

AMENDED IN SENATE JUNE 30, 2016

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 510, 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. The bill would also require the board to create and appoint a Nurse-Midwifery Advisory 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~~ *The* bill would require the committee to consist of a majority of certified nurse-midwives and would require the 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 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 *under that gynecological and obstetric care services authorization without supervision of a physician and surgeon* in certain settings, including, but not limited to, a home setting, as specified. ~~This~~ *The bill would prohibit entities described in those specified settings from interfering with, controlling, or otherwise directing the professional judgment of such a certified nurse-midwife, as specified.* The 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 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 ~~itself~~ *itself* 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 provides prescribed protection against retaliation for health care practitioners who advocate for appropriate health care for their patients. Existing law defines “health care practitioner” for those purposes to mean a person who engages in acts that are the subject of licensure or regulation under specific law or initiative act and who is either a licentiate, as defined, a party to a contract with a payer whose decision, policy, or practice is subject to such advocacy, or an individual designated in a contract with a payer whose decision, policy, or practice is subject to such advocacy, where the individual is granted the right to appeal denials of payment or authorization for treatment under the contract.

This bill would expand that protection against retaliation to certified nurse-midwives.

~~(6)~~

(7) 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 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)~~

(8) 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 510 of the Business and Professions Code
2 is amended to read:

3 510. (a) The purpose of this section is to provide protection
4 against retaliation for health care practitioners who advocate for
5 appropriate health care for their patients pursuant to Wickline v.
6 State of California 192 Cal. App. 3d 1630.

7 (b) It is the public policy of the State of California that a health
8 care practitioner be encouraged to advocate for appropriate health
9 care for his or her patients. For purposes of this section, “to
10 advocate for appropriate health care” means to appeal a payer’s
11 decision to deny payment for a service pursuant to the reasonable
12 grievance or appeal procedure established by a medical group,
13 independent practice association, preferred provider organization,
14 foundation, hospital medical staff and governing body, or payer,
15 or to protest a decision, policy, or practice that the health care
16 practitioner, consistent with that degree of learning and skill
17 ordinarily possessed by reputable health care practitioners with
18 the same license or certification and practicing according to the
19 applicable legal standard of care, reasonably believes impairs the
20 health care practitioner’s ability to provide appropriate health care
21 to his or her patients.

22 (c) The application and rendering by any individual, partnership,
23 corporation, or other organization of a decision to terminate an
24 employment or other contractual relationship with or otherwise
25 penalize a health care practitioner principally for advocating for
26 appropriate health care consistent with that degree of learning and
27 skill ordinarily possessed by reputable health care practitioners
28 with the same license or certification and practicing according to
29 the applicable legal standard of care violates the public policy of
30 this state.

1 (d) This section shall not be construed to prohibit a payer from
2 making a determination not to pay for a particular medical
3 treatment or service, or the services of a type of health care
4 practitioner, or to prohibit a medical group, independent practice
5 association, preferred provider organization, foundation, hospital
6 medical staff, hospital governing body acting pursuant to Section
7 809.05, or payer from enforcing reasonable peer review or
8 utilization review protocols or determining whether a health care
9 practitioner has complied with those protocols.

10 (e) (1) Except as provided in paragraph (2), appropriate health
11 care in a hospital licensed pursuant to Section 1250 of the Health
12 and Safety Code shall be defined by the appropriate hospital
13 committee and approved by the hospital medical staff and the
14 governing body, consistent with that degree of learning and skill
15 ordinarily possessed by reputable health care practitioners with
16 the same license or certification and practicing according to the
17 applicable legal standard of care.

18 (2) To the extent the issue is under the jurisdiction of the medical
19 staff and its committees, appropriate health care in a hospital
20 licensed pursuant to Section 1250 of the Health and Safety Code
21 shall be defined by the hospital medical staff and approved by the
22 governing body, consistent with that degree of learning and skill
23 ordinarily possessed by reputable health care practitioners with
24 the same license or certification and practicing according to the
25 applicable legal standard of care.

26 (f) Nothing in this section shall be construed to prohibit the
27 governing body of a hospital from taking disciplinary actions
28 against a health care practitioner as authorized by Sections 809.05,
29 809.4, and 809.5.

30 (g) Nothing in this section shall be construed to prohibit the
31 appropriate licensing authority from taking disciplinary actions
32 against a health care practitioner.

33 (h) For purposes of this section, “health care practitioner” means
34 *either* a person who is described in subdivision (f) of Section 900
35 and who is either (1) a licentiate as defined in Section 805, or (2)
36 a party to a contract with a payer whose decision, policy, or practice
37 is subject to the advocacy described in subdivision (b), or (3) an
38 individual designated in a contract with a payer whose decision,
39 policy, or practice is subject to the advocacy described in
40 subdivision (b), where the individual is granted the right to appeal

1 denials of payment or authorization for treatment under the
2 ~~contract.~~ *contract, or a person who is described in Section 2746.2.*

3 (i) Nothing in this section shall be construed to revise or expand
4 the scope of practice of any health care practitioner, or to revise
5 or expand the types of health care practitioners who are authorized
6 to obtain medical staff privileges or to submit claims for
7 reimbursement to payers.

8 (j) The protections afforded health care practitioners by this
9 section shall be in addition to the protections available under any
10 other law of this state.

11 **SECTION 1.**

12 *SEC. 2.* Section 650.01 of the Business and Professions Code
13 is amended to read:

14 650.01. (a) Notwithstanding Section 650, or any other law, it
15 is unlawful for a licensee to refer a person for laboratory, diagnostic
16 nuclear medicine, radiation oncology, physical therapy, physical
17 rehabilitation, psychometric testing, home infusion therapy, or
18 diagnostic imaging goods or services if the licensee or his or her
19 immediate family has a financial interest with the person or in the
20 entity that receives the referral.

21 (b) For purposes of this section and Section 650.02, the
22 following shall apply:

23 (1) “Diagnostic imaging” includes, but is not limited to, all
24 X-ray, computed axial tomography, magnetic resonance imaging
25 nuclear medicine, positron emission tomography, mammography,
26 and ultrasound goods and services.

