Report to the Legislature

Drug Manufacturing, Medical Device Manufacturing, and Home Medical Device Retailer Licensing Costs and Fee Analysis Report

2026

Center for Environmental Health
Division of Food and Drug Safety

CDPH
California Department of Public Health

To obtain a copy of the Division of Food and Drug Safety's Report to the Legislature titled, "Drug Manufacturing, Medical Device Manufacturing, and Home Medical Device Retailer Licensing Costs and Fee Analysis Annual Report 2026," contact:

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Drug Manufacturing, Medical Device Manufacturing, and Home Medical Device Retailer Licensing Costs and Fee Analysis Annual Report 2026

The California Health and Safety Code (HSC) section 111656.1 (e) requires the California Department of Public Health (CDPH) to annually submit a report to the Legislature recommending the amount of license fees to be charged to drug manufacturers, medical device manufacturers, and home medical device retailer (HMDR) facilities for each Fiscal Year (FY).

HSC section 111656.1 (e) also requires annual license fees to be based on estimated program costs, including costs for inspections, investigations, enforcement, and other required activities. All collected fees are deposited into the Drug and Device Safety Fund (Fund 3018) to carry out and implement the licensing provisions of HSC Division 104, Part 5, Chapter 6, Article 6.

On or before January 10 of each year, CDPH must submit to the Legislature a report recommending fee rates. The report must:

1. Describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article.
2. Describe the projected license fee amount so license fee revenues are sufficient to cover the estimated program costs.
    - Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs for the upcoming year.

The CDPH, Food and Drug Branch (FDB) is responsible for licensing and regulating all drug and medical device manufacturers in California. Since 1970, CDPH has been mandated to license and inspect drug and medical device manufacturers pursuant to HSC section 111635 and to verify products are safe and effective and that firms are operating in compliance with the HSC and federal Current Good Manufacturing Practices (CGMPs) regulations. Since 2000, FDB has administered the Home Medical Device Retailer (HMDR) Program pursuant to HSC section 111656 et seq. Through this program, CDPH licenses and inspects HMDR facilities and warehouses that sell or rent home medical devices,

and licenses HMDR exemptees (individuals who dispense prescription home medical devices). These inspections verify that the businesses are engaging in sanitary practices so that the devices are maintained in a manner that protects consumers.

I. Introduction

A. Background

The Food and Drug Branch (FDB) resides within the California Department of Public Health's (CDPH) Center for Environmental Health, Division of Food and Drug Safety. FDB is responsible for regulating drug manufacturers, medical device manufacturers, home medical device retailer (HMDR) facilities, HMDR warehouses, and HMDR exemptees (an individual that has the knowledge, training, and experience to provide the qualified supervision of a facility that sells or dispenses prescription medical devices) through inspections and maintenance of its licensing program under provisions of the Sherman Food, Drug, and Cosmetic Law (Sherman Law), under Health and Safety Code (HSC) section 109875 et seq.

In California, the safety, effectiveness, manufacturing, and labeling of drugs and medical devices have been regulated since the enactment of the California Pure Food and Drugs Act of 1906. Beginning in 1963, drug manufacturers and medical device manufacturers were required to obtain licenses from CDPH before initiating manufacturing operations. Since 1970, CDPH has been mandated to license and inspect drug and device manufacturers, pursuant to HSC section 111635. Standards for medical devices were separated from drug standards in 1978 when the federal government promulgated regulations differentiating drugs from medical devices. CDPH began licensing and inspecting HMDR facilities and licensing HMDR exemptees in 2002, replacing licensing programs by the Board of Pharmacy and the Bureau of Household Furnishing and Thermal Insulation pursuant to Assembly Bill (AB) 1496 (Chapter 837, Statutes of 2000).

CDPH is required to inspect and license drug and medical device manufacturers, pursuant to California HSC section 111635. The HSC adopts federal Current Good Manufacturing Practices (CGMPs) for drugs and medical devices (HSC section 110105) that establish baseline quality assurance standards for manufacturers.

The licensing inspection requirements for drugs and medical device manufacturers and HMDR facilities are different. Inspections for HMDR facilities are generally uniform and include pre-licensing and annual inspections, whereas licensing functions for drug and medical device manufacturers fall into two general types:

- new license applicant inspections; or

investigations or inspections "for cause", meaning for a specific, legitimate, and justifiable reason not related to a new license inspection process.

