



March 2024

# THE SCRIPT

BE AWARE & TAKE CARE: Talk to your pharmacist!

## SPECIAL EDITION!

### AB 1286 Patient Safety Measure

### California Becomes National Leader in Pharmacy Safety



[Assembly Bill 1286](#) is a first in the nation patient safety measure that among its requirements includes mandatory reporting of outpatient medication errors. This patient safety measure went into effect January 1, 2024, and it's designed to provide pharmacists and other pharmacy personnel with additional support in their working environment to decrease medication errors. AB 1286 allows the Board of Pharmacy (BOP) access to reports of medication errors, which allows the Board to understand and evaluate where and why medication errors are happening.

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The California State Board of Pharmacy is engaging in the state contracting process to approve a third party vendor for purposes of medication error reporting. Medication error reporting will not begin until the Board approves such an

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# PRESIDENT'S MESSAGE



**By Seung Oh, President,  
Board of Pharmacy**

Welcome to this Special Edition of The Script where we have dedicated this issue to AB 1286, the Patient Safety Measure.

I am equal parts excited as I am grateful for all the hard work the Board has invested in this new bill that focuses on medication error reduction. I would be remiss not to mention all the licensees who took time to carefully articulate their thoughts and concerns to ensure pharmacists are able to provide the best care possible to their patients. This includes the licensees who completed the medication error and reduction survey in the beginning of this process. This set the foundation on what the Board could focus on to support you in keeping patients safe.

What we are doing here in California will set the stage nationwide. AB 1286 will be a model that will be studied and carefully monitored throughout the country in years to come. We

are setting the highest standards for pharmacy care and consumer protection. With AB 1286, we are hoping to build a circle of trust and support that we desperately need. AB 1286 empowers licensees to make decisions that are in the best interest of their patient.

Under AB 1286, reporting medication errors will be an essential part of the process. Using actual data from pharmacists will allow us to understand what needs to improve. We will have a third party collect medication error reporting data. This affords us the opportunity to analyze and study the causes of medication errors, thus in turn allows the Board to provide more clarity and support to pharmacists so that errors can be proactively prevented. These steps that will be taken to advance patient care and set the highest standards in pharmacy that we all truly deserve.

It's been a long process and we appreciate your patience. We want to make sure that every piece of the puzzle is thought out before fully implementing the new law. We also want to make sure licensees understand what is expected of them and what the new law covers, that is why in this special edition issue we have dedicated all of our articles to AB 1286. This includes what is in the current law, the implementation of AB 1286, what steps you can begin doing today, and Frequently Asked Questions (FAQ).

It is our intention to educate and offer the support you need to best understand AB 1286 so we all can focus on what is the most important: providing safe and effective pharmaceutical care for all Californians.

We hope you find the information in this newsletter helpful to you and your practice. Thank you for your continued commitment to California consumers.

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entity. Once there is a system in place, the Board will notify licensees of the date it will become in effect and set an enforcement date. Notification of the enforcement will be sent through several subscriber alerts and will be posted on the website.

In the meantime, licensees should be transitioning to ensure compliance with other requirements.

## AB 1286

### What's New - Summary of Changes

#### Medication Error Reporting

**Prior to 2024,** pharmacies were generally not required to report medication errors unless the medication error was related to the use of automated drug delivery systems or related to settlement agreements.

**What's New:** A community pharmacy is required to report medication errors. 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.

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,
- the wrong route of administration

Errors that are corrected prior to dispensing to the patient or patient's agent or any variation allowed by law are not required to be reported.

The law provides that such reports are confidential and not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act. The Board would be authorized to publish certain deidentified information compiled from the data in the reports in accordance with specified requirements.

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### Minimum Staffing Provisions

**Prior to 2024,** a community pharmacy was prohibited from requiring a pharmacist employee to engage in the practice pharmacy at any time the pharmacy was open to the public, unless either another employee of the pharmacy or, if the pharmacy was located within another establishment, an employee of the establishment within the pharmacy was located, was made available to assist the pharmacist at all times.

**What's New:** Chain community pharmacies are required to be staffed at all times with at least one clerk or pharmacy technician fully dedicated to pharmacy related services, unless any of the following conditions apply:

- If the pharmacist on duty waives the requirement in writing during specified hours based on workload needs.
- The pharmacy is open beyond normal business hours (8:00pm to 7:00pm).
- The prescription volume of the pharmacy is generally less than 75 prescriptions a day and the pharmacist is not required to provide additional services such as immunizations or CLIA waived tests.

### Staffing Decisions

**Prior to 2024,** the pharmacist in charge (PIC) wasn't authorized to make staffing decisions.

**What's New:** The PIC is authorized to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with the pharmacist's ability to practice competently and safely. If the PIC is not available, the pharmacist on duty is authorized to adjust staffing according to workload if needed.

The PIC or the pharmacist on duty is required to immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Store management will be required to take immediate and reasonable steps to address and resolve those conditions, and, if those conditions are not resolved within 24 hours, the PIC or the pharmacist on duty is required to inform the Board of Pharmacy.

Upon a reasonable belief that conditions present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, the executive officer will be required to issue a cease-and-desist order. A failure to comply with the cease-and-desist order will be considered unprofessional conduct.

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## AB 1286 Patient Safety

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### Pharmacy Technician Expanded Duties

**Prior to 2024,** a pharmacy technician was authorized to perform prescribed nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist who was responsible for the duties performed under their supervision by a technician.

**What's New:** A specially trained pharmacy technician is authorized, under the direct supervision and control of a pharmacist, to prepare and administer influenza and COVID-19 vaccines via injection or intranasally. The pharmacy technician is also authorized to prepare and administer epinephrine, perform specimen collection for specified tests receive prescription transfers, and accept clarification on prescriptions under prescribed conditions.

