## AMENDED IN SENATE JUNE 20, 2016 AMENDED IN SENATE JULY 1, 2015 AMENDED IN ASSEMBLY MAY 28, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

## ASSEMBLY BILL

No. 1306

Introduced by Assembly Member Burke (Coauthor: Assembly Member Mark Stone)

February 27, 2015

An act to amend Sections 650.01, 650.02, 2725.1, 2746.2, 2746.5, 2746.51, 2746.52, 4061, 4076, and 4170 of, and to add Section 2746.6 to, the Business and Professions Code, relating to healing arts.

## LEGISLATIVE COUNSEL'S DIGEST

AB 1306, as amended, Burke. Healing arts: certified nurse-midwives: scope of practice.

(1) Existing law, the Nursing Practice Act, provides for the licensure and regulation of the practice of nursing by the Board of Registered Nursing and authorizes the board to issue a certificate to practice nurse-midwifery to a person who meets educational standards established by the board or the equivalent of those educational standards. The act makes the violation of any of its provisions a misdemeanor punishable upon conviction by imprisonment in the county jail for not less than 10 days nor more than one year, or by a fine of not less than \$20 nor more than \$1,000, or by both that fine and imprisonment.

This bill would additionally require an applicant for a certificate to practice nurse-midwifery to provide evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board. This *The* bill would also require

AB 1306 -2-

the board to create and appoint a Nurse-Midwifery Advisory-Council Committee consisting of certified nurse-midwives in good standing with experience in hospital settings, alternative birth settings, and home settings, a nurse-midwife educator, as specified, 2 qualified physicians, and a consumer of midwifery care. This bill would require the council committee to consist of a majority of certified nurse-midwives and would require the council committee to make recommendations to the board on all matters related to nurse-midwifery practice, education, disciplinary actions, standards of care, and other matters specified by the board, and would require the council committee to meet regularly, but at least twice a year. This bill would prohibit corporations and other artificial legal entities from having professional rights, privileges, or powers under the act, except as specified. The bill would authorize specified entities to employ a certified nurse-midwife and charge for professional services rendered by that certified nurse-midwife, as provided.

(2) The act authorizes a certified nurse-midwife, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother, and immediate care for the newborn, and provides that the practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal.

This bill would delete those provisions and would instead authorize a certified nurse-midwife to manage a full range of gynecological and obstetric care services for women from adolescence beyond menopause, as provided. The bill would authorize a certified nurse-midwife to practice in-specified certain settings, including, but not limited to, a home-setting. setting, as specified. This bill would declare that the practice of nurse-midwifery within a health care system provides for consultation, collaboration, or referral as indicated by the health status of the client and the resources of the medical personnel available in the setting of care, and would provide that the practice of nurse-midwifery emphasizes informed consent, preventive care, and early detection and referral of complications to a physician and surgeon.

(3) The act authorizes a certified nurse-midwife to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered

-3- AB 1306

consistently with the certified nurse-midwife's educational preparation in specified facilities and clinics, and only in accordance with standardized procedures and protocols, as specified.

This bill would delete the requirement that drugs or devices are furnished or ordered in accordance with standardized procedures and protocols. The bill would authorize a certified nurse-midwife to furnish and order drugs or devices in connection with care rendered in a home, and would authorize a certified nurse-midwife to directly procure supplies and devices, to order, obtain, and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and that are consistent with nurse-midwifery education preparation.

(4) The act also authorizes a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a licensed acute care hospital and a licensed alternate birth center, if certain requirements are met, including, but not limited to, that episiotomies are performed pursuant to protocols developed and approved by the supervising physician and surgeon.

This bill would also authorize a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a home, and would delete all requirements that those procedures be performed pursuant to protocols developed and approved by the supervising physician and surgeon. The bill would require a certified nurse-midwife to provide emergency care to a patient during times when a physician and surgeon is unavailable.

This bill would provide that a consultative relationship between a certified nurse-midwife and a physician and surgeon by it self is not a basis for finding the physician and surgeon liable for any acts or omissions on the part of the certified nurse-midwife. The bill would also update cross-references as needed.

