

AMENDED IN SENATE APRIL 1, 2013

SENATE BILL

No. 493

Introduced by Senator Hernandez

February 21, 2013

An act to amend ~~Section 4050~~ of 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 ~~pharmacies~~ *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, ~~and states that pharmacy practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and drug-related therapy. 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 would make a technical, nonsubstantive change to that provision.~~

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 physical assessments, and certain other functions, as specified. 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: ~~no~~-yes.
 State-mandated local program: ~~no~~-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) ~~No~~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 ~~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:

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

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

10 (A) Immediately notify the patient and arrange for the drug or
11 device to be delivered to the site or directly to the patient in a
12 timely manner.

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

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

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

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

38 (d) ~~The provisions of this section shall apply to the~~ *This section*
39 *applies to emergency contraception drug therapy and*

1 *self-administered hormonal contraceptives* described in Section
2 4052.3.

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

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

11 *SEC. 2. Section 4016.5 is added to the Business and Professions*
12 *Code, to read:*

13 4016.5. "Advanced practice pharmacist" means a licensed
14 pharmacist who has been recognized as an advanced practice
15 pharmacist by the board, pursuant to Section 4210. A
16 board-recognized advanced practice pharmacist is entitled to
17 practice advanced practice pharmacy as described in Section
18 4052.6, within or outside of a licensed pharmacy as authorized by
19 this chapter.

20 **SECTION 1.**

21 *SEC. 3. Section 4050 of the Business and Professions Code is*
22 *amended to read:*

23 4050. (a) In recognition of and consistent with the decisions
24 of the appellate courts of this state, the Legislature hereby declares
25 the practice of pharmacy to be a profession.

26 (b) Pharmacy practice is a dynamic, patient-oriented health
27 service that applies a scientific body of knowledge to improve and
28 promote patient health by means of appropriate drug use,
29 drug-related therapy, and communication for clinical and
30 consultative purposes. Pharmacy practice is continually evolving
31 to include more sophisticated and comprehensive patient care
32 activities.

33 (c) *The Legislature further declares that pharmacists are health*
34 *care providers who have the authority to provide health care*
35 *services.*

36 *SEC. 4. Section 4051 of the Business and Professions Code is*
37 *amended to read:*

38 4051. (a) Except as otherwise provided in this chapter, it is
39 unlawful for any person to manufacture, compound, furnish, sell,
40 or dispense—~~any~~ a dangerous drug or dangerous device, or to

1 dispense or compound ~~any~~ a prescription pursuant to Section 4040
2 of a prescriber unless he or she is a pharmacist under this chapter.

3 (b) Notwithstanding any other law, a pharmacist may authorize
4 the initiation of a prescription, pursuant to Section 4052.1, 4052.2,
5 ~~or~~ 4052.3, ~~or~~ 4052.6, and otherwise provide clinical advice ~~or~~,
6 *services*, information, or patient consultation, *as set forth in this*
7 *chapter*; if all of the following conditions are met:

8 (1) The clinical advice ~~or~~, *services*, information, or patient
9 consultation is provided to a health care professional or to a patient.

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

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

15 *SEC. 5. Section 4052 of the Business and Professions Code is*
16 *amended to read:*

17 4052. (a) Notwithstanding any other ~~provision~~ of law, a
18 pharmacist may:

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

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

22 (3) ~~Administer, orally or topically, drugs and biologicals~~
23 ~~pursuant to a prescriber's order~~ *drugs and biological products that*
24 *have been ordered by a prescriber.*

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

27 (5) Perform procedures or functions as part of the care provided
28 by a health care facility, a licensed home health agency, a licensed
29 clinic in which there is a physician oversight, a provider who
30 contracts with a licensed health care service plan with regard to
31 the care or services provided to the enrollees of that health care
32 service plan, or a physician, as authorized by Section 4052.2.