27 (2) A “financial interest” includes, but is not limited to, any
28 type of ownership interest, debt, loan, lease, compensation,
29 remuneration, discount, rebate, refund, dividend, distribution,
30 subsidy, or other form of direct or indirect payment, whether in
31 money or otherwise, between a licensee and a person or entity to
32 whom the licensee refers a person for a good or service specified
33 in subdivision (a). A financial interest also exists if there is an
34 indirect financial relationship between a licensee and the referral
35 recipient including, but not limited to, an arrangement whereby a
36 licensee has an ownership interest in an entity that leases property
37 to the referral recipient. Any financial interest transferred by a
38 licensee to any person or entity or otherwise established in any
39 person or entity for the purpose of avoiding the prohibition of this
40 section shall be deemed a financial interest of the licensee. For

1 purposes of this paragraph, “direct or indirect payment” shall not
2 include a royalty or consulting fee received by a physician and
3 surgeon who has completed a recognized residency training
4 program in orthopedics from a manufacturer or distributor as a
5 result of his or her research and development of medical devices
6 and techniques for that manufacturer or distributor. For purposes
7 of this paragraph, “consulting fees” means those fees paid by the
8 manufacturer or distributor to a physician and surgeon who has
9 completed a recognized residency training program in orthopedics
10 only for his or her ongoing services in making refinements to his
11 or her medical devices or techniques marketed or distributed by
12 the manufacturer or distributor, if the manufacturer or distributor
13 does not own or control the facility to which the physician is
14 referring the patient. A “financial interest” shall not include the
15 receipt of capitation payments or other fixed amounts that are
16 prepaid in exchange for a promise of a licensee to provide specified
17 health care services to specified beneficiaries. A “financial interest”
18 shall not include the receipt of remuneration by a medical director
19 of a hospice, as defined in Section 1746 of the Health and Safety
20 Code, for specified services if the arrangement is set out in writing,
21 and specifies all services to be provided by the medical director,
22 the term of the arrangement is for at least one year, and the
23 compensation to be paid over the term of the arrangement is set
24 in advance, does not exceed fair market value, and is not
25 determined in a manner that takes into account the volume or value
26 of any referrals or other business generated between parties.

27 (3) For the purposes of this section, “immediate family” includes
28 the spouse and children of the licensee, the parents of the licensee,
29 and the spouses of the children of the licensee.

30 (4) “Licensee” means a physician as defined in Section 3209.3
31 of the Labor Code, and a certified nurse-midwife as defined in
32 Article 2.5 (commencing with Section 2746) of Chapter 6 of
33 Division 2 of the Business and Professions Code.

34 (5) “Licensee’s office” means either of the following:

35 (A) An office of a licensee in solo practice.

36 (B) An office in which services or goods are personally provided
37 by the licensee or by employees in that office, or personally by
38 independent contractors in that office, in accordance with other
39 provisions of law. Employees and independent contractors shall

1 be licensed or certified when licensure or certification is required
2 by law.

3 (6) “Office of a group practice” means an office or offices in
4 which two or more licensees are legally organized as a partnership,
5 professional corporation, or not-for-profit corporation, licensed
6 pursuant to subdivision (a) of Section 1204 of the Health and Safety
7 Code, for which all of the following apply:

8 (A) Each licensee who is a member of the group provides
9 substantially the full range of services that the licensee routinely
10 provides, including medical care, consultation, diagnosis, or
11 treatment through the joint use of shared office space, facilities,
12 equipment, and personnel.

13 (B) Substantially all of the services of the licensees who are
14 members of the group are provided through the group and are
15 billed in the name of the group and amounts so received are treated
16 as receipts of the group, except in the case of a multispecialty
17 clinic, as defined in subdivision (l) of Section 1206 of the Health
18 and Safety Code, physician services are billed in the name of the
19 multispecialty clinic and amounts so received are treated as receipts
20 of the multispecialty clinic.

21 (C) The overhead expenses of, and the income from, the practice
22 are distributed in accordance with methods previously determined
23 by members of the group.

24 (c) It is unlawful for a licensee to enter into an arrangement or
25 scheme, such as a cross-referral arrangement, that the licensee
26 knows, or should know, has a principal purpose of ensuring
27 referrals by the licensee to a particular entity that, if the licensee
28 directly made referrals to that entity, would be in violation of this
29 section.

30 (d) No claim for payment shall be presented by an entity to any
31 individual, third party payer, or other entity for a good or service
32 furnished pursuant to a referral prohibited under this section.

33 (e) No insurer, self-insurer, or other payer shall pay a charge or
34 lien for any good or service resulting from a referral in violation
35 of this section.

36 (f) A licensee who refers a person to, or seeks consultation from,
37 an organization in which the licensee has a financial interest, other
38 than as prohibited by subdivision (a), shall disclose the financial
39 interest to the patient, or the parent or legal guardian of the patient,
40 in writing, at the time of the referral or request for consultation.

1 (1) If a referral, billing, or other solicitation is between one or
2 more licensees who contract with a multispecialty clinic pursuant
3 to subdivision (l) of Section 1206 of the Health and Safety Code
4 or who conduct their practice as members of the same professional
5 corporation or partnership, and the services are rendered on the
6 same physical premises, or under the same professional corporation
7 or partnership name, the requirements of this subdivision may be
8 met by posting a conspicuous disclosure statement at the
9 registration area or by providing a patient with a written disclosure
10 statement.

11 (2) If a licensee is under contract with the Department of
12 Corrections or the California Youth Authority, and the patient is
13 an inmate or parolee of either respective department, the
14 requirements of this subdivision shall be satisfied by disclosing
15 financial interests to either the Department of Corrections or the
16 California Youth Authority.

17 (g) A violation of subdivision (a) shall be a misdemeanor. In
18 the case of a licensee who is a physician, the Medical Board of
19 California shall review the facts and circumstances of any
20 conviction pursuant to subdivision (a) and take appropriate
21 disciplinary action if the licensee has committed unprofessional
22 conduct. In the case of a licensee who is a certified nurse-midwife,
23 the Board of Registered Nursing shall review the facts and
24 circumstances of any conviction pursuant to subdivision (a) and
25 take appropriate disciplinary action if the licensee has committed
26 unprofessional conduct. Violations of this section may also be
27 subject to civil penalties of up to five thousand dollars (\$5,000)
28 for each offense, which may be enforced by the Insurance
29 Commissioner, Attorney General, or a district attorney. A violation
30 of subdivision (c), (d), or (e) is a public offense and is punishable
31 upon conviction by a fine not exceeding fifteen thousand dollars
32 (\$15,000) for each violation and appropriate disciplinary action,
33 including revocation of professional licensure, by the Medical
34 Board of California, the Board of Registered Nursing, or other
35 appropriate governmental agency.

