

NONRESIDENT PHARMACY INSPECTIONS

BY THE CALIFORNIA STATE BOARD OF PHARMACY

WHAT YOU CAN EXPECT FROM AN INSPECTION AT A NONRESIDENT PHARMACY

The Board of Pharmacy appreciates your cooperation during this inspection. The goal of an inspection is to safeguard the health and safety of California consumers. This is also an important educational opportunity for inspectors to provide guidance and answer your questions about California pharmacy laws and regulations. After the inspection is complete, a copy of the inspection report will be issued which will contain details of the inspection together with any outstanding issues that will need to be addressed. We welcome feedback about your experience and any comments about the inspector and the inspection process.

AN INSPECTOR WILL:

- Identify themselves with a Board-issued badge and provide a business card.
- Be professional and courteous.
- Provide a receipt for any records taken into possession.
- Provide a copy of the inspection report with the pharmacist on duty and/or pharmacist-in-charge.
- Provide information and answer questions about pharmacy laws and regulations.

WHAT THE BOARD EXPECTS FROM YOU

DOCUMENTS FOR INSPECTION

Pharmacies are required to have certain documents readily available for inspectors to review. Hard and electronic copies of records must be available during business hours.

DOCUMENTS TO HAVE AVAILABLE INCLUDE BUT ARE NOT LIMITED TO:

- Written notification for consultation when drugs are delivered to California residents.

- Past inspection reports including reports of inspections performed by other regulatory and accreditation agencies.
- Master list of pharmacists involved in dispensing medications intended for California patients.
- DEA Biennial Inventory.
- Acquisition and disposition records of drugs dispensed to California patients.
- Accompanying records or systems ensuring Drug Supply Chain Security Act (DSCA) compliance.
- California Medication Error Reporting (CAMER) reports for medication errors related to prescriptions dispensed to California residents.
- Controlled Substance Utilization Review and Evaluation System (CURES) reports for controlled substances dispensed to California patients.
- Policies and procedures.

ADDITIONAL ITEMS

THE INSPECTOR ALSO WILL CHECK:

- DEA registration (if applicable).
- Drug expiration or beyond use dates.
- Hot/cold running water (separate from restroom).
- Confidential waste disposal.
- Interpretive services poster.
- Prescription labeling.
- Prescription records.
- Record storage and retention.
- Quarantine area for expired and recalled drugs.
- Refrigerator/freezer temperature logs.
- Facility and medication security features.
- Transmission of CURES data.
- Maintenance of facility, space, fixtures, and equipment.

AFTER THE INSPECTION

Once an inspection has been completed and in addition to the inspection report, the inspector may issue either an order of correction or written notice which indicates noncompliance with California pharmacy law.

If the inspector orders a correction, you will be instructed how to submit a plan or proof of correction to the Board within a specified period.

Keep all documentation related to completing the correction order with the inspection report.

If the inspector suspects a violation of California pharmacy law has occurred, you may receive a written notice. Depending on the type of violation, the Board may:

- Issue a letter of admonishment.
- Issue a citation (with or without a fine).
- Refer the case for disciplinary action against the pharmacy and/or individual licensee.

Letters of admonishment and citations are not considered to be discipline or disciplinary actions by the California State Board of Pharmacy. You may contest a letter of admonishment or citation by requesting an informal office conference. In the case of a citation, you also may request a formal hearing before an administrative law judge. You will receive a letter from the Board about the administrative action process, and you must reply by the specified due date.

REIMBURSEMENT FOR INSPECTION COSTS

Nonresident pharmacies are required to reimburse the California State Board of Pharmacy for the reasonable cost of conducting inspections. This includes, but is not limited to, expenses related to travel, staff time, lodging, meals, and any other costs directly associated with completing the inspection. The Board will send you an invoice detailing the costs incurred.

LET US KNOW HOW WE PERFORMED

The Board welcomes your feedback about the inspection experience. Contact any executive staff member listed on the back of this brochure with questions, comments, or complaints. You also may file an anonymous comment or complaint with the Board's parent agency, the Department of Consumer Affairs (DCA). Visit the DCA website at www.dca.ca.gov, go to the Consumer tab, and click on "File a Complaint."

ADDITIONAL INFORMATION

The Board's policy statement related to nonresident pharmacies is available [here](#).