

Introduced by Senator FigueroaJanuary 6, 2000

An act to add Section 4125 to the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 1339, as introduced, Figueroa. Pharmacy: quality assurance program.

The Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy.

This bill, on and after January 1, 2002, would require every pharmacy to develop and implement a quality assurance program that, at a minimum, documents medication errors attributable, in whole or in part, to that pharmacy or its personnel, as specified.

Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law. All other violations of that law are infractions unless otherwise indicated.

Because a violation of the bill's requirements regarding a quality assurance program 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: 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 4125 is added to the Business and
2 Professions Code, to read:
3 4125. (a) Every pharmacy shall develop and
4 implement a quality assurance program that shall, at a
5 minimum, document medication errors attributable, in
6 whole or in part, to the pharmacy or its personnel. The
7 primary purpose of the quality assurance program shall
8 be to analyze medication errors so the pharmacy may
9 take appropriate action to prevent a recurrence.

10 (b) The quality assurance program shall be described
11 in the pharmacy’s policies and procedures manual and
12 shall be reviewed and revised prior to application for
13 renewal of the pharmacy’s license.

14 (c) For each medication error identified by the
15 pharmacy, the pharmacy shall conduct a quality
16 assurance assessment. The pharmacy shall record in
17 writing at least the following:
18 (1) The time, location, and participants in the quality
19 assurance assessment conducted.
20 (2) A complete recitation of the facts relating to the
21 medication error.
22 (3) Findings and determinations made by the quality
23 assurance assessment team.
24 (4) Remedial efforts undertaken, if any, including
25 communication to pharmacy personnel.

26 (d) Records of all activities undertaken as part of a
27 quality assurance program, including, but not limited to,
28 examination or confirmation of a medication error, shall
29 be maintained for at least three years from the making of
30 the records. Those records shall at all times during normal
31 business hours be accessible and subject to review by the
32 board.

33 (e) A pharmacy’s compliance with this section may be
34 considered by the board as a mitigating factor in the



1 investigation and evaluation of any medication error by
2 the pharmacy.

3 (f) For purposes of this section, “medication error”
4 means dispensing any drug to the patient or patient’s
5 agent that contains any unauthorized variance from the
6 prescription or drug order issued by the prescriber or any
7 variance from any state or federal requirement for
8 dispensing prescriptions.

9 (g) Records generated for and maintained as a
10 component of a pharmacy’s ongoing quality assurance
11 program shall be considered peer review documents and
12 not subject to discovery in any arbitration, civil, or other
13 proceeding, except as provided hereafter. That privilege
14 shall not extend to records, documents, or physical
15 evidence of an incident that becomes the subject of
16 quality assurance review. That privilege shall not prevent
17 review of a pharmacy’s quality assurance program and
18 records maintained as part of that system by the board as
19 necessary to protect the public health and safety or if
20 fraud is alleged by a government agency with jurisdiction
21 over the pharmacy.

22 (h) This section shall become operative on January 1,
23 2002.

24 SEC. 2. The California State Board of Pharmacy shall
25 adopt regulations on or before September 1, 2001,
26 specifying the requirements of quality assurance
27 programs established pursuant to Section 4125 of the
28 Business and Professions Code.

29 SEC. 3. No reimbursement is required by this act
30 pursuant to Section 6 of Article XIII B of the California
31 Constitution because the only costs that may be incurred
32 by a local agency or school district will be incurred
33 because this act creates a new crime or infraction,
34 eliminates a crime or infraction, or changes the penalty
35 for a crime or infraction, within the meaning of Section
36 17556 of the Government Code, or changes the definition
37 of a crime within the meaning of Section 6 of Article
38 XIII B of the California Constitution.

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