

AMENDED IN ASSEMBLY APRIL 17, 2001

AMENDED IN ASSEMBLY MARCH 27, 2001

CALIFORNIA LEGISLATURE—2001-02 REGULAR SESSION

ASSEMBLY BILL

No. 809

Introduced by Assembly Member Salinas

February 22, 2001

An act to add ~~Sections 4017.5, 4040.2, and 4110.1~~ *Section 4186* to the Business and Professions Code, relating to ~~remote pharmacies~~ *automated drug delivery systems*, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 809, as amended, Salinas. ~~Remote pharmacies~~ *Automated drug delivery systems*.

Existing law provides for the licensing and regulation of pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs.

This bill would authorize ~~the board to issue a remote pharmacy license, allowing a pharmacy to use an automated dispensing device, if an applicant can establish that there is a shortage of pharmacists in the proposed service area~~ *automated drug delivery systems to be located in specified clinics located in areas with pharmacist shortages. The bill would require clinics with automated drug delivery systems to develop and implement written policies and procedures.* The bill would also require patient consultation with a pharmacist via a telecommunications link with 2-way audio and video capabilities, and would require that the pharmacist ~~have access to relevant medical~~

~~information— review the prescription and the patient profile, that he or she be located in California, and that he or she initiate and authorize the release of the dangerous drugs or devices from the automated dispensing device drug delivery system. The bill would also further require a pharmacist to —be responsible for— perform the stocking, inventory maintenance, and use of the automated dispensing device review of the operation and maintenance of the system. The dangerous drugs and devices delivered to the remote pharmacy would have to be signed for, and received by, either the pharmacist in charge, or, if he or she were unavailable, a pharmacist that he or she designated. The bill would require the California State Board of Pharmacy to adopt regulations specifying other activities a pharmacist operating a remote pharmacy an automated drug delivery system may engage in.~~

Because this bill would provide additional ~~fees and~~ penalties that would be deposited into the Pharmacy Board Contingent Fund which is continuously appropriated, the bill would make an appropriation.

Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

Because operating a ~~remote pharmacy an automated drug delivery system~~ in violation of the bill’s requirements would be a crime, the bill would impose a state-mandated local program by creating a new crime.

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

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

Vote: ²/₃. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

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

- 1 SECTION 1. ~~Section 4017.5 is added to the Business and~~
- 2 ~~Professions Code, to read:~~
- 3 4017.5. ~~“Automated dispensing device” means a device that~~
- 4 ~~contains secured dangerous drugs and dangerous devices, and~~
- 5 ~~from which dangerous drugs and dangerous devices are packaged~~
- 6 ~~and labeled for dispensing to a patient or patient’s agent.~~
- 7 SEC. 2. ~~Section 4040.2 is added to the Business and~~
- 8 ~~Professions Code, to read:~~



1 ~~4040.2.—“Remote pharmacy” is a licensed pharmacy that uses~~
2 ~~an automated dispensing device, as defined in Section 4017.5, to~~
3 ~~dispense dangerous drugs and dangerous devices to patients from~~
4 ~~that location pursuant to Section 4110.1. Each remote pharmacy~~
5 ~~site shall be individually licensed with the board.~~

6 ~~SEC. 3.— Section 4110.1 is added to the Business and~~
7 ~~Professions Code, to read:~~

8 ~~4110.1.— (a) The board may issue a license to operate a remote~~
9 ~~pharmacy provided that the applicant can establish that a shortage~~
10 ~~of pharmacists exists in the remote pharmacy’s proposed service~~
11 ~~area using the method defined in Appendix F of Chapter 1 of Part~~
12 ~~5 of Title 42 of the Code of Federal Regulations.~~

13 ~~(b) The automated dispensing device used at the remote~~
14 ~~pharmacy shall permit patient consultation with a pharmacist via~~
15 ~~a telecommunications link that has two-way audio and video. Only~~
16 ~~a pharmacist may initiate and authorize the release of the~~
17 ~~dangerous drug or dangerous device from the automated~~
18 ~~dispensing device. The pharmacist operating the automated~~
19 ~~dispensing device shall be located in California, shall provide~~
20 ~~consultation services, and shall have access to the prescription,~~
21 ~~patient profile, or other relevant medical information.~~

