REPORT TO THE LEGISLATURE

DRUG MANUFACTURING, MEDICAL DEVICE MANUFACTURING, AND HOME MEDICAL DEVICE RETAILER LICENSING COSTS AND FEE ANALYSIS ANNUAL REPORT

2021

CENTER FOR ENVIRONMENTAL HEALTH

DIVISION OF FOOD, DRUG, AND CANNABIS SAFETY

To obtain a copy of the Division of Food, Drug, and Cannabis Safety's Report to the Legislature titled, "Drug Manufacturing, Medical Device Manufacturing, and Home Medical Device Retailer Licensing Costs and Fee Analysis Annual Report 2021," contact:

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REPORT TO THE LEGISLATURE

DRUG MANUFACTURING, MEDICAL DEVICE MANUFACTURING, AND HOME MEDICAL DEVICE RETAILER LICENSING COSTS AND FEE ANALYSIS ANNUAL REPORT 2021

California Health and Safety (H&S) Code Section 111656.1 (e) requires the California Department of Public Health (CDPH) to annually publish 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) beginning July 1. Annual license fees are to be based on estimated program costs, taking into account the costs for inspections, investigations, enforcement, and other required activities. The fees collected are deposited into the Drug and Device Safety (DDS) Fund 3018 to carry out and implement the licensing provisions of H&S Code, Division 104, Part 5, Chapter 6, Article 6.

The CDPH Food and Drug Branch (FDB) is responsible for licensing 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 H&S Code Section 111635, to ensure products are safe and effective, and to verify that firms are operating in compliance with the H&S Code and federal Good Manufacturing Practices (GMP) regulations. Since 2000, FDB has also been responsible for the HMDR Program pursuant to H&S Code Section 111656 et seq. Through this program, CDPH licenses and inspects HMDR facilities and warehouses in California that sell and 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 to ensure the devices are being maintained in a manner that protects consumers.

This report describes the activities supported by the DDS Fund and the estimated program revenues and costs for FY 2021-22. The projected revenues for FY 2021-22 are $6.1 million. The program is projecting expenditures of $6.4 million. There will not be a fee increase in FY 2021-22. Revenues in combination with the fund reserve are estimated to be sufficient to cover expenses for FY 2021-22. Ongoing revenue and expenditure levels will continue to be evaluated in future years for potential fee adjustments.

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, Drug, and Cannabis 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 the facility), through inspections and maintenance of its licensing program under provisions of the Sherman Food, Drug, and Cosmetic Law (Sherman Law) under Health and Safety (H&S) Code 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 a license from CDPH before initiating manufacturing operations. Standards for medical devices were not separated from drug standards until 1978 when the federal government promulgated regulations differentiating drugs from medical devices. CDPH began licensing and inspecting HMDR facilities and licensing HMDR exemptees in January 2002, replacing licensing programs by the Board of Pharmacy and the Bureau of Household Furnishing and Thermal Insulation pursuant to Assembly Bill (AB) 1496 (Olberg, Chapter 837, Statutes of 2000).

CDPH is required to inspect and license drug and medical device manufacturers pursuant to California H&S Code Section 111635. The H&S Code adopts federal Good Manufacturing Practices (GMP) regulations for drugs and medical devices (H&S Code Section 110105) that establish basic quality assurance standards for manufacturers.

In 1988, a federal law, the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100-293, 102 Statute 95), was enacted in response to serious public health and safety problems associated with the "diversion market" for prescription drugs. Congress found that adulterated, mislabeled, sub-potent, expired, or counterfeit drugs were easily introduced into the national distribution system due to the existence and operation of a wholesale sub-market, commonly known as the "diversion market," where drug products are obtained from sources outside of normal channels of distribution. In 1990, the U.S. Food and Drug Administration (FDA) published final regulations establishing state guidelines for the minimum requirements for prescription drug storage and security as well as for the treatment of returned, damaged, and outdated prescription drugs. Further, wholesale drug distributors were required to establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs and make these available for inspection and copying by authorized federal, state, or local law enforcement officials. In 1992, California adopted emergency regulations conforming to these FDA requirements, and CDPH began inspecting prescription drug manufacturers for compliance with PDMA regulations.

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 inspections and annual inspections, whereas licensing functions for drug and medical device manufacturers fall into two general types:

- new license applicant evaluation or inspection; or
- for-cause investigations.

B. Statutory Requirements for Report to the Legislature

AB 1496 (Olberg, Chapter 837, Statutes of 2000) required the licensing of HMDR facilities by CDPH. The H&S Code sets specific facility and operational performance standards and requires CDPH to perform inspections prior to licensing each facility. It also requires CDPH to provide an annual report to the Legislature recommending proposed license fee changes based upon the estimated licensing and inspection costs needed to support the program.

