)

24 (c) *Except as otherwise provided in this chapter, it is unlawful*
25 *for any person to perform any prescription review, consultation,*
26 *drug utilization review, medication therapy management, or*
27 *other cognitive services for, pertaining to, or at the request of,*
28 *patients, prescribers, or other care providers in this state, unless*
29 *he or she is a pharmacist licensed under this chapter.*

30 (d) Notwithstanding any other law, a pharmacist *licensed*
31 *under this chapter* may authorize the initiation or adjustment of a
32 prescription, pursuant to Section 4052, and otherwise provide
33 *cognitive services*, clinical advice or information, or patient
34 consultation if all of the following conditions are met:

35 (1) The *cognitive service*, clinical advice, or information or
36 patient consultation is provided to a health care professional or to
37 a patient.

38 (2) The pharmacist has access to prescription *records*, patient
39 ~~profile~~ *profiles*, or other relevant medical information for
40 purposes of *cognitive services*, patient and clinical consultation,

1 and advice, and appropriately reviews that information before
2 performing any of these functions.

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

5 (4) *The pharmacist authorizing initiation or adjustment of a*
6 *prescription, or cognitive services such as clinical advice,*
7 *information, or patient consultation, sets forth a complete log*
8 *and description of all patient records and other patient-specific*
9 *information, including any test results or other pertinent data,*
10 *used, consulted, or relied on by the pharmacist during the*
11 *performance of the function. The board may by regulation*
12 *further define the required content of the log and description.*
13 *This log and description shall be maintained in a readily*
14 *retrievable form, and provided to the board upon request, for a*
15 *period of at least three years from the date of performance of the*
16 *function. The underlying patient records and other*
17 *patient-specific information used, consulted, or relied on by the*
18 *pharmacist during the performance of the function may be*
19 *maintained elsewhere and not kept with the log and description,*
20 *as long as those records and that information are readily*
21 *retrievable and provided to the board upon request for a period*
22 *of at least three years from the date of performance of the*
23 *function. Otherwise, a duplicate copy of the patient records and*
24 *patient-specific information used, consulted or relied on shall*
25 *become part of the records maintained. Where the function to*
26 *which the log and description pertains is performed on the*
27 *premises of a licensed pharmacy, the obligation to keep and*
28 *maintain the foregoing records extends to the pharmacy and its*
29 *pharmacist-in-charge, and to the pharmacist performing the*
30 *function. Where the function to which the log and description*
31 *pertains is performed outside of the premises of a licensed*
32 *pharmacy, the obligation to keep and maintain the foregoing*
33 *records extends only to the performing pharmacist.*

34 SEC. 5. Section 4052 of the Business and Professions Code is
35 amended to read:

36 4052. (a) Notwithstanding any other provision of law, a
37 pharmacist may:

38 (1) Furnish a reasonable quantity of compounded ~~medication~~
39 *drug product* to a prescriber for office use by the prescriber.

40 (2) Transmit a valid prescription to another pharmacist.

1 (3) Administer, orally or topically, drugs and biologicals
2 pursuant to a prescriber's order.

3 (4) Perform ~~the following~~ procedures or functions in a
4 licensed health care facility ~~in accordance with policies,~~
5 ~~procedures, or protocols developed by health professionals,~~
6 ~~including physicians, pharmacists, and registered nurses, with the~~
7 ~~concurrence of the facility administrator:~~

8 (A) ~~Ordering or performing routine drug therapy-related~~
9 ~~patient assessment procedures including temperature, pulse, and~~
10 ~~respiration.~~

11 (B) ~~Ordering drug therapy-related laboratory tests.~~

12 (C) ~~Administering drugs and biologicals by injection pursuant~~
13 ~~to a prescriber's order (the administration of immunizations~~
14 ~~under the supervision of a prescriber may also be performed~~
15 ~~outside of a licensed health care facility):~~

16 (D) ~~Initiating or adjusting the drug regimen of a patient~~
17 ~~pursuant to an order or authorization made by the patient's~~
18 ~~prescriber and in accordance with the policies, procedures, or~~
19 ~~protocols of the licensed health care facility: as authorized by~~
20 ~~Section 4052.1.~~

21 (5) (A) ~~Perform the following procedures or functions as part~~
22 ~~of the care provided by a health care facility, a licensed home~~
23 ~~health agency, a licensed clinic in which there is a physician~~
24 ~~oversight, a provider who contracts with a licensed health care~~
25 ~~service plan with regard to the care or services provided to the~~
26 ~~enrollees of that health care service plan, or a physician, in~~
27 ~~accordance, as applicable, with policies, procedures, or protocols~~
28 ~~of that facility, the home health agency, the licensed clinic, the~~
29 ~~health care service plan, or that physician, in accordance with~~
30 ~~subparagraph (C):~~

31 (i) ~~Ordering or performing routine drug therapy-related patient~~
32 ~~assessment procedures including temperature, pulse, and~~
33 ~~respiration.~~

34 (ii) ~~Ordering drug therapy-related laboratory tests.~~

35 (iii) ~~Administering drugs and biologicals by injection pursuant~~
36 ~~to a prescriber's order (the administration of immunizations~~
37 ~~under the supervision of a prescriber may also be performed~~
38 ~~outside of a licensed health care facility):~~

39 (iv) ~~Initiating or adjusting the drug regimen of a patient~~
40 ~~pursuant to a specific written order or authorization made by the~~

1 individual patient's treating prescriber, and in accordance with
2 the policies, procedures, or protocols of the health care facility,
3 home health agency, licensed clinic, health care service plan, or
4 physician. Adjusting the drug regimen does not include
5 substituting or selecting a different drug, except as authorized by
6 the protocol. The pharmacist shall provide written notification to
7 the patient's treating prescriber, or enter the appropriate
8 information in an electronic patient record system shared by the
9 prescriber, of any drug regimen initiated pursuant to this clause
10 within 24 hours.

11 (B) A patient's treating prescriber may prohibit, by written
12 instruction, any adjustment or change in the patient's drug
13 regimen by the pharmacist.

14 (C) The policies, procedures, or protocols referred to in this
15 paragraph shall be developed by health care professionals,
16 including physicians, pharmacists, and registered nurses, and, at
17 a minimum, meet all of the following requirements:

18 (i) Require that the pharmacist function as part of a
19 multidisciplinary group that includes physicians and direct care
20 registered nurses. The multidisciplinary group shall determine
21 the appropriate participation of the pharmacist and the direct care
22 registered nurse.

23 (ii) Require that the medical records of the patient be available
24 to both the patient's treating prescriber and the pharmacist.

25 (iii) Require that the procedures to be performed by the
26 pharmacist relate to a condition for which the patient has first
27 been seen by a physician.

28 (iv) Except for procedures or functions provided by a health
29 care facility, a licensed clinic in which there is physician
30 oversight, or a provider who contracts with a licensed health care
31 plan with regard to the care or services provided to the enrollees
32 of that health care service plan, require the procedures to be
33 performed in accordance with a written, patient-specific protocol
34 approved by the treating or supervising physician. Any change,
35 adjustment, or modification of an approved preexisting treatment
36 or drug therapy shall be provided in writing to the treating or
37 supervising physician within 24 hours: *as authorized by Section*
38 *4052.2.*

1 (6) Manufacture, measure, fit to the patient, or sell and repair
2 dangerous devices or furnish instructions to the patient or the
3 patient's representative concerning the use of those devices.

4 (7) Provide *cognitive services such as drug utilization review,*
5 *medication therapy management,* consultation to patients, and
6 professional information, including clinical or pharmacological
7 information, advice, or consultation to other health care
8 professionals.

9 ~~(8) (A) Furnish emergency contraception drug therapy in~~
10 ~~accordance with either of the following: as authorized by Section~~
11 ~~4052.3.~~

12 ~~(i) Standardized procedures or protocols developed by the~~
13 ~~pharmacist and an authorized prescriber who is acting within his~~
14 ~~or her scope of practice.~~

15 ~~(ii) Standardized procedures or protocols developed and~~
16 ~~approved by both the board and the Medical Board of California~~
17 ~~in consultation with the American College of Obstetricians and~~
18 ~~Gynecologists, the California Pharmacist Association, and other~~
19 ~~appropriate entities. Both the board and the Medical Board of~~
20 ~~California shall have authority to ensure compliance with this~~
21 ~~clause, and both boards are specifically charged with the~~
22 ~~enforcement of this provision with respect to their respective~~
23 ~~licensees. Nothing in this clause shall be construed to expand the~~
24 ~~authority of a pharmacist to prescribe any prescription~~
25 ~~medication.~~

26 ~~(B) Prior to performing a procedure authorized under this~~
27 ~~paragraph, a pharmacist shall complete a training program on~~
28 ~~emergency contraception that consists of at least one hour of~~
29 ~~approved continuing education on emergency contraception drug~~
30 ~~therapy.~~

31 ~~(C) A pharmacist, pharmacist's employer, or pharmacist's~~
32 ~~agent may not directly charge a patient separate consultation fee~~
33 ~~for emergency contraception drug therapy services initiated~~
34 ~~pursuant to this paragraph, but may charge an administrative fee~~
35 ~~not to exceed ten dollars (\$10) above the retail cost of the drug.~~
36 ~~Upon an oral, telephonic, electronic, or written request from a~~
37 ~~patient or customer, a pharmacist or pharmacist's employee shall~~
38 ~~disclose the total retail price that a consumer would pay for~~
39 ~~emergency contraception drug therapy. As used in this~~
40 ~~subparagraph, total retail price includes providing the consumer~~

1 with specific information regarding the price of the emergency
2 contraception drugs and the price of the administrative fee
3 charged. This limitation is not intended to interfere with other
4 contractually agreed-upon terms between a pharmacist, a
5 pharmacist's employer, or a pharmacist's agent, and a health care
6 service plan or insurer. Patients who are insured or covered and
7 receive a pharmacy benefit that covers the cost of emergency
8 contraception shall not be required to pay an administrative fee.
9 These patients shall be required to pay copayments pursuant to
10 the terms and conditions of their coverage. The provisions of this
11 subparagraph shall cease to be operative for dedicated emergency
12 contraception drugs when these drugs are reclassified as
13 over-the-counter products by the federal Food and Drug
14 Administration.

15 ~~(D)~~ A pharmacist may not require a patient to provide
16 individually identifiable medical information that is not specified
17 in Section 1707.1 of Title 16 of the California Code of
18 Regulations before initiating emergency contraception drug
19 therapy pursuant to this paragraph.

20 ~~(b) (1)~~ Prior to performing any procedure authorized by
21 paragraph (4) of subdivision (a), a pharmacist shall have received
22 appropriate training as prescribed in the policies and procedures
23 of the licensed health care facility.

24 ~~(2)~~ Prior to performing any procedure authorized by paragraph
25 (5) of subdivision (a), a pharmacist shall have either (A)
26 successfully completed clinical residency training or (B)
27 demonstrated clinical experience in direct patient care delivery.

28 ~~(3)~~ For each emergency contraception drug therapy initiated
29 pursuant to paragraph (8) of subdivision (a), the pharmacist shall
30 provide the recipient of the emergency contraception drugs with
31 a standardized factsheet that includes, but is not limited to, the
32 indications for use of the drug, the appropriate method for using
33 the drug, the need for medical followup, and other appropriate
34 information. The board shall develop this form in consultation
35 with the State Department of Health Services, the American
36 College of Obstetricians and Gynecologists, the California
37 Pharmacists Association, and other health care organizations.
38 The provisions of this section do not preclude the use of existing
39 publications developed by nationally recognized medical
40 organizations.

1 (e)
2 (9) Administer immunizations pursuant to a protocol with a
3 prescriber.

4 (b) A pharmacist who is authorized to issue an order to initiate
5 or adjust a controlled substance therapy pursuant to this section
6 shall personally register with the federal Drug Enforcement
7 Administration.

8 (d)
9 (c) Nothing in this section shall affect the requirements of
10 existing law relating to maintaining the confidentiality of medical
11 records.

12 (e)
13 (d) Nothing in this section shall affect the requirements of
14 existing law relating to the licensing of a health care facility.

15 *SEC. 6. Section 4052.1 of the Business and Professions Code*
16 *is amended and renumbered to read:*

17 ~~4052.1.~~

18 4052.4. Notwithstanding Section 2038 or any other provision
19 of law, a pharmacist may perform skin puncture in the course of
20 performing routine patient assessment procedures or in the
21 course of performing any procedure authorized under Section
22 1206.5. For purposes of this section, “routine patient assessment
23 procedures” means: (a) procedures that a patient could, with or
24 without a prescription, perform for himself or herself, or (b)
25 clinical laboratory tests that are classified as waived pursuant to
26 the federal Clinical Laboratory Improvement Amendments of
27 1988 (42 U.S.C. Sec. 263a) and the regulations adopted
28 thereunder by the federal Health Care Financing Administration,
29 as authorized by paragraph (11) of subdivision (a) of Section
30 1206.5. A pharmacist performing these functions shall report the
31 results obtained from a test to the patient and any physician
32 designated by the patient. Any pharmacist who performs the
33 service authorized by this section shall not be in violation of
34 Section 2052.