36 (h) This section shall not apply to referrals for services that are
37 described in and covered by Sections 139.3 and 139.31 of the
38 Labor Code.

39 (i) This section shall become operative on January 1, 1995.

1 ~~SEC. 2.~~

2 *SEC. 3.* Section 650.02 of the Business and Professions Code
3 is amended to read:

4 650.02. The prohibition of Section 650.01 shall not apply to
5 or restrict any of the following:

6 (a) A licensee may refer a patient for a good or service otherwise
7 prohibited by subdivision (a) of Section 650.01 if the licensee's
8 regular practice is located where there is no alternative provider
9 of the service within either 25 miles or 40 minutes traveling time,
10 via the shortest route on a paved road. If an alternative provider
11 commences furnishing the good or service for which a patient was
12 referred pursuant to this subdivision, the licensee shall cease
13 referrals under this subdivision within six months of the time at
14 which the licensee knew or should have known that the alternative
15 provider is furnishing the good or service. A licensee who refers
16 to or seeks consultation from an organization in which the licensee
17 has a financial interest under this subdivision shall disclose this
18 interest to the patient or the patient's parents or legal guardian in
19 writing at the time of referral.

20 (b) A licensee, when the licensee or his or her immediate family
21 has one or more of the following arrangements with another
22 licensee, a person, or an entity, is not prohibited from referring a
23 patient to the licensee, person, or entity because of the arrangement:

24 (1) A loan between a licensee and the recipient of the referral,
25 if the loan has commercially reasonable terms, bears interest at
26 the prime rate or a higher rate that does not constitute usury, is
27 adequately secured, and the loan terms are not affected by either
28 party's referral of any person or the volume of services provided
29 by either party.

30 (2) A lease of space or equipment between a licensee and the
31 recipient of the referral, if the lease is written, has commercially
32 reasonable terms, has a fixed periodic rent payment, has a term of
33 one year or more, and the lease payments are not affected by either
34 party's referral of any person or the volume of services provided
35 by either party.

36 (3) Ownership of corporate investment securities, including
37 shares, bonds, or other debt instruments that may be purchased on
38 terms generally available to the public and that are traded on a
39 licensed securities exchange or NASDAQ, do not base profit
40 distributions or other transfers of value on the licensee's referral

1 of persons to the corporation, do not have a separate class or
2 accounting for any persons or for any licensees who may refer
3 persons to the corporation, and are in a corporation that had, at the
4 end of the corporation’s most recent fiscal year, or on average
5 during the previous three fiscal years, stockholder equity exceeding
6 seventy-five million dollars (\$75,000,000).

7 (4) Ownership of shares in a regulated investment company as
8 defined in Section 851(a) of the federal Internal Revenue Code, if
9 the company had, at the end of the company’s most recent fiscal
10 year, or on average during the previous three fiscal years, total
11 assets exceeding seventy-five million dollars (\$75,000,000).

12 (5) A one-time sale or transfer of a practice or property or other
13 financial interest between a licensee and the recipient of the referral
14 if the sale or transfer is for commercially reasonable terms and the
15 consideration is not affected by either party’s referral of any person
16 or the volume of services provided by either party.

17 (6) A personal services arrangement between a licensee or an
18 immediate family member of the licensee and the recipient of the
19 referral if the arrangement meets all of the following requirements:

- 20 (A) It is set out in writing and is signed by the parties.
- 21 (B) It specifies all of the services to be provided by the licensee
22 or an immediate family member of the licensee.
- 23 (C) The aggregate services contracted for do not exceed those
24 that are reasonable and necessary for the legitimate business
25 purposes of the arrangement.
- 26 (D) A person who is referred by a licensee or an immediate
27 family member of the licensee is informed in writing of the
28 personal services arrangement that includes information on where
29 a person may go to file a complaint against the licensee or the
30 immediate family member of the licensee.
- 31 (E) The term of the arrangement is for at least one year.
- 32 (F) The compensation to be paid over the term of the
33 arrangement is set in advance, does not exceed fair market value,
34 and is not determined in a manner that takes into account the
35 volume or value of any referrals or other business generated
36 between the parties.
- 37 (G) The services to be performed under the arrangement do not
38 involve the counseling or promotion of a business arrangement or
39 other activity that violates any state or federal law.

1 (c) (1) A licensee may refer a person to a health facility, as
2 defined in Section 1250 of the Health and Safety Code, a licensed
3 alternative birth center, as defined in paragraph (4) of subdivision
4 (b) of Section 1204 of the Health and Safety Code, or to any
5 facility, or nationally accredited alternative birth center, owned or
6 leased by a health facility, if the recipient of the referral does not
7 compensate the licensee for the patient referral, and any equipment
8 lease arrangement between the licensee and the referral recipient
9 complies with the requirements of paragraph (2) of subdivision
10 (b).

11 (2) Nothing shall preclude this subdivision from applying to a
12 licensee solely because the licensee has an ownership or leasehold
13 interest in an entire health facility or an entity that owns or leases
14 an entire health facility.

15 (3) A licensee may refer a person to a health facility for any
16 service classified as an emergency under subdivision (a) or (b) of
17 Section 1317.1 of the Health and Safety Code.

18 (4) A licensee may refer a person to any organization that owns
19 or leases a health facility licensed pursuant to subdivision (a), (b),
20 or (f) of Section 1250 of the Health and Safety Code if the licensee
21 is not compensated for the patient referral, the licensee does not
22 receive any payment from the recipient of the referral that is based
23 or determined on the number or value of any patient referrals, and
24 any equipment lease arrangement between the licensee and the
25 referral recipient complies with the requirements of paragraph (2)
26 of subdivision (b). For purposes of this paragraph, the ownership
27 may be through stock or membership, and may be represented by
28 a parent holding company that solely owns or controls both the
29 health facility organization and the affiliated organization.

30 (d) A licensee may refer a person to a nonprofit corporation that
31 provides physician services pursuant to subdivision (l) of Section
32 1206 of the Health and Safety Code if the nonprofit corporation
33 is controlled through membership by one or more health facilities
34 or health facility systems and the amount of compensation or other
35 transfer of funds from the health facility or nonprofit corporation
36 to the licensee is fixed annually, except for adjustments caused by
37 physicians joining or leaving the groups during the year, and is
38 not based on the number of persons utilizing goods or services
39 specified in Section 650.01.

