

AMENDED IN ASSEMBLY JANUARY 13, 2014

AMENDED IN ASSEMBLY JUNE 20, 2013

AMENDED IN SENATE MAY 7, 2013

AMENDED IN SENATE APRIL 18, 2013

SENATE BILL

No. 306

Introduced by Senator Torres
(Principal coauthor: Assembly Member Cooley)

February 15, 2013

An act to amend ~~Sections 4170, 4180, and 4186~~ Section 2732 of the Business and Professions Code, relating to ~~pharmacy~~ nursing.

LEGISLATIVE COUNSEL'S DIGEST

SB 306, as amended, Torres. ~~Pharmacy: dangerous drugs and dangerous devices; automated drug delivery systems. Nursing: licensing criteria.~~

Existing law, the Nursing Practice Act, until January 1, 2016, provides for the licensure and regulation of registered nurses by the Board of Registered Nursing. Existing law prohibits a person from engaging in the practice of nursing, as defined, without holding a license which is in an active status issued under the act, except as specified. Existing law authorizes every licensee to be known as a registered nurse and to place the letters "R.N." after his or her name.

This bill would make technical, nonsubstantive changes to these provisions.

~~Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime.~~

~~Among other provisions, the Pharmacy Law prohibits a prescriber from dispensing dangerous drugs or dangerous devices, as defined, to patients in his or her office unless specified conditions are met. Existing law defines a prescriber for purposes of this provision to mean a person who holds a physician's and surgeon's certificate, or one of other specified health care licenses or certificates, and who is registered to engage in that practice with the appropriate board of this state. Existing law authorizes certain health care professionals, including a certified nurse-midwife or a nurse practitioner, as specified, to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.~~

~~This bill would revise the conditions under which a prescriber may dispense dangerous drugs and dangerous devices. The bill would require a health care professional who is licensed as specified, or his or her designee, to physically furnish the dangerous drug or device to the patient, to be identified, except as specified, by the drug or device manufacturer or wholesaler supplying the drug or device as the recipient of the drug or device, and as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation, and to provide the patient with an oral consultation, as specified. The bill would revise the definition of a prescriber to apply to a person who is licensed to prescribe and dispense dangerous drugs, including, but not limited to, the licensed health care professionals authorized pursuant to existing law. The bill would also authorize a registered nurse who functions within a licensed primary care clinic, federal or state government operated clinic, community or free clinic to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.~~

~~Existing law authorizes clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. Existing law also authorizes an automated drug delivery system, as defined, to be located in any clinic licensed by the board, as specified. Existing law requires an automated drug delivery system to collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.~~

~~This bill would authorize an automated drug delivery to be located in a group practice, as specified. The bill would authorize specified~~

entities, including a group practice, that uses an automated drug delivery system, as described, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon or other prescriber when permitted by law, and would make conforming and related changes.

The bill would also impose new conditions on an automated drug delivery system. Among other requirements, the bill would require that an automated drug delivery system be located within the clinic or office of the group practice, that its contents be secure from access or removal by unauthorized individuals, and that it maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug. The bill would also require that the record of transactions conducted through the automated drug delivery system be made available to authorized agents of the board. The bill would authorize the board to adopt regulations permitting the use of an automated drug delivery system that delivers dispensed medications directly to a patient.

Because of violation of the bill's requirements would be a crime, the 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~~-no.
State-mandated local program: ~~yes~~-no.

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

- 1 SECTION 1. Section 2732 of the Business and Professions
- 2 Code is amended to read:
- 3 2732. ~~No~~-(a) A person shall not engage in the practice of
- 4 nursing, as defined in Section 2725, without holding a license
- 5 which is in an active status ~~license~~ issued under pursuant to this
- 6 chapter except as otherwise provided in this act.
- 7 Every licensee-(b) A person licensed pursuant to this chapter
- 8 may be known as a registered nurse and may place the letter "R.
- 9 N." after his or her name.

