

SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

AB 1286 (Haney)
Version: July 5, 2023
Hearing Date: July 11, 2023
Fiscal: Yes
Urgency: No
AM

SUBJECT

Pharmacy

DIGEST

This bill provides the Board of Pharmacy (Board) with cease and desist authority for specified conditions present in a pharmacy, updates the authority for pharmacy technicians to undertake certain tasks according to qualification and supervision requirements, requires certain medication error reporting, and authorizes pharmacy closure by a pharmacist if certain circumstances exist. The bill requires reports regarding medication errors be kept and reported, as provided, and specifies that these reports are not subject to discovery, subpoena, or disclosed pursuant to the California Public Records Act.

EXECUTIVE SUMMARY

Following national media reports on pharmacy working conditions and medication errors, and in response to issues identified as part of the Board's sunset review, the Board conducted a survey of community pharmacists. Survey results highlighted significant challenges facing pharmacists working in community pharmacies, most notably in community chain pharmacies. In response to the findings, the Board established an ad hoc committee to evaluate the issue of medication errors, workforce challenges, and the intersection between the two. This bill is a result of those efforts.

The bill is sponsored by the California State Board of Pharmacy and is supported by California Labor Federation, AFL-CIO, California Pharmacists Association, United Food and Commercial Workers, Western States Council. It is opposed by the California Community Pharmacy Coalition. This bill passed the Senate Business, Professions and Economic Development Committee on a vote of 8 to 3.

PROPOSED CHANGES TO THE LAW

Existing law:

- 1) Establishes the Board in the Department of Consumer Affairs to administer and enforce the Pharmacy Law, which provides for the licensure and regulation of pharmacists, pharmacies, and pharmacy technicians in the state. (Bus. & Prof. Code) § 4000 et. seq.)
- 2) Requires a pharmacy with only one pharmacist to have no more than one pharmacy technician (PTs). Provides that any additional pharmacists can oversee no more than two PTs, except if those PTs are performing specified clerical functions. Establishes that this ratio applies to all practice settings except for an inpatient of a health facility, a patient of a home health agency, an inmate of a correctional facility, or for a person receiving treatment through specified state services. (Bus. & Prof. Code §4115(f)(1).)
 - a) Authorizes a pharmacist scheduled to supervise a second PT to refuse the duty if he or she determines that the additional PT would interfere with the responsibilities of the pharmacist. (Bus. & Prof. Code § 4115(f)(3).)
 - b) Establishes that the pharmacist on duty is directly responsible for the conduct of a PT that they supervise. (Bus. & Prof. Code § 4115 (h))
- 3) Prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless another employee, as specified, is made available to assist the pharmacist at all times. (Bus. & Prof. Code § 4113.5)
- 4) Prohibits a chain community pharmacy from establishing a quota to measure or evaluate a pharmacist or pharmacy technician's performance of duties, prohibits a chain community pharmacy from communicating the existence of quotas to employees or those it contracts with, and authorizes the Board of Pharmacy to take enforcement action against a community pharmacy that establishes a quota related to a pharmacist or pharmacy technician duties, unless by clear and convincing evidence the community pharmacy can demonstrate the violation was contrary to its policy. (Bus. & Prof. Code § 4113.7.)
- 5) Provides, pursuant to the California Constitution, that the people have the right of access to information concerning the conduct of the people's business, and, therefore, the meetings of public bodies and the writings of public officials and agencies are required to be open to public scrutiny. (Cal. const. art. I, § 3(b)(1).)
 - a) Requires a statute to be broadly construed if it furthers the people's right of access, and narrowly construed if it limits the right of access. (Cal. const. art. I, § 3(b)(1).)