AB1286 prohibits a pharmacy with only one pharmacist from having more than one pharmacy technician performing these additionally authorized tasks and specify that if a pharmacy technician is performing these additionally authorized tasks, a second pharmacy technician is required to be assisting a pharmacist with performing the nondiscretionary tasks currently authorized under existing law.

### Unprofessional Conduct

**Prior to 2024,** the unprofessional conduct code did not include actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with law and regulations, or exercise professional judgement.

**What's New:** The list of specified actions that constitute as unprofessional conduct has been expanded to include actions or conduct that would subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including:

- creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care;
- actions of conduct that would 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;
- actions of conduct that would subvert the efforts of a pharmacist intern or a pharmacy technician to comply with laws or regulations;
- or 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.

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### Surgical Clinic Provisions

**Prior to 2024,** the law required a consulting pharmacist be retained to approve the clinic's policies and procedures in conjunction with the professional director and the administrator and to visit the clinic regularly and at the least quarterly. Previous law required the consulting pharmacist to certify in writing quarterly that the clinic is, or is not, operating in compliance with existing law governing clinics.

**What's New:** A consulting pharmacist, before July 1 of every odd-numbered year, is required to complete a Surgical Clinic Self-Assessment Form. This is to promote compliance through self-examination and education and includes a requirement that the professional director of the clinic and consulting pharmacist make a prescribed certification signed under penalty of perjury, kept on file in the clinic for 3 years, and made available to the board or its designee. The consulting pharmacist is required to certify compliance with the quarterly inspections as part of the clinic renewal process.

### Assembly Bill 1286 Implementation Statement (December 13, 2023)

The California State Board of Pharmacy provides licensees and interested stakeholders with the following information on its policy relating to implementation of provisions contained within Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023).

Assembly Bill 1286 establishes a requirement for the reporting of medication errors that occur in the outpatient setting to an entity approved by the Board under specified conditions. The Enforcement and Compounding Committee will begin its evaluation of entities in the coming months. During this intervening period, reporting of such errors is not required nor will it be retroactive. It is anticipated that reporting of such errors will only be expected after approval of such an entity with an appropriate transition period for implementation. Interested stakeholders are encouraged to participate in relevant public meetings.

Assembly Bill 1286 also establishes a self-assessment process for surgical clinics. Development of the self-assessment form will be undertaken by the Enforcement and Compounding Committee. Upon development and approval of the self-assessment form, the Board will advise licensees and make the form available on its website. During this intervening period, completion of the self-assessment form requirement will be delayed. Interested stakeholders are encouraged to participate in relevant public meetings.

Several additional provisions contained in Assembly Bill 1286 become effective January 1, 2024. The Board encourages licensees to begin taking the necessary steps for compliance immediately. The Board recognizes that despite good faith efforts, there may be delays in achieving compliance by January 1, 2024. During the implementation period, the Board will consider actions taken to secure compliance when areas of non-compliance are identified through the inspection or investigation process. The Board encourages licensees to maintain documentation of actions taken to achieve compliance and to present such information to the Board upon request.

# Collecting and Reporting Medication Errors

## Board of Pharmacy Research Data System to Improve Patient Safety

As part of the implementation of Assembly Bill 1286, a third party, independent vendor will be hired to collect the data from pharmacies. The Department of Consumer Affairs (DCA) will assist the board in securing a contract for the approved vendor consistent with the state contracting process.

The California State Board of Pharmacy (BOP) has received requests from entities interested in serving as the vendor to receive medication error reports under new section 4113.1 of the Business and Professions Code. During the January 23, 2024, Enforcement Committee meeting the DCA provided an overview of the state contracting process. You can watch the [presentation here](#).

In order for the Board to contract an entity to collect and report medication errors, DCA will solicit for the services in a Request for Proposal (RFP) process. Prior to the RFP, the Board will identify the needs necessary for reporting. Once established, the executive officer will initiate the search process with submitting a BSO-47 with DCA, an internal form to begin the RFP. RFP is the solicitation method used to secure complex services calling for technical and/or professional skills and expertise.

When the RFP goes live, vendors can search for active posted solicitations and vendors can find the RFP. The RFP will be advertised on [Cal-eProcure](#) and will be active for at least 30 business days. Vendors will have an opportunity to ask any questions to DCA and questions will be posted publicly.

In an RFP, the department outlines requirements such as administrative and technical specifications, evaluation methodology, bid preparation instructions and contract language. Proposers are responsible to responding to the requirements and how they intend to perform the work.

The estimated turnaround time for an RFP can vary between 3-9 months depending on the complexity of services and/or the requirements of the RFP.

### ***Learning from others...***

To learn more about reporting medication errors, the Board invited two health reporting agencies to the January 23, 2024, Enforcement Committee meeting. Both agencies have seen positive results with medication safety reporting through learning, sharing, and acting to improve healthcare.

The first presentation was on the Canadian Medication Incident Reporting and Prevention System (CMIRPS) by ISMP Canada. ISMP Canada is a national independent, not for profit organization that purposefully partner with organizations, practitioners, consumer, and caregivers to advance medication safety in all health care settings.

A second presentation came from the Agency for Healthcare Research and Quality (AHRQ), a lead federal agency charged with improving the safety and quality of healthcare nationally. The agency manages the Network of Patient Safety Databases (NPSD) that contains information voluntarily submitted by patient safety organizations. The NPSD contains non-identifiable data derived from information voluntarily submitted by patient safety organizations. The data makes it possible to identify and track patient safety concerns for the purpose of learning how to mitigate patient safety risks and reduce harm across healthcare settings nationally. You can watch both [presentations here](#).

# Frequently Asked Questions

## Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which became 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

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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

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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 PIC 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](mailto: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)]

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### 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.

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### 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)]

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