1 SECTION 1. ~~Section 4170 of the Business and Professions Code~~
2 ~~is amended to read:~~

3 ~~4170. (a) No prescriber shall dispense dangerous drugs or~~
4 ~~dangerous devices to patients in his or her office or place of~~
5 ~~practice unless all of the following conditions are met:~~

6 ~~(1) The dangerous drugs or dangerous devices are dispensed to~~
7 ~~the prescriber's own patient. A health care professional who is~~
8 ~~licensed as described in this section, or his or her designee, shall~~
9 ~~physically furnish the dangerous drug or device to the patient.~~

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

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

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

21 ~~(5) Unless the prescriber is employed by or under contract to a~~
22 ~~clinic or group practice that is licensed by the board pursuant to~~
23 ~~Section 4180, the prescriber is identified by the drug manufacturer~~
24 ~~or wholesaler supplying the drugs as the recipient of the drugs and~~
25 ~~identified by name and registration number as the recipient in all~~
26 ~~invoices, bills of lading, state or federal order forms, and other~~
27 ~~documentation. As the recipient of the drugs, the prescriber is~~
28 ~~responsible for ensuring that the drugs are securely and safely~~
29 ~~stored prior to dispensing and is responsible for maintaining all~~
30 ~~required records regarding the receipt, storage, and dispensing or~~
31 ~~other disposition of all drugs and devices.~~

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

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

39 ~~(8) The prescriber provides the patient with an oral consultation~~
40 ~~regarding issues that the prescriber, in his or her professional~~

1 judgment, deems necessary to ensure the safe and effective use of
2 the prescribed drug or device. The oral consultation shall include
3 all subjects that pharmacists are required to discuss pursuant to
4 regulations adopted by the board pursuant to Section 4005.

5 (9) ~~A certified nurse-midwife who functions pursuant to a~~
6 ~~standardized procedure or protocol described in Section 2746.51,~~
7 ~~a nurse practitioner who functions pursuant to a standardized~~
8 ~~procedure described in Section 2836.1, or protocol, a physician~~
9 ~~assistant who functions pursuant to Section 3502.1, a registered~~
10 ~~nurse who functions pursuant to Section 2725.1, or a naturopathic~~
11 ~~doctor who functions pursuant to Section 3640.5, may hand to a~~
12 ~~patient of the supervising physician and surgeon a properly labeled~~
13 ~~prescription drug prepackaged by a physician and surgeon, a~~
14 ~~manufacturer as defined in this chapter, or a pharmacist. Nothing~~
15 ~~in this section shall preclude the use of an automated drug delivery~~
16 ~~system described in Section 4186.~~

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 is~~
27 ~~licensed to prescribe and dispense dangerous drugs and devices,~~
28 ~~including, but not limited to, a person who holds a physician’s and~~
29 ~~surgeon’s certificate, a license to practice optometry, a license to~~
30 ~~practice naturopathic medicine, a license to practice dentistry, a~~
31 ~~license to practice veterinary medicine, or a certificate to practice~~
32 ~~podiatry, and who is duly registered by the Medical Board of~~
33 ~~California, the State Board of Optometry, the Bureau of~~
34 ~~Naturopathic Medicine, the Dental Board of California, the~~
35 ~~Veterinary Medical Board, or the Board of Osteopathic Examiners~~
36 ~~of this state.~~

37 (d) ~~This section shall not prevent a group practice, licensed~~
38 ~~pursuant to Section 4180, from owning an inventory of dangerous~~
39 ~~drugs and devices and dispensing the drugs and devices from the~~

1 inventory owned by the group practice provided that the following
2 conditions are met:

3 (1) Each prescriber dispenses dangerous drugs or devices only
4 to the patients seen or treated by that prescriber, and not to the
5 patient of any other prescriber in the group practice, and the drugs
6 or devices are packaged, labeled, and recorded in accordance with
7 paragraph (4) of subdivision (a).

8 (2) The group practice identifies a responsible prescriber within
9 the group practice who shall be named by the drug manufacturer
10 or wholesaler supplying the drugs as the recipient of the drugs on
11 all invoices, bills of lading, state or federal order forms, and other
12 documentation, and who shall be responsible for the record-keeping
13 and storage of the drug inventory.

14 (3) Records are maintained by each prescriber to identify the
15 identity of the patient and the name, strength, quantity, and
16 directions for use for each dangerous drug dispensed by the
17 prescriber to his or her patient.

18 (4) A daily dispensing log or some other paper or electronic
19 record is created each day, and maintained by the group practice,
20 to identify both of the following:

21 (A) A daily starting inventory of all dangerous drugs that are
22 jointly owned by the prescribers who comprise the group practice.

23 (B) The name, strength, and quantity of all dangerous drugs
24 dispensed by each prescriber.

25 (e) A prescriber employed by, or under contract to, a clinic or
26 group practice licensed under Section 4180 may dispense drugs
27 that are owned by the clinic or group practice.

28 (f) (1) For purposes of this section, a dangerous drug is owned
29 if it is delivered to the possession of a prescriber, clinic, or group
30 practice, and each prescriber, clinic, or group practice has
31 responsibility for the security and recordkeeping associated with
32 possession of the dangerous drugs, regardless of the person or
33 entity responsible for payment for the dangerous drug inventory.

