

AMENDED IN ASSEMBLY JUNE 18, 2014

AMENDED IN ASSEMBLY JUNE 5, 2014

AMENDED IN SENATE MAY 5, 2014

AMENDED IN SENATE APRIL 10, 2014

AMENDED IN SENATE MARCH 28, 2014

**SENATE BILL**

**No. 1039**

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**Introduced by Senator Hernandez**

February 18, 2014

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An act to amend Sections 4052.6 and 4115 of, and to add Sections 4119.6 and 4119.7 to, the Business and Professions Code, and to amend Sections 11150 and 11210 of, and to add Section 1250.06 to, the Health and Safety Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1039, as amended, Hernandez. Pharmacy.

(1) Existing law, the Pharmacy Law, the violation of which is a crime, provides for the licensure and regulation of pharmacies, pharmacists, intern pharmacists, and pharmacy technicians by the California State Board of Pharmacy. The Pharmacy Law authorizes an intern pharmacist to perform all functions of a pharmacist, and authorizes a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks, in each case under supervision of a pharmacist, as specified.

This bill would authorize a pharmacy technician to perform packaging; ~~including emergency supply packaging and sealing in or for hospitals, hospital unit inspections, and other physical,~~ manipulative, repetitive, or other nondiscretionary tasks ~~under supervision~~ *only while assisting*

*and while under the direct supervision and control of a pharmacist, as specified. This bill would also authorize, in a licensed health care facility, as defined, a pharmacy technician's duties to include, among other things, sealing emergency containers for use in the health care facility.*

(2) Existing law authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health and other existing law requirements, as specified.

~~This bill would authorize a pharmacy to furnish a dangerous drug or dangerous device to the emergency medical services system of a licensed general acute care hospital, as defined, for storage in a secured emergency pharmaceutical supplies container maintained within the hospital in accordance with the hospital's policies and procedures. The bill would require both the hospital and the dispensing pharmacy to maintain records pertaining to the dangerous drugs or dangerous devices furnished to the hospital's emergency medical services system for at least 3 years. The bill would also authorize a pharmacy to furnish a dangerous drug or dangerous device to a licensed general acute care hospital pursuant to preprinted or electronic standing orders, order sets, and protocols established under the policies and procedures of a licensed general acute care hospital under specified conditions. The bill would require a pharmacist, a pharmacy technician, or an intern pharmacist, under the direct supervision and control of a pharmacist, to stock, replenish, and inspect the drugs maintained in the hospital at least once per month, and to report any irregularities, as specified. emergency pharmaceutical supplies container and the emergency medical system supplies of a licensed general acute care hospital, as defined.~~

*This bill would authorize an intern pharmacist to inspect the drugs maintained in a licensed health care facility, as defined, pursuant to policies and procedures of the health care facility. This bill would also authorize a licensed health care facility to dispense or furnish dangerous drugs and dangerous devices to inpatients and patients upon discharge pursuant to preprinted or electronic standing orders, order sets, and protocols, as specified. This bill would require licensed health care facilities to store and maintain drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature and in accordance with the manufacturers' guidelines.*

Because a violation of certain provisions of the bill would be a crime, the bill would create a state-mandated local program.

(3) Existing law authorizes a pharmacist recognized by the board as an advanced practice pharmacist to perform specified functions, including performing patient assessments.

This bill would also authorize a pharmacist recognized by the board as an advanced practice pharmacist to order patient assessments.

(4) Existing law authorizes a pharmacist to initiate or adjust the drug regimen of a patient under specified circumstances. Existing law authorizes specified practitioners, including a pharmacist acting within the scope of an authorized pilot project, to prescribe, furnish, or administer controlled substances to a patient suffering from a disease, ailment, injury, or infirmity, but only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment, and only in the quantity and for the length of time as reasonably necessary.

This bill would modify that list of practitioners to include a pharmacist initiating or adjusting the drug regimen of a patient as authorized under existing law.

(5) Existing law provides for the licensure and inspection of health facilities, including general acute care hospitals, by the State Department of Public Health. Existing regulations require a hospital to have a pharmacy on the premises or a pharmacy license, as specified. Existing regulations also require the hospital to consult the pharmacist on the proper methods of, among other things, repackaging and labeling bulk cleaning agents.

