

AMENDED IN SENATE APRIL 24, 2013

AMENDED IN SENATE APRIL 1, 2013

**SENATE BILL**

**No. 493**

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**Introduced by Senator Hernandez**

February 21, 2013

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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~~ *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~~ *patient* 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: 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
- 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

1 cannot be dispensed because the drug or device is not in stock, the  
2 licentiate shall take one of the following actions:

3 (A) Immediately notify the patient and arrange for the drug or  
4 device to be delivered to the site or directly to the patient in a  
5 timely manner.

6 (B) Promptly transfer the prescription to another pharmacy  
7 known to stock the prescription drug or device that is near enough  
8 to the site from which the prescription or order is transferred, to  
9 ensure the patient has timely access to the drug or device.

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

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

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

31 (d) This section applies to emergency contraception drug therapy  
32 and self-administered hormonal contraceptives described in Section  
33 4052.3.

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

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

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

6 4016.5. “Advanced practice pharmacist” means a licensed  
7 pharmacist who has been recognized as an advanced practice  
8 pharmacist by the board, pursuant to Section 4210. A  
9 board-recognized advanced practice pharmacist is entitled to  
10 practice advanced practice pharmacy, as described in Section  
11 4052.6, within or outside of a licensed pharmacy as authorized by  
12 this chapter.

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

15 4050. (a) In recognition of and consistent with the decisions  
16 of the appellate courts of this state, the Legislature hereby declares  
17 the practice of pharmacy to be a profession.

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

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

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

30 4051. (a) Except as otherwise provided in this chapter, it is  
31 unlawful for any person to manufacture, compound, furnish, sell,  
32 or dispense a dangerous drug or dangerous device, or to dispense  
33 or compound a prescription pursuant to Section 4040 of a prescriber  
34 unless he or she is a pharmacist under this chapter.

35 (b) Notwithstanding any other law, a pharmacist may authorize  
36 the initiation of a prescription, pursuant to Section 4052.1, 4052.2,  
37 4052.3, or 4052.6, and otherwise provide clinical advice, services,  
38 information, or patient consultation, as set forth in this chapter, if  
39 all of the following conditions are met:

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

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

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

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

10 4052. (a) Notwithstanding any other law, a pharmacist may:

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

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

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

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

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

24 (6) Perform procedures or functions as authorized by Section  
25 4052.6.

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

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

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

36 (10) Furnish the following medications:

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

39 (B) Prescription ~~smoking cessation~~ *smoking cessation* drugs  
40 and devices, as authorized by Section 4052.9.

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

4 (11) Administer immunizations pursuant to a protocol with a  
5 prescriber.

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

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

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

14 (1) Maintaining the confidentiality of medical records.

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

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

18 4052.3. (a) (1) Notwithstanding any other law, a pharmacist  
19 may furnish self-administered hormonal contraceptives in  
20 accordance with standardized procedures or protocols developed  
21 and approved by both the board and the Medical Board of  
22 California in consultation with the American Congress of  
23 Obstetricians and Gynecologists, the California Pharmacists  
24 Association, and other appropriate entities. The standardized  
25 procedure or protocol shall require that the patient use a  
26 self-screening tool, based on the United States Medical Eligibility  
27 Criteria (USMEC) for Contraceptive Use developed by the federal  
28 Centers for Disease Control and Prevention, and that the pharmacist  
29 refer the patient to the patient's primary care provider or, if the  
30 patient does not have a primary care provider, to nearby clinics.

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

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

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

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

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

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

1 over-the-counter products by the federal Food and Drug  
2 Administration.

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

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

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

23 4052.6. (a) A pharmacist recognized by the board as an  
24 advanced practice pharmacist may do all of the following:

- 25 (1) Perform ~~physical~~ *patient* assessments.
- 26 (2) Order and interpret drug therapy-related tests.
- 27 (3) Refer patients to other health care providers.

28 ~~(b) In addition to the authority provided in subdivision (a), a~~  
29 ~~pharmacist recognized as an advanced practice pharmacist who is~~  
30 ~~acting in collaboration with a patient's health care providers,~~  
31 ~~operating under a protocol with a physician, health care facility,~~  
32 ~~or health plan or disability insurer, or participating in a medical~~  
33 ~~home, accountable care organization, or other system of care, may~~  
34 ~~do both of the following:~~

35 (1) ~~Initiate, adjust, or discontinue drug therapy. As used in this~~  
36 ~~section, "adjust" means changing the dosage, duration, frequency,~~  
37 ~~or potency of a drug.~~

38 (2)

1 (4) Participate in the evaluation and management of diseases  
2 and health conditions in collaboration with other health care  
3 providers.

