

AMENDED IN SENATE MAY 28, 2013

AMENDED IN SENATE APRIL 24, 2013

AMENDED IN SENATE APRIL 1, 2013

SENATE BILL

No. 493

Introduced by Senator Hernandez

February 21, 2013

An act to amend Sections 733, 4050, 4051, 4052, 4052.3, and 4060 of, and to add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210, and 4233 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 493, as amended, Hernandez. Pharmacy practice.

The Pharmacy Law provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. The law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber. Pharmacists may also furnish emergency contraception drug therapy pursuant to standardized procedures if they have completed a training program. A violation of the Pharmacy Law is a crime.

This bill, instead, would authorize a pharmacist to administer drugs and biological products that have been ordered by a prescriber. The bill would expand other functions pharmacists are authorized to perform, including, among other things, to furnish self-administered hormonal contraceptives, prescription smoking cessation drugs, and prescription medications not requiring a diagnosis that are recommended for international travelers, as specified. Additionally, the bill would

authorize pharmacists to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations, as specified. This bill also would establish board recognition for an advanced practice pharmacist, as defined, would specify the criteria for that recognition, and would specify additional functions that may be performed by an advanced practice pharmacist, including, among other things, performing patient assessments, and certain other functions, as specified. *The bill would authorize the board, by regulation, to set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to these provisions, not to exceed \$300.* Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The bill would make other conforming and technical changes.

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 733 of the Business and Professions Code
2 is amended to read:

3 733. (a) A licentiate shall not obstruct a patient in obtaining
4 a 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 law, a licentiate shall dispense
10 drugs and devices, as described in subdivision (a) of Section 4024,
11 pursuant to a lawful order or prescription unless one of the
12 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

1 drug or device would cause a harmful drug interaction or would
2 otherwise adversely affect the patient’s medical condition.

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

7 (A) Immediately notify the patient and arrange for the drug or
8 device to be delivered to the site or directly to the patient in a
9 timely manner.

10 (B) Promptly transfer the prescription to another pharmacy
11 known to stock the prescription drug or device that is near enough
12 to the site from which the prescription or order is transferred, to
13 ensure the patient has timely access to the drug or device.

14 (C) Return the prescription to the patient and refer the patient.
15 The licentiate shall make a reasonable effort to refer the patient to
16 a pharmacy that stocks the prescription drug or device that is near
17 enough to the referring site to ensure that the patient has timely
18 access to the drug or device.

19 (3) The licentiate refuses on ethical, moral, or religious grounds
20 to dispense a drug or device pursuant to an order or prescription.
21 A licentiate may decline to dispense a prescription drug or device
22 on this basis only if the licentiate has previously notified his or
23 her employer, in writing, of the drug or class of drugs to which he
24 or she objects, and the licentiate’s employer can, without creating
25 undue hardship, provide a reasonable accommodation of the
26 licentiate’s objection. The licentiate’s employer shall establish
27 protocols that ensure that the patient has timely access to the
28 prescribed drug or device despite the licentiate’s refusal to dispense
29 the prescription or order. For purposes of this section, “reasonable
30 accommodation” and “undue hardship” shall have the same
31 meaning as applied to those terms pursuant to subdivision (l) of
32 Section 12940 of the Government Code.

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

35 (d) This section applies to emergency contraception drug therapy
36 and self-administered hormonal contraceptives described in Section
37 4052.3.

38 (e) This section imposes no duty on a licentiate to dispense a
39 drug or device pursuant to a prescription or order without payment
40 for the drug or device, including payment directly by the patient

1 or through a third-party payer accepted by the licentiate or payment
2 of any required copayment by the patient.

3 (f) The notice to consumers required by Section 4122 shall
4 include a statement that describes patients' rights relative to the
5 requirements of this section.

6 SEC. 2. Section 4016.5 is added to the Business and Professions
7 Code, to read:

8 4016.5. "Advanced practice pharmacist" means a licensed
9 pharmacist who has been recognized as an advanced practice
10 pharmacist by the board, pursuant to Section 4210. A
11 board-recognized advanced practice pharmacist is entitled to
12 practice advanced practice pharmacy, as described in Section
13 4052.6, within or outside of a licensed pharmacy as authorized by
14 this chapter.

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

17 4050. (a) In recognition of and consistent with the decisions
18 of the appellate courts of this state, the Legislature hereby declares
19 the practice of pharmacy to be a profession.

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

27 (c) The Legislature further declares that pharmacists are health
28 care providers who have the authority to provide health care
29 services.

