

Department of Consumer Affairs

Position Duty Statement

HR-041a (new 7/2015)

Classification Title	Board/Bureau/Division
Inspector, Board of Pharmacy	Board of Pharmacy
Working Title	Office/ Unit/ Section/ Geographic Location
Outsourcing Team Inspector	Enforcement Unit
Position Number	Employee Name and Effective Date
632-110-8876-XXX	

Under the general direction of the Supervising Inspector (SI), the Inspector investigates and inspects board licensed entities and applicants for licensure in connection with the enforcement of the provisions of the laws and regulations governing the practice of pharmacy and most specifically, outsourcing facility practices. The Inspector travels both statewide and out of state to inspect licensed premises and premises applying for outsourcing licensure. The Inspector also provides consultation and education to licensees, consumers, governmental agencies and others regarding a variety of laws and regulations related to the dispensing of prescription drugs and devices, drug diversion, practice issues, drug manufacturing/outsourcing and on matters concerning pharmacology. Duties include but are not limited to:

A. SPECIFIC ASSIGNMENTS [Essential (E)/ Marginal (M) Functions]

55% Inspects Licensed Premises (E)

The Inspector travels both statewide and out of state to perform inspections of resident and nonresident licensed premises and premises applying for outsourcing licensure. Determines and evaluates policies and procedures, sterility, appropriate garbing, testing, process, validation, recordkeeping for beyond use dating, quality assurance programs, cleanliness, security, packaging procedures, dispensing practices, recordkeeping practices, labeling practices, compounding practices, and storage of drug stock. Ascertains any conditions that may be hazardous or illegal and reviews any records or documentation needed to substantiate violations of pharmacy laws or regulations and current Good Manufacturing Practice (cGMP). (35%)

Inspects and evaluates new facilities applying for outsourcing facility licensure to ensure compliance with pharmacy law, regulations and cGMP applicable to outsourcing facilities. Prior to inspection reviews policies and procedures of each outsourcing facility before renewal and initial licensure. Reviews the quantity and type of preparations compounded annually or manufactured annually by each outsourcing facility assigned to the Inspector for review and ensures compliance with operational requirements. (15%)

Issues orders of correction as appropriate and informs licensees about the legal requirements and the standards of practice licensees are expected to meet and issues orders to cease and desist from conducting business as outsourcing facilities. (5%)

35% Investigates and Mediates Complaints (E)

Prepares investigation reports or mediated case reports that include a summary, a detailed synopsis of the violations and the findings of the investigation or mediation. (20%)

Investigates and/or mediates complaints alleging violations of the pharmacy practice act, specifically, laws related to outsourcing and (cGMP) . In the course of investigating suspected misconduct, collects evidence, conducts interviews, prepares correspondence, performs drug audits, participates in undercover operations and assists other governmental or law enforcement agencies. (10%)

An Inspector may assist in arresting and prosecuting violators and serves as an expert witness, providing testimony during administrative or criminal hearings. (5%)

10% Subject Matter Expert/ Represents the Board of Pharmacy (E)

- Attends meetings, office conferences, and joint meetings with other regulatory agencies. Responds to routine inquiries from licensees, the public, government agencies and other interested parties concerning the requirements of state and federal pharmacy laws and regulations.
- Addresses professional associations, consumer groups and updates the profession on emergency standards and practices for outsourcing facilities.
- Keeps abreast of the developments in the practice of pharmacy and with new federal and state guidelines, policies, laws and regulations and makes recommendations concerning procedures and proposed legislation or regulations.
- Responds to complex written inquiries requiring the knowledge of a pharmacist.
- Maintains knowledge of outsourcing processes, standards and federal current good manufacturing practices applicable to outsourcing facilities to retain classification as a subject matter expert.
- Oversees recalls of drugs initiated by outsourcing facilities.
- Provides assistance to other teams as necessary in order to ensure investigations and site inspections are completed timely.

B. Supervision Received

The Inspector reports directly to the SI and receives the majority of assignments from the SI. The Inspector also may receive assignments from the Executive Officer (EO), Assistant Executive Officer, Chief of Enforcement and occasionally from another SI. However, the Inspector works autonomously in the field, away from direct supervision and must manage themselves on the job.

C. Supervising Exercised

None.

D. Administrative Responsibility

None.

E. Personal Contacts

The Inspector typically has daily contact with his or her supervising Inspector, and with applicants and licensees of the board pertaining to open complaint investigations, sterile compounding processes, appropriate licensure, cases investigated, and premises inspected. The Inspector has frequent contact with the board's EO, AEO, CEA, SI, staff managers, enforcement unit and complaint unit staff pertaining to investigation and mediation policies and procedures, open investigations and mediated cases regarding complex and confidential information pertaining to the open cases. The Inspector has occasional contact with staff of other agencies, including the Food and Drug Administration, Department of Health Care Services, the Department of Public Health, the Federal Bureau of Investigation, the Department of Justice and other law enforcement agencies throughout the state, providing critical and

expertise support to those agencies. The Inspector also serves as an expert witness in board disciplinary hearings and citation and fine appeal hearings.

F. Actions and Consequences

Failure to appropriately regulate pharmacists and pharmacies that compound, store, dispense and distribute sterile drug preparations will cause public harm. Patients die from compromised quality in sterile drug preparations. Timely and consistent enforcement of laws and regulations over licensees and applicants preserves the public safety. Failure to act timely will permit health-endangering activities to occur in violation of the board's public protection mandate jeopardizing pharmacists' care and the integrity of the sterile compounded drug preparations shipped within California and nationwide prescription drug supply.

