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CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section ~~4051~~ 4033 of, to add Section 4019.5 to, ~~to~~ repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including “*manufacturer*” and *provides specified exceptions from the definition of a “manufacturer.”*

This bill would ~~delete~~ *revise* the definition of manufacturer *to except only pharmacies that compound or otherwise manufacture on the immediate premises where the drug or device is sold to the ultimate consumer and pharmacies compounding pursuant to a contract with another pharmacy, and would except those pharmacies from registration or licensing as a manufacturer or otherwise complying*

with federal or state laws regulating manufacturers, unless otherwise determined by a federal or state agency regulating manufacturers. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would ~~make other related changes in that regard~~ impose specified requirements on dispensing of compounded drugs. The bill would authorize a pharmacy to contract with another pharmacy to compound products on behalf of its patients, subject to specified requirements. The bill would also impose requirements with respect to recalling a compounded drug product. Because the bill would specify requirements for compounded drug products under the Pharmacy Law, the violation of which would be a crime, it 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 4019.5 is added to the Business and
- 2 Professions Code, to read:
- 3 4019.5. (a) “Compounding” means any of the following
- 4 activities occurring in a pharmacy pursuant to a prescription:
- 5 (1) Altering the dosage form or delivery system of a drug.
- 6 (2) Altering the strength of a drug.
- 7 (3) Combining components or active ingredients.
- 8 (4) Preparing a drug product from bulk chemicals.
- 9 (b) “Compounding” shall not include the reconstitution of a
- 10 drug pursuant to the manufacturer’s direction for oral, rectal, or
- 11 topical administration.
- 12 ~~SEC. 2. Section 4033 of the Business and Professions Code is~~
- 13 ~~repealed.~~
- 14 ~~SEC. 3. Section 4051 of the Business and Professions Code is~~
- 15 ~~amended to read:~~
- 16 4051. (a) ~~Except as otherwise provided in this chapter, it is~~
- 17 ~~unlawful for any person to compound, furnish, sell, or dispense~~

1 any dangerous drug or dangerous device, or to dispense or
2 compound any prescription pursuant to Section 4040 of a
3 prescriber unless he or she is a pharmacist under this chapter.

4 (b) Notwithstanding any other law, a pharmacist may
5 authorize the initiation of a prescription, pursuant to Section
6 4052, and otherwise provide clinical advice or information or
7 patient consultation if all of the following conditions are met:

8 (1) The clinical advice or information or patient consultation is
9 provided to a health care professional or to a patient.

10 (2) The pharmacist has access to prescription, patient profile,
11 or other relevant medical information for purposes of patient and
12 clinical consultation and advice.

13 (3) Access to the information described in paragraph (2) is
14 secure from unauthorized access and use.

15 *SEC. 2. Section 4033 of the Business and Professions Code is*
16 *amended to read:*

17 4033. (a) “Manufacturer” means and includes every person
18 who prepares, derives, produces, compounds, or repackages any
19 drug or device except a pharmacy that manufactures on the
20 immediate premises where the drug or device is sold to the
21 ultimate consumer or a pharmacy compounding pursuant to a
22 contract as provided in Section 4123. Any excepted compounding
23 pharmacy shall not be required to register as a manufacturer
24 with, or seek licensure by, any federal or state agency regulating
25 manufacturers or otherwise comply with any federal or state law
26 regarding manufacturers, absent a determination by a federal or
27 state agency regulating manufacturers that the pharmacy must
28 do so. Neither this definition nor any other provision of this
29 chapter shall impair the authority of a federal or state agency
30 regulating manufacturers to apply laws regulating
31 manufacturers to a pharmacy.

32 (b) Notwithstanding subdivision (a), “manufacturer” shall not
33 mean a pharmacy compounding a drug for parenteral therapy,
34 pursuant to a prescription, for delivery to another pharmacy for
35 the purpose of delivering or administering the drug to the patient
36 or patients named in the prescription, provided that neither the
37 components for the drug nor the drug are compounded,
38 fabricated, packaged, or otherwise prepared prior to receipt of the
39 prescription.

1 ~~(e) Notwithstanding subdivision (a), “manufacturer” shall not~~
2 ~~mean a pharmacy that, at a patient’s request, repackages a drug~~
3 ~~previously dispensed to the patient, or to the patient’s agent,~~
4 ~~pursuant to a prescription.~~

5 ~~SEC. 4.~~

6 ~~SEC. 3.~~ Section 4123 of the Business and Professions Code is
7 repealed.

8 ~~SEC. 5.~~

9 ~~SEC. 4.~~ Section 4123 is added to the Business and
10 Professions Code, to read:

11 4123. (a) A compounded drug product shall only be
12 dispensed or furnished to a patient pursuant to a prescription
13 meeting the requirements of Section 4040.

14 (b) A compounded drug product shall only be dispensed or
15 furnished to a patient where the prescription has been generated
16 solely within an established professional relationship between the
17 prescriber, patient, and dispensing pharmacy.