35 *SEC. 7. Section 4052.1 is added to the Business and*
36 *Professions Code, to read:*

37 4052.1. (a) Notwithstanding any other provision of law, a
38 pharmacist may perform the following procedures or functions in
39 a licensed health care facility in accordance with policies,
40 procedures, or protocols developed by health professionals,

1 including physicians, pharmacists, and registered nurses, with
2 the concurrence of the facility administrator:

3 (1) Ordering or performing routine drug therapy-related
4 patient assessment procedures including temperature, pulse, and
5 respiration.

6 (2) Ordering drug therapy-related laboratory tests.

7 (3) Administering drugs and biologicals by injection pursuant
8 to a prescriber's order.

9 (4) Initiating or adjusting the drug regimen of a patient
10 pursuant to an order or authorization made by the patient's
11 prescriber and in accordance with the policies, procedures, or
12 protocols of the licensed health care facility.

13 (b) Prior to performing any procedure authorized by this
14 section, a pharmacist shall have received appropriate training as
15 prescribed in the policies and procedures of the licensed health
16 care facility.

17 SEC. 8. Section 4052.2 is added to the Business and
18 Professions Code, to read:

19 4052.2. (a) Notwithstanding any other provision of law, a
20 pharmacist may perform the following procedures or functions
21 as part of the care provided by a health care facility, a licensed
22 home health agency, a licensed clinic in which there is a
23 physician oversight, a provider who contracts with a licensed
24 health care service plan with regard to the care or services
25 provided to the enrollees of that health care service plan, or a
26 physician, in accordance with the policies, procedures, or
27 protocols of that facility, home health agency, licensed clinic,
28 health care service plan, or physician, and in accordance with
29 subdivision (c):

30 (1) Ordering or performing routine drug therapy-related
31 patient assessment procedures including temperature, pulse, and
32 respiration.

33 (2) Ordering drug therapy-related laboratory tests.

34 (3) Administering drugs and biologicals by injection pursuant
35 to a prescriber's order.

36 (4) Initiating or adjusting the drug regimen of a patient
37 pursuant to a specific written order or authorization made by the
38 individual patient's treating prescriber, and in accordance with
39 the policies, procedures, or protocols of the health care facility,
40 home health agency, licensed clinic, health care service plan, or

1 physician. Adjusting the drug regimen does not include
2 substituting or selecting a different drug, except as authorized by
3 the protocol. The pharmacist shall provide written notification to
4 the patient's treating prescriber, or enter the appropriate
5 information in an electronic patient record system shared by the
6 prescriber, of any drug regimen initiated pursuant to this
7 paragraph within 24 hours.

8 (b) A patient's treating prescriber may prohibit, by written
9 instruction, any adjustment or change in the patient's drug
10 regimen by the pharmacist.

11 (c) The policies, procedures, or protocols referred to in this
12 subdivision shall be developed by health care professionals,
13 including physicians, pharmacists, and registered nurses, and
14 shall, at a minimum, do all of the following:

15 (1) Require that the pharmacist function as part of a
16 multidisciplinary group that includes physicians and direct care
17 registered nurses. The multidisciplinary group shall determine
18 the appropriate participation of the pharmacist and the direct
19 care registered nurse.

20 (2) Require that the medical records of the patient be
21 available to both the patient's treating prescriber and the
22 pharmacist.

23 (3) Require that the procedures to be performed by the
24 pharmacist relate to a condition for which the patient has first
25 been seen by a physician.

26 (4) Except for procedures or functions provided by a health
27 care facility, a licensed clinic in which there is physician
28 oversight, or a provider who contracts with a licensed health
29 care plan with regard to the care or services provided to the
30 enrollees of that health care service plan, require the procedures
31 to be performed in accordance with a written, patient-specific
32 protocol approved by the treating or supervising physician. Any
33 change, adjustment, or modification of an approved preexisting
34 treatment or drug therapy shall be provided in writing to the
35 treating or supervising physician within 24 hours.

36 (d) Prior to performing any procedure authorized by this
37 section, a pharmacist shall have either:

38 (1) Successfully completed clinical residency training.

39 (2) Demonstrated clinical experience in direct patient care
40 delivery.

1 *SEC. 9. Section 4052.3 is added to the Business and*
2 *Professions Code, to read:*

3 4052.3. (a) *Notwithstanding any other provision of law, a*
4 *pharmacist may furnish emergency contraception drug therapy*
5 *in accordance with either of the following:*

6 (1) *Standardized procedures or protocols developed by the*
7 *pharmacist and an authorized prescriber who is acting within his*
8 *or her scope of practice.*

9 (2) *Standardized procedures or protocols developed and*
10 *approved by both the board and the Medical Board of California*
11 *in consultation with the American College of Obstetricians and*
12 *Gynecologists, the California Pharmacist Association, and other*
13 *appropriate entities. Both the board and the Medical Board of*
14 *California shall have authority to ensure compliance with this*
15 *clause, and both boards are specifically charged with the*
16 *enforcement of this provision with respect to their respective*
17 *licensees. Nothing in this clause shall be construed to expand the*
18 *authority of a pharmacist to prescribe any prescription*
19 *medication.*

20 (b) *Prior to performing a procedure authorized under this*
21 *paragraph, a pharmacist shall complete a training program on*
22 *emergency contraception that consists of at least one hour of*
23 *approved continuing education on emergency contraception drug*
24 *therapy.*

25 (c) *A pharmacist, pharmacist's employer, or pharmacist's*
26 *agent may not directly charge a patient a separate consultation*
27 *fee for emergency contraception drug therapy services initiated*
28 *pursuant to this paragraph, but may charge an administrative fee*
29 *not to exceed ten dollars (\$10) above the retail cost of the drug.*
30 *Upon an oral, telephonic, electronic, or written request from a*
31 *patient or customer, a pharmacist or pharmacist's employee*
32 *shall disclose the total retail price that a consumer would pay for*
33 *emergency contraception drug therapy. As used in this*
34 *subparagraph, total retail price includes providing the consumer*
35 *with specific information regarding the price of the emergency*
36 *contraception drugs and the price of the administrative fee*
37 *charged. This limitation is not intended to interfere with other*
38 *contractually agreed-upon terms between a pharmacist, a*
39 *pharmacist's employer, or a pharmacist's agent, and a health*
40 *care service plan or insurer. Patients who are insured or covered*

1 and receive a pharmacy benefit that covers the cost of emergency
2 contraception shall not be required to pay an administrative fee.
3 These patients shall be required to pay copayments pursuant to
4 the terms and conditions of their coverage. The provisions of this
5 subparagraph shall cease to be operative for dedicated
6 emergency contraception drugs when these drugs are reclassified
7 as over-the-counter products by the federal Food and Drug
8 Administration.

9 (d) A pharmacist may not require a patient to provide
10 individually identifiable medical information that is not specified
11 in Section 1707.1 of Title 16 of the California Code of
12 Regulations before initiating emergency contraception drug
13 therapy pursuant to this section.

14 (e) For each emergency contraception drug therapy initiated
15 pursuant to this section, the pharmacist shall provide the
16 recipient of the emergency contraception drugs with a
17 standardized factsheet that includes, but is not limited to, the
18 indications for use of the drug, the appropriate method for using
19 the drug, the need for medical followup, and other appropriate
20 information. The board shall develop this form in consultation
21 with the State Department of Health Services, the American
22 College of Obstetricians and Gynecologists, the California
23 Pharmacists Association, and other health care organizations.
24 The provisions of this section do not preclude the use of existing
25 publications developed by nationally recognized medical
26 organizations.

27 SEC. 10. Section 4112 of the Business and Professions Code
28 is amended to read:

29 4112. (a) Any pharmacy located outside this state that ships,
30 mails, or delivers, in any manner, controlled substances,
31 dangerous drugs, or dangerous devices ~~into~~ directly to patients in
32 this state, or that performs prescription review, patient
33 consultation, drug utilization review, medication therapy
34 management, or other cognitive pharmacy services for patients
35 in this state, shall be considered a nonresident pharmacy.

36 (b) All nonresident pharmacies shall register with the board.
37 The board may register a nonresident pharmacy that is organized
38 as a limited liability company in the state in which it is licensed.

39 (c) A nonresident pharmacy shall disclose to the board the
40 location, names, and titles of (1) its agent for service of process

1 in this state, (2) all principal corporate officers, if any, *and* (3) all
2 general partners, if any, ~~and (4) all pharmacists who are~~
3 ~~dispensing controlled substances, dangerous drugs, or dangerous~~
4 ~~devices to residents of this state.~~ A report containing this
5 information shall be made on an annual basis and within 30 days
6 after any change of office, corporate officer, *or* partner, ~~or~~
7 pharmacist.

8 (d) All nonresident pharmacies shall comply with all lawful
9 directions and requests for information from the regulatory or
10 licensing agency of the state in which it is licensed as well as
11 with all requests for information made by the board pursuant to
12 this section. The nonresident pharmacy shall maintain, at all
13 times, a valid unexpired license, permit, or registration to
14 conduct the pharmacy in compliance with the laws of the state in
15 which it is a resident. As a prerequisite to registering with the
16 board, the nonresident pharmacy shall submit a copy of the most
17 recent inspection report resulting from an inspection conducted
18 by the regulatory or licensing agency of the state in which it is
19 located.

20 (e) All nonresident pharmacies shall maintain records of
21 controlled substances, dangerous drugs, or dangerous devices
22 dispensed to patients in this state so that the records are readily
23 retrievable from the records of other drugs dispensed.

24 (f) Any pharmacy subject to this section shall, during its
25 regular hours of operation, but not less than six days per week,
26 and for a minimum of 40 hours per week, provide a toll-free
27 telephone service to facilitate communication between patients in
28 this state and a pharmacist at the pharmacy who has access to the
29 patient's records. This toll-free telephone number shall be
30 disclosed on a label affixed to each container of drugs dispensed
31 to patients in this state.

32 (g) The board shall adopt regulations that apply the same
33 requirements or standards for oral consultation to a nonresident
34 pharmacy that operates pursuant to this section and ships, mails,
35 or delivers any controlled substances, dangerous drugs, or
36 dangerous devices to residents of this state, as are applied to an
37 in-state pharmacy that operates pursuant to Section 4037 when
38 the pharmacy ships, mails, or delivers any controlled substances,
39 dangerous drugs, or dangerous devices to residents of this state.
40 The board shall not adopt any regulations that require

1 face-to-face consultation for a prescription that is shipped,
2 mailed, or delivered to the patient. The regulations adopted
3 pursuant to this subdivision shall not result in any unnecessary
4 delay in patients receiving their medication.

5 (h) The registration fee shall be the fee specified in
6 subdivision (a) of Section 4400.

7 (i) The registration requirements of this section shall apply
8 only to a nonresident pharmacy that ships, mails, or delivers
9 controlled substances, dangerous drugs, and dangerous devices
10 into this state pursuant to a prescription.

11 (j) Nothing in this section shall be construed to authorize the
12 dispensing of contact lenses by nonresident pharmacists except
13 as provided by Section 4124.

14 *SEC. 11. Section 4120 of the Business and Professions Code*
15 *is amended to read:*

16 4120. (a) ~~A nonresident pharmacy shall not sell or distribute~~
17 ~~dangerous drugs or dangerous devices in this state through any~~
18 ~~person or media other than a wholesaler who has obtained a~~
19 ~~license pursuant to this chapter or through a selling or~~
20 ~~distribution outlet that is licensed as a wholesaler pursuant to this~~
21 ~~chapter without registering as a nonresident pharmacy.~~

22 (b) Applications for a nonresident pharmacy registration shall
23 be made on a form furnished by the board. The board may
24 require any information as the board deems reasonably necessary
25 to carry out the purposes of this section.

26 (b) *Each application to conduct a nonresident pharmacy shall*
27 *specify the type or types of pharmacy for which the application is*
28 *submitted, pursuant to Section 4037. The applicant shall*
29 *immediately notify the board of any requested addition, deletion,*
30 *or other change in specified pharmacy type prior to licensure.*
31 *After licensure, any change in specified pharmacy type shall be*
32 *reported to the board, on a form to be furnished by the board, at*
33 *least 30 calendar days prior to implementation or elimination of*
34 *any activities permitted by the added, deleted, or changed type*
35 *designation.*

36 (c) The Legislature, by enacting this section, does not intend a
37 license issued to any nonresident pharmacy pursuant to this
38 section to change or affect the tax liability imposed by Chapter 3
39 (commencing with Section 23501) of Part 11 of Division 2 of the
40 Revenue and Taxation Code on any nonresident pharmacy.

1 (d) The Legislature, by enacting this section, does not intend a
2 license issued to any nonresident pharmacy pursuant to this
3 section to serve as any evidence that the nonresident pharmacy is
4 doing business within this state.

