

Senate Bill No. 298

CHAPTER 289

An act to amend Sections 2725.1, 2746.51, 4040, 4060, 4061, 4076, 4170, and 4175 of the Business and Professions Code, and to amend Sections 11026 and 11150 of the Health and Safety Code, relating to nurse-midwives.

[Approved by Governor September 10, 2001. Filed with Secretary of State September 12, 2001.]

LEGISLATIVE COUNSEL'S DIGEST

SB 298, Figueroa. Certified nurse-midwives: drugs and devices.

Existing law permits a certified nurse-midwife who meets certain qualifications, to furnish drugs or medical devices pursuant to standardized procedures. Existing law does not authorize a certified nurse-midwife to order drugs or devices and prohibits him or her from furnishing controlled substances.

This bill would authorize a certified nurse-midwife to furnish or order controlled substances under certain conditions. The bill would define the term "furnishing" to include the ordering of a drug or device pursuant to a standardized procedure or protocol and the transmitting of an order of a supervising physician and surgeon.

Because a willful violation of the bill's requirements with respect to the ordering of dangerous drugs or devices would be a crime, this bill would impose a state-mandated local program by creating a new crime.

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

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

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

SECTION 1. The Legislature finds and declares the following:

(a) Certified nurse-midwives have provided controlled substances, under the supervision of a physician and surgeon, to patients in licensed facilities for over 20 years. In this role, certified nurse-midwives have served and continue to serve as valuable members of the health care team.



(b) To provide controlled substances, certified nurse-midwives must register with the United States Drug Enforcement Administration and provide, as required, documentation related to controlled substances. Certified nurse-midwives are also required, in providing controlled substances, to operate under standardized procedures or protocols developed through collaboration among organized health care systems, administrators, and health professionals, including physicians and surgeons and nurses.

(c) These standardized procedures and protocols are developed by the health care team, physicians and surgeons, certified nurse-midwives, and health care facility administrators as needed and appropriate for the dynamic health care system to allow the health care team to provide patient care.

(d) This act is intended to codify existing furnishing practices in accordance with the interpretation by the Board of Registered Nursing in its document entitled "Administering, Furnishing, and Prescribing Drugs in Modern Medical and Nursing Practice" of the Nursing Practice Act (Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code). Nothing in this act is intended to increase the scope of practice of certified nurse-midwives.

SEC. 2. Section 2725.1 of the Business and Professions Code is amended to read:

2725.1. Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a licensed clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of the Health and Safety Code.

No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

SEC. 3. Section 2746.51 of the Business and Professions Code is amended to read:

2746.51. (a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered to essentially healthy persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For

purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed at least six month's physician and surgeon supervised experience in the furnishing or ordering of drugs or devices and a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph.

(3) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act, (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in a hospital as described in subdivision (a) of Section 1250 of the Health and Safety Code and are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(f) Nothing in this section, nor any other provision of law, shall be construed to authorize a nurse-midwife in solo practice to furnish drugs or devices, under any circumstances.

SEC. 4. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

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

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

SEC. 5. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, or veterinarian, 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, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy,

physician, podiatrist, dentist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

SEC. 6. Section 4061 of the Business and Professions Code is amended to read:

4061. No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, or veterinarian. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may sign for the delivery or receipt of complimentary samples of a dangerous drug or dangerous device that has been requested in writing by his or her supervising physician. Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

SEC. 7. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

- (2) The directions for the use of the drug.
- (3) The name of the patient or patients.

(4) The name of the prescriber and, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

SEC. 8. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug repackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.

SEC. 9. Section 4175 of the Business and Professions Code is amended to read:

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of

Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

SEC. 10. Section 11026 of the Health and Safety Code is amended to read:

11026. “Practitioner” means any of the following:

(a) A physician, dentist, veterinarian, podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, or a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code.

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer, a controlled substance in the course of professional practice or research in this state.

(c) A scientific investigator, or other person licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.

SEC. 11. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section

128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 12. 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.