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

32 4051. (a) Except as otherwise provided in this chapter, it is
33 unlawful for any person to manufacture, compound, furnish, sell,
34 or dispense a dangerous drug or dangerous device, or to dispense
35 or compound a prescription pursuant to Section 4040 of a prescriber
36 unless he or she is a pharmacist under this chapter.

37 (b) Notwithstanding any other law, a pharmacist may authorize
38 the initiation of a prescription, pursuant to Section 4052.1, 4052.2,
39 4052.3, or 4052.6, and otherwise provide clinical advice, services,

1 information, or patient consultation, as set forth in this chapter, if
2 all of the following conditions are met:

3 (1) The clinical advice, services, information, or patient
4 consultation is provided to a health care professional or to a patient.

5 (2) The pharmacist has access to prescription, patient profile,
6 or other relevant medical information for purposes of patient and
7 clinical consultation and advice.

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

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

12 4052. (a) Notwithstanding any other law, a pharmacist may:

13 (1) Furnish a reasonable quantity of compounded drug product
14 to a prescriber for office use by the prescriber.

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

16 (3) Administer drugs and biological products that have been
17 ordered by a prescriber.

18 (4) Perform procedures or functions in a licensed health care
19 facility as authorized by Section 4052.1.

20 (5) Perform procedures or functions as part of the care provided
21 by a health care facility, a licensed home health agency, a licensed
22 clinic in which there is a physician oversight, a provider who
23 contracts with a licensed health care service plan with regard to
24 the care or services provided to the enrollees of that health care
25 service plan, or a physician, as authorized by Section 4052.2.

26 (6) Perform procedures or functions as authorized by Section
27 4052.6.

28 (7) Manufacture, measure, fit to the patient, or sell and repair
29 dangerous devices, or furnish instructions to the patient or the
30 patient's representative concerning the use of those devices.

31 (8) Provide consultation, training, and education to patients
32 about drug therapy, disease management, and disease prevention.

33 (9) Provide professional information, including clinical or
34 pharmacological information, advice, or consultation to other
35 health care professionals, and participate in multidisciplinary
36 review of patient progress, including appropriate access to medical
37 records.

38 (10) Furnish the following medications:

39 (A) Emergency contraception drug therapy and self-administered
40 hormonal contraceptives, as authorized by Section 4052.3.

1 (B) Prescription smoking cessation drugs and devices, as
2 authorized by Section 4052.9.

3 (C) Prescription medications not requiring a diagnosis that are
4 recommended by the federal Centers for Disease Control and
5 Prevention for individuals traveling outside of the United States.

6 (11) Administer immunizations pursuant to a protocol with a
7 prescriber.

8 (12) Order and interpret tests for the purpose of monitoring and
9 managing the efficacy and toxicity of drug therapies.

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

14 (c) This section does not affect the applicable requirements of
15 law relating to either of the following:

16 (1) Maintaining the confidentiality of medical records.

17 (2) The licensing of a health care facility.

18 SEC. 6. Section 4052.3 of the Business and Professions Code
19 is amended to read:

20 4052.3. (a) (1) Notwithstanding any other law, a pharmacist
21 may furnish self-administered hormonal contraceptives in
22 accordance with standardized procedures or protocols developed
23 and approved by both the board and the Medical Board of
24 California in consultation with the American Congress of
25 Obstetricians and Gynecologists, the California Pharmacists
26 Association, and other appropriate entities. The standardized
27 procedure or protocol shall require that the patient use a
28 self-screening tool, based on the United States Medical Eligibility
29 Criteria (USMEC) for Contraceptive Use developed by the federal
30 Centers for Disease Control and Prevention, and that the pharmacist
31 refer the patient to the patient's primary care provider or, if the
32 patient does not have a primary care provider, to nearby clinics.

33 (2) The board and the Medical Board of California are both
34 authorized to ensure compliance with this subdivision, and each
35 board is specifically charged with the enforcement of this
36 subdivision with respect to its respective licensees. This subdivision
37 does not expand the authority of a pharmacist to prescribe any
38 prescription medication.

1 (b) (1) Notwithstanding any other law, a pharmacist may furnish
2 emergency contraception drug therapy in accordance with either
3 of the following:

4 (A) Standardized procedures or protocols developed by the
5 pharmacist and an authorized prescriber who is acting within his
6 or her scope of practice.

7 (B) Standardized procedures or protocols developed and
8 approved by both the board and the Medical Board of California
9 in consultation with the American Congress of Obstetricians and
10 Gynecologists, the California Pharmacists Association, and other
11 appropriate entities. The board and the Medical Board of California
12 are both authorized to ensure compliance with this clause, and
13 each board is specifically charged with the enforcement of this
14 provision with respect to its respective licensees. This subdivision
15 does not expand the authority of a pharmacist to prescribe any
16 prescription medication.