5 *SEC. 12. Section 4201 of the Business and Professions Code*
6 *is amended to read:*

7 4201. (a) Each application to conduct a pharmacy,
8 wholesaler, or veterinary food-animal drug retailer, shall be made
9 on a form furnished by the board, and shall state the name,
10 address, usual occupation, and professional qualifications, if any,
11 of the applicant. If the applicant is other than a natural person,
12 the application shall state the information as to each person
13 beneficially interested therein.

14 (b) *Each application to conduct a pharmacy shall specify the*
15 *type or types of pharmacy for which the application is submitted,*
16 *pursuant to Section 4037. The applicant shall immediately notify*
17 *the board of any requested addition, deletion, or other change in*
18 *specified pharmacy type prior to licensure. After licensure, any*
19 *change in specified pharmacy type shall be reported to the*
20 *board, on a form to be furnished by the board, at least 30*
21 *calendar days prior to implementation or elimination of any*
22 *activities permitted by the added, deleted, or changed type*
23 *designation.*

24 (c) As used in this section, and subject to subdivision (c), the
25 term “person beneficially interested” means and includes:

26 (1) If the applicant is a partnership or other unincorporated
27 association, each partner or member.

28 (2) If the applicant is a corporation, each of its officers,
29 directors, and stockholders, provided that no natural person shall
30 be deemed to be beneficially interested in a nonprofit
31 corporation.

32 (3) If the applicant is a limited liability company, each officer,
33 manager, or member.

34 (e)

35 (d) In any case where the applicant is a partnership or other
36 unincorporated association, is a limited liability company, or is a
37 corporation, and where the number of partners, members, or
38 stockholders, as the case may be, exceeds five, the application
39 shall so state, and shall further state the information required by
40 subdivision (a) as to each of the five partners, members, or

1 stockholders who own the five largest interests in the applicant
2 entity. Upon request by the executive officer, the applicant shall
3 furnish the board with the information required by subdivision
4 (a) as to partners, members, or stockholders not named in the
5 application, or shall refer the board to an appropriate source of
6 that information.

7 ~~(d)~~

8 (e) The application shall contain a statement to the effect that
9 the applicant has not been convicted of a felony and has not
10 violated any of the provisions of this chapter. If the applicant
11 cannot make this statement, the application shall contain a
12 statement of the violation, if any, or reasons which will prevent
13 the applicant from being able to comply with the requirements
14 with respect to the statement.

15 ~~(e)~~

16 (f) Upon the approval of the application by the board and
17 payment of the fee required by this chapter for each pharmacy,
18 wholesaler, or veterinary food-animal drug retailer, the executive
19 officer of the board shall issue a license to conduct a pharmacy,
20 wholesaler, or veterinary food-animal drug retailer, if all of the
21 provisions of this chapter have been complied with.

22 ~~(f)~~

23 (g) Notwithstanding any other provision of law, the pharmacy
24 license shall authorize the holder to conduct a pharmacy. The
25 license shall be renewed annually and shall not be transferable.

26 ~~(g)~~

27 (h) Notwithstanding any other provision of law, the wholesale
28 license shall authorize the holder to wholesale dangerous drugs
29 and dangerous devices. The license shall be renewed annually
30 and shall not be transferable.

31 ~~(h)~~

32 (i) Notwithstanding any other provision of law, the veterinary
33 food-animal drug retailer license shall authorize the holder
34 thereof to conduct a veterinary food-animal drug retailer and to
35 sell and dispense veterinary food-animal drugs as defined in
36 Section 4042.

37 ~~(i)~~

38 (j) For licenses referred to in subdivisions (f), (g), and (h), any
39 change in the proposed beneficial ownership interest shall be

1 reported to the board within 30 days thereafter upon a form to be
2 furnished by the board.

3 ~~(j) This section shall become operative on July 1, 2001.~~

4 *SEC. 13. Section 4207 of the Business and Professions Code*
5 *is amended to read:*

6 4207. (a) Upon receipt of an application for a license and the
7 applicable fee, the board shall make a thorough investigation to
8 determine whether the applicant is qualified for the license being
9 sought. The board shall also determine whether this article has
10 been complied with, and shall investigate all matters directly
11 related to the issuance of the license that may affect the public
12 welfare.

13 (b) The board shall not investigate matters connected with the
14 operation of a premises other than those matters solely related to
15 the furnishing of dangerous drugs or dangerous devices, *or to the*
16 *performance or provision of prescription or drug order*
17 *processing or review services or cognitive services*, that might
18 adversely affect the public welfare.

19 (c) The board shall deny an application for a license if the
20 applicant does not qualify for the license being sought.

21 (d) Notwithstanding any other provision of law, the board may
22 request any information it deems necessary to complete the
23 application investigation required by this section, and a request
24 for information that the board deems necessary in carrying out
25 this section in any application or related form devised by the
26 board shall not be required to be adopted by regulation pursuant
27 to the ~~Administrative Procedures~~ *Procedure Act* (Chapter 3.5
28 (commencing with Section 11340) of Part 1 of Division 3 of Title
29 2 of the Government Code).

30 *SEC. 14. Section 4301 of the Business and Professions Code,*
31 *as added by Section 44 of Chapter 857 of the Statutes of 2004, is*
32 *amended to read:*

33 4301. The board shall take action against any holder of a
34 license who is guilty of unprofessional conduct or whose license
35 has been procured by fraud or misrepresentation or issued by
36 mistake. Unprofessional conduct shall include, but is not limited
37 to, any of the following:

38 (a) Gross immorality.

39 (b) Incompetence.

40 (c) Gross negligence.

1 (d) The clearly excessive furnishing of controlled substances
2 in violation of subdivision (a) of Section 11153 of the Health and
3 Safety Code.

4 (e) The clearly excessive furnishing of controlled substances
5 in violation of subdivision (a) of Section 11153.5 of the Health
6 and Safety Code. Factors to be considered in determining
7 whether the furnishing of controlled substances is clearly
8 excessive shall include, but not be limited to, the amount of
9 controlled substances furnished, the previous ordering pattern of
10 the customer (including size and frequency of orders), the type
11 and size of the customer, and where and to whom the customer
12 distributes its product.

13 (f) The commission of any act involving moral turpitude,
14 dishonesty, fraud, deceit, or corruption, whether the act is
15 committed in the course of relations as a licensee or otherwise,
16 and whether the act is a felony or misdemeanor or not.

17 (g) Knowingly making or signing any certificate or other
18 document that falsely represents the existence or nonexistence of
19 a state of facts.

20 (h) The administering to oneself, of any controlled substance,
21 or the use of any dangerous drug or of alcoholic beverages to the
22 extent or in a manner as to be dangerous or injurious to oneself,
23 to a person holding a license under this chapter, or to any other
24 person or to the public, or to the extent that the use impairs the
25 ability of the person to conduct with safety to the public the
26 practice authorized by the license.

27 (i) Except as otherwise authorized by law, knowingly selling,
28 furnishing, giving away, or administering or offering to sell,
29 furnish, give away, or administer any controlled substance to an
30 addict.

31 (j) The violation of any of the statutes of this state, *of any*
32 *other state*, or of the United States regulating controlled
33 substances and dangerous drugs.

34 (k) The conviction of more than one misdemeanor or any
35 felony involving the use, consumption, or self-administration of
36 any dangerous drug or alcoholic beverage, or any combination of
37 those substances.

38 (l) The conviction of a crime substantially related to the
39 qualifications, functions, and duties of a licensee under this
40 chapter. The record of conviction of a violation of Chapter 13

1 (commencing with Section 801) of Title 21 of the United States
2 Code regulating controlled substances or of a violation of the
3 statutes of this state regulating controlled substances or
4 dangerous drugs shall be conclusive evidence of unprofessional
5 conduct. In all other cases, the record of conviction shall be
6 conclusive evidence only of the fact that the conviction occurred.
7 The board may inquire into the circumstances surrounding the
8 commission of the crime, in order to fix the degree of discipline
9 or, in the case of a conviction not involving controlled substances
10 or dangerous drugs, to determine if the conviction is of an
11 offense substantially related to the qualifications, functions, and
12 duties of a licensee under this chapter. A plea or verdict of guilty
13 or a conviction following a plea of nolo contendere is deemed to
14 be a conviction within the meaning of this provision. The board
15 may take action when the time for appeal has elapsed, or the
16 judgment of conviction has been affirmed on appeal or when an
17 order granting probation is made suspending the imposition of
18 sentence, irrespective of a subsequent order under Section 1203.4
19 of the Penal Code allowing the person to withdraw his or her plea
20 of guilty and to enter a plea of not guilty, or setting aside the
21 verdict of guilty, or dismissing the accusation, information, or
22 indictment.

23 (m) The cash compromise of a charge of violation of Chapter
24 13 (commencing with Section 801) of Title 21 of the United
25 States Code regulating controlled substances or of Chapter 7
26 (commencing with Section 14000) of Part 3 of Division 9 of the
27 Welfare and Institutions Code relating to the Medi-Cal program.
28 The record of the compromise is conclusive evidence of
29 unprofessional conduct.

30 (n) The revocation, suspension, or other discipline by another
31 state of a license to practice pharmacy, operate a pharmacy, or do
32 any other act for which a license is required by this chapter.

33 (o) Violating or attempting to violate, directly or indirectly, or
34 assisting in or abetting the violation of or conspiring to violate
35 any provision or term of this chapter or of the applicable federal
36 and state laws and regulations governing pharmacy, including
37 regulations established by the board *or by any other state or*
38 *federal regulatory agency.*

39 (p) Actions or conduct that would have warranted denial of a
40 license.

1 (q) Engaging in any conduct that subverts or attempts to
2 subvert an investigation of the board.

3 (r) The selling, trading, transferring, or furnishing of drugs
4 obtained pursuant to Section 256b of Title 42 of the United States
5 Code to any person a licensee knows or reasonably should have
6 known, not to be a patient of a covered entity, as defined in
7 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
8 United States Code.

9 (s) The clearly excessive furnishing of dangerous drugs by a
10 wholesaler to a pharmacy that primarily or solely dispenses
11 prescription drugs to patients of long-term care facilities. Factors
12 to be considered in determining whether the furnishing of
13 dangerous drugs is clearly excessive shall include, but not be
14 limited to, the amount of dangerous drugs furnished to a
15 pharmacy that primarily or solely dispenses prescription drugs to
16 patients of long-term care facilities, the previous ordering pattern
17 of the pharmacy, and the general patient population to whom the
18 pharmacy distributes the dangerous drugs. That a wholesaler has
19 established, and employs, a tracking system that complies with
20 the requirements of subdivision (b) of Section 4164 shall be
21 considered in determining whether there has been a violation of
22 this subdivision. This provision shall not be interpreted to require
23 a wholesaler to obtain personal medical information or be
24 authorized to permit a wholesaler to have access to personal
25 medical information except as otherwise authorized by Section
26 56 and following of the Civil Code.

27 (t) This section shall become operative on January 1, 2006.

28 *SEC. 15. Section 4303 of the Business and Professions Code*
29 *is repealed.*

30 ~~4303. (a) The board may deny, revoke, or suspend a~~
31 ~~nonresident pharmacy registration for failure to comply with any~~
32 ~~requirement of Section 4112, 4124, or 4340, for any significant~~
33 ~~or repeated failure to comply with Section 4074 or 4076, or for~~
34 ~~failure to comply with Section 11164 of the Health and Safety~~
35 ~~Code.~~

36 ~~(b) The board may deny, revoke, or suspend a nonresident~~
37 ~~pharmacy registration for conduct that causes serious bodily or~~
38 ~~serious psychological injury to a resident of this state if the board~~
39 ~~has referred the matter to the regulatory or licensing agency in~~
40 ~~the state in which the pharmacy is located and the regulatory or~~

1 ~~licensing agency fails to initiate an investigation within 45 days~~
2 ~~of the referral.~~

3 *SEC. 16. Section 4303 is added to the Business and*
4 *Professions Code, to read:*

5 *4303. (a) The board may report any violation of the laws and*
6 *regulations of this state, any other state, or of the United States,*
7 *including, but not limited to, any violation of this chapter or of*
8 *the regulations established by the board, to the appropriate*
9 *regulatory or licensing agency of the state in which a*
10 *nonresident pharmacy is a resident.*

11 *(b) The board may deny, revoke, or suspend a nonresident*
12 *pharmacy registration, issue a citation or letter of admonishment*
13 *to a nonresident pharmacy, or take any other action against a*
14 *nonresident pharmacy that the board may take against a resident*
15 *pharmacy license, on any of the same grounds upon such action*
16 *might be taken against a resident pharmacy.*

17 *SEC. 17. Section 4306.5 of the Business and Professions*
18 *Code is amended to read:*

19 *4306.5. (a) Unprofessional conduct for a pharmacist may*
20 *include ~~acts~~ any of the following:*

