

**Pharmacy Inspections
By the California State Board of Pharmacy**

**What You Can Expect from an Inspection –
What the Board Expects from You**

The Board of Pharmacy appreciates your cooperation during this inspection. The goal of an inspection is to safeguard the health and safety of consumers. This is also an important educational opportunity for inspectors to provide guidance and answer your questions about pharmacy laws and regulations. After the inspection is complete, we welcome feedback about your experience and any comments about the inspector and the inspection process.

What you can expect

An inspector will:

- Identify himself/herself with a board-issued badge and provide a business card.
- Be professional and courteous.
- Provide a receipt for any records taken into possession.
- Review and leave 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 is expected of you

Pharmacy staff will:

- Provide access to the inspector during regular business hours.
- Provide access to review all stocks of dangerous drugs and devices.
- Provide access to review all records of manufacture, sale, acquisition, receipt, shipment, and disposition.
- Allow the inspector to secure samples or specimens.

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:

- Written notification for consultation when drugs are delivered.
- Past inspection reports.
- Pharmacy self-assessments.
- Copies of staff licenses.
- Master list of pharmacist and technician initials.
- DEA 222 forms.
- Power of attorney to execute DEA 222 forms.
- DEA biennial inventory.
- Drug take-back records.
- Wholesaler invoices.

- Records of drug returns.
- Records of destruction.
- Off-site records waiver.
- Pedigrees for drugs purchased.
- Inventory reconciliation reports.
- Reporting of controlled substance drug losses.
- Controlled substances refill reports.
- Policies:
 - Automatic refill program.
 - Inventory reconciliation.
 - Community pharmacy staffing.
 - Quality assurance reports.
 - QA for medication errors.
 - Theft and impaired licensees.
 - Pharmacy technician job description.
 - Pharmacist absence for meals.
 - After hours deliveries.
 - Interpretive services.
 - Repackaging previously dispensed drugs.
 - Automated Drug Delivery Systems.
 - Common electronic files to prevent unauthorized release of patient information.
- Protocols:
 - Opioid Antagonists.
 - Travel medicine.
 - HIV PrEP/PEP.
 - Refusing to dispense on ethical, moral, religious grounds.
 - Immunizations, including proof of training and basic life support certification.
 - Emergency contraception.
 - Nicotine replacement.
 - Advanced practice pharmacist.
 - Procedures performed pursuant to BPC section 4052.2.

Additional items

The inspector also will check:

- DEA registration.
- Drug expiration dates.
- Drug take-back receptacles.
- Hot/cold running water (separate from restroom).
- Confidential waste disposal.
- Interpretive services poster.
- Notice to consumers poster.
- Restroom location.
- Patient consultation.
- Area suitable for confidential patient counseling
- Posted pharmacy license and renewal.

- Out-of-state licenses.
- Prescription labeling.
- Prescription records.
- Record storage and retention
- Quarantine area for expired and recalled drugs.
- Refrigerator/freezer temperature.
- Security features.
- Staffing ratio.
- Transmission of CURES data.
- Wearing identification or name tag printed in at least 18-point type.
- Possession of keys to the pharmacy.
- Maintenance of facility, space, fixtures, and equipment

After the inspection

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 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. 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.

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."

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**BE AWARE AND TAKE CARE:
Talk to your Pharmacist!**

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