This bill would instead provide that a licensed general acute care hospital or an acute psychiatric hospital, as defined, is not required to consult a pharmacist regarding repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances *except for areas where sterile compounding is performed*.

(6) 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 4052.6 of the Business and Professions  
2 Code is amended to read:

3 4052.6. (a) A pharmacist recognized by the board as an  
4 advanced practice pharmacist may do all of the following:

5 (1) Order and perform patient assessments.

6 (2) Order and interpret drug therapy-related tests.

7 (3) Refer patients to other health care providers.

8 (4) Participate in the evaluation and management of diseases  
9 and health conditions in collaboration with other health care  
10 providers.

11 (5) Initiate, adjust, or discontinue drug therapy in the manner  
12 specified in paragraph (4) of subdivision (a) of Section 4052.2.

13 (b) A pharmacist who adjusts or discontinues drug therapy shall  
14 promptly transmit written notification to the patient's diagnosing  
15 prescriber or enter the appropriate information in a patient record  
16 system shared with the prescriber, as permitted by that prescriber.

17 A pharmacist who initiates drug therapy shall promptly transmit  
18 written notification to, or enter the appropriate information into,  
19 a patient record system shared with the patient's primary care  
20 provider or diagnosing provider, as permitted by that provider.

21 (c) This section shall not interfere with a physician's order to  
22 dispense a prescription drug as written, or other order of similar  
23 meaning.

24 (d) Prior to initiating or adjusting a controlled substance therapy  
25 pursuant to this section, a pharmacist shall personally register with  
26 the federal Drug Enforcement Administration.

27 (e) A pharmacist who orders and interprets tests pursuant to  
28 paragraph (2) of subdivision (a) shall ensure that the ordering of  
29 those tests is done in coordination with the patient's primary care  
30 provider or diagnosing prescriber, as appropriate, including  
31 promptly transmitting written notification to the patient's  
32 diagnosing prescriber or entering the appropriate information in a  
33 patient record system shared with the prescriber, when available  
34 and as permitted by that prescriber.

35 SEC. 2. Section 4115 of the Business and Professions Code is  
36 amended to read:

37 4115. (a) A pharmacy technician may perform packaging,  
38 ~~including emergency supply packaging and sealing in or for~~

1 ~~hospitals, hospital unit inspections, and other physical,~~  
2 ~~manipulative, repetitive, or other nondiscretionary tasks, only while~~  
3 ~~assisting, and while under the direct supervision and control of a~~  
4 ~~pharmacist. *The pharmacist shall be responsible for the duties*~~  
5 ~~*performed under his or her supervision by a technician.*~~

6 (b) This section does not authorize the performance of any tasks  
7 specified in subdivision (a) by a pharmacy technician without a  
8 pharmacist on duty.

9 (c) This section does not authorize a pharmacy technician to  
10 perform any act requiring the exercise of professional judgment  
11 by a pharmacist.

12 (d) The board shall adopt regulations to specify tasks pursuant  
13 to subdivision (a) that a pharmacy technician may perform under  
14 the supervision of a pharmacist. Any pharmacy that employs a  
15 pharmacy technician shall do so in conformity with the regulations  
16 adopted by the board.

17 (e) No person shall act as a pharmacy technician without first  
18 being licensed by the board as a pharmacy technician.

19 (f) (1) A pharmacy with only one pharmacist shall have no  
20 more than one pharmacy technician performing the tasks specified  
21 in subdivision (a). The ratio of pharmacy technicians performing  
22 the tasks specified in subdivision (a) to any additional pharmacist  
23 shall not exceed 2:1, except that this ratio shall not apply to  
24 personnel performing clerical functions pursuant to Section 4116  
25 or 4117. This ratio is applicable to all practice settings, except for  
26 an inpatient of a licensed health facility, a patient of a licensed  
27 home health agency, as specified in paragraph (2), an inmate of a  
28 correctional facility of the Department of Corrections and  
29 Rehabilitation, and for a person receiving treatment in a facility  
30 operated by the State Department of State Hospitals, the State  
31 Department of Developmental Services, or the Department of  
32 Veterans Affairs.