- (5) Because the act makes a violation of any of its provisions a misdemeanor, this bill would expand the scope of an existing crime and therefore this bill would impose a state-mandated local program.
- (6) Existing law prohibits a licensee, as defined, from referring a person for laboratory, diagnostic, nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services if the licensee or his or her immediate family has a financial interest with the person or entity that receives the referral, and makes a violation of that

AB 1306 —4—

prohibition punishable as a misdemeanor. Under existing law, the Medical Board of California is required to review the facts and circumstances of any conviction for violating the prohibition, and to take appropriate disciplinary action if the licensee has committed unprofessional conduct. Existing law provides that, among other exceptions, this prohibition does not apply to a licensee who refers a person to a health facility if specified conditions are met.

This bill would include a certified nurse-midwife under the definition of a licensee, which would expand the scope of an existing crime and therefore impose a state-mandated local program. The bill would require the Board of Registered Nursing to review the facts and circumstances of any conviction of a certified nurse-midwife for violating that prohibition, and would require the board to take appropriate disciplinary action if the certified nurse-midwife has committed unprofessional conduct. The bill would additionally authorize a licensee to refer a person to a licensed alternative birth center, as defined, or a nationally accredited alternative birth center.

(7) 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 650.01 of the Business and Professions 2 Code is amended to read:
- 3 650.01. (a) Notwithstanding Section 650, or any other law, it
- 4 is unlawful for a licensee to refer a person for laboratory, diagnostic 5 nuclear medicine, radiation oncology, physical therapy, physical
- 6 rehabilitation, psychometric testing, home infusion therapy, or
- 7 diagnostic imaging goods or services if the licensee or his or her
- 8 immediate family has a financial interest with the person or in the entity that receives the referral.
- 10 (b) For purposes of this section and Section 650.02, the 11 following shall apply:
- 12 (1) "Diagnostic imaging" includes, but is not limited to, all X-ray, computed axial tomography, magnetic resonance imaging

\_5\_ AB 1306

nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services.

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(2) A "financial interest" includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service specified in subdivision (a). A financial interest also exists if there is an indirect financial relationship between a licensee and the referral recipient including, but not limited to, an arrangement whereby a licensee has an ownership interest in an entity that leases property to the referral recipient. Any financial interest transferred by a licensee to any person or entity or otherwise established in any person or entity for the purpose of avoiding the prohibition of this section shall be deemed a financial interest of the licensee. For purposes of this paragraph, "direct or indirect payment" shall not include a royalty or consulting fee received by a physician and surgeon who has completed a recognized residency training program in orthopedics from a manufacturer or distributor as a result of his or her research and development of medical devices and techniques for that manufacturer or distributor. For purposes of this paragraph, "consulting fees" means those fees paid by the manufacturer or distributor to a physician and surgeon who has completed a recognized residency training program in orthopedics only for his or her ongoing services in making refinements to his or her medical devices or techniques marketed or distributed by the manufacturer or distributor, if the manufacturer or distributor does not own or control the facility to which the physician is referring the patient. A "financial interest" shall not include the receipt of capitation payments or other fixed amounts that are prepaid in exchange for a promise of a licensee to provide specified health care services to specified beneficiaries. A "financial interest" shall not include the receipt of remuneration by a medical director of a hospice, as defined in Section 1746 of the Health and Safety Code, for specified services if the arrangement is set out in writing, and specifies all services to be provided by the medical director, the term of the arrangement is for at least one year, and the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not AB 1306 -6-

determined in a manner that takes into account the volume or value of any referrals or other business generated between parties.

- (3) For the purposes of this section, "immediate family" includes the spouse and children of the licensee, the parents of the licensee, and the spouses of the children of the licensee.
- (4) "Licensee" means a physician as defined in Section 3209.3 of the Labor Code, and a certified nurse-midwife as defined in Article 2.5 (commencing with Section 2746) of Chapter 6 of Division 2 of the Business and Professions Code.
  - (5) "Licensee's office" means either of the following:
  - (A) An office of a licensee in solo practice.
- (B) An office in which services or goods are personally provided by the licensee or by employees in that office, or personally by independent contractors in that office, in accordance with other provisions of law. Employees and independent contractors shall be licensed or certified when licensure or certification is required by law.
- (6) "Office of a group practice" means an office or offices in which two or more licensees are legally organized as a partnership, professional corporation, or not-for-profit corporation, licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, for which all of the following apply:
- (A) Each licensee who is a member of the group provides substantially the full range of services that the licensee routinely provides, including medical care, consultation, diagnosis, or treatment through the joint use of shared office space, facilities, equipment, and personnel.
- (B) Substantially all of the services of the licensees who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group, except in the case of a multispecialty clinic, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code, physician services are billed in the name of the multispecialty clinic and amounts so received are treated as receipts of the multispecialty clinic.
- (C) The overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined by members of the group.
- (c) It is unlawful for a licensee to enter into an arrangement or scheme, such as a cross-referral arrangement, that the licensee