21 *(1) Acts or omissions that involve, in whole or in part, the*
22 *inappropriate exercise of his or her education, training, or*
23 *experience as a pharmacist, whether or not the act or omission*
24 *arises in the course of the practice of pharmacy or the ownership,*
25 *management, administration, or operation of a pharmacy or other*
26 *entity licensed by the board.*

27 *(2) Acts or omissions that involve, in whole or in part, the*
28 *failure to exercise or implement his or her best professional*
29 *judgment or corresponding responsibility with regard to the*
30 *dispensing or furnishing of controlled substances, dangerous*
31 *drugs, or dangerous devices or with regard to the provision of*
32 *cognitive services.*

33 *(3) Acts or omissions that involve, in whole or in part, the*
34 *failure to consult appropriate patient, prescription, and other*
35 *records pertaining to the performance of any pharmacy function.*

36 *(b) For pharmacists who practice outside of a pharmacy*
37 *premises, unprofessional conduct may include acts or omissions*
38 *that involve, in whole or in part, the failure to fully maintain and*
39 *retain appropriate patient-specific information pertaining to the*
40 *performance of any pharmacy function.*

1 *SEC. 18. No reimbursement is required by this act pursuant*
2 *to 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 definition*
8 *of a crime within the meaning of Section 6 of Article XIII B of the*
9 *California Constitution.*

10
11
12
13
14
15

**All matter omitted in this version of the bill
appears in the bill as introduced in
Assembly, February 23, 2006 (JR11)**

*Bills of
Interest*



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2583

VERSION: AMENDED MARCH 27, 2006

AUTHOR: NATION

SPONSOR: AUTHOR

RECOMMENDED POSITION:

SUBJECT: DISPENSING PRESCRIPTION DRUGS AND DEVICES: REFUSAL TO DISPENSE

Existing Law:

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

2) Requires a licentiate to dispense drugs and devices pursuant to a lawful order or prescription unless one of the following circumstances exists: 1) dispensing pursuant the prescription is contrary to law or the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; 2) the prescription drug or device is not in stock; or 3) the licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, and the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects; and the employer can, provide a reasonable accommodation of the licentiate's objection by establishing protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. (B&P 733)

Requires every pharmacy to prominently a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies; alternatively, a written receipt that contains the required information on the notice may be provided to consumers to posting the notice in the pharmacy. (B&P 4122)

Specifies the wording of the Notice to Consumers that must be posted in accordance with B&P section 4122. (CCR 1707.2)

This Bill:

1) Requires the board create and provide to licentiates or licentiate's employers a sign informing patients of the following:

- i. If a licentiate refuses to dispense a prescription drug or device based on ethical, moral, or religious grounds, the patient has a right to timely access to the prescribed drug or device.
- ii. How a patient may file a complaint with the board, including contact information for the board. (B&P 733 Amended)

3) Requires the licentiate or licentiate's employer to place the sign in a location that is visible to patients and that is at or near the entrance of the business if a licentiate, pursuant to B&P 733, declines to dispense a prescription drug or device. (B&P 733 Amended)

Comment:

1) Author's Intent. The author's intent is to "ensure patients receive their prescription drugs in a timely manner, especially when a pharmacist chooses not to fill the prescription based on ethical, moral or religious reasons. A sign notifying a patient that a pharmacist will not dispense a drug or device pursuant to a prescription will allow a patient to, among other options, choose a pharmacy that will fulfill the patient's needs. Waiting in line just to be rejected will only delay access to a prescribed drug or device."

2) Real Issue. The stated goal of SB 644 and AB 2583 has been to ensure that a patient has access to their prescribed medications while preserving a licentiate's has the right to refuse to fill a prescription based on ethical, moral or religious objections. While the goal of the measures has been broad based, almost all of the discussions on the bills have been exclusively on women's access to emergency contraception (EC). If access to EC is the true goal of the legislation, then AB 2583 and related discussions should focus on EC. Currently the board receives fewer than two complaints a year relating to EC access. Given that there are approximately 30,000-licensed pharmacists in the state the actions the bill proposes to fix the problem access to EC appear to be premature.

3) Costs to the Board. The board estimates it would cost \$24,00 in fiscal year 2006-07 to comply with measure; annual cost thereafter would be approximately \$2,400 per fiscal year.

Fiscal Year 2006-07		
0.12 PY (AGPA) to create and gain approval for sign		
Initial Printing of 6,000 sign		\$12,000
Initial mailing cost (includes mailing tubes and postage \$2/sign)		\$12,000
	Total	\$24,000
Annual Cost beyond 2007		
Print and mail 600 sign to newly licensed pharmacies	Total	\$2,400

In cases where a pharmacy is newly licensed the board may include the sign in the same mailing tube as the Notice to Consumers required by B&P 4122; in this situation the cost would be considerably less and limited to the additional postage for additional weight of the sign in the mailing tube.

4) Previous Legislation. SB 644 (Chapter 417, Statutes of 2005) added B&P section 733 to the code to require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. The board gained amendments to the measure that allows the board to cite and fine or issue letters of admonishment for violations of the measure's provisions.

5) Support / Opposition.

Support: California National Organization for Women

Opposition: Capitol Resource Institute
California Society of Health-System Pharmacists

6) History.

2006

- Mar. 28 Re-referred to Com. on B. & P.
- Mar. 27 From committee chair, with author's amendments: Amend, and re-refer
- Mar. 20 Referred to Coms. on B. & P. and HEALTH
- Feb. 27 Read first time.
- Feb. 25 From printer. May be heard in committee March 27.
- Feb. 27 Read first time.
- Feb. 25 From printer. May be heard in committee March 27.
- Feb. 24 Introduced. To print.

ASSEMBLY BILL

No. 2583

Introduced by Assembly Member Nation

February 24, 2006

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

LEGISLATIVE COUNSEL'S DIGEST

AB 2583, as amended, Nation. Dispensing prescription drugs and devices: refusal to dispense.

Existing law prohibits a health care licentiate from obstructing a patient in obtaining a prescription drug or device, and requires the 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 if certain requirements are met. Existing law authorizes the California State Board of Pharmacy to issue a citation for a violation of these provisions and authorizes its executive officer to issue a letter of admonishment for their violation.

This bill would require the board to create and provide a sign informing a patient of his or her right to timely access to a prescribed drug or device that a licentiate has refused to dispense based on ethical, moral, or religious grounds *and informing a patient of how to file a complaint with the board*. The bill would require licentiates authorized to make such a refusal, or their employers, to visibly place the sign at or near the entrance of the business.

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

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

1 SECTION 1. Section 733 of the Business and Professions
2 Code is amended to read:

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

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

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

18 (2) The prescription drug or device is not in stock. If an order,
19 other than an order described in Section 4019, or prescription
20 cannot be dispensed because the drug or device is not in stock,
21 the licentiate shall take one of the following actions:

22 (A) Immediately notify the patient and arrange for the drug or
23 device to be delivered to the site or directly to the patient in a
24 timely manner.

25 (B) Promptly transfer the prescription to another pharmacy
26 known to stock the prescription drug or device that is near
27 enough to the site from which the prescription or order is
28 transferred, to ensure the patient has timely access to the drug or
29 device.

30 (C) Return the prescription to the patient and refer the patient
31 . The licentiate shall make a reasonable effort to refer the patient
32 to a pharmacy that stocks the prescription drug or device that is
33 near enough to the referring site to ensure that the patient has
34 timely access to the drug or device.

35 (3) The licentiate refuses on ethical, moral, or religious
36 grounds to dispense a drug or device pursuant to an order or
37 prescription.

1 (A) A licentiate may decline to dispense a prescription drug or
2 device on this basis only if the licentiate has previously notified
3 his or her employer, in writing, of the drug or class of drugs to
4 which he or she objects, and the licentiate's employer can,
5 without creating undue hardship, provide a reasonable
6 accommodation of the licentiate's objection. The licentiate's
7 employer shall establish protocols that ensure that the patient has
8 timely access to the prescribed drug or device despite the
9 licentiate's refusal to dispense the prescription or order. For
10 purposes of this section, "reasonable accommodation" and
11 "undue hardship" shall have the same meaning as applied to
12 those terms pursuant to subdivision (l) of Section 12940 of the
13 Government Code.

14 (B) The California State Board of Pharmacy shall create and
15 provide to licentiates or licentiate's employers a sign informing
16 patients ~~that, if~~ *of the following:*

17 (i) *If a licentiate refuses to dispense a prescription drug or*
18 *device based on ethical, moral, or religious grounds, the patient*
19 *has a right to timely access to the prescribed drug or device. If*

20 (ii) *How a patient may file a complaint with the board,*
21 *including providing contact information for the board.*

22 (C) *If a licentiate is authorized, pursuant to subparagraph (A),*
23 *to decline to dispense a prescription drug or device, the licentiate*
24 *or licentiate's employer shall place ~~this sign~~ the sign described in*
25 *subparagraph (B) in a location that is visible to patients and that*
26 *is at or near the entrance of the business.*

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

29 (d) The provisions of this section shall apply to the drug
30 therapy described in paragraph (8) of subdivision (a) of Section
31 4052.

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



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2743

VERSION: INTRODUCED

AUTHOR: MATTHEWS

SPONSOR: CA. RETAILERS ASSOCIATION (CRA)

RECOMMENDED POSITION:

SUBJECT: PHARMACISTS: ANCILLARY PERSONNEL

Existing Law:

- 1) Limits the number of intern pharmacists a pharmacist can supervise at any one time to no more than two. (B&P 4114)
- 2) Limits the number of pharmacy technicians a pharmacy with only one pharmacist can have to no more than one. (B&P 4115)
- 3) Caps the ratio of pharmacists to pharmacy technicians for pharmacies with more than one pharmacist to no more than 2:1, after the first pharmacist (when a 1:1 ratio is required). (B&P 4115)
- 4) Limits the number of pharmacy technician trainees a pharmacist may supervise at any time to one. (B&P 4115)
- 5) Permits a pharmacist to determine the number of non-licensed personnel he or she may supervise that perform the duties of typing a prescription label or otherwise enter prescription information into a computer record system. (CCR 1793.3)

This Bill:

- 1) Limits number of ancillary personnel a pharmacy may have to no more than eight per pharmacist. (B&P 4115.3 Added)
- 2) Permits each pharmacist to have discretion as to how many ancillary personnel, within this limit, he or she supervises, subject to the limits set forth in B&P sections 4114, 4115, and 4115.5. (B&P 4115.3 Added)
- 2) Defines "ancillary personnel" to include pharmacy technicians, pharmacy technician trainees, interns, clerks, and typists. (B&P 4115.3 Added)

Comment:

1) Author's Intent. The author and sponsor's intent is to increase the pharmacy technician to pharmacist ratio allowed in a pharmacy. (The current ratio is 2:1 when there are two or more pharmacists in a pharmacy.) The sponsor hopes to achieve the increase by limiting the number of ancillary personnel allowed in a pharmacy. The sponsor is currently working with those that

may oppose the bill. If the sponsor is successful in eliminating opposition to the bill the bill will likely be amended to reflect a new pharmacy technician to pharmacist ratio and ancillary personnel to pharmacist ratio.

2) Board History on Issue. The board reviewed the issue of staffing ratios in the November 2001, *Pharmacy Manpower Task Force Report* and subsequently set the staffing ratio for community pharmacies at 4:1; that is one pharmacist may supervise up to two interns, one technician, and one technician in training. Subsequent legislation authorized a second and additional pharmacist to supervise two technicians (a ration of 5:1). The board removed a regulation on the limit on the number of clerk typist that a pharmacist may supervise.

3) Other States Pharmacy Technicians to Pharmacist Ratios. The staffing ratio of pharmacy technicians to pharmacist varies from state to state; seven states have a ratio of 4:1, three states have a ratio of 3:1, and fifteen states have a ratio similar to California's of 2:1.

4) Suggested Amendment. As currently drafted AB 2743 would restore the "clerk typist" ratio of staff a pharmacist may supervise. If the measure moves forward a definition of "clerk typist" should be amended into the bill.

5) History.

2006

Mar. 20 Referred to Com. on B. & P.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 24 Introduced. To print.

ASSEMBLY BILL

No. 2743

Introduced by Assembly Member Matthews

February 24, 2006

An act to add Section 4115.3 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2743, as introduced, Matthews. Pharmacists: ancillary personnel.

Existing law, the Pharmacy Law, the violation of which is a crime, provides for the licensing and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law provides that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing specified tasks, and makes other provisions for the supervision of intern pharmacists, pharmacy technicians, and pharmacy technician trainees by a pharmacist.

