

## Home Medical Device Retailer (HMDR) Frequently Asked Questions:

### Q) What is an HMDR business?

A) An HMDR facility is defined as any area, place, or premises [other than a licensed pharmacy] in and from which prescription (Rx) devices, home medical devices, or home medical device services are stored, sold, fitted, or dispensed pursuant to a prescription at retail.

### Q) What is an HMDR warehouse facility?

A) An HMDR warehouse is owned by the HMDR facility and is a separate place where Rx home medical devices are stored and transported to the firm's existing licensed HMDR facility (NOT direct to patients' homes). There may not be any fitting, display, or sales at this facility. The warehouse is used for storage only.

### Q) Who needs an HMDR license from the California Department of Public Health, Food and Drug Branch (CDPH/FDB)?

A) Any person conducting an HMDR business (retail facility or warehouse) in the State of California must first obtain a license from CDPH/FDB. A separate license is required for each location. The license must be renewed each year, and the license cannot be transferred to another location, business, or business owner. (Wholesalers of medical devices are not required to obtain an HMDR license, but may be required to obtain a permit with the [Board of Pharmacy \(http://www.pharmacy.ca.gov\)](http://www.pharmacy.ca.gov) if they distribute Rx devices for wholesale purposes.

### Q) What is an out-of-state HMDR facility?

A) An out-of-state HMDR facility is a business outside of California that sells or distributes Rx medical devices in this State by retail. Out-of-state facilities sending prescription medical devices into California residents must obtain an out-of-state HMDR registration.

### Q) Where can I get an HMDR license application or registration and what are the fees?

A) [Applications are available online \(http://www.cdph.ca.gov/certlic/Pages/HMDRLicenseApplication.aspx\)](http://www.cdph.ca.gov/certlic/Pages/HMDRLicenseApplication.aspx) The license fees for HMDR facilities in California are \$1,105 per location per year. The license fee for a warehouse located in California is \$553 per location per year. The out-of-state registration fee is \$195 per year.

License Category		
HMDR Facility License	\$1,105	Annual Renewal
HMDR Warehouse License	\$553	Annual Renewal
HMDR Out-of-State Registration	\$195	Annual Renewal

### Q) Are there exceptions to the kinds of facilities that are required to have an HMDR license?

A) Yes. Some exemptions include physicians' offices, veterinarians, dentists, pharmacies, medical device manufacturers and wholesale distributors who do not sell directly to the patient, and orthotics and prosthetics retailers. For a complete list please refer to California Health and Safety Code, Division 104, Part 5, Section 111656(f). By visiting our website, a copy of the [Sherman Food, Drug, and Cosmetic Law \(http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf\)](http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf) can be found.

**Q) What is the licensing process and how long does the process take?**

A.) Once the HMDR license application and fees are received by the department, the fees are processed through the FDB cashier, and the application is sent to the FDB licensing desk for review (a properly completed HMDR facility license application is then assigned to an investigator in the closest geographic area). The licensing process time depends on the readiness of the firm and the investigator's current case load. The date of issuance is recorded as the date the firm passed inspection, in which the firm may legally begin operating as of that date.

**Q) Can I operate my HMDR business without a valid license?**

A) No. It is illegal to begin operations of the HMDR facility without a valid HMDR license.

**Q) After my facility is inspected, how long afterwards must I wait for my facility license?**

A) The time may vary depending if violations were found. The actual license certificate is issued and mailed after your facility successfully passes the inspection.

**Q) If my facility fails to meet licensing compliance as set forth in the California Health and Safety Code, what happens?**

A) In the case of a new license inspection, your facility will not be approved for an HMDR license until you have corrected any violations noted on the Notice of Violations. Depending on the significance of the violations, the investigator may review mailed-in/faxed documents as proof of correction, or re-inspect the facility to verify compliance. If compliance cannot be reached, you may be issued a denial letter stating grounds for denial and process for appeal.

In the case of a renewal inspection, depending on the significance of the violations, the investigator may review mailed-in/faxed documents as proof of correction, or re-inspect the facility to verify compliance. If compliance cannot be reached, you may be issued a regulatory letter informing you of possible actions including, but not limited to, embargo of all medical devices, the imposition of administrative penalties, or the referral to a prosecuting attorney for civil or criminal action.

