

AMENDED IN ASSEMBLY AUGUST 20, 1998

AMENDED IN ASSEMBLY JUNE 25, 1998

AMENDED IN SENATE MARCH 17, 1998

SENATE BILL

No. 1606

Introduced by Senator Lewis

February 11, 1998

An act to amend Section 1261.5 of, and to add Section 1261.6 to, the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 1606, as amended, Lewis. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy, under the jurisdiction of the California State Board of Pharmacy. It prescribes requirements for the dispensing of drugs, as specified.

Existing law provides for the licensing and regulation of health facilities, including skilled nursing facilities and intermediate care facilities, administered by the State Department of Health Services.

Existing law limits the number of oral dosage form or suppository form drugs provided by a pharmacy to a skilled nursing facility or intermediate care facility for storage in a secured emergency supplies container to 24 and authorizes the department to provide for other specified limitations.

This bill would provide, commencing July 1, 1999, that limitations imposed pursuant to these provisions on the

number or quantity of oral or suppository form drugs provided by a pharmacy to a skilled nursing or intermediate care facility shall not apply to an automated drug delivery system, as defined by the bill, when a pharmacist controls access to the drugs.

The bill would also provide, commencing July 1, 1999, that access to an automated drug delivery system shall be limited to personnel authorized by law to administer drugs and who have an access code to these systems, would set forth requirements of a health facility and pharmacy with regard to the installation, operation, and review of an automated drug delivery system, and would exempt an automated drug delivery system from certain drug labeling requirements.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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

1 SECTION 1. Section 1261.5 of the Health and Safety
 2 Code is amended to read:
 3 1261.5. (a) The number of oral dosage form or
 4 suppository form drugs provided by a pharmacy to a
 5 health facility licensed pursuant to subdivision (c), (d),
 6 or both (c) and (d), of Section 1250 for storage in a
 7 secured emergency supplies container, pursuant to
 8 Section 4035 of the Business and Professions Code, shall
 9 be limited to 24. The State Department of Health Services
 10 may limit the number of doses of each drug available to
 11 not more than four doses of any separate drug dosage
 12 form in each emergency supply.
 13 (b) Any limitations established pursuant to subdivision
 14 (a) on the number and quantity of oral dosage or
 15 suppository form drugs provided by a pharmacy to a
 16 health facility licensed pursuant to subdivision (c), (d),
 17 or both (c) and (d) of Section 1250 for storage in a secured
 18 emergency supplies container shall not apply to an
 19 automated drug delivery system, as defined in Section
 20 1261.6, when a pharmacist controls access to the drugs.
 21 This subdivision shall become operative July 1, 1999.



1 SEC. 2. Section 1261.6 is added to the Health and
2 Safety Code, to read:

3 1261.6. (a) For purposes of this section and Section
4 1261.5, an “automated drug delivery system” means a
5 mechanical system that performs operations or activities,
6 other than compounding or administration, relative to
7 the storage, dispensing, or distribution of ~~drugs and that~~
8 ~~collects, controls, and maintains all transaction~~
9 ~~information so that it accurately reflects the complete~~
10 ~~removal of drugs and provides for security and~~
11 ~~accountability of drug products.~~

12 ~~(b) Access to an automated drug delivery system shall~~
13 ~~be limited to personnel authorized by law to administer~~
14 ~~drugs and who have an access code to the system.~~

15 ~~(c) (1) Prior to the installation of an automated drug~~
16 ~~delivery system, the facility and the pharmacy shall~~
17 ~~develop written policies and procedures to ensure safety,~~
18 ~~accuracy, accountability, security, and patient~~
19 ~~confidentiality, and to define access and limits to access~~
20 ~~to equipment and drugs.~~

21 ~~(2) All policies and procedures shall be maintained at~~
22 ~~the location where the system is being used.~~

23 ~~(d) Drugs dispensed from the automated drug~~
24 ~~delivery system shall be limited to the following:~~

25 ~~(1) Drugs ordered by a prescriber for a patient of the~~
26 ~~facility for administration prior to the next scheduled~~
27 ~~delivery from the pharmacy, or 72 hours, whichever is~~
28 ~~less. These drugs shall be dispensed only upon~~
29 ~~authorization by a pharmacist after the pharmacist has~~
30 ~~reviewed the prescriber’s order.~~

31 ~~(2) Drugs that a prescriber has ordered for a patient~~
32 ~~on an as needed basis, if the utilization of those drugs is~~
33 ~~subject to the ongoing review by a pharmacist.~~

34 ~~(3) Drugs designated by the patient care policy~~
35 ~~committee or pharmaceutical service committee of the~~
36 ~~facility as emergency drugs or acute onset drugs. These~~
37 ~~drugs may be dispensed pursuant to the order of a~~
38 ~~prescriber for emergency or immediate administration to~~
39 ~~a patient of the facility.~~



1 ~~(e)~~drugs. An automated drug delivery system shall
2 collect, control, and maintain all transaction information
3 to accurately track the movement of drugs into and out
4 of the system for security, accuracy, and accountability.