1 (e) A licensee compensated or employed by a university may
2 refer a person for a physician service, to any facility owned or
3 operated by the university, or to another licensee employed by the
4 university, provided that the facility or university does not
5 compensate the referring licensee for the patient referral. In the
6 case of a facility that is totally or partially owned by an entity other
7 than the university, but that is staffed by university physicians,
8 those physicians may not refer patients to the facility if the facility
9 compensates the referring physicians for those referrals.

10 (f) The prohibition of Section 650.01 shall not apply to any
11 service for a specific patient that is performed within, or goods
12 that are supplied by, a licensee's office, or the office of a group
13 practice. Further, the provisions of Section 650.01 shall not alter,
14 limit, or expand a licensee's ability to deliver, or to direct or
15 supervise the delivery of, in-office goods or services according to
16 the laws, rules, and regulations governing his or her scope of
17 practice.

18 (g) The prohibition of Section 650.01 shall not apply to cardiac
19 rehabilitation services provided by a licensee or by a suitably
20 trained individual under the direct or general supervision of a
21 licensee, if the services are provided to patients meeting the criteria
22 for Medicare reimbursement for the services.

23 (h) The prohibition of Section 650.01 shall not apply if a licensee
24 is in the office of a group practice and refers a person for services
25 or goods specified in Section 650.01 to a multispecialty clinic, as
26 defined in subdivision (l) of Section 1206 of the Health and Safety
27 Code.

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

33 (j) The prohibition of Section 650.01 shall not apply to a request
34 by a pathologist for clinical diagnostic laboratory tests and
35 pathological examination services, a request by a radiologist for
36 diagnostic radiology services, or a request by a radiation oncologist
37 for radiation therapy if those services are furnished by, or under
38 the supervision of, the pathologist, radiologist, or radiation
39 oncologist pursuant to a consultation requested by another
40 physician.

1 (k) This section shall not apply to referrals for services that are
2 described in and covered by Sections 139.3 and 139.31 of the
3 Labor Code.

4 (l) This section shall become operative on January 1, 1995.

5 ~~SEC. 3.~~

6 *SEC. 4.* Section 2725.1 of the Business and Professions Code
7 is amended to read:

8 2725.1. (a) Notwithstanding any other law, a registered nurse
9 may dispense drugs or devices upon an order by a licensed
10 physician and surgeon or an order by a certified nurse-midwife,
11 nurse practitioner, or physician assistant issued pursuant to Section
12 2746.51, 2836.1, or 3502.1, respectively, if the registered nurse is
13 functioning within a licensed primary care clinic as defined in
14 subdivision (a) of Section 1204 of, or within a clinic as defined in
15 subdivision (b), (c), (h), or (j) of Section 1206 of, the Health and
16 Safety Code.

17 (b) No clinic shall employ a registered nurse to perform
18 dispensing duties exclusively. No registered nurse shall dispense
19 drugs in a pharmacy, keep a pharmacy, open shop, or drugstore
20 for the retailing of drugs or poisons. No registered nurse shall
21 compound drugs. Dispensing of drugs by a registered nurse, except
22 a certified nurse-midwife who functions pursuant to Section
23 2746.51 or a nurse practitioner who functions pursuant to a
24 standardized procedure described in Section 2836.1, or protocol,
25 shall not include substances included in the California Uniform
26 Controlled Substances Act (Division 10 (commencing with Section
27 11000) of the Health and Safety Code). Nothing in this section
28 shall exempt a clinic from the provisions of Article 13
29 (commencing with Section 4180) of Chapter 9.

30 (c) This section shall not be construed to limit any other
31 authority granted to a certified nurse-midwife pursuant to Article
32 2.5 (commencing with Section 2746), to a nurse practitioner
33 pursuant to Article 8 (commencing with Section 2834), or to a
34 physician assistant pursuant to Chapter 7.7 (commencing with
35 Section 3500).

36 (d) This section shall not be construed to affect the sites or types
37 of health care facilities at which drugs or devices are authorized
38 to be dispensed pursuant to Chapter 9 (commencing with Section
39 4000).

1 ~~SEC. 4.~~

2 *SEC. 5.* Section 2746.2 of the Business and Professions Code
 3 is amended to read:

4 2746.2. (a) Each applicant shall show by evidence satisfactory
 5 to the board that he or she has met the educational standards
 6 established by the board or has at least the equivalent thereof,
 7 including evidence of current advanced level national certification
 8 by a certifying body that meets standards established and approved
 9 by the board.

10 (b) The board shall create and appoint a Nurse-Midwifery
 11 Advisory Committee consisting of certified nurse-midwives in
 12 good standing with experience in hospital settings, alternative birth
 13 center settings, and home settings, a nurse-midwife educator who
 14 has demonstrated familiarity with educational standards in the
 15 delivery of maternal-child health care, a consumer of midwifery
 16 care, and at least two qualified physicians, including an obstetrician
 17 that has experience working with nurse-midwives. The committee
 18 membership shall consist of a majority of certified nurse-midwives
 19 and shall make recommendations to the board on all matters related
 20 to nurse-midwifery practice, education, and other matters as
 21 specified by the board. The committee shall meet regularly, but at
 22 least twice a year.

23 ~~(c) Corporations and other artificial legal entities shall have no~~
 24 ~~professional rights, privileges, or powers. However, the Board of~~
 25 ~~Registered Nursing may in its discretion, after such investigation~~
 26 ~~and review of such documentary evidence as it may require, and~~
 27 ~~under regulations adopted by it, grant approval of the employment~~
 28 ~~of licensees on a salary basis by licensed charitable institutions,~~
 29 ~~foundations, or clinics, if no charge for professional services~~
 30 ~~rendered patients is made by any such institution, foundation, or~~
 31 ~~clinic.~~

32 ~~(d) Notwithstanding subdivision (c), the following entities may~~
 33 ~~employ a certified nurse-midwife and charge for professional~~
 34 ~~services rendered by a certified nurse-midwife; however, the entity~~
 35 ~~shall not interfere with, control, or otherwise direct the professional~~
 36 ~~judgment of a certified nurse-midwife:~~