H&S Code 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 prevent the sale and distribution of drug and medical devices that:

- have been improperly manufactured;
- are adulterated, misbranded, or falsely advertised;
- have not been shown to be safe or effective; or
- have not met medical device design validation requirements.

Inspections and investigations of manufacturers allow for the identification and correction of defective products that put California's population at risk. FDB ensures drug and medical device manufacturers meet GMP 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. Firms cannot legally manufacture drugs or medical devices without a valid license. H&S Code Section 111635 requires manufacturers to provide CDPH with evidence of ownership and any of the following, valid biologics license, valid FDA registration and inspection, ISO (International Organization for Standardization) compliance, and an approved investigational new drug or an approved investigational device exemption issued by the FDA.

If the firm is not able to provide the documented evidence as prescribed under H&S Code 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 the Department makes the determination that the 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 ensure:

- new manufacturers have effective systems in place before they manufacture and ship 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 that 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

H&S Code Section 111656 requires that HMDR facilities may be inspected prior to licensure and annually thereafter. The licensing of HMDR facilities is important to protect California consumers from unsafe, contaminated medical devices, and adulterated prescription medical oxygen. Mandated license inspections ensure that competent and knowledgeable persons (HMDR exemptees) 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. CDPH oversight ensures that HMDR facilities distributing or selling medical devices such as ventilators and oxygen concentrators, drug delivery systems for home medication, hospital beds, traction equipment, and other medical devices safely allows consumers to be treated or convalesce at home. 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 Branch, the Medi-Cal Fraud Prevention Bureau, and Audits and Investigations Division, which includes the Medical Review Branch and the Investigations Branch, 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

H&S Code Sections 111625, 111630, and 111656.1 authorize CDPH to establish and adjust fees for drug manufacturers, medical device manufacturers, and HMDR licenses. The Drug and Device Safety (DDS) Fund (3018) was established to deposit fees to fund the Drug and Medical Device Safety Program.

The projected revenues for FY 2021-22 are $6.1 million. The program is projecting expenditures of $6.4 million. There will not be a fee increase in FY 2021-22. Revenues in combination with the fund reserve are estimated to be sufficient to cover expenses for FY 2021-22. Ongoing revenue and expenditure levels will continue to be evaluated in future years for potential fee adjustments.

The Drug and Medical Device Safety Program issues various license types for drug manufacturers, medical device manufacturers, HMDR facilities, and HMDR exemptee licensees under the current licensing fee schedule. Table I provides an existing inventory of current license types with existing fees for FY 2020-21. Table II provides the estimated number of applications, the renewal frequency, and estimated revenue for each type of license for new applicants for FY 2021-22. Table III provides the estimated number of applications, the renewal frequency, and estimated revenue for each type of license for renewal applicants for FY 2021-22.

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

License Type	Total Inventory*	FY 2020-21 Fee	License Renewal Frequency
Drug Manufacturing License	468	$4,187	One-time Biennial
Prescription Drug Marketing Act	269	New $100 Renewal $200	One-time Biennial
Medical Device Manufacturing License	1401	$4,187	One-time Biennial
Home Medical Device Retailer	1073	$1,369	Annual
Home Medical Device Retailer Out of State	343	$242	Annual
Home Medical Device Retailer Warehouse	24	$686	Annual
Home Medical Device Retailer Exemptee	2230	New $403 Renewal $242	One-time 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 2021-22

Revenue Source (by License Type)	Projected Incoming Applications	FY 2021-22 License Fee	Estimated FY 2021-22 Revenue
Drug Manufacturing License	34	$4,187	$142,358
Prescription Drug Marketing Act	24	$100*	$2,400
Medical Device Manufacturing License	144	$4,187	$602,928
Home Medical Device Retailer	150	$1,369	$205,350
HMDR Out of State	68	$242	$16,456
HMDR Warehouse	6	$686	$4,116
HMDR Exemptee	511	$403	$205,933
Total - New	**937**		**$1,179,541**

*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 2021-22

Revenue Source (by License Type)	Projected Incoming Renewal Applications	Proposed FY 2021-22 License Fee	Estimated FY 2021-22 Revenue
Drug Manufacturing License	221	$4,187	$925,327
Prescription Drug Marketing Act	148	$200*	$29,600
Medical Device Manufacturing License	520	$4,187	$2,177,240
Home Medical Device Retailer	975	$1,369	$1,334,775
HMDR Out of State	250	$242	$60,500
HMDR Warehouse	12	$686	$8,232
HMDR Exemptee	1745	$242	$422,290
Total - Renewal	**3,871**		**$4,957,964**
Total Revenue			**$6,137,505**

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

To support all licensing and inspection activities, as well as operational activities, the program requires 29.5 staff and associated budget of $6.4 million in FY 2021-22. The number of field and office 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 and license drug and medical device manufacturers pursuant to H&S Code Section 111635, the Department is required to follow-up on drug, medical device, and HMDR complaints, alerts, referrals, and recalls. During FY 2020-21, these consisted of 34 additional follow-up activities.

