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.


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

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

   733. (a) A licentiate shall not 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 or administrative action by his or her licensing agency.

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

   (1) Based solely on the licentiate’s professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that 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. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

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

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

(C) Return the prescription to the patient and refer the patient.

The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if 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 licentiate’s employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate’s objection. The licentiate’s employer shall establish 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. For purposes of this section, “reasonable accommodation” and “undue hardship” shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

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

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

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient.
or through a third-party payer accepted by the licentiate or payment
of any required copayment by the patient.
(f) The notice to consumers required by Section 4122 shall
include a statement that describes patients’ rights relative to the
requirements of this section.
SEC. 2. Section 4016.5 is added to the Business and Professions
Code, to read:
4016.5. “Advanced practice pharmacist” means a licensed
pharmacist who has been recognized as an advanced practice
pharmacist by the board, pursuant to Section 4210. A
board-recognized advanced practice pharmacist is entitled to
practice advanced practice pharmacy, as described in Section
4052.6, within or outside of a licensed pharmacy as authorized by
this chapter.
SEC. 3. Section 4050 of the Business and Professions Code is
amended to read:
4050. (a) In recognition of and consistent with the decisions
of the appellate courts of this state, the Legislature hereby declares
the practice of pharmacy to be a profession.
(b) 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,
drug-related therapy, and communication for clinical and
consultative purposes. Pharmacy practice is continually evolving
to include more sophisticated and comprehensive patient care
activities.
(c) The Legislature further declares that pharmacists are health
care providers who have the authority to provide health care
services.
SEC. 4. Section 4051 of the Business and Professions Code is
amended to read:
4051. (a) Except as otherwise provided in this chapter, it is
unlawful for any person to manufacture, compound, furnish, sell,
or dispense a dangerous drug or dangerous device, or to dispense
or compound a prescription pursuant to Section 4040 of a prescriber
unless he or she is a pharmacist under this chapter.
(b) Notwithstanding any other law, a pharmacist may authorize
the initiation of a prescription, pursuant to Section 4052.1, 4052.2,
4052.3, or 4052.6, and otherwise provide clinical advice, services,
information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

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

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

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

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

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

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

(2) Transmit a valid prescription to another pharmacist.

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

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

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

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

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

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

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

(10) Furnish the following medications:

(A) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.
(B) Prescription smoking cessation drugs and devices, as authorized by Section 4052.9.

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

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

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

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

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

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

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

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

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.
(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

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

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

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

(3) A pharmacist, pharmacist’s employer, or pharmacist’s agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist’s employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist’s employer, or a pharmacist’s agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage.
This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

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

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

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

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

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

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

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

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

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

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

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

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

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

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

(2) Be certified in basic life support.

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

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

SEC. 9. Section 4052.9 is added to the Business and Professions Code, to read:
A pharmacist may furnish prescription smoking
cessation drugs and devices, and provide smoking cessation
services if all of the following conditions are met:
(a) The pharmacist maintains records of all prescription drugs
and devices furnished for a period of at least three years for
purposes of notifying other health care providers and monitoring
the patient.
(b) The pharmacist notifies the patient’s primary care provider
of any drugs or devices furnished to the patient. If the patient does
not have a primary care provider, the pharmacist provides the
patient with a written record of the drugs or devices furnished and
advises the patient to consult a physician of the patient’s choice.
(c) The pharmacist is certified in smoking cessation therapy by
an organization recognized by the board.
(d) The pharmacist completes one hour of continuing education
focused on smoking cessation therapy biennially.
(e) The pharmacist shall consult with the patient’s primary care
provider before furnishing a smoking cessation drug to the patient
that may produce serious neuropsychiatric events.

SEC. 10. Section 4060 of the Business and Professions Code
is amended to read:
A person shall not possess any controlled substance,
except that furnished to a person upon the prescription of a
physician, dentist, podiatrist, optometrist, veterinarian, or
naturopathic doctor pursuant to Section 3640.7, or furnished
pursuant to a drug order issued by a certified nurse-midwife
pursuant to Section 2746.51, a nurse practitioner pursuant to
Section 2836.1, a physician assistant pursuant to Section 3502.1,
a naturopathic doctor pursuant to Section 3640.5, or a pharmacist
pursuant to Section 4052.1, 4052.2, or 4052.6. This section does
not apply to the possession of any controlled substance by a
manufacturer, wholesaler, pharmacy, pharmacist, physician,
podiatrist, dentist, optometrist, veterinarian, naturopathic doctor,
certified nurse-midwife, nurse practitioner, or physician assistant,
if in stock in containers correctly labeled with the name and address
of the supplier or producer.
This section does not authorize a certified nurse-midwife, a nurse
practitioner, a physician assistant, or a naturopathic doctor, to order
his or her own stock of dangerous drugs and devices.
SEC. 11. Section 4210 is added to the Business and Professions Code, to read:

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

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

(2) Satisfy any two of the following criteria:

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

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

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

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

(4) Pay the applicable fee to the board.

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

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

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

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

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

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