22 ~~(c) The dangerous drugs and dangerous devices dispensed at~~
23 ~~the remote pharmacy shall be provided to the patient or the~~
24 ~~patient’s agent by a pharmacy technician or a licensed health care~~
25 ~~provider after patient consultation with a pharmacist has been~~
26 ~~initiated.~~

27 ~~(d) The remote pharmacy shall be subject to all federal and state~~
28 ~~laws that apply to pharmacies, except for those statutes or~~
29 ~~regulations specifically waived by the board.~~

30 ~~(e) The stocking, inventory maintenance, and use of the~~
31 ~~automated dispensing devices shall be the responsibility of a~~
32 ~~pharmacist. The dangerous drugs and dangerous devices ordered~~
33 ~~for dispensing at the remote pharmacy shall be delivered to the~~
34 ~~licensed premises and signed for, and received by, the~~
35 ~~pharmacist in charge or, in his or her absence, another pharmacist~~
36 ~~designated by the pharmacist in charge.~~

37 ~~(f) The fee for licensure of a remote pharmacy shall be the same~~
38 ~~as for a pharmacy licensed pursuant to Section 4110.~~

39 ~~SEC. 4.~~



1 SECTION 1. Section 4186 is added to the Business and
2 Professions Code, to read:

3 4186. (a) Automated drug delivery systems, as defined in
4 subdivision (h), may be located in any clinic licensed by the board
5 pursuant to Section 4180 and located in an area with a pharmacist
6 shortage, as determined by the method defined in Appendix F of
7 Chapter 1 of Part 5 of Title 42 of the Code of Federal Regulations.
8 If an automated drug delivery system is located in a clinic, the
9 clinic shall develop and implement written policies and procedures
10 to ensure safety, accuracy, accountability, security, patient
11 confidentiality, and maintenance of the quality, potency, and
12 purity of drugs. All policies and procedures shall be maintained at
13 the location where the automated drug system is being used.

14 (b) Drugs shall be removed from the automated drug delivery
15 system only upon authorization by a pharmacist after the
16 pharmacist has reviewed the prescription and the patient's profile
17 for potential contraindications and adverse drug reactions. Drugs
18 removed from the automated drug delivery system shall be
19 provided to the patient by a health professional licensed pursuant
20 to this division.

21 (c) The stocking of an automated drug delivery system shall be
22 performed by a pharmacist.

23 (d) Review of the drugs contained within, and the operation
24 and maintenance of, the automated drug delivery system shall be
25 the responsibility of the clinic. The review shall be conducted on
26 a monthly basis by a pharmacist and shall include a physical
27 inspection of the drugs in the automated drug delivery system, an
28 inspection of the automated drug delivery system machine for
29 cleanliness, and a review of all transaction records in order to
30 verify the security and accountability of the system.

31 (e) The automated drug delivery system used at the clinic shall
32 provide for patient consultation pursuant to Section 1707.2 of Title
33 16 of the California Code of Regulations with a pharmacist via a
34 telecommunications link that has two-way audio and video.

35 (f) The pharmacist operating the automated drug delivery
36 system shall be located in California.

37 (g) Drugs dispensed from the automated drug delivery system
38 shall comply with the labeling requirements in Section 4076.

39 (h) For purposes of this section, an "automated drug delivery
40 system" means a mechanical system controlled remotely by a



1 *pharmacist that performs operations or activities, other than*
2 *compounding or administration, relative to the storage,*
3 *dispensing, or distribution of dangerous drugs or dangerous*
4 *devices. An automated drug delivery system shall collect, control,*
5 *and maintain all transaction information to accurately track the*
6 *movement of drugs into and out of the system for security,*
7 *accuracy, and accountability.*

8 *SEC. 2.* The California State Board of Pharmacy shall adopt
9 regulations on or before January 1, 2003, specifying the other
10 activities a pharmacist may engage in when operating an
11 automated ~~dispensing device~~ *drug delivery system* pursuant to
12 Section ~~4410.1~~ *4186* of the Business and Professions Code.

13 ~~SEC. 5.~~

14 *SEC. 3.* No reimbursement is required by this act pursuant to
15 Section 6 of Article XIII B of the California Constitution because
16 the only costs that may be incurred by a local agency or school
17 district will be incurred because this act creates a new crime or
18 infraction, eliminates a crime or infraction, or changes the penalty
19 for a crime or infraction, within the meaning of Section 17556 of
20 the Government Code, or changes the definition of a crime within
21 the meaning of Section 6 of Article XIII B of the California
22 Constitution.

