

California Expands “No Pharmacist Left Alone” Pharmacy Staffing Requirements and Also Enacts New Safety Measures

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Introduction

Pharmacy employees at some CVS and Walgreens stores, including pharmacists, technicians, and support staff, recently walked off of their jobs to protest insufficient staffing and dangerous workloads that they claim jeopardize patient safety.

The California Board of Pharmacy (the “Board”) and the California Pharmacists Association have both advocated that it is essential for pharmacists to have sufficient time and support to engage in the pharmacy practice, including but not limited to performing the following daily tasks:

- Dispense drugs and biological products that a prescriber has ordered.
- Provide consultation, training, and patient education about drug therapy, disease management, and disease prevention.
- Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.
- Order and interpret tests to monitor and manage the efficacy and toxicity of drug therapies in coordination with the patient’s provider or prescriber.
- Administer immunizations under a protocol with a prescriber or applicable law.
- Furnish emergency contraception drug therapy, self-administered hormonal contraceptives, HIV preexposure and postexposure prophylaxis, and nicotine replacement products, subject to specified requirements.

California Board of Pharmacy Workforce Survey

Medication error complaints are among the most common consumer complaints the Board receives. In the fiscal year 2020-2021, the Board initiated 521 investigations with allegations of a prescription error, with 367 indicating patient harm.

As part of the Board's evaluation of medication errors, and in response to information at the national level suggesting that workforce issues may be a contributing factor to these types of errors, the Board developed a workforce survey intended to focus on pharmacists who reported working in a community chain or independent pharmacy environment in California.

The survey inquired about the average prescription volume during:

- shifts,
- workload metrics used,
- work queue that monitors the wait time for prescription services provided at the pharmacy,
- requirement to perform the services,
- number of immunizations administered during a typical work shift, and
- average number of medication errors that occur in a month.

The Board survey results identified significant concerns regarding workloads for pharmacists working in community chain pharmacies:

- 91 percent of pharmacists working in community chain pharmacies versus 37 percent of pharmacists working in independent pharmacies indicated they did not believe staffing in their pharmacy is appropriate to ensure adequate patient care;
- 83 percent of chain store pharmacists versus 32 percent working in independent pharmacies indicated they do not believe they have sufficient time to provide appropriate patient consultation;
- 78 percent of chain store pharmacists versus 44 percent of independent pharmacists do not believe they have sufficient time to provide adequate screening before the administration of immunizations, and;
- 90 percent of pharmacists in community chain pharmacies indicated that their pharmacy has a work queue that monitors the wait time for a prescription.

California Board of Pharmacy Ad Hoc Committee

In response to the survey findings, the Board established an ad hoc committee (the "Committee") to evaluate the identified issues. As part of the Committee's process, the Board consulted with retail pharmacy experts, reviewed pharmacy staffing and patient safety authorities in other states, and gained an understanding of national pharmacy medication error findings and best practices.

Assembly Bill 1286

Based on the Committee's recommendations, Assembly Bill 1286 (hereinafter referred to as "the Law") was promulgated by the Board and sponsored by (Haney) and known as the Stop Dangerous Pharmacies Act, amends sections 4113, 4113.5, 4115, 4192, 4204, and 4301 of, and add to sections 4113.1 and 4316.5 of the Business and Professions Code to:

1. authorize pharmacists-in-charge to make staffing decisions,
2. update the authority for pharmacy technicians to undertake certain tasks according to qualification and supervision requirements,
3. require a community pharmacy to report medication errors to a Board-approved entity,
4. require a chain community pharmacy to be staffed at all times with at least one clerk or pharmacy technician dedicated to pharmacy-related services,
5. require 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, and
6. provide the Board with cease and desist authority for specified conditions present in a pharmacy.

The Law will go into effect on January 1, 2024. All pharmacies should review the Law and, if applicable, should revise and/or develop and implement policies and procedures and compliance program monitoring and auditing tools to ensure compliance with each of the specific requirements of the Law summarized below.

Pharmacist in Charge Pharmacy Staffing Authority

Each pharmacy must designate a "pharmacist-in-charge," subject to approval by the Board. This pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations regarding the practice of pharmacy.

The Law authorizes the pharmacist-in-charge to make certain staffing and pharmacy operations decisions that the pharmacist-in-charge believes to be in the best interest of the pharmacy, pharmacy staff, and pharmacy patients.

Staffing Decisions

The Law 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. If the pharmacist-in-charge is unavailable, a pharmacist on duty may

adjust staffing according to workload if needed. This authority would be delegated to the pharmacist on duty if the pharmacist-in-charge is unavailable. *Business and Professions Code 4113(c)(2)*.

Store Management Notification of Unsafe Conditions

The Law 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.

Pharmacy store management must 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.

Business and Professions Code 4113(d)(1).

The conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to:

1. workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff; or
2. sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions or vermin infestation that poses a risk to the safety or efficacy of the medicine. *Business and Professions Code 4113(d)(3)*. If conditions are not resolved within 24 hours, the pharmacist-in-charge or pharmacists on duty must ensure that the Board is notified timely. *Business and Professions Code 4113(d)(1)*.

Upon receipt of such notice and following an evaluation and assessment of the relevant evidence, the Board is authorized to issue an order to the pharmacy to immediately cease and desist those pharmacy operations affected by the conditions at issue.

This cease-and-desist order will remain in effect until the Board determines that the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff have been decreased or for no more than 30 days, whichever date is earlier. *Business and Professions Code 4113(d)(4)*.

Pharmacy Staffing Minimums

The Law requires that a chain community pharmacy be always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services unless waived by the pharmacist on duty. The clerk/pharmacy technician staffing requirement does not apply beyond regular business hours or to pharmacies with an average daily prescription volume of less than 75 prescriptions per day. However, this exception is not

applicable if the pharmacist is expected to provide immunizations and CLIA-waived tests. *Business and Professions Code 4113.6(a)*.

The Law also provides that where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunchtime for all pharmacy staff shall be established and publicly posted and included on the outgoing pharmacy telephone message. *Business and Professions Code 4113.6(b)*.

Medication Errors Reporting

The Law requires a community pharmacy to report all medication errors to a Board-approved entity no later than 14 days after discovering the error. The Law specifies that those reports are deemed confidential and are not subject to discovery, subpoena, or disclosure under the California Public Records Act.

The medication error reporting will be done in aggregate, without punitive measures against individual pharmacists. The Law specifies that a medication error report shall not subject a community pharmacy to discipline or other enforcement action based solely on the report, but if the Board receives additional information regarding the medication error, that information may serve as the basis for discipline or other enforcement by the Board. *Business and Professions Code 4113.1*

Pharmacy Technician Scope of Practice Expansion

The Law permits pharmacists to delegate non-discretionary tasks to professionally trained pharmacy technicians by expanding the scope of pharmacy technician practice. The Law authorizes a pharmacy technician to administer vaccines, administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive verbal prescriptions, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

- The pharmacist-in-charge of the pharmacy at which the tasks are being performed has deemed the pharmacy technician competent to perform such tasks and documented such determination in writing.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist in performing the tasks. A pharmacy technician who qualifies to perform the additional tasks would then not count in the Pharmacy Law's 1:1 ratio, and another pharmacy technician would be required to assist with other tasks.
- The pharmacy technician is certified by a program accredited by the National Commission for Certifying Agencies that the Board approves.
- The pharmacy technician has successfully completed at least six hours of practical.
- Training approved by the Accreditation Council for Pharmacy Education includes hands-on injection techniques, recognizing and treating emergency reactions to vaccines, and an assessment of the pharmacy

technician's injection technique.

Business and Professions Code 4115(b).

Unprofessional Conduct

The Law adds the following to the list of violations that constitute unprofessional conduct:

- Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations or exercise professional judgment, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or authorizing an environment that may jeopardize patient care. *Business and Professions Code 4301(v).*
- Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgment, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner. *Business and Professions Code 4301(w).*
- Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or pharmacy technician to comply with laws or regulations. *Business and Professions Code 4301(x).*
- Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless those guarantees are required by law or to meet contractual requirements. *Business and Professions Code 4301(y).*

Conclusion

As the recent walkout by pharmacy employees indicates, the workload pressure of pharmacists and pharmacy staff is significant. The Law results from governmental interest in providing tools and training, adding staff to help alleviate the pressure, enhancing workflow, adjusting store hours of operation, cross-training employees to assist in the pharmacy, and providing additional resources as necessary to help alleviate the workload pressure faced.

For example, the National Association of Boards of Pharmacy suggested “best practices” to address pharmacy staffing challenges, including:

- Review daily workflow reports to identify pharmacies needing assistance and route additional staff to support those locations.
- Promote a contingency plan for an understaffed pharmacy relative to patient demand to ensure safe staffing levels.
- Provide opportunities for pharmacy staff for uninterrupted rest periods and meal breaks.
- Delegate non-discretionary tasks to professionally trained pharmacy technicians or pharmacist interns.

- Encourage pharmacy managers to utilize alternative methods to monitor the individual pharmacists' work patterns to prevent burnout.
- Encourage the pharmacist in charge or pharmacy manager to utilize a Board pharmacy staffing report form and report violations and/or unsafe conditions to the Board.
- Develop policies and procedures related to continuous quality improvement programs and error reporting.
- Aggregate medication error data that can be shared with the Board and industry.
- Let patients know if the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner.
- Provide an option for patients to have their prescriptions delivered or shipped to their homes for convenience.

Hinshaw attorneys have significant experience advising health care organizations on pharmacy law matters. For further information, please contact [Michael A. Dowell](#) or your [Hinshaw attorney](#).

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