37 ~~(1) A clinic operated under subdivision (h) or (p) of Section~~
 38 ~~1206 of the Health and Safety Code.~~

1 ~~(2) A hospital owned and operated by a health care district~~
2 ~~pursuant to Division 23 (commencing with Section 32000) of the~~
3 ~~Health and Safety Code.~~

4 ~~(3) A clinic operated primarily for the purpose of medical~~
5 ~~education or nursing education by a public or private nonprofit~~
6 ~~university medical school, which is approved by the Medical Board~~
7 ~~or the Osteopathic Medical Board of California, provided the~~
8 ~~certified nurse-midwife holds an academic appointment on the~~
9 ~~faculty of the university, including, but not limited to, the~~
10 ~~University of California medical schools and hospitals.~~

11 ~~(4) A licensed alternative birth center, as defined in paragraph~~
12 ~~(4) of subdivision (b) of Section 1204 of the Health and Safety~~
13 ~~Code, or a nationally accredited alternative birth center owned or~~
14 ~~operated by a nursing corporation, as defined in Section 2775 of~~
15 ~~the Business and Professions Code.~~

16 ~~(5) A health facility described in Section 1250 of the Health~~
17 ~~and Safety Code if the certified nurse-midwife is practicing under~~
18 ~~the supervision of a physician and surgeon.~~

19 ~~(6) A clinic operated under subdivision (a) of Section 1204 of~~
20 ~~the Health and Safety code.~~

21 ~~(e) As used in this section, supervision shall not be construed~~
22 ~~to require the physical presence of a supervising physician and~~
23 ~~surgeon. A facility described in paragraphs (1) to (4), inclusive,~~
24 ~~of subdivision (d) that employs a certified nurse-midwife shall not~~
25 ~~require supervision by a physician and surgeon of the~~
26 ~~certified nurse-midwife.~~

27 ~~SEC. 5.~~

28 *SEC. 6.* Section 2746.5 of the Business and Professions Code
29 is amended to read:

30 2746.5. (a) The certificate to practice nurse-midwifery
31 authorizes the holder to manage a full range of primary
32 gynecological and obstetric care services for women from
33 adolescence to beyond menopause, consistent with the Core
34 Competencies for Basic Midwifery practice promulgated by the
35 American College of Nurse-Midwives, or its successor national
36 professional organization, as approved by the board. These services
37 include, but are not limited to, primary health care, gynecologic
38 and family planning services, preconception care, care during
39 pregnancy, childbirth, and the postpartum period, immediate care
40 of the newborn, and treatment of male partners for sexually

1 transmitted infections, utilizing consultation, collaboration, or
2 referral to appropriate levels of health care services, as indicated.

3 (b) A certified nurse-midwife may practice *under this section*
4 *without supervision of a physician and surgeon* in the following
5 settings:

6 (1) A licensed clinic as described in Chapter 1 (commencing
7 with Section 1200) of Division 2 of the Health and Safety Code.

8 (2) A facility as described in Chapter 2 (commencing with
9 Section 1250) of Division 2 of the Health and Safety Code.

10 (3) A facility as described in Chapter 2.5 (commencing with
11 Section 1440) of Division 2 of the Health and Safety Code.

12 (4) A medical group practice, including a professional medical
13 corporation, a medical partnership, a medical foundation exempt
14 from licensure pursuant to Section 1206 of the Health and Safety
15 Code, or another lawfully organized group of physicians that
16 delivers, furnishes, or otherwise arranges for or provides health
17 care services.

18 (5) A licensed alternative birth center, as described in Section
19 1204 of the Health and Safety Code, or nationally accredited birth
20 center.

21 (6) A nursing corporation, as defined in Section 2775 of the
22 Business and Professions Code.

23 (7) A home setting.

24 (A) Except as provided in subparagraph (B), a certified
25 nurse-midwife shall only attend during normal, low-risk pregnancy
26 and childbirth in the home setting when all of the following
27 conditions apply:

28 (i) There is the absence of all of the following:

29 (I) Any preexisting maternal disease or condition creating risks
30 beyond that of a normal, low-risk pregnancy or birth, as defined
31 in the American College of Nurse-Midwives' standard-setting
32 documents and any future changes to those documents.

33 (II) Disease arising from or during the pregnancy creating risks
34 beyond that of a normal, low-risk pregnancy or birth, as defined
35 in the American College of Nurse-Midwives' standard-setting
36 documents and any future changes to those documents.

37 (III) Prior caesarean delivery.

38 (ii) There is a singleton fetus.

39 (iii) There is cephalic presentation at the onset of labor.

1 (iv) The gestational age of the fetus is greater than 370/7 weeks
2 and less than 420/7 completed weeks of pregnancy at the onset of
3 labor.

4 (v) Labor is spontaneous or induced in an outpatient setting.

5 (B) If a potential certified nurse-midwife client meets the
6 conditions specified in subclauses (I) and (II) of clause (i) and
7 clauses (ii) to (v), inclusive, of subparagraph (A), but fails to meet
8 the condition specified in subclause (III) of clause (i) of
9 subparagraph (A), and the woman still desires to be a client of the
10 certified nurse-midwife, the certified nurse-midwife shall provide
11 the woman with a referral for an examination by a physician and
12 surgeon trained in obstetrics and gynecology. A certified
13 nurse-midwife may assist the woman in pregnancy and childbirth
14 only if an examination by a physician and surgeon trained in
15 obstetrics and gynecology is obtained and, based upon review of
16 the client's medical file, the certified nurse-midwife determines
17 that the risk factors presented by the woman's condition do not
18 increase the woman's risk beyond that of a normal, low-risk
19 pregnancy and birth. The certified nurse-midwife may continue
20 care of the client during a reasonable interval between the referral
21 and the initial appointment with the physician and surgeon.

22 (c) *An entity described in subdivision (b) shall not interfere*
23 *with, control, or otherwise direct the professional judgment of a*
24 *certified nurse-midwife functioning pursuant to this section in a*
25 *manner prohibited by Section 510 or any other law.*

26 (e)

27 (d) As used in this chapter, the practice of nurse-midwifery
28 within a health care system provides for consultation, collaboration,
29 or referral as indicated by the health status of the patient and the
30 resources and medical personnel available in the setting of care.
31 The practice of nurse-midwifery care emphasizes informed consent,
32 preventive care, and early detection and referral of complications
33 to physicians and surgeons. While practicing in a hospital setting,
34 the certified nurse-midwife shall collaboratively care for women
35 with more complex health needs.

