1.1 Role of the State Board of Pharmacy Inspector

It is the role of the State Board of Pharmacy Inspector to inspect during business hours all pharmacies, wholesalers, dispensaries, stores or places where drugs or devices are compounded, prepared, furnished, dispensed or stored. When the inspector is performing the inspection of the pharmacy, the inspector is allowed to remove the pharmacy’s files, records, and any documentation that is the subject of the inspection. Upon the completion of the inspection, the inspector must provide a signed receipt to the pharmacy detailing all documentation that is being removed.

During the course of the investigation, the licensee may be asked for more documents and/or statements regarding the events that were alleged to have occurred.

1.2 Order of Correction

After the inspector reviews the documentation and believes that a violation of Pharmacy Law did in fact take place, then the licensee may be advised of the alleged violation through an Order of Correction. The Order of Correction simply outlines the alleged violations of the law that the inspector believes occurred. The licensee is directed to respond within 30 days by submitting a corrective plan to fix the problem to the inspector.

Upon receipt of the response to the Order of Correction, the investigation is fully reviewed by an inspector or enforcement analyst to determine if the law was violated. If a violation is found, then a supervising inspector reviews this violation. If the supervising inspector determines that there was no violation, or the violation is minimal, the action may be closed and the case goes no further.

In the event the supervising inspector determines that further action is warranted, the case is referred to the Board’s executive officer. Upon review, the executive officer will determine the appropriate course of action, which can include the following:

1) Case Closure: The executive officer may determine that no further action is necessary because of the following:
   a. There was no violation
   b. Violation did occur, but was too minimal to warrant further action
   c. Mitigating circumstances are such that it would be best not to pursue an action

2) Order of Correction: An Order of Correction is sent to the licensee who is required to do one of the following:
   a. Contest the order by requesting an office conference with the executive officer; or
   b. Comply with the Order. By complying with the Order, the licensee’s action is not an admission of the noted violation. The Order of Correction is not the Board’s final determination of the matter. If the licensee complies with the Order, a copy of the Order of Correction and the corrective action plan must be maintained at the pharmacy for at least three years from the date of the Order of Correction.

3) Further Investigation: The executive officer may determine that more information is necessary to conclude there was a violation. By doing so, the matter is returned to the investigational officer for further investigation.
4) Letter of Admonishment: After determining that the licensee failed to comply with Pharmacy Law, the executive officer requests that a Letter of Admonishment be issued. The letter will indicate which State statute or regulation was violated and a notice to the licensee of his or her available appeal rights.

5) Citation and Fine: The following factors can be taken into consideration by the executive officer to determine the issuance of citations and fines:
   a. Severity of the violation
   b. Good or bad faith of the cited person or entity
   c. History of previous violations
   d. Evidence regarding the severity of the intent underlying the violation
   e. The licensee’s cooperation with the Board during the investigation
   f. Extent to which the licensee or entity has mitigated or attempted to mitigate any damage or injury resulting from the violation
   g. The number of violations discovered during the investigation
   h. Other matters as may be appropriate

6) Order of Abatement: The Board can also issue an Order of Abatement in addition to a citation requiring the licensee to submit a corrective action plan to demonstrate how future compliance with Pharmacy Law will be accomplished as well as complete continuing education courses in the subject matter specified in the Order of Abatement.

7) Fine Amount: State Regulations allow the Board to fine up to $5,000.00 per licensee for each citation. When the investigation involves multiple licensees, (e.g., the pharmacy, the pharmacist-in-charge, a staff pharmacist, and the pharmacy technician), each licensee may be cited and fined based upon the criteria set forth above.

1.3 Explanation of Disciplinary Terms

1) Effective Date of Action: The date the disciplinary action goes into operation.

2) Revocation or Revoked: The Board revokes the license as a result of disciplinary action and the licensee’s right to practice or operate a Board-licensed entity is ended.

3) Revoked, Stayed: The license is revoked, but the revocation is postponed until the Board determines whether the licensee has failed to comply with specific probationary conditions, which may include suspension of the licensee’s right to practice.

4) Stayed: The revocation or suspension action is postponed and the licensee is put on probation.

5) Probation: The licensee may continue to practice or operate a Board-licensed entity under specific terms and conditions for a specific period of time.

6) Voluntary Surrender: The licensee has agreed to surrender his or her license and the right to practice or operate a Board-licensed entity is ended.

7) Suspension: The licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time.

8) Suspension/Probation: The licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time, and the right to practice or operate is contingent upon meeting specific terms and conditions during the probationary period.

9) PC 23 Order Issued: The licensee is restricted from practicing or operating a Board-licensed entity by a court order that is issued under the provisions of Penal Code section 23.
10) Public Reprimand: Resulting from a disciplinary action, the licensee is issued a letter of public reprimand.

11) Accusation Filed: An accusation is the document containing the charges and allegations filed when an agency is seeking to discipline a license.

12) Reinstatement of License: A previously revoked or suspended license is reinstated with specified terms and conditions.

13) Statement of Issues: A legal document that details the factual or legal basis for refusing to grant or issue a license.

1.4 STATE BOARD OF PHARMACY INSPECTION: EVENTS AND CHECKLIST

The Board may be prompted to visit the pharmacy for an inspection when certain events happen. The purpose of the inspection is to ensure that the pharmacy is in compliance with all aspects of pharmacy law.

1.5 State Board of Pharmacy Inspection Events

Following is a list of events that can prompt the Board to make a visit and a subsequent inspection.

1) New pharmacy permit is issued: A new pharmacy self-assessment form is necessary.

2) New pharmacist-in-charge (PIC) is employed: A new pharmacy self-assessment form is necessary, and the pharmacist-in-charge leaving and PIC arriving MUST notify the Board within 30 days.

3) Complaint: A consumer files a complaint against the pharmacy. While the pharmacy is not aware that a complaint has been filed, most likely the complaint is filed because of a major event occurring at the pharmacy. Dispensing errors qualify as a major event.

4) In the area: The Board of Pharmacy is visiting other pharmacies in the local area.

5) Compliance issues: To confirm or reject a suspicion or report of compliance issues.

1.6 State Board of Pharmacy Inspection Checklist

Following is a general checklist of the most common information, including operation procedures, policies and procedures that are requested, inspected and reviewed by the Board inspector during an inspection:

1) Biennial Pharmacy Self-Assessment: Make sure you have your most current Self-Assessment(s) in "Section B" of the License Protection Handbook. In addition, include in “Section B” any previous Self-Assessment(s). Retain your Self-Assessments for up to 3 years for review during a Board inspection. Download from the Board’s web site the latest form(s) listed below. Do not use any old forms when completing your Self-Assessment. The Board requires the following two Self-Assessments:
   a) The Board requires that the pharmacist-in-charge complete a “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment” on Form 17M-13 (Rev 5/13). The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever:
      i) a new pharmacy permit has been issued,
      ii) there is a change in the pharmacist-in-charge,
      iii) there is a change in the licensed location of the pharmacy.