33 (6) *Perform procedures or functions as authorized by Section*
34 *4052.6.*

35 ~~(6)~~

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

39 ~~(7)~~

1 (8) Provide consultation, *training, and education* to patients
2 ~~and about drug therapy, disease management, and disease~~
3 ~~prevention.~~

4 (9) *Provide professional information, including clinical or*
5 *pharmacological information, advice, or consultation to other*
6 *health care professionals, and participate in multidisciplinary*
7 *review of patient progress, including appropriate access to medical*
8 *records.*

9 ~~(8) Furnish emergency~~

10 (10) *Furnish the following medications:*

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

13 (B) *Prescription smoking-cessation drugs and devices, as*
14 *authorized by Section 4052.9.*

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

18 ~~(9)~~

19 (11) *Administer immunizations pursuant to a protocol with a*
20 *prescriber.*

21 (12) *Order and interpret tests for the purpose of monitoring*
22 *and managing the efficacy and toxicity of drug therapies.*

23 (b) *A pharmacist who is authorized to issue an order to initiate*
24 *or adjust a controlled substance therapy pursuant to this section*
25 *shall personally register with the federal Drug Enforcement*
26 *Administration.*

27 ~~(e) Nothing in this section shall affect the requirements of~~
28 ~~existing law relating to maintaining the confidentiality of medical~~
29 ~~records.~~

30 ~~(d) Nothing in this section shall affect the requirements of~~
31 ~~existing law relating to the licensing of a health care facility.~~

32 (c) *This section does not affect the applicable requirements of*
33 *law relating to either of the following:*

34 (1) *Maintaining the confidentiality of medical records.*

35 (2) *The licensing of a health care facility.*

36 *SEC. 6. Section 4052.3 of the Business and Professions Code*
37 *is amended to read:*

38 4052.3. (a) (1) *Notwithstanding any other law, a pharmacist*
39 *may furnish self-administered hormonal contraceptives in*
40 *accordance with standardized procedures or protocols developed*

1 *and approved by both the board and the Medical Board of*
2 *California in consultation with the American Congress of*
3 *Obstetricians and Gynecologists, the California Pharmacists*
4 *Association, and other appropriate entities. The standardized*
5 *procedure or protocol shall require that the patient use a*
6 *self-screening tool, based on the United States Medical Eligibility*
7 *Criteria (USMEC) for Contraceptive Use developed by the federal*
8 *Centers for Disease Control and Prevention, and that the*
9 *pharmacist refer the patient to the patient's primary care provider*
10 *or, if the patient does not have a primary care provider, to nearby*
11 *clinics.*

12 *(2) The board and the Medical Board of California are both*
13 *authorized to ensure compliance with this subdivision, and each*
14 *board is specifically charged with the enforcement of this*
15 *subdivision with respect to its respective licensees. This subdivision*
16 *does not expand the authority of a pharmacist to prescribe any*
17 *prescription medication.*

18 *(b) (1) Notwithstanding any other provision of law, a pharmacist*
19 *may furnish emergency contraception drug therapy in accordance*
20 *with either of the following:*

21 ~~(1)~~

22 *(A) Standardized procedures or protocols developed by the*
23 *pharmacist and an authorized prescriber who is acting within his*
24 *or her scope of practice.*

25 ~~(2)~~

26 *(B) Standardized procedures or protocols developed and*
27 *approved by both the board and the Medical Board of California*
28 *in consultation with the American—College Congress of*
29 *Obstetricians and Gynecologists, the California—Pharmacist*
30 *Pharmacists Association, and other appropriate entities. Both the*
31 *The board and the Medical Board of California shall have authority*
32 *are both authorized to ensure compliance with this clause, and*
33 *both boards—each board is specifically charged with the*
34 *enforcement of this provision with respect to their its respective*
35 *licensees. Nothing in this clause shall be construed to This*
36 *subdivision does not expand the authority of a pharmacist to*
37 *prescribe any prescription medication.*

38 ~~(b)~~

39 *(2) Prior to performing a procedure authorized under this*
40 *paragraph subdivision, a pharmacist shall complete a training*

1 program on emergency contraception that consists of at least one
2 hour of approved continuing education on emergency contraception
3 drug therapy.