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

6 ~~(e)~~

7 (b) A pharmacist who adjusts or discontinues drug therapy shall  
8 promptly transmit written notification to the patient’s diagnosing  
9 prescriber or enter the appropriate information in a patient record  
10 system shared with the prescriber. A pharmacist who initiates drug  
11 therapy shall promptly transmit written notification to, or enter the  
12 appropriate information into, a patient record system shared with  
13 the patient’s primary care provider or diagnosing provider, as  
14 appropriate.

15 ~~(d)~~

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

19 ~~(e)~~

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

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

25 4052.8. (a) In addition to the authority provided in paragraph  
26 (9) of subdivision (a) of Section 4052, a pharmacist may  
27 independently initiate and administer vaccines listed on the routine  
28 immunization schedules recommended by the federal Advisory  
29 Committee on Immunization Practices (ACIP), in compliance with  
30 individual ACIP vaccine recommendations, and published by the  
31 federal Centers for Disease Control and Prevention (CDC) for  
32 persons three years of age and older.

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

35 (1) Complete an immunization training program endorsed by  
36 the CDC or the Accreditation Council for Pharmacy Education  
37 that, at a minimum, includes hands-on injection technique, clinical  
38 evaluation of indications and contraindications of vaccines, and  
39 the recognition and treatment of emergency reactions to vaccines,  
40 and shall maintain that training.

1 (2) Be certified in basic life support.

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

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

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

13 4052.9. A pharmacist may furnish prescription  
14 ~~smoking-cessation~~ *smoking cessation* drugs and devices, and  
15 provide ~~smoking-cessation~~ *smoking cessation* services if all of the  
16 following conditions are met:

17 (a) The pharmacist maintains records of all prescription drugs  
18 and devices furnished for a period of at least three years for  
19 purposes of notifying other health care providers and monitoring  
20 the patient.

21 (b) The pharmacist notifies the patient’s primary care provider  
22 of any drugs or devices furnished to the patient. If the patient does  
23 not have a primary care provider, the pharmacist provides the  
24 patient with a written record of the drugs or devices furnished and  
25 advises the patient to consult a physician of the patient’s choice.

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

28 (d) The pharmacist completes one hour of continuing education  
29 focused on ~~smoking-cessation~~ *smoking cessation* therapy  
30 biennially.

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

33 4060. A person shall not possess any controlled substance,  
34 except that furnished to a person upon the prescription of a  
35 physician, dentist, podiatrist, optometrist, veterinarian, or  
36 naturopathic doctor pursuant to Section 3640.7, or furnished  
37 pursuant to a drug order issued by a certified nurse-midwife  
38 pursuant to Section 2746.51, a nurse practitioner pursuant to  
39 Section 2836.1, a physician assistant pursuant to Section 3502.1,  
40 a naturopathic doctor pursuant to Section 3640.5, or a pharmacist

1 pursuant to Section 4052.1, 4052.2, or 4052.6. This section does  
2 not apply to the possession of any controlled substance by a  
3 manufacturer, wholesaler, pharmacy, pharmacist, physician,  
4 podiatrist, dentist, optometrist, veterinarian, naturopathic doctor,  
5 certified nurse-midwife, nurse practitioner, or physician assistant,  
6 if in stock in containers correctly labeled with the name and address  
7 of the supplier or producer.

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

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

13 4210. (a) A person who seeks recognition as an advanced  
14 practice pharmacist shall meet all of the following requirements:

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

17 (2) Satisfy any ~~one~~ two of the following criteria:

18 (A) Earn certification in a relevant area of practice, *including,*  
19 *but not limited to, ambulatory care, critical care, nuclear*  
20 *pharmacy, nutrition support pharmacy, oncology pharmacy,*  
21 *pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy,*  
22 ~~from an organization approved by a board-recognized accrediting~~  
23 ~~agency recognized by the Accreditation Council for Pharmacy~~  
24 *Education* or another entity recognized by the board.

25 (B) Complete a one-year postgraduate residency *through an*  
26 *accredited postgraduate institution* where at least 50 percent of  
27 the experience includes the provision of direct patient care services  
28 with interdisciplinary teams.

29 (C) Have actively managed patients for at least one year under  
30 a collaborative practice agreement or protocol with a physician,  
31 advanced practice pharmacist, pharmacist practicing collaborative  
32 drug therapy management, or health system.

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

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

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

39 (c) *The board shall adopt regulations establishing the means*  
40 *of documenting completion of the requirements in this section.*

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

3 4233. A pharmacist who is recognized as an advanced practice  
4 pharmacist shall complete 10 hours of continuing education each  
5 renewal cycle in addition to the requirements of Section 4231. The  
6 subject matter shall be in one or more areas of practice relevant to  
7 the pharmacist’s clinical practice.

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

O