5 (b) Transaction information shall be made readily
6 available in a written format for review and inspection by
7 individuals authorized by law. These records shall be
8 maintained in the facility for a minimum of three years.

9 (c) Individualized and specific access to automated
10 drug delivery systems shall be limited to facility and
11 contract personnel authorized by law to administer
12 drugs.

13 (d) (1) The facility and the pharmacy shall develop
14 and implement written policies and procedures to ensure
15 safety, accuracy, accountability, security, patient
16 confidentiality, and maintenance of the quality, potency,
17 and purity of stored drugs. Policies and procedures shall
18 define access to the automated drug delivery system and
19 limits to access to equipment and drugs.

20 (2) All policies and procedures shall be maintained at
21 the location where the automated drug delivery system
22 is being used.

23 (e) Drugs removed from the automated drug delivery
24 system shall be limited to the following:

25 (1) A new drug order given by a prescriber for a
26 patient of the facility for administration prior to the next
27 scheduled delivery from the pharmacy, or 72 hours,
28 whichever is less. The drugs shall be retrieved only upon
29 authorization by a pharmacist and after the pharmacist
30 has reviewed the prescriber's order and the patient's
31 profile for potential contraindications and adverse drug
32 reactions.

33 (2) Drugs that a prescriber has ordered for a patient
34 on an as-needed basis, if the utilization and retrieval of
35 those drugs are subject to ongoing review by a
36 pharmacist.

37 (3) Drugs designed by the patient care policy
38 committee or pharmaceutical service committee of the
39 facility as emergency drugs or acute onset drugs. These
40 drugs may be retrieved from an automated drug delivery



1 system pursuant to the order of a prescriber for
2 emergency or immediate administration to a patient of
3 the facility. Within 48 hours after retrieval under this
4 paragraph, the case shall be reviewed by a pharmacist.

5 (f) The stocking of an automated drug delivery system
6 shall be performed by a pharmacist. If the automated
7 drug delivery system utilizes removable packets or
8 drawers, *or similar technology*, the stocking system may
9 be done outside of the facility and be delivered to the
10 facility if all of the following conditions are met:

11 (1) The task of placing drugs into the removable
12 packets or drawers is performed by a pharmacist or by
13 ~~pharmacy personnel~~, *an intern pharmacist, or a*
14 *pharmacy technician working under the direct*
15 supervision of a pharmacist.

16 (2) The removable packets or drawers are transported
17 ~~to~~ *between the pharmacy and* the facility in a secure
18 tamper-evident container.

19 (3) The facility, in conjunction with the pharmacy, has
20 developed policies and procedures to ensure that the
21 packets or drawers are properly placed into the
22 automated drug delivery system.

23 ~~(f)~~

24 (g) Review of the drugs contained within, and the
25 operation and maintenance of, the automated drug
26 delivery system shall be done in accordance with law and
27 shall be the responsibility of the pharmacy. The review,
28 which shall be conducted on a ~~bimonthly~~ *monthly*
29 *basis, by a pharmacist and* shall include a physical
30 inspection of the drugs in the automated drug delivery
31 system, an inspection of the automated drug delivery
32 system machine for cleanliness, and a review of ~~the~~
33 ~~dispensing and stocking~~ *all transaction* records in order to
34 verify the security and accountability of the system.

35 ~~(g)~~

36 (h) Drugs dispensed from an automated drug delivery
37 system that meets the requirements of this section shall
38 not be subject to the labeling requirements of Section
39 4076 of the Business and Professions Code or Section
40 111480 of this code if the drugs to be placed into the



1 automated drug delivery system are in unit dose
2 packaging or unit of use and if the information required
3 by Section 4076 of the Business and Professions Code and
4 Section 111480 of this code is readily available at the time
5 of drug administration.

6 (h) This section shall become operative July 1, 1999.

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