

ASSEMBLY BILL

No. 1306

Introduced by Assembly Member Burke

February 27, 2015

An act to amend Sections 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 introduced, 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 bill would also require the board to create and appoint a Nurse-Midwifery Advisory Council consisting of certified nurse-midwives in good standing with experience in hospital and nonhospital practice settings, a nurse-midwife educator, as specified, and a consumer of midwifery care. This bill would require the council to make recommendations to the board on all matters related

to nurse-midwifery practice, education, and other matters specified by the board, and would require the council to meet regularly, but at least twice a year.

(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 primary health care services for women from adolescence beyond menopause, including, but not limited to, gynecologic and family planning services. The bill would authorize a certified nurse-midwife to practice in all settings, including, but not limited to, a home. 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. This bill would authorize a certified nurse-midwife to provide peripartum care in an out-of-hospital setting to low-risk women with uncomplicated singleton-term pregnancies who are expected to have uncomplicated birth.

(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 patient's 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.

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 2725.1 of the Business and Professions
2 Code is amended to read:
3 2725.1. (a) Notwithstanding any other ~~provision of law~~, a
4 registered nurse may dispense drugs or devices upon an order by
5 a licensed physician and surgeon or an order by a certified

1 nurse-midwife, nurse practitioner, or physician assistant issued
2 pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, if
3 the registered nurse is functioning within a licensed primary care
4 clinic as defined in subdivision (a) of Section 1204 of, or within
5 a clinic as defined in subdivision (b), (c), (h), or (j) of Section 1206
6 of, the Health and Safety Code.

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

21 (c) ~~Nothing in this~~ This section shall *not* be construed to limit
22 any other authority granted to a certified nurse-midwife pursuant
23 to Article 2.5 (commencing with Section 2746), to a nurse
24 practitioner pursuant to Article 8 (commencing with Section 2834),
25 or to a physician assistant pursuant to Chapter 7.7 (commencing
26 with Section 3500).

27 (d) ~~Nothing in this~~ This section shall *not* be construed to affect
28 the sites or types of health care facilities at which drugs or devices
29 are authorized to be dispensed pursuant to Chapter 9 (commencing
30 with Section 4000).

31 SEC. 2. Section 2746.2 of the Business and Professions Code
32 is amended to read:

33 2746.2. (a) Each applicant shall show by evidence satisfactory
34 to the board that he *or she* has met the educational standards
35 established by the board or has at least the equivalent thereof. ~~The~~
36 ~~board is authorized to appoint a committee of qualified physicians~~
37 ~~and nurses, including, but not limited to, obstetricians and~~
38 ~~nurse-midwives, to develop the necessary standards relating to~~
39 ~~educational requirements, ratios of nurse-midwives to supervising~~
40 ~~physicians, and associated matters: thereof, including evidence of~~

1 *current advanced level national certification by a certifying body*
2 *that meets standards established and approved by the board.*

3 *(b) The board shall create and appoint a Nurse-Midwifery*
4 *Advisory Council consisting of certified nurse-midwives in good*
5 *standing with experience in hospital and nonhospital practice*
6 *settings, a nurse-midwife educator who has demonstrated*
7 *familiarity with consumer needs, collegial practice and*
8 *accompanied liability, and related educational standards in the*
9 *delivery of maternal-child health care, and a consumer of*
10 *midwifery care. The council shall make recommendations to the*
11 *board on all matters related to nurse-midwifery practice,*
12 *education, and other matters as specified by the board. The council*
13 *shall meet regularly, but at least twice a year.*

14 SEC. 3. Section 2746.5 of the Business and Professions Code
15 is amended to read:

16 2746.5. (a) The certificate to practice nurse-midwifery
17 authorizes the holder, under the supervision of a licensed physician
18 and surgeon, to attend cases of normal childbirth and to provide
19 prenatal, intrapartum, and postpartum care, including
20 family-planning care, for the mother, and immediate care for the
21 newborn. holder to manage a full range of primary health care
22 services for women from adolescence to beyond menopause. These
23 services include, but are not limited to, primary health care,
24 gynecologic and family planning services, preconception care,
25 care during pregnancy, childbirth, and the postpartum period,
26 immediate care of the newborn, and treatment of male partners
27 for sexually transmitted infections. A certified nurse-midwife is
28 authorized to practice in all settings, including, but not limited to,
29 private practice, clinics, hospitals, birth centers, and homes.