36 (d)

37 (e) A certified nurse-midwife practicing under subdivision (a)
38 shall be subject to all credentialing and quality standards held by
39 the facility in which he or she practices. The peer review body
40 shall include nurse-midwives as part of the peer review body that

1 reviews nurse-midwives. The peer review body of that facility
2 shall impose standards that ensure quality and patient safety in
3 their facility. The standards shall be approved by the relevant
4 governing body unless found by a court to be arbitrary and
5 capricious.

6 ~~(e)~~

7 (f) The practice of nurse-midwifery does not include the assisting
8 of childbirth by any forcible or mechanical means or the
9 performance of a version.

10 ~~(f)~~

11 (g) A certified nurse-midwife is not authorized to practice
12 medicine and surgery by the provisions of this chapter.

13 ~~(g)~~

14 (h) Any regulations promulgated by a state department that
15 affect the scope of practice of a certified nurse-midwife shall be
16 developed in consultation with the board and the Nurse-Midwifery
17 Advisory Committee.

18 ~~SEC. 6.~~

19 SEC. 7. Section 2746.51 of the Business and Professions Code
20 is amended to read:

21 2746.51. (a) Neither this chapter nor any other law shall be
22 construed to prohibit a certified nurse-midwife from furnishing or
23 ordering drugs or devices, including controlled substances
24 classified in Schedule II, III, IV, or V under the California Uniform
25 Controlled Substances Act (Division 10 (commencing with Section
26 11000) of the Health and Safety Code), when the drugs or devices
27 are furnished or ordered related to the provision of any of the
28 following:

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

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

33 (3) Care rendered, consistent with the certified nurse-midwife's
34 educational preparation or for which clinical competency has been
35 established and maintained, to persons within a facility specified
36 in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the
37 Health and Safety Code, a clinic as specified in Section 1204 of
38 the Health and Safety Code, a general acute care hospital as defined
39 in subdivision (a) of Section 1250 of the Health and Safety Code,
40 a licensed birth center as defined in Section 1204.3 of the Health

1 and Safety Code, or a special hospital specified as a maternity
2 hospital in subdivision (f) of Section 1250 of the Health and Safety
3 Code.

4 (4) Care rendered in a home pursuant to subdivision (a) of
5 Section 2746.5.

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

19 (2) The board has certified in accordance with paragraph (1)
20 that the certified nurse-midwife has satisfactorily completed a
21 course in pharmacology covering the drugs or devices to be
22 furnished or ordered under this section. The board shall establish
23 the requirements for satisfactory completion of this paragraph.

24 (3) Certified nurse-midwives who are certified by the board and
25 hold an active furnishing number, who are currently authorized to
26 furnish Schedule II controlled substances, and who are registered
27 with the United States Drug Enforcement Administration shall
28 provide documentation of continuing education specific to the use
29 of Schedule II controlled substances in settings other than a hospital
30 based on standards developed by the board.

31 (c) Drugs or devices furnished or ordered by a certified
32 nurse-midwife may include Schedule II controlled substances
33 under the California Uniform Controlled Substances Act (Division
34 10 (commencing with Section 11000) of the Health and Safety
35 Code) when the drugs and devices are furnished or ordered in
36 accordance with requirements referenced in paragraphs (1) to (3),
37 inclusive, of subdivision (b). In a nonhospital setting, a Schedule
38 II controlled substance shall be furnished by a certified
39 nurse-midwife only during labor and delivery and only after a
40 consultation with a physician and surgeon.

1 (d) Furnishing of drugs or devices by a certified nurse-midwife
2 means the act of making a pharmaceutical agent or agents available
3 to the patient.

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

17 (f) A certified nurse-midwife is authorized to directly procure
18 supplies and devices, to order, obtain, and administer drugs and
19 diagnostic tests, to order laboratory and diagnostic testing, and to
20 receive reports that are necessary to his or her practice as a certified
21 nurse-midwife and consistent with nurse-midwifery education
22 preparation.

23 ~~SEC. 7.~~

24 *SEC. 8.* Section 2746.52 of the Business and Professions Code
25 is amended to read:

26 2746.52. (a) Notwithstanding Section 2746.5, the certificate
27 to practice nurse-midwifery authorizes the holder to perform and
28 repair episiotomies, and to repair first-degree and second-degree
29 lacerations of the perineum, in a licensed acute care hospital, as
30 defined in subdivision (a) of Section 1250 of the Health and Safety
31 Code, in a licensed alternate birth center, as defined in paragraph
32 (4) of subdivision (b) of Section 1204 of the Health and Safety
33 Code, or a nationally accredited birth center, and in a home
34 pursuant to paragraph (7) of subdivision (b) of Section 2746.5.

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

38 (1) Ensure that all complications are referred to a physician and
39 surgeon immediately.

1 (2) Ensure immediate care of patients who are in need of care
2 beyond the scope of practice of the certified nurse-midwife, or
3 provide emergency care for times when a physician and surgeon
4 is not available.

5 ~~SEC. 8.~~

6 *SEC. 9.* Section 2746.6 is added to the Business and Professions
7 Code, to read:

8 2746.6. A consultative relationship between a certified
9 nurse-midwife and a physician and surgeon shall not, by itself,
10 provide the basis for finding a physician and surgeon liable for
11 any act or omission of the certified nurse-midwife.

12 ~~SEC. 9.~~

13 *SEC. 10.* Section 4061 of the Business and Professions Code
14 is amended to read:

15 4061. (a) A manufacturer's sales representative shall not
16 distribute any dangerous drug or dangerous device as a
17 complimentary sample without the written request of a physician,
18 dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
19 pursuant to Section 3640.7. However, a certified nurse-midwife
20 who functions pursuant to Section 2746.51, a nurse practitioner
21 who functions pursuant to a standardized procedure described in
22 Section 2836.1, or protocol, a physician assistant who functions
23 pursuant to a protocol described in Section 3502.1, or a
24 naturopathic doctor who functions pursuant to a standardized
25 procedure or protocol described in Section 3640.5, may sign for
26 the request and receipt of complimentary samples of a dangerous
27 drug or dangerous device that has been identified in the
28 standardized procedure, protocol, or practice agreement.
29 Standardized procedures, protocols, and practice agreements shall
30 include specific approval by a physician. A review process,
31 consistent with the requirements of Section 2725, 3502.1, or
32 3640.5, of the complimentary samples requested and received by
33 a nurse practitioner, certified nurse-midwife, physician assistant,
34 or naturopathic doctor, shall be defined within the standardized
35 procedure, protocol, or practice agreement.