This bill would prohibit a pharmacy from employing more than 8 ancillary personnel, as defined, per pharmacist. The bill would give a pharmacist discretion as to how many personnel he or she supervises, subject to the limits of existing law. Because this bill would create a new prohibition under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4115.3 is added to the Business and
2 Professions Code, to read:
3 4115.3. (a) A pharmacy shall have no more than eight
4 ancillary personnel per pharmacist. Each pharmacist shall have
5 individual discretion as to how many ancillary personnel, within
6 this limit, he or she supervises, subject to the limits set forth in
7 Sections 4114, 4115, and 4115.5.
8 (b) For purposes of this section, "ancillary personnel" includes
9 pharmacy technicians, pharmacy technician trainees, interns,
10 clerks, and typists.
11 SEC. 2. No reimbursement is required by this act pursuant to
12 Section 6 of Article XIII B of the California Constitution because
13 the only costs that may be incurred by a local agency or school
14 district will be incurred because this act creates a new crime or
15 infraction, eliminates a crime or infraction, or changes the
16 penalty for a crime or infraction, within the meaning of Section
17 17556 of the Government Code, or changes the definition of a
18 crime within the meaning of Section 6 of Article XIII B of the
19 California Constitution.

O



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2986

VERSION: AMENDED APRIL 5, 2006

AUTHOR: MULLIN

SPONSOR: DEPARTMENT OF JUSTICE

RECOMMENDED POSITION:

SUBJECT: CONTROLLED SUBSTANCES: PRESCRIPTION REQUIREMENTS

Existing Law:

- 1) Describes the required security features of controlled substances prescription forms.
(H&S 11162.1)
- 2) Describes the required information that must be on a controlled substances prescription form for a person to fill, compound, or dispense a prescription for a controlled substance.
(H&S 11164)
- 3) Authorizes a prescriber or any agent of the prescriber on behalf of the prescriber to orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV.
(H&S 11164)
- 4) Requires DOJ to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for monitoring the prescribing and dispensing of Schedule II and III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(H&S 11165)
- 5) Requires pharmacies to report the following information to DOJ for Schedule II and III controlled substances: full name, address, gender, and date of birth of the patient; the prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility; pharmacy prescription number, license number, and federal controlled substance registration number; the NDC (National Drug Code) number of the controlled substance dispensed; the quantity of the controlled substance dispensed; the diagnosis code; date of the prescription and date of the dispensing the prescription.
(H&S 11165)
- 6) Permits a licensed health care practitioner eligible to prescribe Schedule II or III controlled substances or a pharmacist to make a written request for, and the DOJ to release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
(H&S 11165.1)
- 7) Requires every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II to make a record that, as to the transaction, shows all of the information in H&S 11165.
(H&S 11190)

This Bill:

1) Requires secure tamper-resistant prescription forms to include the following preprinted information on the forms in addition to what is currently required:

- The name, address, and telephone number of the ultimate user or research subject, or the contact information as determined by the Secretary of the United States Department of Health and Human Services.
- Check boxes so that the prescriber must indicate the number of refills and whether the prescription is a first-time request.
- The date of origin of the prescription.

(H&S 11162.1 Amended)

2) Requires information listed in H&S 11162.1 to be on the security prescription form for a person to fill, compound, or dispense a prescription for a controlled substance. (H&S 11164 Amended)

3) Requires a dispensing pharmacy to provide DOJ the following information, in addition to what is currently required, for each Schedule II, III, or IV prescription it dispenses:

- The name, address, and telephone number of the ultimate user or research subject, or the contact information as determined by the Secretary of the United States Department of Health and Human Services.
- Check boxes so that the prescriber may indicate the number of refills and whether the prescription is a first time request.
- The date of origin of the prescription.

(H&S 11165 Amended)

4) Requires the CURES program to monitor and report the prescribing and dispensing of Schedule II, III, IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. (H&S 11165 and 11165.1 Amended)

5) Requires every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified as Schedule II to make a record that, as to the transaction, shows all of the information in H&S 11165. (H&S 11190 Amended)

6) Changes the controlled substances reporting requirement to DOJ from monthly to weekly. (H&S 11190 Amended)

Comment:

1) Author's Intent. The bill is sponsored the DOJ. The author's intent is to align California's Prescription Monitoring Program (PMP) with the federal National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER Act). This proposal will ensure state compliance with new federal mandates.

2) NASPER Act and CURES. The NASPER Act was signed into law by President Bush on August 11, 2005. The Act requires all states to establish a PMP or enhance their current state PMP.

The NASPER Act imposes several mandates not previously required by DOJ's Controlled Substances Utilization Review and Evaluation System (CURES) program. These mandates include:

- Capturing Schedule IV controlled substances data.
- Requiring dispensers to report to states within one week of each dispensing of a controlled substance

- Requiring specific data, such as patient telephone number, number of refills, and whether the prescription is for a refill or a first-time prescription.
- Requiring secure prescription forms include a refill notation; under current law this notation is optional at the prescriber's request.
- Requiring dispensers to report information in an electronic format specified by the U.S. Secretary of Health and Human Services, with an exception that the state may waive the required format with respect to individual dispensers.

3) Concerns with the Measure. The board reviewed AB 2986 as a legislative proposal at the board's meeting in February 2006. At that meeting discussion among board members and staff yielded two main concerns with the proposal as now contained in AB 2986, they are:

1. What happens if a patient cannot provide a telephone number or an address? (Can a pharmacist add this information?)
2. "Date of issue" versus "date of origin."

Not discussed at the meeting, but may be raised as a related issue is, is there a necessity to continue to use specialized prescription forms for controlled substances? This issue is raised in SB 1366, a related bill, that would amend overlapping sections of law delete the requirement that prescriptions for controlled substances be written on security printer prescription forms.

4) Related Legislation. SB 1366 (Aanestad) would eliminate the required use of specialized prescription forms by physicians and surgeons when issuing prescriptions for controlled substances. SB 1366 is set to be heard in the Senate Public Safety Committee on April 24, 2006.

5) Previous Legislation. SB 734 (Chapter 487, Statutes of 2005), sponsored the DOJ, provided clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. Among other provisions the measure transferred the approval of security printers from the board to the DOJ. The board sought a technical amendment to cap board spending for CURES to the amount of money appropriated by the state budget.

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

AB 2018 (Chapter 1092, Statutes of 2002) provided changes to the triplicate pad and established a process for correction of prescription errors.

AB 2693 (Chapter 789, Statutes of 1998) exempted Schedule II controlled substances for patients with terminal illnesses from triplicate prescription form requirements.

AB 3042 (Chapter 738, Statutes of 1996) created the CURES program on a pilot basis.

6) Support / Opposition.

Support: California Narcotic Officers' Association

Opposition: None on file at this time.

7) History.

2006

Feb. 27 Read first time.

Feb. 25 From printer. May be heard in committee March 27.

Feb. 24 Introduced. To print.

AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005-06 REGULAR SESSION

ASSEMBLY BILL

No. 2986

Introduced by Assembly Member Mullin

February 24, 2006

An act to amend Sections 11162.1, 11164, 11165, 11165.1, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2986, as amended, Mullin. Controlled substances: prescription requirements.

(1) Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless the prescription complies with specified requirements; the prescription must be printed with specified features and must set forth specified information. Unless otherwise specified, a violation of any of these provisions is a misdemeanor, punishable as specified.

This bill would require the prescription forms to also include the *name, address, and* telephone number of the ultimate user or research subject, or the contact information as determined by the U.S. Secretary of Health and Human Services; check boxes so that the prescriber may indicate ~~that a prescription is a first-time request or that a specified~~ *the* number of refills of the prescription have been ordered since the first prescription; and the date of origin of the prescription ~~and whether the prescription is a first-time request or a refill.~~

(2) Existing law provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II and Schedule III controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would provide that the CURES program shall also monitor and report on the prescribing and dispensing of Schedule IV controlled substances.

(3) Existing law provides that every practitioner, other than a pharmacist, who prescribes or administers a Schedule II controlled substance shall make a record of the transaction and shall provide the Department of Justice with information relating to the transaction on a monthly basis, as specified.

This bill would instead require the information to be provided to the Department of Justice on a weekly basis.

(4) The bill would make conforming changes to related provisions. By revising existing crimes, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 11162.1 of the Health and Safety Code
2 is amended to read:
3 11162.1. (a) The prescription forms for controlled substances
4 shall be printed with the following features:
5 (1) A latent, repetitive "void" pattern shall be printed across
6 the entire front of the prescription blank; if a prescription is
7 scanned or photocopied, the word "void" shall appear in a pattern
8 across the entire front of the prescription.
9 (2) A watermark shall be printed on the backside of the
10 prescription blank; the watermark shall consist of the words
11 "California Security Prescription."

1 (3) A chemical void protection that prevents alteration by
2 chemical washing.

3 (4) A feature printed in thermo-chromic ink.

4 (5) An area of opaque writing so that the writing disappears if
5 the prescription is lightened.

6 (6) A description of the security features included on each
7 prescription form.

8 (7) (A) Six quantity check off boxes shall be printed on the
9 form and the following quantities shall appear:

10 1-24

11 25-49

12 50-74

13 75-100

14 101-150

15 151 and over.

16 (B) In conjunction with the quantity boxes, a space shall be
17 provided to designate the units referenced in the quantity boxes
18 when the drug is not in tablet or capsule form.

19 (8) Prescription blanks shall contain a statement printed on the
20 bottom of the prescription blank that the "Prescription is void if
21 the number of drugs prescribed is not noted."

22 (9) The preprinted name, category of licensure, license
23 number, federal controlled substance registration number of the
24 prescribing practitioner.

25 (10) The telephone number of the ultimate user or research
26 subject, or the contact information as determined by the
27 Secretary of the United States Department of Health and Human
28 Services.

29 (11) Check boxes shall be printed on the form so that the
30 ~~prescriber may indicate that a prescription is a first-time request~~
31 ~~or that a specified number of refills of the prescription have been~~
32 ~~ordered since the first prescription.~~ *prescriber may indicate the*
33 *number of refills ordered and whether the prescription is a*
34 *first-time request or a refill.*

35 (12) The date of origin of the prescription.

36 (13) A check box indicating the prescriber's order not to
37 substitute.

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

1 (15) (A) A check box by the name of each prescriber when a
2 prescription form lists multiple prescribers.

3 (B) Each prescriber who signs the prescription form shall
4 identify himself or herself as the prescriber by checking the box
5 by their name.

6 (b) Each batch of controlled substance prescription forms shall
7 have the lot number printed on the form and each form within
8 that batch shall be numbered sequentially beginning with the
9 numeral one.

10 (c) (1) A prescriber designated by a licensed health care
11 facility, a clinic specified in Section 1200, or a clinic specified in
12 subdivision (a) of Section 1206 that has 25 or more physicians or
13 surgeons may order controlled substance prescription forms for
14 use by prescribers when treating patients in that facility without
15 the information required in paragraph (9) of subdivision (a) or
16 paragraph (3) of this subdivision.

17 (2) Forms ordered pursuant to this subdivision shall have the
18 name, category of licensure, license number, and federal
19 controlled substance registration number of the designated
20 prescriber and the name, address, category of licensure, and
21 license number of the licensed health care facility the clinic
22 specified in Section 1200, or the clinic specified in subdivision
23 (a) of Section 1206 that has 25 or more physicians or surgeons
24 preprinted on the form.

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

29 (4) (A) Except as provided in subparagraph (B), the designated
30 prescriber shall maintain a record of the prescribers to whom the
31 controlled substance prescription forms are issued, that shall
32 include the name, category of licensure, license number, federal
33 controlled substance registration number, and the quantity of
34 controlled substance prescription forms issued to each prescriber
35 and be maintained in the health facility for three years.

36 (B) Forms ordered pursuant to this subdivision that are printed
37 by a computerized prescription generation system shall not be
38 subject to the requirements set forth in subparagraph (A) or
39 paragraph (7) of subdivision (a). Forms printed pursuant to this
40 subdivision that are printed by a computerized prescription

1 generation system may contain the prescriber's name, category of
2 professional licensure, license number, federal controlled
3 substance registration number, and the date of the prescription.

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

5 SEC. 2. Section 11164 of the Health and Safety Code is
6 amended to read:

7 11164. Except as provided in Section 11167, no person shall
8 prescribe a controlled substance, nor shall any person fill,
9 compound, or dispense a prescription for a controlled substance,
10 unless it complies with the requirements of this section.

11 (a) Each prescription for a controlled substance classified in
12 Schedule II, III, IV, or V, except as authorized by subdivision
13 (b), shall be made on a controlled substance prescription form as
14 specified in Section 11162.1 and shall meet the following
15 requirements:

16 (1) The prescription shall be signed and dated by the
17 prescriber in ink and shall contain the prescriber's address and
18 telephone number; the *name, address, and* telephone number of
19 the ultimate user or research subject, or contact information as
20 determined by the Secretary of the United States Department of
21 Health and Human Services; refill information, such as the
22 number of refills ordered and whether the prescription is a
23 first-time request or a refill; the date of origin of the prescription;
24 and the name, quantity, strength, and directions for use of the
25 controlled substance prescribed.