17 (2) Prior to performing a procedure authorized under this
18 subdivision, a pharmacist shall complete a training program on
19 emergency contraception that consists of at least one hour of
20 approved continuing education on emergency contraception drug
21 therapy.

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

1 This paragraph shall become inoperative for dedicated emergency
2 contraception drugs if these drugs are reclassified as
3 over-the-counter products by the federal Food and Drug
4 Administration.

5 (4) A pharmacist shall not require a patient to provide
6 individually identifiable medical information that is not specified
7 in Section 1707.1 of Title 16 of the California Code of Regulations
8 before initiating emergency contraception drug therapy pursuant
9 to this subdivision.

10 (c) For each emergency contraception drug therapy or
11 self-administered hormonal contraception initiated pursuant to this
12 section, the pharmacist shall provide the recipient of the drug with
13 a standardized factsheet that includes, but is not limited to, the
14 indications and contraindications for use of the drug, the
15 appropriate method for using the drug, the need for medical
16 followup, and other appropriate information. The board shall
17 develop this form in consultation with the State Department of
18 Public Health, the American Congress of Obstetricians and
19 Gynecologists, the California Pharmacists Association, and other
20 health care organizations. This section does not preclude the use
21 of existing publications developed by nationally recognized
22 medical organizations.

23 SEC. 7. Section 4052.6 is added to the Business and Professions
24 Code, to read:

25 4052.6. (a) A pharmacist recognized by the board as an
26 advanced practice pharmacist may do all of the following:

- 27 (1) Perform patient assessments.
- 28 (2) Order and interpret drug therapy-related tests.
- 29 (3) Refer patients to other health care providers.
- 30 (4) Participate in the evaluation and management of diseases
31 and health conditions in collaboration with other health care
32 providers.

33 (5) Initiate, adjust, or discontinue drug therapy in the manner
34 specified in paragraph (4) of subdivision (a) of Section 4052.2.

35 (b) A pharmacist who adjusts or discontinues drug therapy shall
36 promptly transmit written notification to the patient's diagnosing
37 prescriber or enter the appropriate information in a patient record
38 system shared with the prescriber. A pharmacist who initiates drug
39 therapy shall promptly transmit written notification to, or enter the
40 appropriate information into, a patient record system shared with

1 the patient’s primary care provider or diagnosing provider, as
2 appropriate.

3 (c) This section shall not interfere with a physician’s order to
4 dispense a prescription drug as written, or other order of similar
5 meaning.

6 (d) Prior to initiating or adjusting a controlled substance therapy
7 pursuant to this section, a pharmacist shall personally register with
8 the federal Drug Enforcement Administration.

9 SEC. 8. Section 4052.8 is added to the Business and Professions
10 Code, to read:

11 4052.8. (a) In addition to the authority provided in paragraph
12 (9) of subdivision (a) of Section 4052, a pharmacist may
13 independently initiate and administer vaccines listed on the routine
14 immunization schedules recommended by the federal Advisory
15 Committee on Immunization Practices (ACIP), in compliance with
16 individual ACIP vaccine recommendations, and published by the
17 federal Centers for Disease Control and Prevention (CDC) for
18 persons three years of age and older.

19 (b) In order to initiate and administer an immunization described
20 in subdivision (a), a pharmacist shall do all of the following:

21 (1) Complete an immunization training program endorsed by
22 the CDC or the Accreditation Council for Pharmacy Education
23 that, at a minimum, includes hands-on injection technique, clinical
24 evaluation of indications and contraindications of vaccines, and
25 the recognition and treatment of emergency reactions to vaccines,
26 and shall maintain that training.

27 (2) Be certified in basic life support.

28 (3) Comply with all state and federal recordkeeping and
29 reporting requirements, including providing documentation to the
30 patient’s primary care provider and entering information in the
31 appropriate immunization registry designated by the immunization
32 branch of the State Department of Public Health.

33 (c) A pharmacist administering immunizations pursuant to this
34 section, or paragraph (9) of subdivision (a) of Section 4052, may
35 also initiate and administer epinephrine or diphenhydramine by
36 injection for the treatment of a severe allergic reaction.

37 SEC. 9. Section 4052.9 is added to the Business and Professions
38 Code, to read:

1 4052.9. A pharmacist may furnish prescription smoking
2 cessation drugs and devices, and provide smoking cessation
3 services if all of the following conditions are met:

4 (a) The pharmacist maintains records of all prescription drugs
5 and devices furnished for a period of at least three years for
6 purposes of notifying other health care providers and monitoring
7 the patient.