36 (b) Each written request shall contain the names and addresses
37 of the supplier and the requester, the name and quantity of the
38 specific dangerous drug desired, the name of the certified
39 nurse-midwife, nurse practitioner, physician assistant, or
40 naturopathic doctor, if applicable, receiving the samples pursuant

1 to this section, the date of receipt, and the name and quantity of
2 the dangerous drugs or dangerous devices provided. These records
3 shall be preserved by the supplier with the records required by
4 Section 4059.

5 (c) Nothing in this section is intended to expand the scope of
6 practice of a certified nurse-midwife, nurse practitioner, physician
7 assistant, or naturopathic doctor.

8 ~~SEC. 10.—Section 4076 of the Business and Professions Code~~
9 ~~is amended to read:~~

10 ~~4076.—(a) A pharmacist shall not dispense any prescription~~
11 ~~except in a container that meets the requirements of state and~~
12 ~~federal law and is correctly labeled with all of the following:~~

13 ~~(1) Except when the prescriber or the certified nurse-midwife~~
14 ~~who functions pursuant to Section 2746.51, the nurse practitioner~~
15 ~~who functions pursuant to a standardized procedure described in~~
16 ~~Section 2836.1 or protocol, the physician assistant who functions~~
17 ~~pursuant to Section 3502.1, the naturopathic doctor who functions~~
18 ~~pursuant to a standardized procedure or protocol described in~~
19 ~~Section 3640.5, or the pharmacist who functions pursuant to a~~
20 ~~policy, procedure, or protocol pursuant to Section 4052.1, 4052.2,~~
21 ~~or 4052.6 orders otherwise, either the manufacturer’s trade name~~
22 ~~of the drug or the generic name and the name of the manufacturer.~~
23 ~~Commonly used abbreviations may be used. Preparations~~
24 ~~containing two or more active ingredients may be identified by~~
25 ~~the manufacturer’s trade name or the commonly used name or the~~
26 ~~principal active ingredients.~~

27 ~~(2) The directions for the use of the drug.~~

28 ~~(3) The name of the patient or patients.~~

29 ~~(4) The name of the prescriber or, if applicable, the name of the~~
30 ~~certified nurse-midwife who functions pursuant to Section 2746.51,~~
31 ~~the nurse practitioner who functions pursuant to a standardized~~
32 ~~procedure described in Section 2836.1 or protocol, the physician~~
33 ~~assistant who functions pursuant to Section 3502.1, the naturopathic~~
34 ~~doctor who functions pursuant to a standardized procedure or~~
35 ~~protocol described in Section 3640.5, or the pharmacist who~~
36 ~~functions pursuant to a policy, procedure, or protocol pursuant to~~
37 ~~Section 4052.1, 4052.2, or 4052.6.~~

38 ~~(5) The date of issue.~~

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

- 1 ~~(7) The strength of the drug or drugs dispensed.~~
- 2 ~~(8) The quantity of the drug or drugs dispensed.~~
- 3 ~~(9) The expiration date of the effectiveness of the drug~~
- 4 ~~dispensed.~~
- 5 ~~(10) The condition or purpose for which the drug was prescribed~~
- 6 ~~if the condition or purpose is indicated on the prescription.~~
- 7 ~~(11) (A) Commencing January 1, 2006, the physical description~~
- 8 ~~of the dispensed medication, including its color, shape, and any~~
- 9 ~~identification code that appears on the tablets or capsules, except~~
- 10 ~~as follows:~~
- 11 ~~(i) Prescriptions dispensed by a veterinarian.~~
- 12 ~~(ii) An exemption from the requirements of this paragraph shall~~
- 13 ~~be granted to a new drug for the first 120 days that the drug is on~~
- 14 ~~the market and for the 90 days during which the national reference~~
- 15 ~~file has no description on file.~~
- 16 ~~(iii) Dispensed medications for which no physical description~~
- 17 ~~exists in any commercially available database.~~
- 18 ~~(B) This paragraph applies to outpatient pharmacies only.~~
- 19 ~~(C) The information required by this paragraph may be printed~~
- 20 ~~on an auxiliary label that is affixed to the prescription container.~~
- 21 ~~(D) This paragraph shall not become operative if the board,~~
- 22 ~~prior to January 1, 2006, adopts regulations that mandate the same~~
- 23 ~~labeling requirements set forth in this paragraph.~~
- 24 ~~(b) If a pharmacist dispenses a prescribed drug by means of a~~
- 25 ~~unit dose medication system, as defined by administrative~~
- 26 ~~regulation, for a patient in a skilled nursing, intermediate care, or~~
- 27 ~~other health care facility, the requirements of this section will be~~
- 28 ~~satisfied if the unit dose medication system contains the~~
- 29 ~~mentioned information or the information is otherwise readily~~
- 30 ~~available at the time of drug administration.~~
- 31 ~~(c) If a pharmacist dispenses a dangerous drug or device in a~~
- 32 ~~facility licensed pursuant to Section 1250 of the Health and Safety~~
- 33 ~~Code, it is not necessary to include on individual unit dose~~
- 34 ~~containers for a specific patient, the name of the certified~~
- 35 ~~nurse-midwife who functions pursuant to Section 2746.51, the~~
- 36 ~~nurse practitioner who functions pursuant to a standardized~~
- 37 ~~procedure described in Section 2836.1 or protocol, the physician~~
- 38 ~~assistant who functions pursuant to Section 3502.1, the naturopathic~~
- 39 ~~doctor who functions pursuant to a standardized procedure or~~
- 40 ~~protocol described in Section 3640.5, or the pharmacist who~~

1 functions pursuant to a policy, procedure, or protocol pursuant to
2 Section 4052.1, 4052.2, or 4052.6.