34 (2) For the purposes of this section, "group practice" means
35 more than one prescriber practicing under a single professional
36 corporation or license, including a medical group or risk-bearing
37 organization as defined in the Knox-Keene Health Care Service
38 Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340)
39 of Division 2 of the Health and Safety Code).

SEC. 2.—Section 4180 of the Business and Professions Code is amended to read:

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following entities may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, or other prescriber when permitted by law, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice, as defined in Section 4170, that uses an automated drug delivery system, as described in Section 4186.

(2) The clinic or group practice shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic or group practice shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic or group practice shall notify the board of any change in the address of the clinic or group practice on a form furnished by the board.

SEC. 3.—Section 4186 of the Business and Professions Code is amended to read:

1 ~~4186. (a) An automated drug delivery system, as defined in~~
2 ~~subdivision (i), may be located in any clinic or group practice~~
3 ~~licensed by the board as described in Section 4180.~~

4 ~~(b) (1) If an automated drug delivery system is located in a~~
5 ~~clinic, the clinic shall develop and implement written policies and~~
6 ~~procedures to ensure safety, accuracy, accountability, security,~~
7 ~~patient confidentiality, and maintenance of the quality, potency,~~
8 ~~and purity of drugs. All policies and procedures shall be maintained~~
9 ~~at the location where the automated drug system is being used.~~

10 ~~(2) If an automated drug delivery system is located in a group~~
11 ~~practice, the group practice shall develop and implement written~~
12 ~~policies and procedures to ensure safety, accuracy, accountability,~~
13 ~~security, patient confidentiality, and maintenance of the quality,~~
14 ~~potency, and purity of drugs. All prescribers who will be dispensing~~
15 ~~drugs from the automated drug delivery system and all health care~~
16 ~~professionals and delegated personnel authorized to stock, refill,~~
17 ~~or retrieve the drugs inventory from the automated drug delivery~~
18 ~~system shall be required to comply with the policies and procedures~~
19 ~~developed by the group practice. All policies and procedures shall~~
20 ~~be maintained at the location where the automated drug system is~~
21 ~~being used.~~

22 ~~(c) Drugs shall be removed from the automated drug delivery~~
23 ~~system only upon authorization by a pharmacist or prescriber after~~
24 ~~the pharmacist or prescriber has reviewed the prescription and the~~
25 ~~patient's profile for potential contraindications and adverse drug~~
26 ~~reactions. Drugs removed from the automated drug delivery system~~
27 ~~shall be provided to the patient by a health professional licensed~~
28 ~~pursuant to this division or an individual operating under the~~
29 ~~supervision of the prescriber.~~

30 ~~(d) The stocking of an automated drug delivery system shall be~~
31 ~~performed by a pharmacist or, in a clinic or group practice, by a~~
32 ~~prescriber or a designee of the prescriber.~~

33 ~~(e) Review of the drugs contained within, and the operation and~~
34 ~~maintenance of, the automated drug delivery system shall be the~~
35 ~~responsibility of the clinic in a clinic setting or by the responsible~~
36 ~~prescriber in a group practice. The review shall be conducted on~~
37 ~~a monthly basis by a pharmacist or responsible prescriber and shall~~
38 ~~include a physical inspection of the drugs in the automated drug~~
39 ~~delivery system, an inspection of the automated drug delivery~~
40 ~~system machine for cleanliness, and a review of all transaction~~

1 records in order to verify the security and accountability of the
2 system.

3 (f) The automated drug delivery system used at the clinic or
4 group practice shall provide for patient consultation pursuant to
5 Section 1707.2 of Title 16 of the California Code of Regulations
6 with a pharmacist via a telecommunications link that has two-way
7 audio and video, unless a consultation is provided by the prescriber
8 pursuant to paragraph (8) of subdivision (a) of Section 4170.

9 (g) A pharmacist operating the automated drug delivery system
10 shall be licensed in California.

11 (h) Drugs dispensed from the automated drug delivery system
12 shall comply with the labeling requirements in Section 4076.

13 (i) For purposes of this section, an “automated drug delivery
14 system” means a mechanical system controlled remotely by a
15 pharmacist, or, if used to facilitate prescriber dispensing by a
16 prescriber, that performs operations or activities, other than
17 compounding or administration, relative to the storage, dispensing,
18 or distribution of prepackaged dangerous drugs or dangerous
19 devices. An automated drug delivery system shall collect, control,
20 and maintain all transaction information to accurately track the
21 movement of drugs into and out of the system for security,
22 accuracy, and accountability and shall meet all of the following
23 requirements:

24 (1) The system shall be located within the clinic or office of the
25 group practice, and its contents shall be secure from access or
26 removal by unauthorized individuals.

