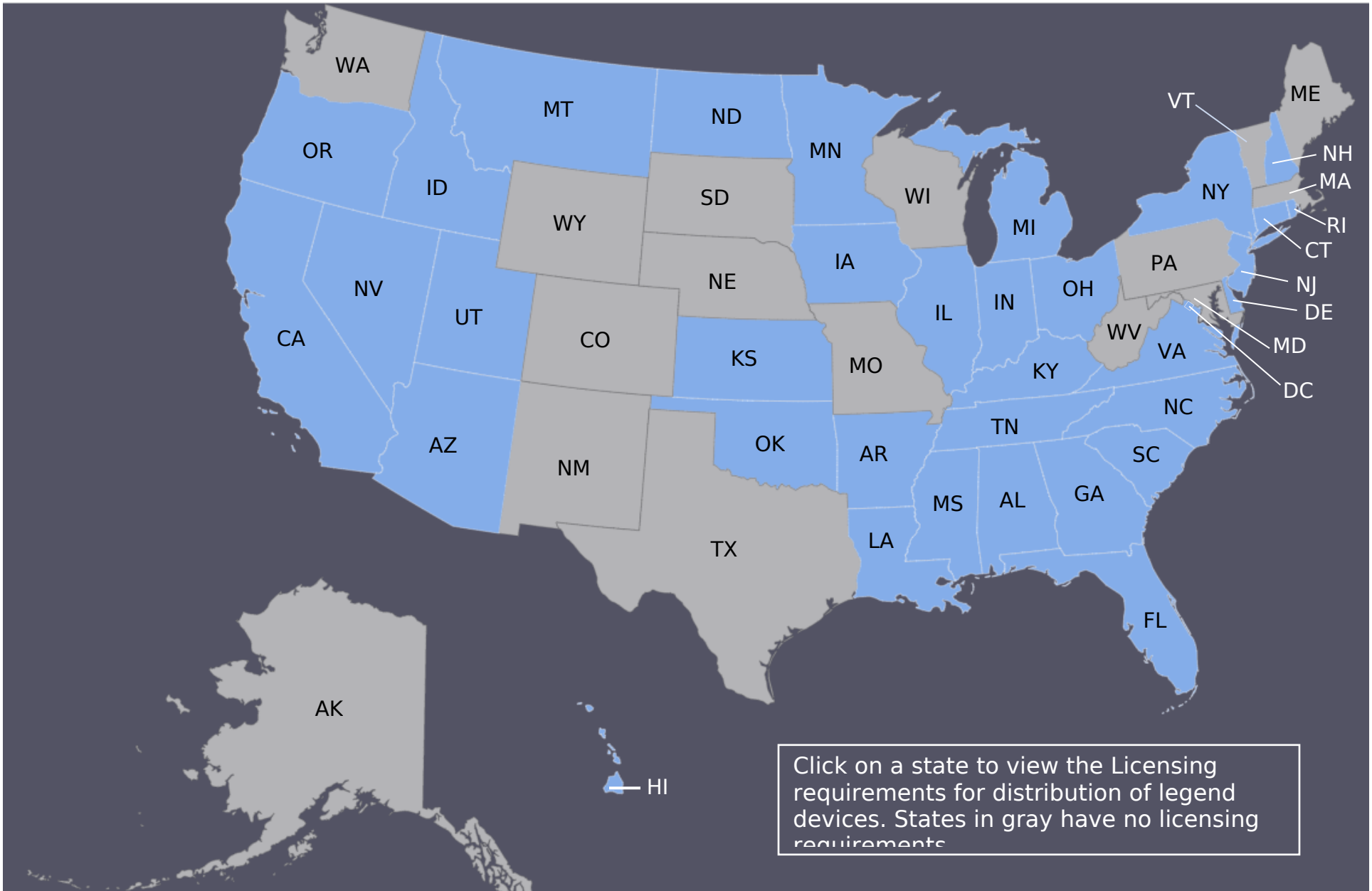
State Legend Device License Requirements