For cause inspections and 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 legal and administrative actions.

Investigators will complete and conduct drug, medical device, and HMDR for-cause inspections, complaint referrals, and investigations of a firm's overall compliance with

California laws and regulations. Pre-license inspections of drug manufacturers will require an extensive examination of the facility, quality control, employee qualifications, process validation, packaging, labeling, and documentation.

Investigations are conducted by sworn investigators with firms or individuals that are 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. These actions brought on by sworn staff have protected public health and safety, and abated health care fraud.

In addition, program staff review and analyze licensing applications and other required documents, provide technical assistance, provide support to the program, and oversee financial operations. Table IV reflects the operational budget detail for the Drug and Medical Device Safety Program for FY 2021-22.

Table IV - Drug and Medical Device Safety Program Operational Costs FY 2021-22

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
Section Chief	$212,671	$36,000	$248,671	1.0	$248,671
	Manage investigative, scientific, 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.				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
Staff Services Manager I	$116,172	$26,000	$142,172	0.5	$71,086
	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 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 DDS Fund. Respond to complex issues related to inventory, licensing and fees within the Program. Prepare reports for management.				
Investigator	$142,868	$36,000	$178,868	8.0	$1,430,944
	Train and lead staff in the performance of field investigations and conduct the more complex criminal, civil, and/or administrative investigations to detect or verify suspected violations of laws. Conduct comprehensive criminal/civil investigations of individuals and firms suspected of major health fraud. Comprehensive investigation includes 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	$112,408	$34,000	$146,408	11.0	$1,610,488
	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.				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
Senior Environmental Scientist	$175,883	$26,000	$201,883	2.0	$403,766
	Provide supervision and training related to surveys and investigations 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 investigations of typical medical device manufacturing and HMDR practices.				
Supervising Food and Drug Investigator	$156,840	$36,000	$192,840	2.0	$385,680
	Provide supervision and training, evaluate inspection and license 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 inspection data entry. Provide investigator field training. Conduct complex compliance investigations. Prepare investigation reports. Complete complex compliance actions. Prepare regulatory letters. Conduct hearings and other enforcement actions.				
Food and Drug Program Specialist	$170,209	$36,000	$206,209	2.0	$412,418
	Oversee, coordinate, and facilitate investigations, inspections, 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 device manufacturing industry. Coordinate and oversee special projects and survey activities with Branch scientific staff. Complete complex FDA referral investigations of firm's overall compliance; check quality control, review employee training and experience, and issue notices of violation. Act as the statewide CDPH expert on drug, medical device manufacturing, and HMDR issues. Develop correspondence and publications that clarify or explain laws, regulations, and FDB enforcement policies.				

Position and Function	Salary and Benefits	Operating Expenses	Total cost per FTE	FTE	Total Cost
Staff Services Analyst	$81,563	$26,000	$107,563	1.0	$107,563
	Oversee financial operations and provide program support. Review and analyze licensing applications and other required documents. Search existing master data file for information on the licensee and analyze data for consistency with new application. Identify and notify applicants of deficiencies and/or other outstanding violations identified by the investigators via written correspondence. Verify license eligibility based on compliance with statutory and regulatory requirements, licensing criteria and knowledge of the H&S Code. Prepare licenses in accordance with Unit procedures. Monitor license status by gathering confidential information from a variety of sources. Analyze personal disclosure statements submitted by drug manufacturer applicants.				
Associate Governmental Program Analyst	$98,093	$26,000	$124,093	1.0	$124,093
	The incumbent will perform a variety of tasks including the more independent, responsible and complex, analytical work for the Drug and Medical Device Compliance and Enforcement Section (DMDCES); Drug/Medical Device/Cosmetic/HMDR/Exemptee licensing. Programmatic duties such a developing, implementing and monitoring licensing procedures and databases. The AGPA 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. Responding to complex inquiries from the public, external and internal stakeholders regarding licensing requirements. The incumbent will have primary responsibility for all MDSU projects and activity. The incumbent will act as a team leader and coordinate the efforts of multidisciplinary drug and device teams.				
Unit Chief	$193,552	$36,000	$229,552	1.0	$229,552
	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 units. 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 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. Oversee the scientific, legal, investigative, educational, and enforcement activities specific to the work of their respective unit.		
Total Staff Cost			**$5,024,261**
Department Distributed and Administrative Costs			**$1,389,050**
Total Staff and Programmatic Estimated Cost		**29.5**	**$6,413,311**