4 (e)

5 (3) A pharmacist, pharmacist’s employer, or pharmacist’s agent
6 ~~may shall~~ not directly charge a patient a separate consultation fee
7 for emergency contraception drug therapy services initiated
8 pursuant to this ~~paragraph~~ *subdivision*, but may charge an
9 administrative fee not to exceed ten dollars (\$10) above the retail
10 cost of the drug. Upon an oral, telephonic, electronic, or written
11 request from a patient or customer, a pharmacist or pharmacist’s
12 employee shall disclose the total retail price that a consumer would
13 pay for emergency contraception drug therapy. As used in this
14 ~~subparagraph~~ *paragraph*, total retail price includes providing the
15 consumer with specific information regarding the price of the
16 emergency contraception drugs and the price of the administrative
17 fee charged. This limitation is not intended to interfere with other
18 contractually agreed-upon terms between a pharmacist, a
19 pharmacist’s employer, or a pharmacist’s agent, and a health care
20 service plan or insurer. Patients who are insured or covered and
21 receive a pharmacy benefit that covers the cost of emergency
22 contraception shall not be required to pay an administrative fee.
23 These patients shall be required to pay copayments pursuant to the
24 terms and conditions of their coverage. ~~The provisions of this~~
25 ~~subparagraph shall cease to be operative~~ *This paragraph shall*
26 *become inoperative* for dedicated emergency contraception drugs
27 ~~when~~ *if* these drugs are reclassified as over-the-counter products
28 by the federal Food and Drug Administration.

29 (d)

30 (4) A pharmacist ~~may shall~~ not require a patient to provide
31 individually identifiable medical information that is not specified
32 in Section 1707.1 of Title 16 of the California Code of Regulations
33 before initiating emergency contraception drug therapy pursuant
34 to this ~~section~~ *subdivision*.

35 (e)

36 (c) For each emergency contraception drug therapy *or*
37 *self-administered hormonal contraception* initiated pursuant to
38 this section, the pharmacist shall provide the recipient of the
39 ~~emergency contraception drugs~~ *drug* with a standardized factsheet
40 that includes, but is not limited to, the indications *and*

1 *contraindications* for use of the drug, the appropriate method for
2 using the drug, the need for medical followup, and other
3 appropriate information. The board shall develop this form in
4 consultation with the State Department of Public Health, the
5 American College Congress of Obstetricians and Gynecologists,
6 the California Pharmacists Association, and other health care
7 organizations. ~~The provisions of this section do~~ *This section does*
8 not preclude the use of existing publications developed by
9 nationally recognized medical organizations.

10 *SEC. 7. Section 4052.6 is added to the Business and Professions*
11 *Code, to read:*

12 *4052.6. (a) A pharmacist recognized by the board as an*
13 *advanced practice pharmacist may do all of the following:*

- 14 *(1) Perform physical assessments.*
- 15 *(2) Order and interpret drug therapy-related tests.*
- 16 *(3) Refer patients to other health care providers.*

17 *(b) In addition to the authority provided in subdivision (a), a*
18 *pharmacist recognized as an advanced practice pharmacist who*
19 *is acting in collaboration with a patient's health care providers,*
20 *operating under a protocol with a physician, health care facility,*
21 *or health plan or disability insurer, or participating in a medical*
22 *home, accountable care organization, or other system of care, may*
23 *do both of the following:*

- 24 *(1) Initiate, adjust, or discontinue drug therapy. As used in this*
25 *section, "adjust" means changing the dosage, duration, frequency,*
26 *or potency of a drug.*
- 27 *(2) Participate in the evaluation and management of diseases*
28 *and health conditions in collaboration with other health care*
29 *providers.*

30 *(c) A pharmacist who adjusts or discontinues drug therapy shall*
31 *promptly transmit written notification to the patient's diagnosing*
32 *prescriber or enter the appropriate information in a patient record*
33 *system shared with the prescriber. A pharmacist who initiates drug*
34 *therapy shall promptly transmit written notification to, or enter*
35 *the appropriate information into, a patient record system shared*
36 *with the patient's primary care provider or diagnosing provider,*
37 *as appropriate.*

38 *(d) This section shall not interfere with a physician's order to*
39 *dispense a prescription drug as written, or other order of similar*
40 *meaning.*

1 (e) Prior to initiating or adjusting a controlled substance
2 therapy pursuant to this section, a pharmacist shall personally
3 register with the federal Drug Enforcement Administration.

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

6 4052.8. (a) In addition to the authority provided in paragraph
7 (9) of subdivision (a) of Section 4052, a pharmacist may
8 independently initiate and administer vaccines listed on the routine
9 immunization schedules recommended by the federal Advisory
10 Committee on Immunization Practices (ACIP), in compliance with
11 individual ACIP vaccine recommendations, and published by the
12 federal Centers for Disease Control and Prevention (CDC) for
13 persons three years of age and older.