8 (b) The pharmacist notifies the patient’s primary care provider
9 of any drugs or devices furnished to the patient. If the patient does
10 not have a primary care provider, the pharmacist provides the
11 patient with a written record of the drugs or devices furnished and
12 advises the patient to consult a physician of the patient’s choice.

13 (c) The pharmacist is certified in smoking cessation therapy by
14 an organization recognized by the board.

15 (d) The pharmacist completes one hour of continuing education
16 focused on smoking cessation therapy biennially.

17 (e) *The pharmacist shall consult with the patient’s primary care*
18 *provider before furnishing a smoking cessation drug to the patient*
19 *that may produce serious neuropsychiatric events.*

20 SEC. 10. Section 4060 of the Business and Professions Code
21 is amended to read:

22 4060. A person shall not possess any controlled substance,
23 except that furnished to a person upon the prescription of a
24 physician, dentist, podiatrist, optometrist, veterinarian, or
25 naturopathic doctor pursuant to Section 3640.7, or furnished
26 pursuant to a drug order issued by a certified nurse-midwife
27 pursuant to Section 2746.51, a nurse practitioner pursuant to
28 Section 2836.1, a physician assistant pursuant to Section 3502.1,
29 a naturopathic doctor pursuant to Section 3640.5, or a pharmacist
30 pursuant to Section 4052.1, 4052.2, or 4052.6. This section does
31 not apply to the possession of any controlled substance by a
32 manufacturer, wholesaler, pharmacy, pharmacist, physician,
33 podiatrist, dentist, optometrist, veterinarian, naturopathic doctor,
34 certified nurse-midwife, nurse practitioner, or physician assistant,
35 if in stock in containers correctly labeled with the name and address
36 of the supplier or producer.

37 This section does not authorize a certified nurse-midwife, a nurse
38 practitioner, a physician assistant, or a naturopathic doctor, to order
39 his or her own stock of dangerous drugs and devices.

1 SEC. 11. Section 4210 is added to the Business and Professions
2 Code, to read:

3 4210. (a) A person who seeks recognition as an advanced
4 practice pharmacist shall meet all of the following requirements:

5 (1) Hold an active license to practice pharmacy issued pursuant
6 to this chapter that is in good standing.

7 (2) Satisfy any two of the following criteria:

8 (A) Earn certification in a relevant area of practice, including,
9 but not limited to, ambulatory care, critical care, nuclear pharmacy,
10 nutrition support pharmacy, oncology pharmacy, pediatric
11 pharmacy, pharmacotherapy, or psychiatric pharmacy, from an
12 organization recognized by the Accreditation Council for Pharmacy
13 Education or another entity recognized by the board.

14 (B) Complete a one-year postgraduate residency through an
15 accredited postgraduate institution where at least 50 percent of the
16 experience includes the provision of direct patient care services
17 with interdisciplinary teams.

18 (C) Have actively managed patients for at least one year under
19 a collaborative practice agreement or protocol with a physician,
20 advanced practice pharmacist, pharmacist practicing collaborative
21 drug therapy management, or health system.

22 (3) File an application with the board for recognition as an
23 advanced practice pharmacist.

24 (4) Pay the applicable fee to the board.

25 (b) An advanced practice pharmacist recognition issued pursuant
26 to this section shall be valid for two years, coterminous with the
27 certificate holder's license to practice pharmacy.

28 (c) The board shall adopt regulations establishing the means of
29 documenting completion of the requirements in this section.

30 (d) *The board shall, by regulation, set the fee for the issuance
31 and renewal of advanced practice pharmacist recognition at the
32 reasonable cost of regulating advanced practice pharmacists
33 pursuant to this chapter. The fee shall not exceed three hundred
34 dollars (\$300).*

35 SEC. 12. Section 4233 is added to the Business and Professions
36 Code, to read:

37 4233. A pharmacist who is recognized as an advanced practice
38 pharmacist shall complete 10 hours of continuing education each
39 renewal cycle in addition to the requirements of Section 4231. The

1 subject matter shall be in one or more areas of practice relevant to
2 the pharmacist’s clinical practice.

3 SEC. 13. No reimbursement is required by this act pursuant to
4 Section 6 of Article XIII B of the California Constitution because
5 the only costs that may be incurred by a local agency or school
6 district will be incurred because this act creates a new crime or
7 infraction, eliminates a crime or infraction, or changes the penalty
8 for a crime or infraction, within the meaning of Section 17556 of
9 the Government Code, or changes the definition of a crime within
10 the meaning of Section 6 of Article XIII B of the California
11 Constitution.

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