State	Regulations
AL	**License required to distribute: Insulin Pumps, Respiratory, Urological.** (Back to Map) (4) Home Medical Equipment (HME) means medical devices usable in a residential setting. Home Medical Equipment is any equipment that provides therapeutic benefits or enables the consumer to perform certain tasks that he or she is unable to undertake otherwise due to certain medical conditions and/or illnesses. Home Medical Equipment is considered to be equipment that can withstand repeated use and is primarily and customarily used to serve a medical purpose. Home Medical Equipment includes, but is not limited to: (c) any product, intended for use in the home, which is a device, instrument, apparatus, machine, or other similar article whose label bears the statement: "Caution: Federal law requires dispensing by or on the order of a physician." (6) Home Medical Equipment Services Provider means a corporation, other business entity, or person engaged in the business of providing home medical equipment, either directly or through a contractual arrangement, to an unrelated sick or disabled individual in the residence of that individual. (6) No one may operate as a Home Medical Equipment Services Provider without a valid license, including during the time a license application is pending **Source** The licensure requirements of this chapter do not apply to the following entities or practitioners: (9) Mail order companies, as defined by rule of the board. **Source 2**
AR	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory.** (Back to Map) 17-92-901. Definitions (1) "**Home medical equipment**, **legend device**, and medical gas supplier" means a person licensed to supply home medical equipment, medical gases, or legend devices, or any combination thereof, to patients on an order from medical practitioners licensed to order, use, or administer these products and to other licensed suppliers of home medical equipment, medical gases, or legend devices, or any combination thereof; (3) "Legend device" means a device which, because of any potential for harmful effect or the method of its use, is not safe except under the supervision of a practitioner; 17-92-902. License required (1) No person or entity subject to licensure shall sell or rent or offer to sell or rent directly to patients in this state any home medical equipment, legend devices, or medical gases, or any combination thereof, unless the person or entity is licensed as required by this subchapter. **Source** (click "Pharmacy Lawbook" under the Rules and Regulations tab for the most current version of Arkansas Pharmacy Lawbook)
AZ	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) R4-23-693

	A. Permit. A person shall not sell, lease, or supply durable medical equipment or a compressed medical gas to a patient or consumer in Arizona for use in a home or residence without a current Board-issued resident or nonresident durable medical equipment and compressed medical gas supplier permit.
State	**Regulations**
CA	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological, Needles & Syringes.** **(Back to Map)** "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 prescription (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." **Source** (b) "**Home medical device**" means a device intended for use in a home care setting including, but not limited to, all of the following: (10) Prescription devices. **Source 2**
CT	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological, Needles & Syringes.** **(Back to Map)** Sec. 20-571. (Formerly Sec. 20-184a). Definitions (13) "**Legend device**" means a device that is required by applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only or that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN."; **Source** Wholesaler of Drugs, Medical Devices, and/or Cosmetics Outside of the State of Connecticut: "This registration is required for businesses that reside outside the State of Connecticut and supply controlled substances, legend drugs, over-the-counter drugs, medical devices (legend or non-legend), or cosmetics to other wholesalers, manufacturers, prescribing practitioners, hospitals, pharmacies, grocery stores, gas stations, etc." **Source 2** Per email communication between the Gemcore Compliance team and CT BOP:

	“Can you confirm that an out-of-state business shipping Legend Devices direct-to-consumer into Connecticut requires a Wholesaler license with the CT BOP?” “Yes, that would be correct it would require a wholesaler’s license in the State of Connecticut.” **The email for this communication can be provided upon request.**