26 (2) The prescription shall also contain the address of the
27 person for whom the controlled substance is prescribed. If the
28 prescriber does not specify this address on the prescription, the
29 pharmacist filling the prescription or an employee acting under
30 the direction of the pharmacist shall write or type the address on
31 the prescription or maintain this information in a readily
32 retrievable form in the pharmacy.

33 (b) (1) Notwithstanding paragraph (1) of subdivision (a) of
34 Section 11162.1, any controlled substance classified in Schedule
35 III, IV, or V may be dispensed upon an oral or electronically
36 transmitted prescription, which shall be produced in hard copy
37 form and signed and dated by the pharmacist filling the
38 prescription or by any other person expressly authorized by
39 provisions of the Business and Professions Code. Any person
40 who transmits, maintains, or receives any electronically

1 transmitted prescription shall ensure the security, integrity,
2 authority, and confidentiality of the prescription.

3 (2) The date of issue of the prescription and all the information
4 required for a written prescription by subdivision (a) shall be
5 included in the written record of the prescription; the pharmacist
6 need not include the address, telephone number, license
7 classification, or federal registry number of the prescriber or the
8 address of the patient on the hard copy, if that information is
9 readily retrievable in the pharmacy.

10 (3) Pursuant to an authorization of the prescriber, any agent of
11 the prescriber on behalf of the prescriber may orally or
12 electronically transmit a prescription for a controlled substance
13 classified in Schedule III, IV, or V, if in these cases the written
14 record of the prescription required by this subdivision specifies
15 the name of the agent of the prescriber transmitting the
16 prescription.

17 (c) The use of commonly used abbreviations shall not
18 invalidate an otherwise valid prescription.

19 (d) Notwithstanding any provision of subdivisions (a) and (b),
20 prescriptions for a controlled substance classified in Schedule V
21 may be for more than one person in the same family with the
22 same medical need.

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

24 SEC. 3. Section 11165 of the Health and Safety Code is
25 amended to read:

26 11165. (a) To assist law enforcement and regulatory
27 agencies in their efforts to control the diversion and resultant
28 abuse of Schedule II, Schedule III, and Schedule IV controlled
29 substances, and for statistical analysis, education, and research,
30 the Department of Justice shall, contingent upon the availability
31 of adequate funds from the Contingent Fund of the Medical
32 Board of California, the Pharmacy Board Contingent Fund, the
33 State Dentistry Fund, the Board of Registered Nursing Fund, and
34 the Osteopathic Medical Board of California Contingent Fund,
35 maintain the Controlled Substance Utilization Review and
36 Evaluation System (CURES) for the electronic monitoring of the
37 prescribing and dispensing of Schedule II, Schedule III, and
38 Schedule IV controlled substances by all practitioners authorized
39 to prescribe or dispense these controlled substances.

1 (b) The reporting of Schedule III and Schedule IV controlled
2 substance prescriptions to CURES shall be contingent upon the
3 availability of adequate funds from the Department of Justice.
4 The Department of Justice may seek and use grant funds to pay
5 the costs incurred from the reporting of controlled substance
6 prescriptions to CURES. Funds shall not be appropriated from
7 the Contingent Fund of the Medical Board of California, the
8 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
9 Board of Registered Nursing Fund, the Naturopathic Doctor's
10 Fund, or the Osteopathic Medical Board of California Contingent
11 Fund to pay the costs of reporting Schedule III and Schedule IV
12 controlled substance prescriptions to CURES.

13 (c) CURES shall operate under existing provisions of law to
14 safeguard the privacy and confidentiality of patients. Data
15 obtained from CURES shall only be provided to appropriate
16 state, local, and federal persons or public agencies for
17 disciplinary, civil, or criminal purposes and to other agencies or
18 entities, as determined by the Department of Justice, for the
19 purpose of educating practitioners and others in lieu of
20 disciplinary, civil, or criminal actions. Data may be provided to
21 public or private entities, as approved by the Department of
22 Justice, for educational, peer review, statistical, or research
23 purposes, provided that patient information, including any
24 information that may identify the patient, is not compromised.
25 Further, data disclosed to any individual or agency as described
26 in this subdivision shall not be disclosed, sold, or transferred to
27 any third party.

28 (d) For each prescription for a Schedule II, Schedule III, or
29 Schedule IV controlled substance, the dispensing pharmacy shall
30 provide the following information to the Department of Justice in
31 a frequency and format specified by the Department of Justice:

32 (1) Full name, address, *and the* telephone number of the
33 ultimate user or research subject, or contact information as
34 determined by the Secretary of the United States Department of
35 Health and Human Services, *and the* gender, and date of birth of
36 the patient.

37 (2) The prescriber's category of licensure and license number;
38 federal controlled substance registration number; and the state
39 medical license number of any prescriber using the federal

- 1 controlled substance registration number of a
2 government-exempt facility.
- 3 (3) Pharmacy prescription number, license number, and
4 federal controlled substance registration number.
- 5 (4) NDC (National Drug Code) number of the controlled
6 substance dispensed.
- 7 (5) Quantity of the controlled substance dispensed.
- 8 (6) ICD-9 (diagnosis code), if available.
- 9 (7) Number of refills ordered.
- 10 (8) Whether the drug was dispensed as a refill ~~or~~ of a
11 prescription or as a first-time request.
- 12 (9) Date of origin of the prescription.
- 13 (10) Date of dispensing of the prescription.
- 14 (e) This section shall become operative on January 1, 2005.
- 15 SEC. 4. Section 11165.1 of the Health and Safety Code is
16 amended to read:
- 17 11165.1. (a) (1) A licensed health care practitioner eligible
18 to prescribe Schedule II, Schedule III, or Schedule IV controlled
19 substances or a pharmacist may make a written request for, and
20 the Department of Justice may release to that practitioner or
21 pharmacist, the history of controlled substances dispensed to an
22 individual under his or her care based on data contained in
23 CURES.
- 24 (2) Any request for, or release of, a controlled substance
25 history pursuant to this section shall be made in accordance with
26 guidelines developed by the Department of Justice.
- 27 (b) In order to prevent the inappropriate, improper, or illegal
28 use of Schedule II, Schedule III, or Schedule IV controlled
29 substances, the Department of Justice may initiate the referral of
30 the history of controlled substances dispensed to an individual
31 based on data contained in CURES to licensed health care
32 practitioners, pharmacists, or both, providing care or services to
33 the individual.
- 34 (c) The history of controlled substances dispensed to an
35 individual based on data contained in CURES that is received by
36 a practitioner or pharmacist from the Department of Justice
37 pursuant to this section shall be considered medical information
38 subject to the provisions of the Confidentiality of Medical
39 Information Act contained in Part 2.6 (commencing with Section
40 56) of Division 1 of the Civil Code.

1 SEC. 5. Section 11190 of the Health and Safety Code is
2 amended to read:

3 11190. (a) Every practitioner, other than a pharmacist, who
4 prescribes or administers a controlled substance classified in
5 Schedule II shall make a record that, as to the transaction, shows
6 all of the following:

7 (1) The name and address of the patient.

8 (2) The date.

9 (3) The character, including the name and strength, and
10 quantity of controlled substances involved.

11 (b) The prescriber's record shall show the pathology and
12 purpose for which the controlled substance was administered or
13 prescribed.

14 (c) (1) For each prescription for a Schedule II or Schedule III
15 controlled substance that is dispensed by a prescriber pursuant to
16 Section 4170 of the Business and Professions Code, the
17 prescriber shall record and maintain the following information:

18 (A) Full name, address, *and the* telephone number of the
19 ultimate user or research subject, or contact information as
20 determined by the Secretary of the United States Department of
21 Health and Human Services, *and the* gender, and date of birth of
22 the patient.

23 (B) The prescriber's category of licensure and license number;
24 federal controlled substance registration number; and the state
25 medical license number of any prescriber using the federal
26 controlled substance registration number of a
27 government-exempt facility.

28 (C) NDC (National Drug Code) number of the controlled
29 substance dispensed.

30 (D) Quantity of the controlled substance dispensed.

31 (E) ICD-9 (diagnosis code), if available.

32 (F) Number of refills ordered.

33 (G) Whether the drug was dispensed as a refill of a
34 prescription or as a first-time request.

35 (H) Date of origin of the prescription.

36 (2) Each prescriber that dispenses controlled substances shall
37 provide the Department of Justice the information required by
38 this subdivision on a weekly basis in a format set by the
39 Department of Justice pursuant to regulation.

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

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

O



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1366

VERSION: AMENDED APRIL 4, 2006

AUTHOR: AANESTAD

SPONSOR: CALIFORNIA MEDICAL ASSOCIATION

RECOMMENDED POSITION:

SUBJECT: CONTROLLED SUBSTANCES: SPECIALIZED PRESCRIPTION PADS

Existing Law:

- 1) Requires physicians and surgeons to obtain and use forms for controlled substances from printers that have been approved by the Department of Justice when prescribing controlled substances. (H&S 11161.5)
- 2) Specifies the preprinted requirements for controlled substances forms. (H&S 11162.1)
- 3) Specifies the type of information that is required to be filled in on a prescription for schedule II-V drugs. (H&S 11162.1)

This Bill:

- 1) Eliminates the required use of specialized secure prescription pads for prescribing all scheduled drugs. As such, requirements to license security printers are also repealed. (H&S 11161, 11161.7, 11162.6, 11167 Amended, 11161.5, 11162.1 Repealed)
- 2) Retains the requirements that prescriptions for Schedule II-V drugs contain specified information, such as the prescription shall be signed and dated by the prescriber, in ink and shall contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed. (H&S 11164 Amended)
- 3) Repeals the terminally ill or H&S 11159.2 exemption prescriptions. Repeals the requirement that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2 Repealed)
- 4) Eliminates the requirement that the board must notify security printers when a prescriber's authority to prescribe controlled substances is restricted by law enforcement or licensing board. (H&S 11161.7 Amended)

Comment:

1) Author's Intent. The author's intent is to eliminate special prescription forms for prescribing controlled substance drugs, because in part, there is no evidence available to show that the use of specialized pads has reduced the level of illegal use or dissemination of controlled drugs. The author believes the public is better served by tracking controlled substances through the

Controlled Substance Utilization Review and Evaluation System (CURES) electronic surveillance system.

2) Brief History of Controlled Substance Forms and Tracking in CA. In 1939, California became the first state to institute the use of specialized triplicate prescription forms to stem the abuse of selected dangerous drugs. Over the years the types of prescribed drugs requiring a triplicate form was expanded to include Schedule II-V drugs. In 2004, SB 151 eliminated the requirement for the use of triplicate forms and replaced it with a requirement to use new security printer forms issued by licensed printers.

In 1996, CURES was created to electronically monitor the prescribing, dispensing, and use of schedule II drugs. While this program initiated as a pilot program it has since become a permanent program and been expanded to track schedule II and III drugs.

In 2006, California has the distinction of being one of three states that still requires the use of specialized prescription forms for prescribing schedule drugs (see attached chart). Most other states have moved away from the specialized forms and rely on CURES, like monitoring programs to identify the misuse and abuse of scheduled drugs.

3) Related Legislation. AB 2986 (Mullin) Controlled substances, prescription requirements, sponsored by the Department of Justice, would require security prescription forms to also include the telephone number of the ultimate user or research subject, or the contact information as determined by the U.S. Secretary of Health and Human Services; check boxes so that the prescriber may indicate that a prescription is a first-time request or that a specified number of refills of the prescription have been ordered since the first prescription; and the date of origin of the prescription.

4) Previous Legislation.

SB 734 (Chapter 487, Statutes of 2005) made clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. Among other provisions it transferred the approval of security printers from the board to the Department of Justice.

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

AB 2018 (Chapter 1092, Statutes of 2002) provided changes to the triplicate pad and established a process for correction of prescription errors.

AB 2693 (Chapter 789, Statutes of 1998) exempted Schedule II controlled substances for patients with terminal illnesses from triplicate prescription form requirements.

AB 3042 (Chapter 738, Statutes of 1996) created the CURES program on a pilot basis.

5) History.

2006

Apr. 6 Set for hearing April 25.

Apr. 5 Re-referred to Com. on PUB. S.

Apr. 4 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

Mar. 2 To Com. on RLS.

Feb. 22 From print. May be acted upon on or after March 24.

Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

STATES WITH PRESCRIPTION MONITORING PROGRAMS
January 2006

	STATE	PROGRAM TYPE	SCHEDULES COVERED	YEAR ENACTED
1	AL	Electronic	C II - V	2004
2	CO	Electronic	C II - V	2005
3	CA	Single-Copy Serialized Electronic	C II - V	2005
4	HI	Electronic	C II - IV	2002
5	ID	Electronic	C II - V	2001
6	IL	Electronic	C II	1999
7	IN	Electronic	C II - V	2004
8	KY	Electronic	C II - V	1998
9	ME	Electronic	C II - IV	2003
10	MA	Electronic	C II	1992
11	MI	Electronic	C II - V	2002
12	NC	Electronic	CII - V	2005
13	NM	Electronic	CII - IV	2004
14	NV	Electronic	C II - IV	1995
15	NY	Single-copy, serialized/Electronic (state-issued)	C II, Benzos	1998
16	OH	Electronic	C II - V	2005
17	OK	Electronic	C II	1990
18	RI	Electronic	C II, III	1997
19	TN	Electronic	C II - IV	2002
20	TX	Single-copy, serialized/Electronic (state-Issued)	C II	1997
21	UT	Electronic	C II - V	1995
22	VA	Electronic	C II - V	2002
23	WV	Electronic	C II - IV	1995

Introduced by Senator Aanestad

February 21, 2006

An act to amend Sections 11159.2, 11161, 11162.6, 11164, 11164.1, 11165, 11167, and 11167.5 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1366, as amended, Aanestad. Controlled substances.