\_7\_ AB 1306

knows, or should know, has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would be in violation of this section.

- (d) No claim for payment shall be presented by an entity to any individual, third party payer, or other entity for a good or service furnished pursuant to a referral prohibited under this section.
- (e) No insurer, self-insurer, or other payer shall pay a charge or lien for any good or service resulting from a referral in violation of this section.
- (f) A licensee who refers a person to, or seeks consultation from, an organization in which the licensee has a financial interest, other than as prohibited by subdivision (a), shall disclose the financial interest to the patient, or the parent or legal guardian of the patient, in writing, at the time of the referral or request for consultation.
- (1) If a referral, billing, or other solicitation is between one or more licensees who contract with a multispecialty clinic pursuant to subdivision (*l*) of Section 1206 of the Health and Safety Code or who conduct their practice as members of the same professional corporation or partnership, and the services are rendered on the same physical premises, or under the same professional corporation or partnership name, the requirements of this subdivision may be met by posting a conspicuous disclosure statement at the registration area or by providing a patient with a written disclosure statement.
- (2) If a licensee is under contract with the Department of Corrections or the California Youth Authority, and the patient is an inmate or parolee of either respective department, the requirements of this subdivision shall be satisfied by disclosing financial interests to either the Department of Corrections or the California Youth Authority.
- (g) A violation of subdivision (a) shall be a misdemeanor. In the case of a licensee who is a physician, the Medical Board of California shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed unprofessional conduct. In the case of a licensee who is a certified nurse-midwife, the Board of Registered Nursing shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed

AB 1306 —8—

unprofessional conduct. Violations of this section may also be subject to civil penalties of up to five thousand dollars (\$5,000) for each offense, which may be enforced by the Insurance Commissioner, Attorney General, or a district attorney. A violation of subdivision (c), (d), or (e) is a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars (\$15,000) for each violation and appropriate disciplinary action, including revocation of professional licensure, by the Medical Board of California, the Board of Registered Nursing, or other appropriate governmental agency.

- (h) This section shall not apply to referrals for services that are described in and covered by Sections 139.3 and 139.31 of the Labor Code.
  - (i) This section shall become operative on January 1, 1995.
- SEC. 2. Section 650.02 of the Business and Professions Code is amended to read:
- 650.02. The prohibition of Section 650.01 shall not apply to or restrict any of the following:
- (a) A licensee may refer a patient for a good or service otherwise prohibited by subdivision (a) of Section 650.01 if the licensee's regular practice is located where there is no alternative provider of the service within either 25 miles or 40 minutes traveling time, via the shortest route on a paved road. If an alternative provider commences furnishing the good or service for which a patient was referred pursuant to this subdivision, the licensee shall cease referrals under this subdivision within six months of the time at which the licensee knew or should have known that the alternative provider is furnishing the good or service. A licensee who refers to or seeks consultation from an organization in which the licensee has a financial interest under this subdivision shall disclose this interest to the patient or the patient's parents or legal guardian in writing at the time of referral.
- (b) A licensee, when the licensee or his or her immediate family has one or more of the following arrangements with another licensee, a person, or an entity, is not prohibited from referring a patient to the licensee, person, or entity because of the arrangement:
- (1) A loan between a licensee and the recipient of the referral, if the loan has commercially reasonable terms, bears interest at the prime rate or a higher rate that does not constitute usury, is adequately secured, and the loan terms are not affected by either

-9- AB 1306

party's referral of any person or the volume of services provided by either party.