DC	**License required to distribute: Insulin Pumps, Pump Supplies, Respiratory, Needles & Syringes.** **(Back to Map)** (6) The term "**medical device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (B) Intended for use in the diagnosis of disease or any other condition, or in the cure, mitigation, treatment, or prevention of disease in man or other animal; or **Source** As of October 28, 2016 The District of Columbia Medical Device Regulations, Title 22-B (PUBLIC HEALTH AND MEDICINE), Chapter 102 (LICENSING OF MEDICAL DEVICES – DISTRIBUTORS, MANUFACTURERS, INITIAL IMPORTERS, AND VENDORS), requires that each person engaged in distributing, manufacturing, importing, or the vending of medical devices to or within the District of Columbia must be licensed with DC Department of Health (DOH). **Source 2**
DE	**License required to distribute: Needles & Syringes.** **(Back to Map)** (a) A licensed pharmacist, or pharmacist intern or pharmacy student under the supervision of a pharmacist, may provide hypodermic syringes or hypodermic needles, including pen needles for the administration of prescription medications by injection in the State of Delaware without a prescription, but only to persons who have attained the age of 18 years and who will self-administer prescription medications by injection or administer prescription medications to a minor child for whom they are the parent or legal guardian. When providing hypodermic syringes or hypodermic needles without a prescription, the above-mentioned pharmacist, pharmacist intern or pharmacy student must require proof of identification that validates the individual's age. **Source**

FL	**License required to distribute: Insulin Pumps, Respiratory.** (Back to Map) (6) "**Home medical equipment**" includes any product as defined by the Food and Drug Administration's Federal Food, Drug, and Cosmetic Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. **Source** (7) "**Home medical equipment provider**" means any person or entity that sells or rents or offers to sell or rent to or for a consumer: (a) Any home medical equipment and services; or (b) Home medical equipment that requires any home medical equipment services. **Source 2** 400.93 Licensure required; exemptions; unlawful acts; penalties.— (1) Any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services is subject to licensure under this part. **Source 3**
GA	**License required to distribute: Respiratory, Urological.** (Back to Map) Pharmacies shall keep syringes for injections behind the dispensing counter in their prescription departments and in no other place. No person other than a licensed pharmacist or a pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, shall sell, distribute, exchange, or give, to any person a hypodermic syringe or needle designed or marketed primarily for human use. No hypodermic needle or syringe shall be sold by a pharmacist or pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, if such person has reasonable cause to believe that it will be used for an unlawful purpose. **Source**

HI	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory.** (Back to Map) Under Chapter 321-562 HRS, **durable medical equipment** is defined as: • Equipment that is considered a selected product under the Centers for Medicare and Medicaid Services durable medical equipment such as prosthetics, orthotics, and supplies competitive bidding program that can stand repeated use; • Is primarily and customarily used to serve a medical purpose; • Is generally not useful to a person in the absence of an illness or injury; • Is appropriate for use in the home; • Does not contain any prescription drug; and • Is not considered to be a specialty item, equipment, or service. Chapter 321-542 HRS also defines a **DME supplier** as a person who sells, dispenses, delivers, or services durable medical equipment. Chapter 321-542 HRS mandates that for any person to operate as a DME supplier in the state, the supplier shall first obtain a Hawaii license from the Department of Health, Office of Health Care Assurance. The license shall be for a three (3) year term unless it is earlier revoked or suspended. A DME supplier who applies for a state license shall attest and provide corroborating documentation to the department that the supplier: **Source**
IA	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory.** (Back to Map) (1)License required. A person engaged in the following activities shall obtain a limited distributor license prior to distribution in or into Iowa: a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order. **Source** "**Medical device**" means durable medical equipment or mobility enhancing equipment intended to be prescribed by a practitioner for human use. See rule 701-231.8(423) for definitions of those terms. **Source 2**