B. Statutory Requirements for Report to the Legislature

Assembly Bill (AB) 1496 (Chapter 837, Statutes of 2000) required the licensing of HMDR facilities by what is now CDPH. The statutes (HSC sections 111656 through 111656.13) set specific facility and operational performance standards and requires CDPH to perform inspections prior to licensing each facility. The bill also established a requirement for CDPH to provide an annual report to the Legislature recommending proposed license fee changes based on the estimated licensing and inspection costs needed to support the program.

HSC section 111656.1 (e) states:

> *Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.*

II. License Inspection and Investigative Activities

A. Drug and Medical Device Manufacturing License Inspections and Investigations

The purpose of the Drug and Medical Device Manufacturing License Program is to protect public health by ensuring that drugs or medical devices are manufactured in accordance with the Current Good Manufacturing Practices (CGMPs) established by the US Food and Drug Administration (FDA), and prevent the sale and distribution of drugs and medical devices that:

- have not been shown to be safe or effective, or
- are adulterated, misbranded, or falsely advertised

Inspections and investigations of manufacturers allow for the identification and correction of defective products that put California's population at risk. FDB verifies that drug and medical device manufacturers meet CGMP requirements and comply with all applicable statutory and regulatory provisions to prevent unqualified and unprepared firms from placing dangerous drugs and medical devices into the hands of medical practitioners and consumers. Manufacturers cannot legally manufacture drugs or medical devices without a valid license. HSC section 111635 requires manufacturers to provide CDPH with evidence of ownership and any of the following: valid biologics license, valid FDA registration and inspection, International Organization for Standardization compliance, or an approved investigational new drug or an approved investigational device exemption issued by the FDA.

If the firm cannot provide the documented evidence as prescribed under HSC section 111635, CDPH is required to inspect the place of manufacture prior to issuing a new drug and medical device manufacturing license.

After the initial license is issued, CDPH can inspect or investigate a manufacturer for cause when CDPH determines that public health and safety is at risk. Inspections and investigations may additionally be conducted due to complaints, product recalls, or upon request by the FDA to assist with enforcement activities. A license may be denied, suspended, or revoked by CDPH if the manufacturer is found in violation of any applicable part of the Sherman Law.

CDPH drug and medical device manufacturer licensing inspections and investigations verify that:

- new manufacturers have effective quality systems in place before they manufacture and distribute drugs and medical devices,
- firms have qualified personnel performing critical process steps,
- all critical drug manufacturing processes, such as purification operations and potency testing, are validated to be appropriate, effective, reproducible, precise, and that firms consistently follow validated processes,
- medical devices are designed and processed with proper validation,
- critical process steps such as sterilization are validated to be effective and firms consistently follow validated procedures,
- firms investigate all problems that are identified during manufacturing or reported by customers and that corrective and preventive actions are taken to prevent future problems,

- education is provided as needed to help industry understand and comply with manufacturing requirements,
- CDPH has a means to identify when enforcement action is needed to prevent the distribution of unsafe or ineffective drugs; and
- divergent market drug products are not introduced into the national distribution system.

B. Home Medical Device Retailer License Inspections and Investigations

HSC section 111656 requires inspection of HMDR facilities prior to licensure and annually thereafter. Licensing HMDR facilities is important to protect California consumers from unsafe, contaminated medical devices, and adulterated prescription medical oxygen. Mandated license inspections authorize competent and knowledgeable persons (HMDR exemptees) to dispense, repair, calibrate, and maintain prescription devices, and sell prescription medical oxygen. The wide variety of medical devices, and how they are assembled, maintained, cleaned, sanitized, and utilized, requires regulatory oversight.

Prescription medical oxygen is inspected by CDPH to ensure it is suitable for life support. CDPH coordinates its inspection findings with the California Department of Health Care Services (DHCS) Medi-Cal Provider Enrollment Division and the Medi-Cal Fraud Prevention Bureau Audits and Investigations program, which has several divisions with the shared mission to eliminate fraud by identifying HMDR facilities that falsely bill for products never sold or utilized.

III. License Fees and Cost Analysis

Program License Fees, Revenue, and Program Costs

HSC sections 111625, 111630, and 111656.1 authorize CDPH to establish and adjust licensing fees for drug manufacturers, medical device manufacturers, and HMDR licenses. The Drug and Device Safety (DDS) Fund was established to deposit fees to fund the Drug and Medical Device Safety Program.