- (2) A lease of space or equipment between a licensee and the recipient of the referral, if the lease is written, has commercially reasonable terms, has a fixed periodic rent payment, has a term of one year or more, and the lease payments are not affected by either party's referral of any person or the volume of services provided by either party.
- (3) Ownership of corporate investment securities, including shares, bonds, or other debt instruments that may be purchased on terms generally available to the public and that are traded on a licensed securities exchange or NASDAQ, do not base profit distributions or other transfers of value on the licensee's referral of persons to the corporation, do not have a separate class or accounting for any persons or for any licensees who may refer persons to the corporation, and are in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous three fiscal years, stockholder equity exceeding seventy-five million dollars (\$75,000,000).
- (4) Ownership of shares in a regulated investment company as defined in Section 851(a) of the federal Internal Revenue Code, if the company had, at the end of the company's most recent fiscal year, or on average during the previous three fiscal years, total assets exceeding seventy-five million dollars (\$75,000,000).
- (5) A one-time sale or transfer of a practice or property or other financial interest between a licensee and the recipient of the referral if the sale or transfer is for commercially reasonable terms and the consideration is not affected by either party's referral of any person or the volume of services provided by either party.
- (6) A personal services arrangement between a licensee or an immediate family member of the licensee and the recipient of the referral if the arrangement meets all of the following requirements:
  - (A) It is set out in writing and is signed by the parties.
- (B) It specifies all of the services to be provided by the licensee or an immediate family member of the licensee.
- (C) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- (D) A person who is referred by a licensee or an immediate family member of the licensee is informed in writing of the

AB 1306 — 10 —

personal services arrangement that includes information on where a person may go to file a complaint against the licensee or the immediate family member of the licensee.

- (E) The term of the arrangement is for at least one year.
- (F) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- (G) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
- (c) (1) A licensee may refer a person to a health facility, as defined in Section 1250 of the Health and Safety Code, a licensed alternative birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, or to any facility, or nationally accredited alternative birth center, owned or leased by a health facility, if the recipient of the referral does not compensate the licensee for the patient referral, and any equipment lease arrangement between the licensee and the referral recipient complies with the requirements of paragraph (2) of subdivision (b).
- (2) Nothing shall preclude this subdivision from applying to a licensee solely because the licensee has an ownership or leasehold interest in an entire health facility or an entity that owns or leases an entire health facility.
- (3) A licensee may refer a person to a health facility for any service classified as an emergency under subdivision (a) or (b) of Section 1317.1 of the Health and Safety Code.
- (4) A licensee may refer a person to any organization that owns or leases a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code if the licensee is not compensated for the patient referral, the licensee does not receive any payment from the recipient of the referral that is based or determined on the number or value of any patient referrals, and any equipment lease arrangement between the licensee and the referral recipient complies with the requirements of paragraph (2) of subdivision (b). For purposes of this paragraph, the ownership may be through stock or membership, and may be represented by

-11- AB 1306

a parent holding company that solely owns or controls both the health facility organization and the affiliated organization.

- (d) A licensee may refer a person to a nonprofit corporation that provides physician services pursuant to subdivision (*l*) of Section 1206 of the Health and Safety Code if the nonprofit corporation is controlled through membership by one or more health facilities or health facility systems and the amount of compensation or other transfer of funds from the health facility or nonprofit corporation to the licensee is fixed annually, except for adjustments caused by physicians joining or leaving the groups during the year, and is not based on the number of persons utilizing goods or services specified in Section 650.01.
- (e) A licensee compensated or employed by a university may refer a person for a physician service, to any facility owned or operated by the university, or to another licensee employed by the university, provided that the facility or university does not compensate the referring licensee for the patient referral. In the case of a facility that is totally or partially owned by an entity other than the university, but that is staffed by university physicians, those physicians may not refer patients to the facility if the facility compensates the referring physicians for those referrals.
- (f) The prohibition of Section 650.01 shall not apply to any service for a specific patient that is performed within, or goods that are supplied by, a licensee's office, or the office of a group practice. Further, the provisions of Section 650.01 shall not alter, limit, or expand a licensee's ability to deliver, or to direct or supervise the delivery of, in-office goods or services according to the laws, rules, and regulations governing his or her scope of practice.
- (g) The prohibition of Section 650.01 shall not apply to cardiac rehabilitation services provided by a licensee or by a suitably trained individual under the direct or general supervision of a licensee, if the services are provided to patients meeting the criteria for Medicare reimbursement for the services.
- (h) The prohibition of Section 650.01 shall not apply if a licensee is in the office of a group practice and refers a person for services or goods specified in Section 650.01 to a multispecialty clinic, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code.