ID	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) **12.DME Outlet**. A registered outlet that may hold for sale at retail durable medical equipment (DME) and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection. **Source** (8) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article including any component part or accessory which is: (a) Recognized in the official United States Pharmacopoeia or official National Formulary, other drug compendia or any supplement to them; (b) Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment or prevention of disease in man or other animal (c) Intended to affect the structure or any function of the body of man or other animal, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes **Source 2**
IL	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Needles & Syringes.** (Back to Map) (6) "**Home medical equipment**" means technologically sophisticated medical devices, apparatuses, machines, or other similar articles bearing a label that states "Caution: federal law requires dispensing by or on the order of a physician.", which are usable in a home care setting, including but not limited to: (A) oxygen and oxygen delivery systems; (B) ventilators; (C) respiratory disease management devices, excluding compressor driven nebulizers; (D) wheelchair seating systems; (E) apnea monitors; (F) transcutaneous electrical nerve stimulator (TENS) units; (G) low air-loss cutaneous pressure management devices; (H) sequential compression devices; (I) neonatal home phototherapy devices; (J) enteral feeding pumps; and (K) other similar equipment as defined by the Board.

	(4) "**Home medical equipment and services provider**" or "provider" means a legal entity, as defined by State law, engaged in the business of providing home medical equipment and services, whether directly or through a contractual arrangement, to an unrelated sick individual or an unrelated individual with a disability where that individual resides. **Source**

IN	**License required to distribute: Insulin Pumps, CGM, Respiratory, Needles & Syringes.** (Back to Map) IC 25-26-21-2 "**Home medical equipment**" Sec. 2. (a) As used in this chapter, "home medical equipment" means equipment that: (1) is prescribed by a health care provider; (2) sustains, restores, or supplants a vital bodily function; and (3) is technologically sophisticated and requires individualized adjustment or regular maintenance. (b) The term does not include the following: (1) Walkers. (2) Ambulatory aids. (3) Commodes. (4) Any other home medical equipment determined by the board in rules adopted under section 7 of this chapter. As added by P.L.122-2005, SEC.1. Amended by P.L.105-2008, SEC.50. **Source** Sec. 4. As used in this chapter, "**provider**" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence. **Source 2** Sec. 8. (a) A provider must be licensed by the board before the provider may provide home medical equipment services. If a provider provides home medical equipment services from more than one (1) location in Indiana, the provider must obtain a license under this chapter for each location. **Source 3**
KS	**License required to distribute: Insulin Pumps, CGM, Respiratory.** (Back to Map) (x) "**Durable medical equipment**" means equipment that: (1) Provides therapeutic benefits or enables an individual to perform certain tasks that the individual is unable to otherwise undertake due to certain medical conditions or illnesses; (2) is primarily and customarily used to serve a medical purpose; (3) generally is not useful to a person in the absence of an illness or injury; (4) can withstand repeated use; (5) is appropriate for use in the home, long-term care facility or medical care facility, but may be transported to other locations to allow the individual to complete instrumental activities of daily living that are more complex tasks required for independent living; and (6) may include devices and medical supplies or other similar equipment determined by the board in rules and regulations adopted by the board. (o) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part or accessory that: (1) (A) Is recognized in the official national formulary, or the United States pharmacopoeia, or any supplement thereof; (B) is intended for use in the diagnosis of disease or other conditions; (C) is used for the cure, mitigation, treatment or prevention of disease in human or other animals; or (D) is intended to affect the structure or any function of the body of human or other animals; and (2) (A) does not achieve its primary intended purposes through chemical action within or on the body of human or other animals; and (B) is not dependent upon being metabolized for the achievement of any of its primary intended purposes. **Source** (definitions begin on page 26)