27 (2) A policy and procedure manual shall be developed and
28 maintained and shall include the type or name of the system
29 including a serial number or other identifying nomenclature and
30 a description of the security provisions, stocking processes, and
31 other documentation practices of the clinic or group practice.

32 (3) The system shall have a method to ensure security of the
33 system to prevent unauthorized access to dangerous drugs or
34 devices contained within the system. The method may include the
35 use of electronic passwords, biometric identification, including
36 optic scanning or fingerprint, or other coded identification.

37 (4) The clinic or group practice shall employ a process of filling
38 and stocking the system with drugs. The stocking or restocking of
39 a drug shall only be completed by a pharmacist, prescriber, or

1 personnel designated by the pharmacist or prescriber and all of the
2 following shall apply:

3 (A) The cartridges or containers to be stocked or restocked shall
4 be provided by a licensed wholesale drug distributor or repackaged
5 by the pharmacy or prescriber in compliance with state and federal
6 law. The licensed wholesale drug distributor shall have a method
7 of receiving and disposing of rejected, expired, or unused
8 medications consistent with state or federal law.

9 (B) The individual cartridge or container shall be transported
10 to the dispensing site in a secure, tamper-evident package.

11 (C) The system shall use a bar code verification, electronic
12 verification, weight verification, radio frequency identification, or
13 similar process to ensure that the cartridge or container is accurately
14 stocked or restocked into the automated system. The system shall
15 provide for alerts to the responsible pharmacist or prescriber if a
16 cartridge or container is not recorded in the automated system.

17 (D) The pharmacist or prescriber responsible for the dispensed
18 drug shall be responsible if the cartridge or container is stocked
19 or restocked incorrectly by the personnel designated to load the
20 cartridges or containers.

21 (5) The system shall maintain an electronic or hard copy record
22 of medication filled into the system, including the product
23 identification, lot number, and expiration date.

24 (6) The system shall maintain a readily retrievable electronic
25 record to identify all pharmacists, registered pharmacy technicians,
26 prescribers, and all other personnel involved in the dispensing of
27 a drug.

28 (7) The system shall be able to comply with product recalls
29 generated by any manufacturer or distributor and shall have a
30 process in place to isolate affected lot numbers.

31 (8) The record of transactions conducted through the automated
32 drug delivery system shall be available to authorized agents of the
33 board. The record of transactions shall, only to the extent
34 authorized or permitted by state or federal law, include the
35 following:

36 (A) Name of the patient.

37 (B) Name, strength, and dosage form of the drug product
38 dispensed.

39 (C) Quantity of drug dispensed.

40 (D) Date and time of dispensing.

1 (E) ~~Prescription number or other unique serial number assigned~~
2 ~~to the transaction.~~

3 (F) ~~Name of prescriber.~~

4 (G) ~~Identity of the pharmacist who approved the prescription,~~
5 ~~or of the prescriber.~~

6 (H) ~~Identity of the person to whom the drug was released.~~

7 (9) ~~Unless the prescriber provides consultation pursuant to~~
8 ~~regulations adopted by the board pursuant to Section 4005, the~~
9 ~~system shall provide patients with telephonic access to consultation~~
10 ~~by a California-licensed pharmacist.~~

11 (10) ~~In the case of dangerous drugs that require reconstitution,~~
12 ~~the prescriber or his or her designee shall reconstitute the~~
13 ~~medication for the patient.~~

14 (j) ~~The board is authorized to adopt regulations authorizing the~~
15 ~~use of an automated drug delivery system that delivers dispensed~~
16 ~~medications directly to a patient. The regulations shall be based,~~
17 ~~in part, upon the board's assessment of the safety of the systems.~~

18 ~~SEC. 4. No reimbursement is required by this act pursuant to~~
19 ~~Section 6 of Article XIII B of the California Constitution because~~
20 ~~the only costs that may be incurred by a local agency or school~~
21 ~~district will be incurred because this act creates a new crime or~~
22 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
23 ~~for a crime or infraction, within the meaning of Section 17556 of~~
24 ~~the Government Code, or changes the definition of a crime within~~
25 ~~the meaning of Section 6 of Article XIII B of the California~~
26 ~~Constitution.~~