G. Functional Requirements

The Inspector normally works an average of 40 hours per week from a home office with artificial light and temperature control. Daily hours of work can be variable, dependent on the business hours of a licensed premises and the work that needs to be completed. Inherent in the job is the responsibility and expectation that work weeks of longer duration may be necessary. The ability to use a personal laptop computer on a daily basis is essential, as is daily use of a telephone and a fax machine. The position requires occasional reaching, grasping, bending and stooping to retrieve records and or pharmaceuticals from high or low shelves when conducting an inspection or investigation. The position requires occasional lifting and carrying up to 45 pounds and occasional standing, walking, climbing, sometimes in inclement weather.

Environmental Requirements - The Inspector is required to inspect licensed entities for compliance with pharmacy laws including for sanitary standards to ensure that the fixtures and equipment are maintained in a clean, orderly, well ventilated and dust free environment. The Inspector may be occasionally exposed to toxic materials and pharmaceuticals that would be found in a pharmacy.

H. Other Information

The Inspector must maintain a home office and adhere to home office agreement policies. The Inspector must maintain proper use, security and maintenance of board-issued equipment including routine maintenance if in possession of a board-provided vehicle. The Inspector must report activities to the SI, submit a weekly itinerary, record activities on an activity tracker, retrieve and transmit electronic files and access e-mail in accordance with board procedures. The Inspector must possess good communication skills, both written and verbal; use good judgment in decision-making; exercises creativity, resourcefulness and flexibility in problem identification and resolution; manage his or her time and resources effectively, be able to work cooperatively with others as a member of a team, and be responsive to management needs and have good attendance. The Inspector must be able to make and keep accurate and complete records and accurately document, retrieve and maintain exhibits and evidence according to board policies.

Additionally, the Inspector must be self-directed and able to manage his or her workload with minimal oversight. The Inspector must maintain a working knowledge of the various laws, rules and regulations specific to the practice of pharmacy including but not limited to the Business and Professions Code, the Health and Safety Code, the California Code of Regulations and the Code of Federal Regulations. The Inspector must also keep abreast of emerging issues of pharmaceutical practices. The Inspector is required to attend specific statewide meetings; staff and team meetings and participate in workshops, seminars and training sessions. The Inspector is required to travel as directed to accomplish the primary responsibilities of

investigating complaints and inspecting licensed premises. The Inspector also performs other related duties as required.

In all job functions, employees are responsible for creating an inclusive, safe, and secure work environment that values diverse cultures, perspectives, and experiences, and is free from discrimination. Employees are expected to provide all members of the public equitable services and treatment, collaborate with underserved communities and tribal governments, and work toward improving outcomes for all Californians.

Special physical characteristics include: Ability to maintain good health, the mobility necessary to travel and drive within California and occasionally throughout the United States and to enter into public and private buildings to inspect and investigate licensees; normal hearing and vision or hearing and vision corrected to normal, medical clearance is required.

Special personal characteristics: Willingness to work in various locations throughout the state and the United States for short periods of time, adapt to changes in board policies and procedures, maintain a professional appearance, use professional and courtesy behavior toward others, and possess a keenness of observation.

Licenses: The Inspector must possess and maintain a current, valid California pharmacist license and possess and maintain a valid California driver's license. The Inspector must maintain a good driving record.

Criminal Offender Record Information (CORI)

Title 11, section 703 (d) of the California Code of Regulations requires criminal record checks of all personnel who have access to Criminal Offender Record Information (CORI). Pursuant to this requirement, applicants for this position will be required to submit fingerprints to the Department of Justice and be cleared before hiring. In accordance to Department of Consumer Affairs' (CORI) procedures, clearance shall be maintained while employed in a CORI-designated position. Additionally, the position routinely works with sensitive and confidential issues and/or materials and is expected to maintain the privacy and confidentiality of documents and topics pertaining to individuals or to sensitive program matters at all times.

Conflict of Interest (COI)

This position is subject to Title 16, section 3830 of the California Code of Regulations, the Department of Consumer Affairs' Conflict of Interest Regulations. The incumbent is required to submit a Statement of Economic Interests (Form 700) within 30 days of assuming office, annually by April 1st, and within 30 days of leaving office.

DMV Employer Pull Notice Program (EPN)

The incumbent shall participate in DMV's Employer Pull Notice Program (EPN), which is a process for providing the Department with a report showing the driver's current public record as recorded by the DMV, and any subsequent convictions, failures to appear, accidents, driver's license suspensions, driver's license revocations, or any other actions taken against the driving privilege or license, added to the driver's DMV record.

Work Week Group E

The incumbent is a Work Week Group E employee and is expected to work an average of 40 hours per week each year, and may be required to work specified hours based on the business needs of the office.

Travel

The incumbent is required to travel throughout an assigned geographical area by various methods of transportation.

I have read and understand the duties listed above and I can perform these duties with or without reasonable accommodation. (If you believe reasonable accommodation is necessary, discuss your concerns with the hiring supervisor. If unsure of a need for reasonable accommodation, inform the hiring supervisor, who will discuss your concerns with the Health & Safety analyst.)

Employee Signature

Date

Printed Name

I have discussed the duties of this position with and have provided a copy of this duty statement to the employee named above.

Supervisor Signature

Date

Printed Name

New: February 2017
Revised: March 2018