30 (b) As used in this chapter, the practice of nurse-midwifery
31 constitutes the furthering or undertaking by any certified person,
32 under the supervision of a licensed physician and surgeon who has
33 current practice or training in obstetrics, to assist a woman in
34 childbirth so long as progress meets criteria accepted as normal.
35 All complications shall be referred to a physician immediately.
36 The practice of nurse-midwifery does not include the assisting of
37 childbirth by any artificial, forcible, or mechanical means, nor the
38 performance of any version. within a health care system provides
39 for consultation, collaboration, or referral as indicated by the
40 health status of the patient and the resources and medical

1 *personnel available in the setting of care. When providing*
2 *peripartum care in out-of-hospital settings, the certified*
3 *nurse-midwife shall only provide care to low-risk women with*
4 *uncomplicated singleton-term pregnancies who are expected to*
5 *have an uncomplicated birth. The practice of nurse-midwifery care*
6 *emphasizes informed consent, preventive care, and early detection*
7 *and referral of complications to physicians and surgeons. While*
8 *practicing in a hospital setting, the certified nurse-midwife shall*
9 *collaboratively care for women with more complex health needs.*

10 ~~(e) As used in this article, “supervision” shall not be construed~~
11 ~~to require the physical presence of the supervising physician.~~

12 ~~(d)~~

13 (c) A certified nurse-midwife is not authorized to practice
14 medicine and surgery by the provisions of this chapter.

15 ~~(e)~~

16 (d) Any regulations promulgated by a state department that
17 affect the scope of practice of a certified nurse-midwife shall be
18 developed in consultation with the board.

19 SEC. 4. Section 2746.51 of the Business and Professions Code
20 is amended to read:

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

28 ~~(1) The the~~ drugs or devices are furnished or ordered ~~incidentally~~
29 *related* to the provision of any of the following:

30 ~~(A)~~

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

33 ~~(B)~~

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

36 ~~(C)~~

37 (3) Care rendered, consistent with the certified nurse-midwife’s
38 educational preparation or for which clinical competency has been
39 established and maintained, to persons within a facility specified
40 in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the

1 Health and Safety Code, a clinic as specified in Section 1204 of
2 the Health and Safety Code, a general acute care hospital as defined
3 in subdivision (a) of Section 1250 of the Health and Safety Code,
4 a licensed birth center as defined in Section 1204.3 of the Health
5 and Safety Code, or a special hospital specified as a maternity
6 hospital in subdivision (f) of Section 1250 of the Health and Safety
7 Code.

8 *(4) Care rendered in a home pursuant to subdivision (a) of*
9 *Section 2746.5.*

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

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

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

22 ~~(C) The extent of physician and surgeon supervision.~~

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

26 ~~(3) If Schedule II or III controlled substances, as defined in~~
27 ~~Sections 11055 and 11056 of the Health and Safety Code, are~~
28 ~~furnished or ordered by a certified nurse-midwife, the controlled~~
29 ~~substances shall be furnished or ordered in accordance with a~~
30 ~~patient-specific protocol approved by the treating or supervising~~
31 ~~physician and surgeon. For Schedule II controlled substance~~
32 ~~protocols, the provision for furnishing the Schedule II controlled~~
33 ~~substance shall address the diagnosis of the illness, injury, or~~
34 ~~condition for which the Schedule II controlled substance is to be~~
35 ~~furnished.~~

36 ~~(4) The furnishing or ordering of drugs or devices by a certified~~
37 ~~nurse-midwife occurs under physician and surgeon supervision.~~
38 ~~For purposes of this section, no physician and surgeon shall~~
39 ~~supervise more than four certified nurse-midwives at one time.~~
40 ~~Physician and surgeon supervision shall not be construed to require~~

1 the physical presence of the physician, but does include all of the
2 following:

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

5 (B) Approval of the standardized procedure or protocol.