AB 1306 — 12 —

(i) The prohibition of Section 650.01 shall not apply to health care services provided to an enrollee of a health care service plan licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

- (j) The prohibition of Section 650.01 shall not apply to a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy if those services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician.
- (k) This section shall not apply to referrals for services that are described in and covered by Sections 139.3 and 139.31 of the Labor Code.
  - (*l*) This section shall become operative on January 1, 1995. SEC. 3. Section 2725.1 of the Business and Professions Code
- 19 is amended to read:
  - 2725.1. (a) Notwithstanding any other law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon or an order by a certified nurse-midwife, nurse practitioner, or physician assistant issued pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, if the registered nurse is functioning within a licensed primary care clinic as defined in subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b), (c), (h), or (j) of Section 1206 of, the Health and Safety Code.
  - (b) 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 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

-13 - AB 1306

shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

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- (c) This section shall not be construed to limit any other authority granted to a certified nurse-midwife pursuant to Article 2.5 (commencing with Section 2746), to a nurse practitioner pursuant to Article 8 (commencing with Section 2834), or to a physician assistant pursuant to Chapter 7.7 (commencing with Section 3500).
- (d) This section shall not be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Chapter 9 (commencing with Section 4000).
- SEC. 4. Section 2746.2 of the Business and Professions Code is amended to read:
- 2746.2. (a) Each applicant shall show by evidence satisfactory to the board that he or she has met the educational standards established by the board or has at least the equivalent thereof, including evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board.
- (b) The board shall create and appoint a Nurse-Midwifery Advisory—Council Committee consisting of nurse-midwives in good standing with experience in hospital settings, alternative birth center settings, and home settings, a nurse-midwife educator who has demonstrated familiarity with educational standards in the delivery of maternal-child health care, a consumer of midwifery care, and at least two qualified physicians appointed by the Medical Board of California, physicians, including an obstetrician that has experience working with nurse-midwives. The council committee membership shall consist of a majority of certified nurse-midwives and shall make recommendations to the board on all matters related to nurse-midwifery practice, education, and other matters as specified by the board. The council committee shall meet regularly, but at least twice a year.
- (c) Corporations and other artificial legal entities shall have no professional rights, privileges, or powers. However, the Board of Registered Nursing may in its discretion, after such investigation and review of such documentary evidence as it may require, and under regulations adopted by it, grant approval of the employment of licensees on a salary basis by licensed charitable institutions,

AB 1306 — 14 —

1 foundations, or clinics, if no charge for professional services 2 rendered patients is made by any such institution, foundation, or 3 clinic.

- (d) Notwithstanding subdivision (c), the following entities may employ a certified nurse-midwife and charge for professional services rendered by a certified nurse-midwife; however, the entity shall not interfere with, control, or otherwise direct the professional judgment of a certified nurse-midwife:
- (1) A clinic operated under subdivision (h) or (p) of Section 1206 of the Health and Safety Code.
- (2) A hospital owned and operated by a health care district pursuant to Division 23 (commencing with Section 32000) of the Health and Safety Code.
- (3) A clinic operated primarily for the purpose of medical education or nursing education by a public or private nonprofit university medical school, which is approved by the Medical Board or the Osteopathic Medical Board of California, provided the certified nurse-midwife holds an academic appointment on the faculty of the university, including, but not limited to, the University of California medical schools and hospitals.
- (4) A licensed alternative birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, or a nationally accredited alternative birth center owned or operated by a nursing corporation, as defined in Section 2775 of the Business and Professions Code.
- (5) A health facility described in Section 1250 of the Health and Safety Code if the certified-nurse midwife is practicing under the supervision of a physician and surgeon.
- (6) A clinic operated under subdivision (a) of Section 1204 of the Health and Safety code.
- (e) As used in this section, supervision shall not be construed to require the physical presence of a supervising physician and surgeon. A facility described in paragraphs (1) to (4), inclusive, of subdivision (d) that employs a certified-nurse midwife shall not require supervision by a physician and surgeon of the certified-nurse midwife.
- 37 SEC. 5. Section 2746.5 of the Business and Professions Code is amended to read:
- 39 2746.5. (a) The certificate to practice nurse-midwifery 40 authorizes the holder to manage a full range of primary