The projected revenues for FY 2026-27, with the proposed fee increase, are expected to be $7.5 million. The program is projecting total state operations expenses of $8.4 million for FY 2026-27. While the fund balance assists with covering the difference between expected versus projected costs, it is insufficient to cover all ongoing estimated program costs, as a result there will be a five percent fee increase in FY 2026-27. Ongoing revenue and expenditure levels will continue to be evaluated in future years to ensure the program remains solvent.

The Drug and Medical Device Safety Program issues various license types for drug manufacturers, medical device manufacturers, HMDR facilities, and HMDR exemptees under the current licensing fee schedule. Table I provides an existing inventory of current license types with existing fees for FY 2025-26. Table II provides the estimated number of applications, the renewal frequency, and estimated revenue for each type of license for new applicants for FY 2026-27. Table III provides the estimated number of renewal applications, the renewal frequency, and estimated revenue for each type of license for renewal for FY 2026-27.

Table I – Current Drug and Medical Device Safety Program License Types, Inventory, and Fees*

License Type	Total Inventory*	FY 2025-26 Fee	License Renewal Frequency
Drug Manufacturing License	448	$4,616	Biennial
Prescription Drug Marketing Act	346	$200	Biennial
Medical Device Manufacturing License	1,434	$4,616	Biennial
Home Medical Device Retailer	1,017	$1,509	Annual
HMDR Out of State	351	$267	Annual
HMDR Warehouse	19	$754	Annual
HMDR Exemptee	1,877	New $444 Renewal $267	Annual

*Inventory totals are a point-in-time

Table II – Drug and Medical Device Safety Program Projected Revenue by License Type - Estimated New Applications FY 2026-27

Revenue Source (by License Type)	Projected Incoming Applications	FY 2026-27 License Fee	Estimated FY 2026-27 Revenue
Drug Manufacturing License	48	$4,847	$232,656
Prescription Drug Marketing Act	32	$200*	$6,400
Medical Device Manufacturing License	265	$4,847	$1,284,455
Home Medical Device Retailer	124	$1,584	$196,416
HMDR Out of State	35	$280	$9,800
HMDR Warehouse	5	$792	$3,960
HMDR Exemptee	382	$466	$178,012
Total - New	**891**		**$1,911,699**

*Licensing fees for Prescription Drug Marketing Act are set in statute; no fee increase implemented.

Table III – Drug and Medical Device Safety Program Projected Revenue by License Type - Estimated Renewal Applications FY 2026-27

Revenue Source (by License Type)	Projected Incoming Renewal Applications	FY 2026-27 License Fee	Estimated FY 2026-27 Revenue
Drug Manufacturing License	207	$4,847	$1,003,329
Prescription Drug Marketing Act	156	$200*	$31,200
Medical Device Manufacturing License	524	$4,847	$2,539,828
Home Medical Device Retailer	973	$1,584	$1,541,232
HMDR Out of State	245	$280	$68,600
HMDR Warehouse	14	$792	$11,088
HMDR Exemptee	1,528	$280	$427,840
Total - Renewal	**3,647**		**$5,623,117**
Total Revenue (Sum of total new and renewal from table II & III)			**$7,534,816**

*Licensing fees for Prescription Drug Marketing Act are set in statute, no fee increase implemented.

To support all licensing, inspection and operational activities, the program requires 28.5 staff and a state operations budget of $8.4 million in estimated expenditures for FY 2026-27. The number of staff and the cost of the Drug and Medical Device programs are based on the estimated time to complete inspections, compliance investigations, and enforcement activities. In addition to CDPH's requirements to inspect license drug and medical device manufacturers pursuant to HSC section 111635, CDPH is required to review and evaluate drug, medical device, and HMDR complaints, alerts, referrals, and recalls to determine if an investigation is necessary to ensure compliance with laws and regulations. During FY 2024-25, these consisted of 36 additional investigational activities.

For cause inspections or investigations generally take more time than a new license inspection to complete. These types of investigations are more in-depth and consist of examining corrective actions from the previous inspections, following up on product failures, auditing newly established production processes and resulting records, and evaluating changes and new products. Additional time is necessary to investigate fraudulent activities and develop enforcement and legal actions.