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

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

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

26 (3) ~~A physician and surgeon may determine the extent of~~
27 ~~supervision necessary pursuant to this section in the furnishing or~~
28 ~~ordering of drugs and devices.~~

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

34 (5)

35 (3) Certified nurse-midwives who are certified by the board and
36 hold an active furnishing number, who are currently authorized
37 through standardized procedures or protocols to furnish Schedule
38 II controlled substances, and who are registered with the United
39 States Drug Enforcement Administration shall provide
40 documentation of continuing education specific to the use of

1 Schedule II controlled substances in settings other than a hospital
2 based on standards developed by the board.

3 (c) Drugs or devices furnished or ordered by a certified
4 nurse-midwife may include Schedule II controlled substances
5 under the California Uniform Controlled Substances Act (Division
6 10 (commencing with Section 11000) of the Health and Safety
7 Code) ~~under the following conditions:~~

8 ~~(1) The~~ *when the* drugs and devices are furnished or ordered in
9 accordance with requirements referenced in ~~paragraphs (2) to (4),~~
10 ~~inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive,~~
11 ~~of subdivision (b).~~

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

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

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

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

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

1 (f) A certified nurse-midwife is authorized to directly procure
2 supplies and devices, to order, obtain, and administer drugs and
3 diagnostic tests, to order laboratory and diagnostic testing, and
4 to receive reports that are necessary to his or her practice as a
5 certified nurse-midwife and consistent with nurse-midwifery
6 education preparation.

7 SEC. 5. Section 2746.52 of the Business and Professions Code
8 is amended to read:

9 2746.52. (a) Notwithstanding Section 2746.5, the certificate
10 to practice nurse-midwifery authorizes the holder to perform and
11 repair episiotomies, and to repair first-degree and second-degree
12 lacerations of the perineum, in a licensed acute care hospital, as
13 defined in subdivision (a) of Section 1250 of the Health and Safety
14 Code, ~~and in a licensed alternate birth center, as defined in~~
15 ~~paragraph (4) of subdivision (b) of Section 1204 of the Health and~~
16 ~~Safety Code, but only if all of the following conditions are met:~~
17 ~~and in a home pursuant to subdivision (a) of Section 2746.5.~~

18 ~~(a) The supervising physician and surgeon and any backup~~
19 ~~physician and surgeon is credentialed to perform obstetrical care~~
20 ~~in the facility.~~

21 ~~(b) The episiotomies are performed pursuant to protocols~~
22 ~~developed and approved by all of the following:~~

23 ~~(1) The supervising physician and surgeon.~~

24 ~~(2) The certified nurse-midwife.~~

25 ~~(3) The director of the obstetrics department or the director of~~
26 ~~the family practice department, or both, if a physician and surgeon~~
27 ~~in the obstetrics department or the family practice department is~~
28 ~~a supervising physician and surgeon, or an equivalent person if~~
29 ~~there is no specifically identified obstetrics department or family~~
30 ~~practice department.~~

31 ~~(4) The interdisciplinary practices committee, if applicable.~~

32 ~~(5) The facility administrator or his or her designee.~~

33 ~~(e)~~

34 (b) The protocols, and the procedures which shall be developed
35 pursuant to the protocols, shall relate to the performance and repair
36 of episiotomies and the repair of certified nurse-midwife performing
37 and repairing first-degree and second-degree lacerations of the
38 perineum, and perineum shall do all both of the following:

39 (1) Ensure that all complications are referred to a physician and
40 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 ~~the supervising a~~ physician and surgeon is not on the premises. *available*.