33 (2) The board may adopt regulations establishing the ratio of  
34 pharmacy technicians performing the tasks specified in subdivision  
35 (a) to pharmacists applicable to the filling of prescriptions of an  
36 inpatient of a licensed health facility and for a patient of a licensed  
37 home health agency. Any ratio established by the board pursuant  
38 to this subdivision shall allow, at a minimum, at least one pharmacy  
39 technician for a single pharmacist in a pharmacy and two pharmacy  
40 technicians for each additional pharmacist, except that this ratio

1 shall not apply to personnel performing clerical functions pursuant  
2 to Section 4116 or 4117.

3 (3) A pharmacist scheduled to supervise a second pharmacy  
4 technician may refuse to supervise a second pharmacy technician  
5 if the pharmacist determines, in the exercise of his or her  
6 professional judgment, that permitting the second pharmacy  
7 technician to be on duty would interfere with the effective  
8 performance of the pharmacist's responsibilities under this chapter.  
9 A pharmacist assigned to supervise a second pharmacy technician  
10 shall notify the pharmacist in charge in writing of his or her  
11 determination, specifying the circumstances of concern with respect  
12 to the pharmacy or the pharmacy technician that have led to the  
13 determination, within a reasonable period, but not to exceed 24  
14 hours, after the posting of the relevant schedule. No entity  
15 employing a pharmacist may discharge, discipline, or otherwise  
16 discriminate against any pharmacist in the terms and conditions  
17 of employment for exercising or attempting to exercise in good  
18 faith the right established pursuant to this paragraph.

19 (g) Notwithstanding subdivisions (a) and (b), the board shall  
20 by regulation establish conditions to permit the temporary absence  
21 of a pharmacist for breaks and lunch periods pursuant to Section  
22 512 of the Labor Code and the orders of the Industrial Welfare  
23 Commission without closing the pharmacy. During these temporary  
24 absences, a pharmacy technician may, at the discretion of the  
25 pharmacist, remain in the pharmacy but may only perform  
26 nondiscretionary tasks. The pharmacist shall be responsible for a  
27 pharmacy technician and shall review any task performed by a  
28 pharmacy technician during the pharmacist's temporary absence.  
29 Nothing in this subdivision shall be construed to authorize a  
30 pharmacist to supervise pharmacy technicians in greater ratios  
31 than those described in subdivision (f).

32 (h) The pharmacist on duty shall be directly responsible for the  
33 conduct of a pharmacy technician supervised by that pharmacist.

34 (i) *In a health care facility licensed under subdivision (a) of*  
35 *Section 1250 of the Health and Safety Code, a pharmacy*  
36 *technician's duties may include any of the following.*

37 (1) *Packaging emergency supplies for use in the health care*  
38 *facility and the hospital's emergency medical system as authorized*  
39 *under Section 4119.*

1 (2) *Sealing emergency containers for use in the health care*  
2 *facility.*

3 (3) *Performing monthly checks of the drug supplies stored*  
4 *throughout the health care facility. Irregularities shall be reported*  
5 *within 24 hours to the pharmacist in charge and the director or*  
6 *chief executive officer of the health care facility in accordance*  
7 *with the health care facility's policies and procedures.*

8 SEC. 3. Section 4119.6 is added to the Business and Professions  
9 Code, to read:

10 ~~4119.6. (a) Notwithstanding any other law, a pharmacy may~~  
11 ~~furnish a dangerous drug or dangerous device to the emergency~~  
12 ~~medical services system of a licensed general acute care hospital,~~  
13 ~~as defined in subdivision (a) of Section 1250 of the Health and~~  
14 ~~Safety Code, for storage in a secured emergency pharmaceutical~~  
15 ~~supplies container maintained within the hospital in accordance~~  
16 ~~with the hospital's policies and procedures. A pharmacy technician~~  
17 ~~or~~

18 *4119.6. An intern pharmacist under the direct supervision and*  
19 *control, as defined in Section 4023.5, of a pharmacist may stock,*  
20 *replenish, and inspect the hospital's emergency pharmaceutical*  
21 *supplies container and the emergency medical system supplies of*  
22 *a licensed general acute care hospital, as defined in subdivision*  
23 *(a) of Section 1250 of the Health and Safety Code.*

24 ~~(b) Both the hospital and the dispensing pharmacy acting under~~  
25 ~~this section shall maintain records of each request by, and~~  
26 ~~dangerous drugs or dangerous devices furnished to, the hospital's~~  
27 ~~emergency medical services system, for at least three years.~~