Investigators conduct investigations of civil/criminal investigations activities involving the manufacturing and/or distribution of dangerous drugs or medical devices. The investigations involve a wide variety of criminal conduct, including street level sales of foreign counterfeit, unapproved, and misbranded drugs, diversion of prescription drugs, and other regulated products.

Investigations are conducted by sworn investigators who contact firms or individuals that are alleged to be illegally manufacturing or distributing unapproved new drugs or medical devices. Partnerships with other state and federal regulatory and law enforcement counterparts lead to investigations against illegal importers of unapproved new drug and medical devices. These investigations and enforcement actions can lead to civil or criminal charges or the development of administrative penalty actions protecting public health and safety, and abating health fraud.

In addition, program staff review and analyze licensing applications and other required documents, provide support to the program, and oversee financial operations. Table IV reflects the operational budget for the Drug and Medical Device Safety Program for FY 2026-27.

Table IV - Drug and Medical Device Safety Program Operational Costs FY 2026-27

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
Chief, Food and Drug Section	$282,861	$38,476	$321,337	1.0	$321,337
	Manage regulatory inspectors, sworn peace officers, scientific and administrative support, and second-level supervisory section staff of law enforcement personnel; responsible for implementing and monitoring the activities specific to the drug and medical device units and its licensing program. Coordinate the licensing and enforcement activities, assuring resources and expertise are available to implement the program and identify unlicensed and non-compliant firms. Prepare performance evaluations, probation reports, and oversee staff development. Organize and direct the coordination of scientific and technical activities to assure consistency of investigative, inspectional, law enforcement, and other activities with other departmental, local, state and federal programs. Develop, maintain, and carry out statewide drug, medical device, and HMDR program plans, policies, procedures, budgets, training, education efforts and all other activities necessary to assure product safety. Provide CDPH technical and public health input to regulatory processes; assess effectiveness of implemented processes. Provide advice and consultation to CDPH and other state, local, and federal agencies regarding technical matters related to drugs and medical devices; represent CDPH at relevant intradepartmental, interagency, and/or public meetings.				
Staff Services Manager I	$167,566	$38,476	$206,042	0.5	$103,021
	Perform analysis of program data collected. Provide technical assistance requiring high level of program knowledge and expertise. Oversee maintenance of complex databases. Develop and maintain a tracking system for FDB to track and monitor retail outlets dispensing medical devices for home use for compliance with licensure requirements and individuals licensed to dispense these products. Analyze program data and prepare management reports. Oversee and coordinate development and establishment of licensing and registration processes with written procedures for new and renewal licensing, issuance/denial criteria, and				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
	administrative processes. Discuss denied licenses with applicants and issue denial letters when appropriate. Track program budget to monitor all revenue and expenditures. Coordinate the revenue monitoring and solvency of the Drug and Device Safety Fund. Respond to complex issues related to inventory, licensing and fees within the Program. Prepare reports for management.				
Investigator	$212,621	$48,476	$261,097	6.0	$1,566,582
	Conduct criminal/civil investigations of individuals and firms suspected of illegal activities involving drugs and medical devices. The investigations include gathering evidence as prescribed by law; interviewing/interrogating witnesses and suspects; developing investigation plans; developing operational plans and safely executing them; conducting surveillance and covert activities; preparing detailed reports and making recommendations based on state and federal laws/regulations; preparing and executing search warrants, inspection warrants, arrest warrants and subpoenas; and testifying in court or administrative proceedings. Prevent unapproved new drugs and medical devices from being received into commerce and/or from being sold outside the normal distribution chain.				
Environmental Scientist	$159,653	$48,476	$208,129	11.0	$2,289,419
	Inspect drug and medical device manufacturers and HMDR facilities. Perform preliminary and secondary analysis, research, and surveys of typical drug and medical device manufacturing and HMDR practices. Prepare for inspection activities and complete license inspections to determine ownership, adequacy of facilities, personnel qualifications, and compliance with applicable regulations. Impose regulatory action for non-compliance with state law and federal regulations.				
Senior Environmental Scientist (Specialist)	$184,035	$48,476	$232,511	2.0	$465,022