~~Existing law regulates the prescription of controlled substances, as specified.~~

~~This bill would make technical, nonsubstantive changes to these provisions.~~

Existing law requires an authorized prescriber to write prescriptions for controlled substances on a specialized secured prescription form, and makes exceptions therefore.

This bill would remove the requirement that authorized persons write prescriptions for controlled substances on a specialized secured prescription form and delete the exceptions therefore.

Existing law allows a court to require a prescriber to turn over his or her specialized secured prescription forms for controlled substances when the prescriber is charged with a specified felony offense.

This bill would allow the court to issue an order prohibiting the prescriber from prescribing controlled substances when the prescriber is charged with a specified felony offense. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

Existing law makes it a crime to counterfeit a secured controlled substance prescription form.

This bill would repeal that crime.

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: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

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

1 ~~SECTION 1. Section 11159.2 of the Health and Safety Code~~
2 ~~is amended to read:~~
3 ~~11159.2. (a) Notwithstanding any other provision of law, a~~
4 ~~prescription for a controlled substance for use by a patient who~~
5 ~~has a terminal illness may be written on a prescription form that~~
6 ~~does not meet the requirements of Section 11162.1 if the~~
7 ~~prescription meets the following requirements:~~
8 ~~(1) Contain the information specified in subdivision (a) of~~
9 ~~Section 11164.~~
10 ~~(2) Indicate that the prescriber has certified that the patient is~~
11 ~~terminally ill by the words "11159.2 exemption."~~
12 ~~(b) A pharmacist may fill a prescription pursuant to this~~
13 ~~section when there is a technical error in the certification~~
14 ~~required by paragraph (2) of subdivision (a), provided that he or~~
15 ~~she has personal knowledge of the patient's terminal illness, and~~
16 ~~subsequently returns the prescription to the prescriber for~~
17 ~~correction within 72 hours.~~
18 ~~(c) For purposes of this section, "terminally ill" means a~~
19 ~~patient who meets all of the following conditions:~~
20 ~~(1) In the reasonable medical judgment of the prescribing~~
21 ~~physician, the patient has been determined to be suffering from~~
22 ~~an illness that is incurable and irreversible.~~
23 ~~(2) In the reasonable medical judgment of the prescribing~~
24 ~~physician, the patient's illness will, if the illness takes its normal~~
25 ~~course, bring about the death of the patient within a period of one~~
26 ~~year.~~

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

5 *SECTION 1. Section 11159.2 of the Health and Safety Code*
6 *is repealed.*

7 ~~11159.2. (a) Notwithstanding any other provision of law, a~~
8 ~~prescription for a controlled substance for use by a patient who~~
9 ~~has a terminal illness may be written on a prescription form that~~
10 ~~does not meet the requirements of Section 11162.1 if the~~
11 ~~prescription meets the following requirements:~~

12 ~~(1) Contain the information specified in subdivision (a) of~~
13 ~~Section 11164.~~

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

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

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

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

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

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

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

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

38 ~~11161. (a) When a practitioner is named in a warrant of~~
39 ~~arrest or is charged in an accusatory pleading with a felony~~
40 ~~violation of Section 11153, 11154, 11156, 11157, 11170, 11173,~~

1 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5,
2 11379, 11379.5, or 11379.6, the court in which the accusatory
3 pleading is filed or the magistrate who issued the warrant of
4 arrest shall, upon the motion of a law enforcement agency which
5 is supported by reasonable cause, issue an order ~~which requires~~
6 ~~the practitioner to surrender to the clerk of the court all controlled~~
7 ~~substance prescription forms in the practitioner's possession at a~~
8 ~~time set in the order and which prohibits the practitioner from~~
9 ~~obtaining, ordering, or using any additional prescription forms.~~
10 *prohibiting the practitioner from prescribing controlled*
11 *substances.* The law enforcement agency obtaining the order
12 shall notify the Department of Justice of this order. Except as
13 provided in subdivisions (b) and (e) of this section, the order
14 shall remain in effect until further order of the court. Any
15 practitioner ~~possessing prescription forms who prescribes~~
16 *controlled substances* in violation of the order is guilty of a
17 misdemeanor.

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

39 (c) The defendant may elect to challenge the order issued
40 under subdivision (a) at the preliminary examination. At that

1 hearing, the evidence shall be limited to that set forth in
2 subdivision (b) and any other evidence otherwise admissible at
3 the preliminary examination.

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

12 (e) Notwithstanding subdivision (d), any practitioner who is
13 diverted pursuant to Chapter 2.5 (commencing with Section
14 1000) of Title 7 of Part 2 of the Penal Code may file a motion to
15 vacate the order issued under subdivision (a).

16 *SEC. 3. Section 11161.5 of the Health and Safety Code is*
17 *repealed.*

18 ~~11161.5.—(a) Prescription forms for controlled substance~~
19 ~~prescriptions shall be obtained from security printers approved~~
20 ~~by the Department of Justice.~~

21 ~~(b) The department may approve security printer applications~~
22 ~~after the applicant has provided the following information:~~

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

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

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

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

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

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

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

5 ~~(C) Any applicant described in subdivision (b) shall submit his~~
6 ~~or her fingerprint images and related information to the~~
7 ~~department, for the purpose of the department obtaining~~
8 ~~information as to the existence and nature of a record of state,~~
9 ~~federal, or foreign level convictions and state, federal, or foreign~~
10 ~~level arrests for which the department establishes that the~~
11 ~~applicant was released on bail or on his or her own recognizance~~
12 ~~pending trial, as described in subdivision (I) of Section 11105 of~~
13 ~~the Penal Code. Requests for federal level criminal offender~~
14 ~~record information received by the department pursuant to this~~
15 ~~section shall be forwarded to the Federal Bureau of Investigation~~
16 ~~by the department.~~

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

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

28 ~~(e) The department may, within 60 calendar days of receipt of~~
29 ~~the application from the applicant, deny the security printer~~
30 ~~application.~~

31 ~~(d) The department may deny a security printer application on~~
32 ~~any of the following grounds:~~

33 ~~(1) The applicant, any individual owner, partner, corporate~~
34 ~~officer, manager, agent, representative, employee, or~~
35 ~~subcontractor for the applicant, who has direct access,~~
36 ~~management, or control of controlled substance prescription~~
37 ~~forms, has been convicted of a crime. A conviction within the~~
38 ~~meaning of this paragraph means a plea or verdict of guilty or a~~
39 ~~conviction following a plea of nolo contendere. Any action~~
40 ~~which a board is permitted to take following the establishment of~~

1 a conviction may be taken when the time for appeal has elapsed;
2 the judgment of conviction has been affirmed on appeal, or when
3 an order granting probation is made suspending the imposition of
4 sentence, irrespective of a subsequent order under the provisions
5 of Section 1203.4 of the Penal Code.

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

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

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

14 (5) The department determines that the applicant failed to
15 demonstrate adequate security procedures relating to the
16 production and distribution of controlled substance prescription
17 forms.

18 (6) The department determines that the applicant has
19 submitted an incomplete application.

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

26 (e) An approved applicant shall submit an exemplar of a
27 controlled substance prescription form, with all security features,
28 to the Department of Justice within 30 days of initial production.

29 (f) The department shall maintain a list of approved security
30 printers and the department shall make this information available
31 to prescribers and other appropriate government agencies,
32 including the Board of Pharmacy.

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

38 (h) Controlled substance prescription forms shall be provided
39 directly to the prescriber either in person, by certified mail, or by

1 ~~a means that requires a signature signifying receipt of the~~
2 ~~package and provision of that signature to the security printer.~~

3 ~~(i) Security printers shall retain ordering and delivery records~~
4 ~~in a readily retrievable manner for individual prescribers for three~~
5 ~~years.~~

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

9 ~~(k) (1) The department may revoke its approval of a security~~
10 ~~printer for a violation of this division or action that would permit~~
11 ~~a denial pursuant to subdivision (d) of this section.~~

12 ~~(2) When the department revokes its approval, it shall notify~~
13 ~~the appropriate licensing boards and remove the security printer~~
14 ~~from the list of approved security printers.~~

15 *SEC. 4. Section 11161.7 of the Health and Safety Code is*
16 *amended to read:*

17 11161.7. (a) When a prescriber's authority to prescribe
18 controlled substances is restricted by civil, criminal, or
19 administrative action, or by an order of the court issued pursuant
20 to Section 11161, the law enforcement agency or licensing board
21 that sought the restrictions shall provide the name, category of
22 licensure, license number, and the nature of the restrictions
23 imposed on the prescriber to ~~security printers~~, the Department of
24 Justice, and the Board of Pharmacy.

25 (b) The Board of Pharmacy shall make available the
26 information required by subdivision (a) to pharmacies and
27 ~~security printers~~ to prevent the dispensing of controlled substance
28 prescriptions issued by the prescriber ~~and the ordering of~~
29 ~~additional controlled substance prescription forms by the~~
30 ~~restricted prescriber.~~

31 *SEC. 5. Section 11162.1 of the Health and Safety Code is*
32 *repealed.*

33 ~~11162.1. (a) The prescription forms for controlled substances~~
34 ~~shall be printed with the following features:~~

35 ~~(1) A latent, repetitive "void" pattern shall be printed across~~
36 ~~the entire front of the prescription blank; if a prescription is~~
37 ~~scanned or photocopied, the word "void" shall appear in a pattern~~
38 ~~across the entire front of the prescription.~~

1 ~~(2) A watermark shall be printed on the backside of the~~
2 ~~prescription blank; the watermark shall consist of the words~~
3 ~~“California Security Prescription.”~~

4 ~~(3) A chemical void protection that prevents alteration by~~
5 ~~chemical washing.~~

6 ~~(4) A feature printed in thermo-chromic ink.~~

7 ~~(5) An area of opaque writing so that the writing disappears if~~
8 ~~the prescription is lightened.~~

9 ~~(6) A description of the security features included on each~~
10 ~~prescription form.~~

11 ~~(7) (A) Six quantity check off boxes shall be printed on the~~
12 ~~form and the following quantities shall appear:~~

13 ~~1-24~~

14 ~~25-49~~

15 ~~50-74~~

16 ~~75-100~~

17 ~~101-150~~

18 ~~151 and over.~~

19 ~~(B) In conjunction with the quantity boxes, a space shall be~~
20 ~~provided to designate the units referenced in the quantity boxes~~
21 ~~when the drug is not in tablet or capsule form.~~

22 ~~(8) Prescription blanks shall contain a statement printed on the~~
23 ~~bottom of the prescription blank that the “Prescription is void if~~
24 ~~the number of drugs prescribed is not noted.”~~

25 ~~(9) The preprinted name, category of licensure, license~~
26 ~~number, federal controlled substance registration number of the~~
27 ~~prescribing practitioner.~~

28 ~~(10) A check box indicating the prescriber’s order not to~~
29 ~~substitute.~~

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

32 ~~(12) (A) A check box by the name of each prescriber when a~~
33 ~~prescription form lists multiple prescribers.~~

34 ~~(B) Each prescriber who signs the prescription form shall~~
35 ~~identify himself or herself as the prescriber by checking the box~~
36 ~~by their name.~~

37 ~~(b) Each batch of controlled substance prescription forms shall~~
38 ~~have the lot number printed on the form and each form within~~
39 ~~that batch shall be numbered sequentially beginning with the~~
40 ~~numeral one.~~

1 ~~(e) (1) A prescriber designated by a licensed health care~~
2 ~~facility, a clinic specified in Section 1200, or a clinic specified in~~
3 ~~subdivision (a) of Section 1206 that has 25 or more physicians or~~
4 ~~surgeons may order controlled substance prescription forms for~~
5 ~~use by prescribers when treating patients in that facility without~~
6 ~~the information required in paragraph (9) of subdivision (a) or~~
7 ~~paragraph (3) of this subdivision.~~

8 ~~(2) Forms ordered pursuant to this subdivision shall have the~~
9 ~~name, category of licensure, license number, and federal~~
10 ~~controlled substance registration number of the designated~~
11 ~~prescriber and the name, address, category of licensure, and~~
12 ~~license number of the licensed health care facility the clinic~~
13 ~~specified in Section 1200, or the clinic specified in subdivision~~
14 ~~(a) of Section 1206 that has 25 or more physicians or surgeons~~
15 ~~preprinted on the form.~~

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

20 ~~(4) (A) Except as provided in subparagraph (B), the designated~~
21 ~~prescriber shall maintain a record of the prescribers to whom the~~
22 ~~controlled substance prescription forms are issued, that shall~~
23 ~~include the name, category of licensure, license number, federal~~
24 ~~controlled substance registration number, and the quantity of~~
25 ~~controlled substance prescription forms issued to each prescriber~~
26 ~~and be maintained in the health facility for three years.~~

27 ~~(B) Forms ordered pursuant to this subdivision that are printed~~
28 ~~by a computerized prescription generation system shall not be~~
29 ~~subject to the requirements set forth in subparagraph (A) or~~
30 ~~paragraph (7) of subdivision (a). Forms printed pursuant to this~~
31 ~~subdivision that are printed by a computerized prescription~~
32 ~~generation system may contain the prescriber's name, category of~~
33 ~~professional licensure, license number, federal controlled~~
34 ~~substance registration number, and the date of the prescription.~~

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

36 ~~SEC. 3:~~

37 ~~SEC. 6. Section 11162.6 of the Health and Safety Code is~~
38 ~~amended to read:~~

39 ~~11162.6. (a) Every person who counterfeits a controlled~~
40 ~~substance prescription form shall be guilty of a misdemeanor~~

1 punishable by imprisonment in a county jail for not more than
2 one year, by a fine not exceeding one thousand dollars (\$1,000),
3 or by both that imprisonment and fine.