-15- AB 1306

gynecological and obstetric care services for women from adolescence to beyond menopause, consistent with the Core Competencies for Basic Midwifery practice promulgated by the American College of Nurse-Midwives, or its successor national professional organization, as approved by the board. These services include, but are not limited to, primary health care, gynecologic and family planning services, preconception care, care during pregnancy, childbirth, and the postpartum period, immediate care of the newborn, and treatment of male partners for sexually transmitted infections, utilizing consultation, collaboration, or referral to appropriate levels of health care services, as indicated.

- (b) A certified nurse-midwife may practice in the following settings:
- (1) A licensed clinic as described in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.
- (2) A facility as described in Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.
- (3) A facility as described in Chapter 2.5 (commencing with Section 1440) of Division 2 of the Health and Safety Code.
- (4) A medical group practice, including a professional medical corporation, a medical partnership, a medical foundation exempt from licensure pursuant to Section 1206 of the Health and Safety Code, or another lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services.
- (5) A licensed alternative birth center, as described in Section 1204 of the Health and Safety Code, or nationally accredited birth center.
- (6) A nursing corporation, as defined in Section 2775 of the Business and Professions Code.
  - (7) A home setting.

- (A) Except as provided in subparagraph (B) of this paragraph, (B), a certified nurse-midwife shall—assist only attend during normal, low-risk pregnancy and childbirth in the home setting only when all of the following conditions apply:
  - (i) There is the absence of all of the following:
- (I) Any preexisting maternal disease or condition—likely to complicate the pregnancy. creating risks beyond that of a normal, low-risk pregnancy or birth, as defined in the American College

AB 1306 — 16 —

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of Nurse-Midwives' standard-setting documents and any future
 changes to those documents.
 (II) Disease arising from or during the pregnancy-likely to cause

- (II) Disease arising from or during the pregnancy likely to cause significant maternal and/or fetal compromise. creating risks beyond that of a normal, low-risk pregnancy or birth, as defined in the American College of Nurse-Midwives' standard-setting documents and any future changes to those documents.
  - (III) Prior caesarean delivery.
  - (ii) There is a singleton fetus.
  - (iii) There is cephalic presentation at the onset of labor.
- (iv) The gestational age of the fetus is greater than 370/7 weeks and less than 420/7 completed weeks of pregnancy at the onset of labor.
  - (v) Labor is spontaneous or induced in an outpatient setting.
- (B) If a potential certified nurse-midwife client meets the conditions specified in subclauses (I) and (II) of clause (i) and clauses (ii) to (v), inclusive, of subparagraph (A), but fails to meet the conditions condition specified in subclause (III) of clause (i) of subparagraph (A), and the woman still desires to be a client of the certified nurse-midwife, the certified nurse-midwife shall consult with provide the woman with a referral for an examination by a physician and surgeon trained in obstetrics and gynecology. A certified nurse-midwife may assist the woman in pregnancy and childbirth only if an examination by a physician and surgeon trained in obstetrics and gynecology is consulted and the physician and surgeon who performed the consultation determines that the risk factors presented by her disease or condition are not likely to significantly affect the course of pregnancy and childbirth. obtained and, based upon review of the client's medical file, the certified nurse-midwife determines that the risk factors presented by the woman's condition do not increase the woman's risk beyond that of a normal, low-risk pregnancy and birth. The certified nurse-midwife may continue care of the client during a reasonable interval between the referral and the initial appointment with the physician and surgeon.
- (c) As used in this chapter, the practice of nurse-midwifery within a health care system provides for consultation, collaboration, or referral as indicated by the health status of the patient and the resources and medical personnel available in the setting of care. The practice of nurse-midwifery care emphasizes informed consent,

-17- AB 1306

preventive care, and early detection and referral of complications to physicians and surgeons. While practicing in a hospital setting, the certified nurse-midwife shall collaboratively care for women with more complex health needs.