~~(3) Establish the number of certified nurse-midwives that a supervising physician and surgeon may supervise.~~

SEC. 6. 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 it self, provide the basis for finding a physician and surgeon liable for any act or omission of the certified nurse-midwife.

SEC. 7. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) ~~No~~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 ~~a standardized procedure or protocol described in~~ Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, 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 specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, physician assistant, or 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. 8. Section 4076 of the Business and Professions Code is
9 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 ~~a standardized procedure or protocol~~
15 ~~described in Section 2746.51~~, the nurse practitioner who functions
16 pursuant to a standardized procedure described in Section 2836.1
17 or protocol, the physician assistant who functions pursuant to
18 Section 3502.1, the naturopathic doctor who functions pursuant
19 to a standardized procedure or protocol described in Section
20 3640.5, or the pharmacist who functions pursuant to a policy,
21 procedure, or protocol pursuant to Section 4052.1, 4052.2, or
22 4052.6 orders otherwise, either the manufacturer's trade name of
23 the drug or the generic name and the name of the manufacturer.
24 Commonly used abbreviations may be used. Preparations
25 containing two or more active ingredients may be identified by
26 the manufacturer's trade name or the commonly used name or the
27 principal active ingredients.

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

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

30 (4) The name of the prescriber or, if applicable, the name of the
31 certified nurse-midwife who functions pursuant to ~~a standardized~~
32 ~~procedure or protocol described in Section 2746.51~~, the nurse
33 practitioner who functions pursuant to a standardized procedure
34 described in Section 2836.1 or protocol, the physician assistant
35 who functions pursuant to Section 3502.1, the naturopathic doctor
36 who functions pursuant to a standardized procedure or protocol
37 described in Section 3640.5, or the pharmacist who functions
38 pursuant to a policy, procedure, or protocol pursuant to Section
39 4052.1, 4052.2, or 4052.6.

40 (5) The date of issue.

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

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

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

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

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

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

13 (i) Prescriptions dispensed by a veterinarian.

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

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

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

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

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

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

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

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

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

16 SEC. 9. Section 4170 of the Business and Professions Code is
17 amended to read:

18 4170. (a) ~~No~~A prescriber shall *not* dispense drugs or dangerous
19 devices to patients in his or her office or place of practice unless
20 all of the following conditions are met:

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

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

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

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

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

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

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

8 (8) A certified nurse-midwife who functions pursuant to a
9 ~~standardized procedure or protocol described in~~ Section 2746.51,
10 a nurse practitioner who functions pursuant to a standardized
11 procedure described in Section 2836.1, or protocol, a physician
12 assistant who functions pursuant to Section 3502.1, or a
13 naturopathic doctor who functions pursuant to Section 3640.5,
14 may hand to a patient of the supervising physician and surgeon a
15 properly labeled prescription drug prepackaged by a physician and
16 surgeon, a manufacturer as defined in this chapter, or a pharmacist.

17 (b) The Medical Board of California, the State Board of
18 Optometry, the Bureau of Naturopathic Medicine, the Dental Board
19 of California, the Osteopathic Medical Board of California, the
20 Board of Registered Nursing, the Veterinary Medical Board, and
21 the Physician Assistant Committee shall have authority with the
22 California State Board of Pharmacy to ensure compliance with
23 this section, and those boards are specifically charged with the
24 enforcement of this chapter with respect to their respective
25 licensees.

26 (c) "Prescriber," as used in this section, means a person, who
27 holds a physician's and surgeon's certificate, a license to practice
28 optometry, a license to practice naturopathic medicine, a license
29 to practice dentistry, a license to practice veterinary medicine, or
30 a certificate to practice podiatry, and who is duly registered by the
31 Medical Board of California, the State Board of Optometry, the
32 Bureau of Naturopathic Medicine, the Dental Board of California,
33 the Veterinary Medical Board, or the Board of Osteopathic
34 Examiners of this state.

35 SEC. 10. No reimbursement is required by this act pursuant to
36 Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 for a crime or infraction, within the meaning of Section 17556 of

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

O