

Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which becomes effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term “community pharmacy” includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a), (c), and (e)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term “medication error” includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient’s agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity?

A: The Board is in the process of identifying an entity to receive AB 1286 medication error reports. Until the Board has approved the entity, medication errors do not need to be reported under BPC 4113.1. The Board reminds licensees, however, that provisions for documenting medication errors as established in California Code of Regulations (CCR), title 16, section 1711 (relating to quality assurance programs) remain effective. AB 1286 does not impact the quality assurance documentation requirements.

[Reference: BPC 4113.1(a); 16 CCR 1711]

4. Q: Given the delay in implementation for reporting medication errors under AB 1286, how will I know when the medication error reporting becomes effective?

A: The Board will use a variety of means to announce the approval of the entity and the implementation timeframe, including through the Board’s subscriber alert system and posting information on its website.

Note: As a reminder, all licensees are required to enroll in the Board's subscriber alert system. Additional information is available [here](#).

[Reference: BPC 4013]

5. Q: I work in an outpatient hospital pharmacy. Do AB 1286's requirements for medication error reporting apply to our pharmacy?

A: Yes. However, pursuant to subdivision (e) of BPC 4113.1, an outpatient hospital pharmacy shall not be required to report to the Board-approved entity a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to section 1279.1 of the Health and Safety Code (HSC). The State Department of Public Health may share any such report with the Board.

[Reference: BPC 4113.1(e)]

6. Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

[Reference: BPC 4113.1]

7. Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

Minimum Staffing Provisions

8. Q: What minimum staffing requirements does AB 1286 establish?

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.

- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, CLIA-waived tests, or any other ancillary services provided by law, this exemption does not apply.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6(a)]

Staffing Decisions

9. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may 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. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

10. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

11. Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required 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. 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, any of the following:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

12. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to 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. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

13. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

14. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: -- PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,

- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

15. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

16. Q: What are the expanded duties pharmacy technicians may perform pursuant to AB 1286?

A: Effective January 1, 2024, qualified pharmacy technicians may perform the following duties under specified conditions:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as waived under CLIA
- Receive prescription transfers
- Accept clarification on prescriptions

[Reference: BPC 4115(b)]

17. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (*i.e.*, packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.
- The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b)(1)]

Unprofessional Conduct

18. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

19. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board [online](#). Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

20. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

Surgical Clinic Provisions

21. Q: Under new requirements established by AB 1286, our surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form is currently being developed. Upon approval, the Board will release a subscriber alert and post the form on its website. The form will be available [here](#).

[Reference: BPC 4192(b)]

22. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

23. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available [here](#).

[Reference: BPC 4192(b), 4204(c)]

24. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee. It is recommended that licensees consider mailing the renewal application form, fee, and self-assessment form to the Board's office for handling, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

[Reference: BPC 4204(c)]

December 21, 2023