- b) Requires a statute that limits the public's right of access to be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest. (Cal. const. art. I, § 3(b)(1).)
- 6) Governs the disclosure of information collected and maintained by public agencies pursuant to the CPRA. (Gov. Code §§ 7920.000 et seq.)
- a) States that the Legislature, mindful of the individual right to privacy, finds and declares that access to information concerning the conduct of the people's business is a fundamental and necessary right of every person in this state. (Gov. Code § 7921.000.)
 - b) Defines "public records" as any writing containing information relating to the conduct of the public's business prepared, owned, used, or retained by any state or local agency regardless of physical form or characteristics. (Gov. Code § 7920.530.)
 - a) Provides that all public records are accessible to the public upon request, unless the record requested is exempt from public disclosure. (Gov. Code § 7922.530.)

This bill:

- 1) Authorizes the pharmacist-in-charge to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. Specifies that, if the pharmacist-in-charge is not available, a pharmacist on duty may adjust staffing according to workload if needed.
- 2) Requires the pharmacist-in-charge or pharmacist on duty to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. States store management will take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. States that if conditions are not resolved within 24 hours, the pharmacist-in-charge or pharmacists on duty will ensure the board is timely notified.
- 3) Specifies that conditions which present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, among other things, hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- 4) Requires a community pharmacy to report all medication errors to a Board-approved entity no later than 14 days following the date of the discovery of the error. Specifies that those reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the CPRA.

COMMENTS

1. Stated need for the bill

The author writes:

Community chain pharmacies and the pharmacists who work for them are instrumental in delivering care to Californians. However, recent news reports have highlighted alarming medication errors in this setting – including errors that have led to death. The root cause of medication errors in the community chain setting can be tied to pharmacy working conditions, like insufficient staffing, unsanitary conditions, or lack of autonomy to make clinical decisions in the best interest of the patient. Unfortunately, there is no requirement under current law for pharmacies to track medication errors or to consider the pharmacy working conditions that lead to medication errors. To address the root cause of medication errors and major faults in Pharmacy Law, AB 1286 will establish a first in the nation mandatory reporting of medication errors to allow for robust evaluation of the causes of medication errors. It also gives licensed pharmacy staff autonomy over their working conditions so they can provide better patient care and services for Californians.

2. Limitation on the access to medication error reports

The brunt of this bill relates to the responsibility of the pharmacist in charge, staffing requirements, tasks a PT is authorized to perform, and actions that constitute unprofessional conduct under the Pharmacy Law. These issues fall within the jurisdiction of the Senate Business Professions and Economic Development Committee; that Committee's analysis of this bill is incorporated herein by reference.

For this Committee's purposes, the bill requires a community pharmacy to report all medication errors to a Board-approved entity no later than 14 days following the date of the discovery of the error. The Board notes that this provision will ensure that the Board has the necessary tools to protect California patients by providing the Board the authority to establish a mandatory medication error reporting requirement that will provide licensees, the Legislature, and the Board with a transparent understanding of the frequency of medication errors, causes of errors, and shared learning, with the goal of reducing medication errors from occurring in community pharmacies. These provisions are intended to build upon existing requirements under the Pharmacy Law that requires each pharmacy to establish a quality assurance program that, at a minimum, documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (Bus. & Prof. Code § 4125.) The purpose of the quality assurance program is to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence. Records generated for and maintained as a component of a pharmacy's on going quality assurance program are to be considered peer review

documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided, due to the sensitive information regarding patients that can be contained within.

In recognition that the information contained in these medication error reports contains sensitive patient information, the bill provides that these reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the CPRA. California generally recognizes that public access to information concerning the conduct of the people's business is a fundamental and necessary right. At the same time, the state recognizes that this right must be balanced against the right to privacy. The general right of access to public records may, therefore, be limited where records include personal information. In light of the sensitive nature of information contained in medication error reports, the potential limiting of access to public records in this bill seems warranted.

3. Proposed amendment

The author and sponsor have indicated that the intent of the error medication reporting is to provide licensees, the Legislature, and the Board with a transparent understanding of the frequency of medication errors. However, the current language in the bill provides that the reports are confidential and not subject to disclosure, but does not grant the Board the authority to release information gleaned from the data in the reports so long as no identifying information is disclosed. As such, the author may wish to amend the bill to authorize the Board to publish deidentified information compiled from the data in the reports.