4 ~~(b) Every person who knowingly possesses a counterfeited~~
5 ~~controlled substance prescription form shall be guilty of a~~
6 ~~misdemeanor punishable by imprisonment in a county jail not~~
7 ~~exceeding six months, by a fine not exceeding one thousand~~
8 ~~dollars (\$1,000), or by both that imprisonment and fine.~~

9 (e) Every person who attempts to obtain or obtains a
10 controlled substance prescription form under false pretenses shall
11 be guilty of a misdemeanor punishable by imprisonment in a
12 county jail not exceeding six months, by a fine not exceeding one
13 thousand dollars (\$1,000), or by both that imprisonment and fine.

14 ~~(d) Every person who fraudulently produces controlled~~
15 ~~substance prescription forms shall be guilty of a misdemeanor~~
16 ~~punishable by imprisonment in a county jail not exceeding six~~
17 ~~months, by a fine not exceeding one thousand dollars (\$1,000), or~~
18 ~~by both that imprisonment and fine.~~

19 SEC. 4.

20 SEC. 7. Section 11164 of the Health and Safety Code is
21 amended to read:

22 11164. Except as provided in Section 11167, no person shall
23 prescribe a controlled substance, nor shall any person fill,
24 compound, or dispense a prescription for a controlled substance,
25 unless it complies with the requirements of this section.

26 (a) Each prescription for a controlled substance classified in
27 Schedule II, III, IV, or V, except as authorized by subdivision
28 (b), shall be made on a controlled substance prescription form as
29 specified in Section 11162.1 and shall meet the following
30 requirements:

31 (1) The prescription shall be signed and dated by the
32 prescriber in ink and shall contain the prescriber's address and
33 telephone number; the name of the person for whom the
34 controlled substance is prescribed; and the name, quantity,
35 strength, and directions for use of the controlled substance
36 prescribed.

37 (2) The prescription shall also contain the address of the
38 person for whom the controlled substance is prescribed. If the
39 prescriber does not specify this address on the prescription, the
40 pharmacist filling the prescription or an employee acting under

1 the direction of the pharmacist shall write or type the address on
2 the prescription or maintain this information in a readily
3 retrievable form in the pharmacy.

4 (b) (1) Notwithstanding paragraph (1) of subdivision (a) of
5 Section 11162.1, any controlled substance classified in Schedule
6 III, IV, or V may be dispensed upon an oral or electronically
7 transmitted prescription, which shall be produced in hard copy
8 form and signed and dated by the pharmacist filling the
9 prescription or by any other person expressly authorized by
10 provisions of the Business and Professions Code. Any person
11 who transmits, maintains, or receives any electronically
12 transmitted prescription shall ensure the security, integrity,
13 authority, and confidentiality of the prescription.

14 (2) The date of issue of the prescription and all the information
15 required for a written prescription by subdivision (a) shall be
16 included in the written record of the prescription; the pharmacist
17 need not include the address, telephone number, license
18 classification, or federal registry number of the prescriber or the
19 address of the patient on the hard copy, if that information is
20 readily retrievable in the pharmacy.

21 (3) Pursuant to an authorization of the prescriber, any agent of
22 the prescriber on behalf of the prescriber may orally or
23 electronically transmit a prescription for a controlled substance
24 classified in Schedule III, IV, or V, if in these cases the written
25 record of the prescription required by this subdivision specifies
26 the name of the agent of the prescriber transmitting the
27 prescription.

28 (c) The use of commonly used abbreviations shall not
29 invalidate an otherwise valid prescription.

30 (d) Notwithstanding any provision of subdivisions (a) and (b),
31 prescriptions for a controlled substance classified in Schedule V
32 may be for more than one person in the same family with the
33 same medical need.

34 ~~SEC. 5.~~

35 *SEC. 8.* Section 11164.1 of the Health and Safety Code is
36 amended to read:

37 11164.1. (a) (1) Notwithstanding any other provision of
38 law, a prescription for a controlled substance issued by a
39 prescriber in another state for delivery to a patient in another
40 state may be dispensed by a California pharmacy, if the

1 prescription conforms with the requirements for controlled
2 substance prescriptions in the state in which the controlled
3 substance was prescribed.

4 (2) All prescriptions for Schedule II and Schedule III
5 controlled substances dispensed pursuant to this subdivision shall
6 be reported by the dispensing pharmacy to the Department of
7 Justice in the manner prescribed by subdivision (d) of Section
8 11165.

9 (b) Pharmacies may dispense prescriptions for Schedule III,
10 Schedule IV, and Schedule V controlled substances from
11 out-of-state prescribers pursuant to Section 4005 of the Business
12 and Professions Code and Section 1717 of Title 16 of the
13 California Code of Regulations.

14 ~~SEC. 6.~~

15 *SEC. 9.* Section 11165 of the Health and Safety Code is
16 amended to read:

17 11165. (a) To assist law enforcement and regulatory
18 agencies in their efforts to control the diversion and resultant
19 abuse of Schedule II and Schedule III controlled substances, and
20 for statistical analysis, education, and research, the Department
21 of Justice shall, contingent upon the availability of adequate
22 funds from the Contingent Fund of the Medical Board of
23 California, the Pharmacy Board Contingent Fund, the State
24 Dentistry Fund, the Board of Registered Nursing Fund, and the
25 Osteopathic Medical Board of California Contingent Fund,
26 maintain the Controlled Substance Utilization Review and
27 Evaluation System (CURES) for the electronic monitoring of the
28 prescribing and dispensing of Schedule II and Schedule III
29 controlled substances by all practitioners authorized to prescribe
30 or dispense these controlled substances.

31 (b) The reporting of Schedule III controlled substance
32 prescriptions to CURES shall be contingent upon the availability
33 of adequate funds from the Department of Justice. The
34 Department of Justice may seek and use grant funds to pay the
35 costs incurred from the reporting of controlled substance
36 prescriptions to CURES. Funds shall not be appropriated from
37 the Contingent Fund of the Medical Board of California, the
38 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
39 Board of Registered Nursing Fund, the Naturopathic Doctor's
40 Fund, or the Osteopathic Medical Board of California Contingent

1 Fund to pay the costs of reporting Schedule III controlled
2 substance prescriptions to CURES.

3 (c) CURES shall operate under existing provisions of law to
4 safeguard the privacy and confidentiality of patients. Data
5 obtained from CURES shall only be provided to appropriate
6 state, local, and federal persons or public agencies for
7 disciplinary, civil, or criminal purposes and to other agencies or
8 entities, as determined by the Department of Justice, for the
9 purpose of educating practitioners and others in lieu of
10 disciplinary, civil, or criminal actions. Data may be provided to
11 public or private entities, as approved by the Department of
12 Justice, for educational, peer review, statistical, or research
13 purposes, provided that patient information, including any
14 information that may identify the patient, is not compromised.
15 Further, data disclosed to any individual or agency as described
16 in this subdivision shall not be disclosed, sold, or transferred to
17 any third party.

18 (d) For each prescription for a Schedule II or Schedule III
19 controlled substance, the dispensing pharmacy shall provide the
20 following information to the Department of Justice in a
21 frequency and format specified by the Department of Justice:

22 (1) Full name, address, gender, and date of birth of the patient.

23 (2) The prescriber's category of licensure and license number;
24 federal controlled substance registration number; and the state
25 medical license number of any prescriber using the federal
26 controlled substance registration number of a
27 government-exempt facility.

28 (3) Pharmacy prescription number, license number, and
29 federal controlled substance registration number.

30 (4) NDC (National Drug Code) number of the controlled
31 substance dispensed.

32 (5) Quantity of the controlled substance dispensed.

33 (6) ICD-9 (diagnosis code), if available.

34 (7) Date of issue of the prescription.

35 (8) Date of dispensing of the prescription.

36 ~~SEC. 7.~~

37 *SEC. 10.* Section 11167 of the Health and Safety Code is
38 amended to read:

39 11167. Notwithstanding subdivision (a) of Section 11164, in
40 an emergency where failure to issue a prescription may result in

1 loss of life or intense suffering, an order for a controlled
2 substance may be dispensed on an oral order, an electronic data
3 transmission order, or a written order ~~not made on a controlled~~
4 ~~substance form as specified in Section 11162.1~~, subject to all of
5 the following requirements:

6 (a) The order contains all information required by subdivision
7 (a) of Section 11164.

8 (b) Any written order is signed and dated by the prescriber in
9 ink, and the pharmacy reduces any oral or electronic data
10 transmission order to hard copy form prior to dispensing the
11 controlled substance.

12 (c) The prescriber provides a written prescription ~~on a~~
13 ~~controlled substance prescription form that meets the~~
14 ~~requirements of Section 11162.1~~, by the seventh day following
15 the transmission of the initial order; a postmark by the seventh
16 day following transmission of the initial order shall constitute
17 compliance.

18 (d) If the prescriber fails to comply with subdivision (c), the
19 pharmacy shall so notify the Bureau of Narcotic Enforcement in
20 writing within 144 hours of the prescriber's failure to do so and
21 shall make and retain a hard copy, readily retrievable record of
22 the prescription, including the date and method of notification of
23 the Bureau of Narcotic Enforcement.

24 ~~SEC. 8.~~

25 *SEC. 11.* Section 11167.5 of the Health and Safety Code is
26 amended to read:

27 ~~11167.5.~~ (a) An order for a controlled substance classified in
28 Schedule II for a patient of a licensed skilled nursing facility, a
29 licensed intermediate care facility, a licensed home health
30 agency, or a licensed hospice may be dispensed upon an oral or
31 electronically transmitted prescription. If the prescription is
32 transmitted orally, the pharmacist shall, prior to filling the
33 prescription, reduce the prescription to writing in ink in the
34 handwriting of the pharmacist on a form developed by the
35 pharmacy for this purpose. If the prescription is transmitted
36 electronically, the pharmacist shall, prior to filling the
37 prescription, produce, sign, and date a hard copy prescription.
38 The prescriptions shall contain the date the prescription was
39 orally or electronically transmitted by the prescriber, the name of
40 the person for whom the prescription was authorized, the name

1 and address of the licensed skilled nursing facility, licensed
2 intermediate care facility, licensed home health agency, or
3 licensed hospice in which that person is a patient, the name and
4 quantity of the controlled substance prescribed, the directions for
5 use, and the name, address, category of professional licensure,
6 license number, and federal controlled substance registration
7 number of the prescriber. The original shall be properly endorsed
8 by the pharmacist with the pharmacy's state license number, the
9 name and address of the pharmacy, and the signature of the
10 person who received the controlled substances for the licensed
11 skilled nursing facility, licensed intermediate care facility,
12 licensed home health agency, or licensed hospice. A licensed
13 skilled nursing facility, a licensed intermediate care facility, a
14 licensed home health agency, or a licensed hospice shall forward
15 to the dispensing pharmacist a copy of any signed telephone
16 orders, chart orders, or related documentation substantiating each
17 oral or electronically transmitted prescription transaction under
18 this section.

19 *SEC. 12. No reimbursement is required by this act pursuant*
20 *to Section 6 of Article XIII B of the California Constitution*
21 *because the only costs that may be incurred by a local agency or*
22 *school district will be incurred because this act creates a new*
23 *crime or infraction, eliminates a crime or infraction, or changes*
24 *the penalty for a crime or infraction, within the meaning of*
25 *Section 17556 of the Government Code, or changes the definition*
26 *of a crime within the meaning of Section 6 of Article XIII B of the*
27 *California Constitution.*