28 ~~(c) Controlled substances shall be furnished to the hospital's~~  
29 ~~emergency medical services system under this section in~~  
30 ~~accordance with the California Uniform Controlled Substances~~  
31 ~~Act (Division 10 (commencing with Section 11000) of the Health~~  
32 ~~and Safety Code).~~

33 SEC. 4. Section 4119.7 is added to the Business and Professions  
34 Code, to read:

35 ~~4119.7. (a) Notwithstanding any other law, a pharmacy may~~  
36 ~~furnish a dangerous drug or dangerous device to a licensed general~~  
37 ~~acute care hospital, as defined in A health care facility licensed~~  
38 ~~under subdivision (a) of Section 1250 of the Health and Safety~~  
39 ~~Code, may administer, dispense, or furnish dangerous drugs and~~  
40 ~~dangerous devices to inpatients or patients upon discharge~~

1 pursuant to preprinted or electronic standing orders, order sets,  
2 and protocols established under the policies and procedures of the  
3 hospital, ~~as approved according to the policies of the hospital's~~  
4 ~~governing body, health care facility,~~ if the order is promptly dated,  
5 timed, and authenticated in the medical record of the patient to  
6 whom the dangerous drug or dangerous device ~~is dispensed by the~~  
7 ~~ordering practitioner or another practitioner responsible for the~~  
8 ~~care of that patient and authorized by the hospital's policies and~~  
9 ~~procedures to write orders.~~ *will be provided.*

10 (b) ~~The hospital~~ *A health care facility licensed under subdivision*  
11 *(a) of Section 1250 of the Health and Safety Code shall store and*  
12 *maintain drugs in accordance with national standards regarding*  
13 *the storage area and refrigerator or freezer temperature, and*  
14 *otherwise pursuant to the manufacturer's guidelines. The health*  
15 *care facility's policies and procedures shall specify these storage*  
16 *parameters.*

17 (c) ~~(1) A pharmacist, pharmacy technician, or an~~ *An intern*  
18 *pharmacist under the direct supervision and control, as defined in*  
19 *Section 4023.5, of a pharmacist, shall inspect the drugs maintained*  
20 *in the hospital health care facility at least once per month. The*  
21 *hospital health care facility shall establish specific written policies*  
22 *and procedures for inspections pursuant to this paragraph.*

23 ~~(2) The person conducting the inspection pursuant to paragraph~~  
24 ~~(1) shall report any irregularities to the director or chief executive~~  
25 ~~officer of the hospital, or other person holding an equivalent~~  
26 ~~position, and in accordance with the hospital's policy.~~

27 SEC. 5. Section 1250.06 is added to the Health and Safety  
28 Code, immediately following Section 1250.05, to read:

29 1250.06. A licensed general acute care hospital, as defined  
30 pursuant to subdivision (a) of Section 1250, or an acute psychiatric  
31 hospital, as defined pursuant to subdivision (b) of Section 1250,  
32 is not required to consult a pharmacist regarding repackaging and  
33 labeling of bulk cleaning agents, solvents, chemicals, and nondrug  
34 hazardous substances used throughout the ~~hospital:~~ *hospital except*  
35 *for areas where sterile compounding is performed.*

36 SEC. 6. Section 11150 of the Health and Safety Code is  
37 amended to read:

38 11150. No person other than a physician, dentist, podiatrist,  
39 or veterinarian, or naturopathic doctor acting pursuant to Section  
40 3640.7 of the Business and Professions Code, or pharmacist acting

1 within the scope of a project authorized under Article 1  
2 (commencing with Section 128125) of Chapter 3 of Part 3 of  
3 Division 107 or within the scope of Section 4052.1, 4052.2, or  
4 4052.6 of the Business and Professions Code, a registered nurse  
5 acting within the scope of a project authorized under Article 1  
6 (commencing with Section 128125) of Chapter 3 of Part 3 of  
7 Division 107, a certified nurse-midwife acting within the scope of  
8 Section 2746.51 of the Business and Professions Code, a nurse  
9 practitioner acting within the scope of Section 2836.1 of the  
10 Business and Professions Code, a physician assistant acting within  
11 the scope of a project authorized under Article 1 (commencing  
12 with Section 128125) of Chapter 3 of Part 3 of Division 107 or  
13 Section 3502.1 of the Business and Professions Code, a  
14 naturopathic doctor acting within the scope of Section 3640.5 of  
15 the Business and Professions Code, or an optometrist acting within  
16 the scope of Section 3041 of the Business and Professions Code,  
17 or an out-of-state prescriber acting pursuant to Section 4005 of the  
18 Business and Professions Code shall write or issue a prescription.