**Q) If I move or sell my business, can my license be transferred?**

A) The existing HMDR license is not transferable to another location or another owner. A change of address or a change in ownership (including incorporation) requires that the facility submit a new application with new fees regardless of when the existing license is due to expire. If you fail to notify FDB, you are conducting business illegally and your ability to bill Medi-Cal and/or Medicare may be jeopardized.

**Q) What is a Temporary License, and what are the criteria for receiving one?**

A) The Health and Safety Code does allow an HMDR licensed facility that is in compliance with FDB to apply for a temporary HMDR license. This is allowable only in the case of an ownership change. When FDB receives a temporary HMDR license application, a supplemental questionnaire is sent to the facility for completion. FDB Staff will review the questionnaire and facility history for compliance, and if approved, a temporary HMDR license will be issued - valid for up to one year. A verification inspection will follow to ensure the HMDR facility is in compliance. When the verification inspection is completed and the HMDR facility has passed, FDB will replace the temporary license with a renewable HMDR license.

**Q) What are dangerous devices?**

A) Dangerous devices may also be referred to as prescription or Rx devices as defined in the California Business and Professions Code Section 4022 (b). These are devices that bear a label stating: “Caution --Federal law prohibits the dispensing of this product without a valid prescription from a physician...,” “Rx Only.” Prescription devices cannot be sold over-the-counter (OTC), but can only be dispensed by an authorized healthcare professional, including an HMDR exemptee. Examples of prescription devices include: respiratory equipment (O2 concentrators, nebulizers, masks, and tubing), TENS units, enteral feeding kits, CPAP machines, and urinary catheters. HMDR facilities are not allowed to sell hypodermic syringes or needles (including insulin syringes).

**Q) I wish to dispense prescription medical devices from my HMDR. Do I need a special license?**

A) In order to dispense prescription (Rx) devices from your HMDR facility you must employ either a licensed pharmacist, or a licensed HMDR exemptee. For a description of HMDR exemptee requirements, please refer to the California Health and Safety Code, Division 104, Part 5, Section 111656.4 (a). By visiting our website, a copy of the [Sherman Food, Drug, and Cosmetic Law](http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf) (<http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf>) can be found.

**Q) How can I obtain an HMDR exemptee license?**

A) An individual may submit an application for an exemptee license on their own behalf or a licensed HMDR operator may submit an exemptee license application for a current employee for the purpose of dispensing prescription medical devices from that particular facility. In either case, the applicant must meet the required knowledge and training mandated by California Health and Safety Code, Division 104, Part 5, Section 111656.4 (a). This law requires one year of work experience in a facility where dangerous drugs and/or dangerous devices are dispensed, evidence of high school graduation or GED equivalent, and evidence that the applicant has completed a training course that addresses areas of HMDR knowledge and training. The initial license application requires a non-refundable fee of \$130 to cover the review and processing of the application, and \$195 for issuance of the actual license. The HMDR exemptee license annual renewal fee is \$195.

License Category		
Exemptee Application Fee/License Fee	\$325	New (Never licensed as Exemptee with FDB)
Exemptee License Fee	\$195	Annual Renewal

**Q) What about HMDR renewal inspections? How frequently are they conducted?**

A) Renewal inspections can take place annually, unannounced, at any HMDR facility during normal business hours. A customer complaint or other referral may also trigger an inspection.

**Q) What are some common inspection violations found?**

A) Common violations of the California Health and Safety Code include: Dispensing prescription devices without a valid HMDR exemptee on the premise; Lack of dispensing records for prescription devices; Inadequate procedures for the cleaning and maintenance of rental devices; Inadequate staff training or patient/caregiver consultation; Inadequate quality assurance procedures and/or lack of documentation of quality assurance procedures.

**Q) How can I get a copy of the HMDR Law?**

**A)** The HMDR Law can be found in the California Health and Safety Code, Sections 111656 through 111656.13 of the Sherman Food, Drug, and Cosmetic Law. By visiting our website, a copy of the [Sherman Food, Drug, and Cosmetic Law](http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf) (<http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf>) can be found.