18 (c) A pharmacy may conduct anticipatory compounding of a
19 drug product in limited quantity, as defined by regulation of the
20 board, before receipt of a prescription order for that drug product,
21 where the quantity of each drug product compounded in
22 anticipation of receipt of prescription orders is based on a
23 documented history of receipt of prescription orders generated
24 solely within an established professional relationship between
25 prescribers, patients of the pharmacy, and the pharmacy.

26 (d) A pharmacy may contract with another pharmacy to
27 compound drug products on behalf of its patients, *provided that*
28 *all of the following requirements are met:*

29 *(1) Any pharmacy that compounds a drug product for another*
30 *pharmacy shall report that contractual arrangement to the*
31 *board. The information shall be reported by the pharmacy*
32 *performing the compounding services within 30 days of*
33 *commencing that compounding.*

34 *(2) The drug product shall not be compounded prior to receipt*
35 *of the prescription by the pharmacy doing the compounding.*

36 *(3) Both the pharmacist that compounds the drug product and*
37 *the pharmacist that dispenses or furnishes the compounded drug*
38 *product to the patient pursuant to a prescription shall have*
39 *access to and appropriately review the patient’s medication*
40 *profile and other pertinent patient information prior to*

1 *compounding and prior to dispensing or furnishing the drug*
2 *product to the patient.*

3 *(4) Both the pharmacy that compounds the drug product and*
4 *the pharmacy under contract that dispenses or furnishes the*
5 *compounded drug product to the patient pursuant to a*
6 *prescription shall maintain complete and adequate records of the*
7 *required drug therapy review performed by each prior to*
8 *compounding, dispensing, or furnishing the drug product.*

9 *(5) The pharmacy that compounds the drug product shall*
10 *supply the pharmacy under contract that dispenses or furnishes*
11 *the compounded drug product to the patient with documentation*
12 *regarding the compounded drug product sufficient to enable the*
13 *pharmacist dispensing or furnishing the compounded drug*
14 *product to the patient to both adequately perform the required*
15 *drug therapy review and provide consultation to the patient, as*
16 *required by regulation of the board.*

17 *(6) Both the pharmacy that compounds the drug product and*
18 *the pharmacy under contract that dispenses or furnishes the*
19 *compounded drug product to the patient shall retain on the*
20 *licensed premises in a readily retrievable form for a period of*
21 *three years from the date of creation all records of the required*
22 *drug utilization review performed by each pharmacy, as well as*
23 *all documentation regarding the compounded drug product*
24 *shared between the two pharmacies.*

25 *(7) The pharmacy that compounds the drug product and the*
26 *pharmacy that dispenses or furnishes the compounded drug*
27 *product to the patient shall both be responsible for ensuring that*
28 *the prescription has been properly filled and that the*
29 *compounded drug product has been safely delivered to the*
30 *patient.*

31 *(e) A pharmacy may only base its anticipatory compounding*
32 *on a documented history of prescription orders received for its*
33 *own patients or customers, and not those patients or customers of*
34 *pharmacies with which it has a contractual relationship.*

35 *(f) Notwithstanding any other provision of this chapter, a*
36 *pharmacist may do both of the following:*

37 ~~*(1) Compound a drug product pursuant to a prescription, for*~~
38 ~~*delivery to another pharmacy pursuant to a contract for the*~~
39 ~~*purpose of dispensing or furnishing the drug product to the*~~

1 patient named in the prescription, provided that the drug is not
2 compounded prior to the receipt of the prescription.

3 ~~(2) Repackage-repackage~~ a drug previously dispensed to the
4 patient at the request of the patient or the patient’s agent.

5 *(g) A pharmacy shall recall a compounded drug product that*
6 *is misbranded, adulterated, or has the potential for adverse*
7 *effects or patient harm with continued use of the drug product.*
8 *Within two business days of discovery of a drug product that is*
9 *misbranded, adulterated, or has the potential for adverse effects*
10 *or patient harm, the pharmacy shall notify the prescriber and*
11 *patient of the nature of the recall, the problems identified, and*
12 *any recommended actions to ensure patient safety. Any recall*
13 *that is initiated by a pharmacy pursuant to this section shall also*
14 *be reported to the board and to the Food and Drug Branch of the*
15 *State Department of Health Services within two business days.*

16 ~~SEC. 6.~~

17 *SEC. 5.* No reimbursement is required by this act pursuant to
18 Section 6 of Article XIII B of the California Constitution because
19 the only costs that may be incurred by a local agency or school
20 district will be incurred because this act creates a new crime or
21 infraction, eliminates a crime or infraction, or changes the
22 penalty for a crime or infraction, within the meaning of Section
23 17556 of the Government Code, or changes the definition of a
24 crime within the meaning of Section 6 of Article XIII B of the
25 California Constitution.