	From the KS Board of Pharmacy's Durable Medical Equipment application form: "Use this form if you do not have a pharmacy registration/permit and are providing only Durable Medical Equipment directly to consumers as defined by K.S.A. 65-1626(x)." **Source 2**
KY	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** **(Back to Map)** (3) "**Home medical equipment**" means durable medical equipment which: (a) Withstands repeated use; (b) Is primarily and customarily used to serve a medical purpose; (c) Is generally not useful to a person in the absence of illness or injury; and (d) Is appropriate for use in the home; (5) "**Home medical equipment and services provider**" or "provider" means a person engaged in the business of providing home medical equipment and services, either directly or through a contractual arrangement, to an unrelated sick or disabled person in the residence of that person; and **Source**
LA	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** **(Back to Map)** A. No person or other entity shall sell, rent or provide, or offer to sell, rent or provide, directly or indirectly, to consumers in this state any durable medical equipment, legend devices, and/or medical gas until such person has obtained a durable medical equipment (DME) permit from the board **Source** **Durable Medical Equipment (DME)**-technologically sophisticated medical devices that may be used in a residence, including the following: a. oxygen and oxygen delivery system; b. ventilators; c. respiratory disease management devices; d. continuous positive airway pressure (CPAP) devices; e. electronic and computerized wheelchairs and seating systems; f. apnea monitors; g. transcutaneous electrical nerve stimulator (TENS) units; h. low air loss cutaneous pressure management devices; i. sequential compression devices; j. feeding pumps; k. home phototherapy devices; l. infusion delivery devices; m. distribution of medical gases to end users for human consumption; n. hospital beds; o. nebulizers; and p. other similar equipment as determined by rule. **Legend**-an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or

	state law requires dispensing by or on the order of a physician" and/or "Rx Only," or any other designation required under federal law. **Source 2**

MI	**License required to distribute: Insulin Pumps, CGM, Respiratory, Urological.** (Back to Map) (2) "**Device**" means an instrument, apparatus, or contrivance, including its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or to affect the structure or function of the body of human beings or other animals. **Source** (7) "**Wholesale distributor**" means a person, other than a manufacturer or wholesale distributor-broker, that supplies, distributes, sells, offers for sale, barters, or otherwise disposes of, to other persons for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device. A wholesale distributor does not include a pharmacy unless the pharmacy meets the requirements of section 17748f. **Source 2**
MN	**License required to distribute: Needles & Syringes.** (Back to Map) Subdivision 1.Generally. It is unlawful for any person to possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except for: (1) the following persons when acting in the course of their practice or employment: (ii) licensed pharmacies and their employees or agents; **Source**
MS	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory.** (Back to Map) G. The term "**Legend Device**" shall mean any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory which is required under federal or state law to be prescribed or ordered by a physician and/or practitioner. 1. Permit required: Pursuant to Mississippi Pharmacy Practice Act Section 73-21-108 no person, business or entity subject to this chapter shall sell, rent or provide or offer to sell, rent or provide directly or indirectly to consumers in this state any home medical equipment, legend devices, and/or medical gas unless such person, business or entity first obtains a Medical Equipment Suppliers Permit from the Mississippi Board of Pharmacy **Source**

MT	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** **(Back to Map)** Per state of Montana Board of Pharmacy, license is required; See email below from MT BOP “Montana currently has only two options for DME suppliers (distributing legend devices): a mail-order pharmacy license (product going directly to consumer – requires pharmacist-in-charge) or a wholesale drug distributor license (product being shipped to a facility/business for dispensing – no pharmacist-in-charge required). We were looking to implement a DME supplier license type this summer, but specific wording in current statute prevented the Board from being able to do so, so said license type is at least one year out.” **A copy of this email communication provided upon request.**
NC	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** **(Back to Map)** (e) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, whose label or labeling bears the statement "Caution: federal law requires dispensing by or on the order of a physician." § 90-85.22. Device and medical equipment permits; exemptions. (a) Devices. – Each place, whether located in this State or out-of-state, where devices are dispensed or delivered to the user in this State shall register annually with the Board on a form provided by the Board and obtain a device permit. A business that has a current pharmacy permit does not have to register and obtain a device permit. Records of devices dispensed in pharmacies or other places shall be kept in accordance with rules adopted by the Board. **Source** (first link, “North Carolina Pharmacy Practice Act” for the most up to date NC pharmacy law)