- (d) A certified nurse-midwife practicing under subdivision (a) shall be subject to all credentialing and quality standards held by the facility in which he or she practices. The peer review body shall include nurse-midwives as part of the peer review body that reviews nurse-midwives. The peer review body of that facility shall impose standards that assure ensure quality and patient safety in their facility. The standards shall be approved by the relevant governing body unless found by a court to be arbitrary and capricious.
- (e) The practice of nurse-midwifery does not include the assisting of childbirth by any-forcible, forcible or mechanical means, nor means or the performance of any version of those means. a version.
- (f) A certified nurse-midwife is not authorized to practice medicine and surgery by the provisions of this chapter.
- (g) Any regulations promulgated by a state department that affect the scope of practice of a certified nurse-midwife shall be developed in consultation with the board and the Nurse-Midwifery Advisory—Council. Committee.
- SEC. 6. Section 2746.51 of the Business and Professions Code is amended to read:
- 2746.51. (a) Neither this chapter nor any other law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when the drugs or devices are furnished or ordered related to the provision of any of the following:
- (1) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.
- (2) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.
- (3) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified

AB 1306 — 18 —

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.

- (4) Care rendered in a home pursuant to subdivision (a) of Section 2746.5.
- (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 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) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.
- (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) when the drugs and devices are furnished or ordered in

-19- AB 1306

accordance with requirements referenced in paragraphs (1) to (3), inclusive, of subdivision (b). In a nonhospital setting, a Schedule II controlled substance shall be furnished by a certified nurse-midwife only during labor and delivery and only after a consultation with a physician and surgeon.

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- (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.
- (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 law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of a 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) A certified nurse-midwife is authorized to directly procure supplies and devices, to order, obtain, and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and consistent with nurse-midwifery education preparation.
- SEC. 7. Section 2746.52 of the Business and Professions Code is amended to read:
- 2746.52. (a) Notwithstanding Section 2746.5, the certificate to practice nurse-midwifery authorizes the holder to perform and repair episiotomies, and to repair first-degree and second-degree lacerations of the perineum, in a licensed acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, in a licensed alternate birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, or a nationally accredited birth center, and in a home pursuant to paragraph (7) of subdivision (b) of Section 2746.5.

AB 1306 — 20 —

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(b) The certified nurse-midwife performing and repairing first-degree and second-degree lacerations of the perineum shall do both of the following:

- (1) Ensure that all complications are referred to a physician and surgeon immediately.
- (2) Ensure immediate care of patients who are in need of care beyond the scope of practice of the certified nurse-midwife, or provide emergency care for times when a physician and surgeon is not available.
- SEC. 8. Section 2746.6 is added to the Business and Professions Code, to read:
  - 2746.6. A consultative relationship between a certified nurse-midwife and a physician and surgeon shall not, by itself, provide the basis for finding a physician and surgeon liable for any act or omission of the certified nurse-midwife.
  - SEC. 9. Section 4061 of the Business and Professions Code is amended to read:
  - 4061. (a) A manufacturer's sales representative shall not distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. However, a certified nurse-midwife who functions pursuant to Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.
  - (b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the

-21- AB 1306

specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor, 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.

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- (c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor.
- SEC. 10. 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 when the prescriber or the certified nurse-midwife who functions pursuant to Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 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 or, if applicable, the name of the certified nurse-midwife who functions pursuant to Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

AB 1306 — 22 —

(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 or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
- (11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
  - (i) Prescriptions dispensed by a veterinarian.
- (ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
- (iii) Dispensed medications for which no physical description exists in any commercially available database.
  - (B) This paragraph applies to outpatient pharmacies only.
- (C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
- (D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.
- (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 Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician

-23 - AB 1306

assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

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- (d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.
- SEC. 11. Section 4170 of the Business and Professions Code is amended to read:
- 4170. (a) A prescriber shall not 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).

AB 1306 — 24 —

(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 Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon, if applicable, a properly labeled prescription drug prepackaged 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 Bureau of Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, 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 naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.
- SEC. 12. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB 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

<u>\_\_ 25 \_\_</u> **AB 1306** 

- the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
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