3 ~~(d) If a pharmacist dispenses a prescription drug for use in a
4 facility licensed pursuant to Section 1250 of the Health and Safety
5 Code, it is not necessary to include the information required in
6 paragraph (11) of subdivision (a) when the prescription drug is
7 administered to a patient by a person licensed under the Medical
8 Practice Act (Chapter 5 (commencing with Section 2000)), the
9 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
10 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
11 with Section 2840)), who is acting within his or her scope of
12 practice.~~

13 *SEC. 11. Section 4076 of the Business and Professions Code*
14 *is amended to read:*

15 4076. (a) A pharmacist shall not dispense any prescription
16 except in a container that meets the requirements of state and
17 federal law and is correctly labeled with all of the following:

18 (1) Except when the prescriber or the certified nurse-midwife
19 who functions pursuant to ~~a standardized procedure or protocol~~
20 ~~described in~~ Section 2746.51, the nurse practitioner who functions
21 pursuant to a standardized procedure described in Section 2836.1
22 or protocol, the physician assistant who functions pursuant to
23 Section 3502.1, the naturopathic doctor who functions pursuant
24 to a standardized procedure or protocol described in Section
25 3640.5, or the pharmacist who functions pursuant to a policy,
26 procedure, or protocol pursuant to Section 4052.1, 4052.2, or
27 4052.6 orders otherwise, either the manufacturer’s trade name of
28 the drug or the generic name and the name of the manufacturer.
29 Commonly used abbreviations may be used. Preparations
30 containing two or more active ingredients may be identified by
31 the manufacturer’s trade name or the commonly used name or the
32 principal active ingredients.

33 (2) The directions for the use of the drug.

34 (3) The name of the patient or patients.

35 (4) The name of the prescriber or, if applicable, the name of the
36 certified nurse-midwife who functions pursuant to ~~a standardized~~
37 ~~procedure or protocol described in~~ Section 2746.51, the nurse
38 practitioner who functions pursuant to a standardized procedure
39 described in Section 2836.1 or protocol, the physician assistant
40 who functions pursuant to Section 3502.1, the naturopathic doctor

1 who functions pursuant to a standardized procedure or protocol
2 described in Section 3640.5, or the pharmacist who functions
3 pursuant to a policy, procedure, or protocol pursuant to Section
4 4052.1, 4052.2, or 4052.6.

5 (5) The date of issue.

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

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

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

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

12 (10) The condition or purpose for which the drug was prescribed
13 if the condition or purpose is indicated on the prescription.

14 (11) (A) Commencing January 1, 2006, the physical description
15 of the dispensed medication, including its color, shape, and any
16 identification code that appears on the tablets or capsules, except
17 as follows:

18 (i) Prescriptions dispensed by a veterinarian.

19 (ii) An exemption from the requirements of this paragraph shall
20 be granted to a new drug for the first 120 days that the drug is on
21 the market and for the 90 days during which the national reference
22 file has no description on file.

23 (iii) Dispensed medications for which no physical description
24 exists in any commercially available database.

25 (B) This paragraph applies to outpatient pharmacies only.

26 (C) The information required by this paragraph may be printed
27 on an auxiliary label that is affixed to the prescription container.

28 (D) This paragraph shall not become operative if the board,
29 prior to January 1, 2006, adopts regulations that mandate the same
30 labeling requirements set forth in this paragraph.

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

38 (c) If a pharmacist dispenses a dangerous drug or device in a
39 facility licensed pursuant to Section 1250 of the Health and Safety
40 Code, it is not necessary to include on individual unit dose

1 containers for a specific patient, the name of the certified
 2 nurse-midwife who functions pursuant to a standardized procedure
 3 or protocol described in Section 2746.51, the nurse practitioner
 4 who functions pursuant to a standardized procedure described in
 5 Section 2836.1 or protocol, the physician assistant who functions
 6 pursuant to Section 3502.1, the naturopathic doctor who functions
 7 pursuant to a standardized procedure or protocol described in
 8 Section 3640.5, or the pharmacist who functions pursuant to a
 9 policy, procedure, or protocol pursuant to Section 4052.1, 4052.2,
 10 or 4052.6.

11 (d) If a pharmacist dispenses a prescription drug for use in a
 12 facility licensed pursuant to Section 1250 of the Health and Safety
 13 Code, it is not necessary to include the information required in
 14 paragraph (11) of subdivision (a) when the prescription drug is
 15 administered to a patient by a person licensed under the Medical
 16 Practice Act (Chapter 5 (commencing with Section 2000)), the
 17 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
 18 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
 19 with Section 2840)), who is acting within his or her scope of
 20 practice.

21 (e) A pharmacist shall use professional judgment to provide a
 22 patient with directions for use that enhance the patient's
 23 understanding of those directions, consistent with the prescriber's
 24 instructions.

25 ~~SEC. 11.~~

26 *SEC. 12.* Section 4170 of the Business and Professions Code
 27 is amended to read:

28 4170. (a) A prescriber shall not dispense drugs or dangerous
 29 devices to patients in his or her office or place of practice unless
 30 all of the following conditions are met:

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

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

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

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

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

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

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

18 (8) A certified nurse-midwife who functions pursuant to Section
19 2746.51, a nurse practitioner who functions pursuant to a
20 standardized procedure described in Section 2836.1, or protocol,
21 a physician assistant who functions pursuant to Section 3502.1, or
22 a naturopathic doctor who functions pursuant to Section 3640.5,
23 may hand to a patient of the supervising physician and surgeon,
24 if applicable, a properly labeled prescription drug prepackaged by
25 a physician and surgeon, a manufacturer as defined in this chapter,
26 or a pharmacist.

27 (b) The Medical Board of California, the State Board of
28 Optometry, the Bureau of Naturopathic Medicine, the Dental Board
29 of California, the Osteopathic Medical Board of California, the
30 Board of Registered Nursing, the Veterinary Medical Board, and
31 the Physician Assistant Committee shall have authority with the
32 California State Board of Pharmacy to ensure compliance with
33 this section, and those boards are specifically charged with the
34 enforcement of this chapter with respect to their respective
35 licensees.

36 (c) "Prescriber," as used in this section, means a person, who
37 holds a physician's and surgeon's certificate, a license to practice
38 optometry, a license to practice naturopathic medicine, a license
39 to practice dentistry, a license to practice veterinary medicine, or
40 a certificate to practice podiatry, and who is duly registered by the

1 Medical Board of California, the State Board of Optometry, the
2 Bureau of Naturopathic Medicine, the Dental Board of California,
3 the Veterinary Medical Board, or the Board of Osteopathic
4 Examiners of this state.

5 ~~SEC. 12.~~

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

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