The specific amendment is:¹

Section 4113.1 as added to the Business and Professions Code, is amended to read:

4113.1.

(a) A community pharmacy licensed pursuant to this article shall report all medication errors to an entity approved by the board. A community pharmacy shall submit the report no later than 14 days following the date of discovery of the error. These reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government ~~Code~~ Code), *except that the board may publish deidentified information compiled from the data in the reports*. The community pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make these records immediately available at the request of

¹ The amendments may also include technical, nonsubstantive changes recommended by the Office of Legislative Counsel.

an inspector. A medication error report made pursuant to this section shall not be subject to discipline or other enforcement action by the board based solely on the report. However, if the board receives other information regarding the medication error, that information may serve as basis for discipline or other enforcement by the board.

(b) For purposes of this section, “community pharmacy” includes any pharmacy that dispenses medication to an outpatient.

4. Statements in support

The California Board of Pharmacy, sponsor of the bill, writes:

As part of the Board’s Sunset Review process in November 2020, oversight committees asked the Board if there were opportunities for statutory changes that would potentially reduce the frequency of medication errors resulting in patient harm. Assembly Bill 1286 is a culmination of a yearlong effort undertaken by an ad hoc committee specifically focused on evaluating medication errors, working conditions, and the intersection of the two. As part of the Committee’s process, members heard from experts in the field, learned about authorities in other jurisdictions, and gained an understanding about findings and activities under way at the national level. It is incumbent upon the Board to act now on these findings to promote patient care.

As a compliment to the efforts of the ad hoc committee, the Board’s licensing committee also undertook a comprehensive review of the pharmacy technician licensing program with listening sessions, a dedicated summit, and several public discussions. The provisions related to pharmacy technicians reflect the outcomes of that effort, to assist pharmacists in performing authorized duties in a safe manner, allowing pharmacists to be redirected to perform more comprehensive patient care activities to promote patient safety. The goal of this provision is to ensure that information regarding medication errors are reported to the Board for review, but that the individual instances of medication error and kept private due to the sensitive nature of the information. The bill includes the following finding regarding the need for the limited disclosure in this bill:

To advance patient safety through medication error reduction, the primary purpose of the medication error reporting is to advance error prevention by analyzing individually and collectively medication error data that occurs in the community pharmacy setting to identify contributing factors and to broadly disseminate information on preventative measures and best practices for safe medication use, to advise regulators as part of its ongoing activities to monitor and improve the safety of medication use, and to advise policymakers to advance patient safety.

5. Statements in opposition

The California Community Pharmacy Coalition is opposed to the bill stating that as currently written [it] will undermine patient access to pharmacy services and be detrimental to the health equity goals of California policymakers. Specifically they have concerns with:

- the staffing floor requirements in the bill being too rigid and unrealistic;
- the pharmacy to PT ratio; and
- that the medication error reporting is restricted to one organization.

In regards to the medication error reporting they write:

While CCPC is supportive of the goal of AB 1286 to reduce medication errors, we do not believe that requiring medication errors to be reported to a single organization – in this case the Institute for Safe Medication Practices (ISMP) - is the appropriate solution. Instead, we believe pharmacies should have the option to report this information more broadly to any patient safety organization (PSOs).

They also do not want the board to have any access to these medication error reports.

SUPPORT

California State Board of Pharmacy (sponsors)
California Labor Federation, AFL-CIO
California Pharmacists Association
United Food and Commercial Workers, Western States Council

OPPOSITION

California Community Pharmacy Coalition

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation: None Known.

PRIOR VOTES

Senate Business, Professions and Economic Development Committee (Ayes 8, Noes 3)

Assembly Floor (Ayes 57, Noes 10)

Assembly Appropriations Committee (Ayes 12, Noes 2)

Assembly Business and Professions Committee (Ayes 11, Noes 1)