	Provide training related to surveys and inspections of drug and medical device manufacturing and HMDR practices. Prepare Environmental Scientist work plans. Assist Environmental Scientist Supervisor with evaluation of inspection reports. Audit/review employee performance. Lead and conduct the most highly technical and complex				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
	inspections. Provide Environmental Scientist field training. Assist in the evaluation of preliminary and secondary analysis, research, surveys, and inspections of typical medical device manufacturing and HMDR practices. When applicable, provide training related to conducting FDA medical device contract inspections, review reports, track, and monitor the contract status.				
Senior Environmental Scientist (Supervisory)	$247,936	$43,476	$291,412	2.0	$582,824
	Provide supervision and training related to surveys and inspections of drug and medical device manufacturing and HMDR practices. Prepare Environmental Scientist work assignments. Evaluate inspection reports. Audit/review employee performance. Prepare Individual Development/Employee Appraisal Plans and probation reports. Supervise and conduct the most highly technical and complex inspections. Provide Environmental Scientist field training. Evaluate results of preliminary and secondary analysis, research, surveys, and inspections of typical medical device manufacturing and HMDR practices.				
Supervising Food and Drug Investigator	$247,124	$43,476	$290,600	1.0	$290,600
	Provide supervision and training, evaluate investigation reports, and coordinate investigations and enforcement. Prepare investigator work assignments. Evaluate inspection reports. Audit/review employee performance. Prepare Individual Development/Employee Appraisal Plans and probation reports. Evaluate investigation data entry. Provide investigator field training. Conduct complex compliance investigations. Prepare investigation reports. Complete complex compliant actions. Conduct hearings and other enforcement actions.				
Food and Drug Program Specialist	$261,032	$43,476	$301,952	2.0	$609,016
	Oversee, coordinate, and facilitate investigations, evidence collection and sampling, and enforcement activities to ensure overall statewide goals and objectives for program areas are being met. Identify strengths and deficiencies of such programs and provide administrative and technical consultation to improve and correct program deficiencies. Review and evaluate monthly activity and inspection reports to determine patterns or trends in the drug, and medical				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
	device manufacturing industry. Coordinate and oversee special projects and survey activities with Branch scientific staff. Complete complex investigations of firm's overall compliance; check quality control, review employee training and experience, and issue notices of violations Act as the statewide CDPH expert on drug and medical device manufacturing, and HMDR issues. Develop correspondence and publications that clarify or explain laws, regulations, and FDB enforcement policies.				
Associate Governmental Program Analyst	$125,959	$38,476	$164,435	2.0	$328,870
	Perform a variety of tasks including the more independent, responsible, and complex analytical work for Drug and Medical Device Compliance and Enforcement Sections (DMDCES); Drug/Medical Device/Cosmetic/HMDR/Exemptee licensing. Programmatic duties such as developing, implementing, and monitoring licensing procedures and databases. The incumbent will interpret the Sherman Food, Drug, and Cosmetic Laws Act and the Board of Pharmacy Law to make informed decisions and align business practices for DMDCES. Respond to complex inquiries from the public and external and internal stakeholders regarding licensing requirements. The incumbents will have primary responsibilities for all MDSU projects and activity.				
Chief, Food and Drug Unit	$261,019	$38,476	$299,495	1.0	$299,495
	Second line supervisor of regulatory and law enforcement personnel. Manage program staff performing activities specific to the drug and medical device units and its licensing program. Coordinate the licensing activities assuring resources are available to implement the licensing program and identify unlicensed and non-compliant firms. Prepare performance evaluations, probation reports, and oversee staff development. Oversee the legal, investigative, educational, and enforcement activities specific to the drug and medical device unit. Track and forecast emerging public health trends affecting the licensed industries and develop regulatory strategies to address them. Develop and direct staff specifically to respond to 1) adulterated, misbranded, falsely advertised, or otherwise unsafe drugs and medical devices; 2) unsafe or otherwise improper production and processing practices; and 3) drug and medical device recalls				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
	and complaint investigations. Assure utilization of state-of-the-art scientific and technical developments that can detect and prevent consumers from being exposed to unsafe products and production practices. Evaluate and audit statewide licensing program plans, policies, procedures, budgets, training, education efforts, and all other activities necessary to assure product safety. Collaborate with the FDA, Board of Pharmacy, Medical Board of California, and other regulatory agencies to develop work plans and share issues and concerns to protect public health.				
Total Staff Cost				**28.5**	**$ 6,856,186**
CDPH Distributed and Administrative Costs					**$ 1,549,849**
Total State Operations Estimated Cost					**$ 8,406,035**