19 SEC. 7. Section 11210 of the Health and Safety Code is  
20 amended to read:

21 11210. A physician, surgeon, dentist, veterinarian, naturopathic  
22 doctor acting pursuant to Section 3640.7 of the Business and  
23 Professions Code, or podiatrist, or pharmacist acting within the  
24 scope of a project authorized under Article 1 (commencing with  
25 Section 128125) of Chapter 3 of Part 3 of Division 107 or within  
26 the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and  
27 Professions Code, or registered nurse acting within the scope of a  
28 project authorized under Article 1 (commencing with Section  
29 128125) of Chapter 3 of Part 3 of Division 107, or physician  
30 assistant acting within the scope of a project authorized under  
31 Article 1 (commencing with Section 128125) of Chapter 3 of Part  
32 3 of Division 107, or naturopathic doctor acting within the scope  
33 of Section 3640.5 of the Business and Professions Code, or an  
34 optometrist acting within the scope of Section 3041 of the Business  
35 and Professions Code may prescribe for, furnish to, or administer  
36 controlled substances to his or her patient when the patient is  
37 suffering from a disease, ailment, injury, or infirmities attendant  
38 upon old age, other than addiction to a controlled substance.

39 The physician, surgeon, dentist, veterinarian, naturopathic doctor  
40 acting pursuant to Section 3640.7 of the Business and Professions

1 Code, or podiatrist, or pharmacist acting within the scope of a  
2 project authorized under Article 1 (commencing with Section  
3 128125) of Chapter 3 of Part 3 of Division 107 or within the scope  
4 of Section 4052.1, 4052.2, or 4052.6 of the Business and  
5 Professions Code, or registered nurse acting within the scope of a  
6 project authorized under Article 1 (commencing with Section  
7 128125) of Chapter 3 of Part 3 of Division 107, or physician  
8 assistant acting within the scope of a project authorized under  
9 Article 1 (commencing with Section 128125) of Chapter 3 of Part  
10 3 of Division 107, or naturopathic doctor acting within the scope  
11 of Section 3640.5 of the Business and Professions Code, or an  
12 optometrist acting within the scope of Section 3041 of the Business  
13 and Professions Code shall prescribe, furnish, or administer  
14 controlled substances only when in good faith he or she believes  
15 the disease, ailment, injury, or infirmity requires the treatment.

16 The physician, surgeon, dentist, veterinarian, or naturopathic  
17 doctor acting pursuant to Section 3640.7 of the Business and  
18 Professions Code, or podiatrist, or pharmacist acting within the  
19 scope of a project authorized under Article 1 (commencing with  
20 Section 128125) of Chapter 3 of Part 3 of Division 107 or within  
21 the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and  
22 Professions Code, or registered nurse acting within the scope of a  
23 project authorized under Article 1 (commencing with Section  
24 128125) of Chapter 3 of Part 3 of Division 107, or physician  
25 assistant acting within the scope of a project authorized under  
26 Article 1 (commencing with Section 128125) of Chapter 3 of Part  
27 3 of Division 107, or a naturopathic doctor acting within the scope  
28 of Section 3640.5 of the Business and Professions Code, or an  
29 optometrist acting within the scope of Section 3041 of the Business  
30 and Professions Code shall prescribe, furnish, or administer  
31 controlled substances only in the quantity and for the length of  
32 time as are reasonably necessary.

33 SEC. 8. No reimbursement is required by this act pursuant to  
34 Section 6 of Article XIII B of the California Constitution because  
35 the only costs that may be incurred by a local agency or school  
36 district will be incurred because this act creates a new crime or  
37 infraction, eliminates a crime or infraction, or changes the penalty  
38 for a crime or infraction, within the meaning of Section 17556 of  
39 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California  
2 Constitution.

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