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

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

23 (2) Be certified in basic life support.

24 (3) Comply with all state and federal recordkeeping and
25 reporting requirements, including providing documentation to the
26 patient's primary care provider and entering information in the
27 appropriate immunization registry designated by the immunization
28 branch of the State Department of Public Health.

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

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

35 4052.9. A pharmacist may furnish prescription
36 smoking-cessation drugs and devices, and provide
37 smoking-cessation services if all of the following conditions are
38 met:

39 (a) The pharmacist maintains records of all prescription drugs
40 and devices furnished for a period of at least three years for

1 *purposes of notifying other health care providers and monitoring*
2 *the patient.*

3 *(b) The pharmacist notifies the patient's primary care provider*
4 *of any drugs or devices furnished to the patient. If the patient does*
5 *not have a primary care provider, the pharmacist provides the*
6 *patient with a written record of the drugs or devices furnished and*
7 *advises the patient to consult a physician of the patient's choice.*

8 *(c) The pharmacist is certified in smoking-cessation therapy by*
9 *an organization recognized by the board.*

10 *(d) The pharmacist completes one hour of continuing education*
11 *focused on smoking-cessation therapy biennially.*

12 *SEC. 10. Section 4060 of the Business and Professions Code*
13 *is amended to read:*

14 4060. ~~No~~A person shall *not* possess any controlled substance,
15 except that furnished to a person upon the prescription of a
16 physician, dentist, podiatrist, optometrist, veterinarian, or
17 naturopathic doctor pursuant to Section 3640.7, or furnished
18 pursuant to a drug order issued by a certified nurse-midwife
19 pursuant to Section 2746.51, a nurse practitioner pursuant to
20 Section 2836.1, a physician assistant pursuant to Section 3502.1,
21 a naturopathic doctor pursuant to Section 3640.5, or a pharmacist
22 pursuant to either Section 4052.1 ~~or~~, 4052.2, *or* 4052.6. This
23 section ~~shall~~ *does* not apply to the possession of any controlled
24 substance by a manufacturer, wholesaler, pharmacy, pharmacist,
25 physician, podiatrist, dentist, optometrist, veterinarian, naturopathic
26 doctor, certified nurse-midwife, nurse practitioner, or physician
27 assistant, ~~when~~ *if* in stock in containers correctly labeled with the
28 name and address of the supplier or producer.

29 ~~Nothing in this section authorizes~~

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

33 *SEC. 11. Section 4210 is added to the Business and Professions*
34 *Code, to read:*

35 4210. (a) *A person who seeks recognition as an advanced*
36 *practice pharmacist shall meet all of the following requirements:*

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

39 (2) *Satisfy any one of the following criteria:*

1 (A) Earn certification in a relevant area of practice from an
2 organization approved by a board-recognized accrediting agency
3 or another entity recognized by the board.

4 (B) Complete a one-year postgraduate residency where at least
5 50 percent of the experience includes the provision of direct patient
6 care services with interdisciplinary teams.

7 (C) Have actively managed patients for at least one year under
8 a collaborative practice agreement or protocol with a physician,
9 advanced practice pharmacist, pharmacist practicing collaborative
10 drug therapy management, or health system.

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

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

14 (b) An advanced practice pharmacist recognition issued
15 pursuant to this section shall be valid for two years, coterminous
16 with the certificate holder’s license to practice pharmacy.

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

19 4233. A pharmacist who is recognized as an advanced practice
20 pharmacist shall complete 10 hours of continuing education each
21 renewal cycle in addition to the requirements of Section 4231. The
22 subject matter shall be in one or more areas of practice relevant
23 to the pharmacist’s clinical practice.

24 SEC. 13. No reimbursement is required by this act pursuant
25 to Section 6 of Article XIII B of the California Constitution because
26 the only costs that may be incurred by a local agency or school
27 district will be incurred because this act creates a new crime or
28 infraction, eliminates a crime or infraction, or changes the penalty
29 for a crime or infraction, within the meaning of Section 17556 of
30 the Government Code, or changes the definition of a crime within
31 the meaning of Section 6 of Article XIII B of the California
32 Constitution.

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