ND	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) 8. "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is required under federal or North Dakota law to be prescribed by a practitioner and dispensed by a pharmacist. 9. "**Durable medical equipment**" means medical devices, equipment, or supplies that may be used in a residence, including oxygen and oxygen delivery systems and supplies, ventilators, respiratory disease management devices, continuous positive airway pressure (CPAP) devices, electronic and computerized wheelchairs and seating systems, apnea monitors, transcutaneous medical nerve stimulator (TENS) units, low air cutaneous pressure management devices, sequential compression devices, feeding pumps, home phototherapy devices, infusion delivery devices, distribution of medical gases to end users for human consumption, hospital beds, nebulizers, and other similar equipment as may be determined by the board by rule. 43-15.3-11. Retail durable medical equipment retailers - Reciprocity. 1. A person may not sell or deliver durable medical equipment directly to a consumer unless licensed by the board as a retail durable medical equipment retailer **Source** (“Laws, Rules and Regulations” link for the most up to date ND BOP regulations)
NH	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological, Needles & Syringes.** (Back to Map) XVI-a. "**Prescription device**'' or "**legend device**'' means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is restricted for distribution and use only upon the order of a licensed practitioner. VII-a. "Limited retail drug distributor'' means a distributor of **legend devices** or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner. **Source** I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. **Source 2**
NJ	**License required to distribute: Respiratory, Needles & Syringes.** (Back to Map) 1. a. Notwithstanding any State law, rule, or regulation to the contrary, a licensed pharmacy [may] shall sell a hypodermic syringe or needle, or any other instrument adapted for the administration of drugs by injection, to a

	person over 18 years of age who presents valid photo identification to demonstrate proof of age or who otherwise satisfies the seller that he is over 18 years of age, as follows: (1) without a prescription if sold in quantities of between one and up to 10 [or fewer]; and (2) pursuant to a prescription issued by a person authorized to prescribe under State law if sold in quantities of more than 10
NV	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** **(Back to Map)** NAC 639.6935 "Medical products" defined. (NRS 639.070) 1. "**Medical products**" includes **medical devices**, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6936 "Medical products provider" defined. (NRS 639.070) 1. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide **medical products** to a consumer in this State. **Source** This application is required if Medical Devices, Equipment and Gases (MDEG) products will be sold directly to a patient by a prescription. **Source 2**
NY	**License required to distribute: Needles & Syringes.** **(Back to Map)** § 3381. Sale and possession of hypodermic syringes and hypodermic needles. 1. It shall be unlawful for any person to sell or furnish to another person or persons, a hypodermic syringe or hypodermic needle except: (a) pursuant to a prescription of a practitioner, which for the purposes of this section shall include a patient specific prescription form as provided for in the education law; or **Source**
OH	**License required to distribute: Insulin Pumps, Respiratory.** **(Back to Map)** (B) "**Home medical equipment**" means equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, is not useful to a person in the absence of illness or injury, is appropriate for use in the home, and is one or more of the following: (1) Life-sustaining equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing; (2) Technologically sophisticated medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by a home medical equipment services provider to maintain a patient's health care condition or the effectiveness of the equipment; (3) An item specified by the state board of pharmacy in rules adopted under division (B) of section 4752.17 of the Revised Code.

	(C) "**Home medical equipment services**" means the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment. (D) "**Home medical equipment services provider**" means a person engaged in offering home medical equipment services to the public. **Source**

OK	**License required to distribute: Respiratory.** (Back to Map) 2. a. "Durable medical equipment" means equipment for which a prescription is required, including for repair and replacement parts, and that: (1) can stand repeated use, (2) has an expected useful life of at least three (3) years, (3) is primarily and customarily used to serve a medical purpose, (4) is not generally useful to a person in the absence of illness or injury, (5) is appropriate for use in the home, and (6) is intended for use by the consumer. 3. "Supplier" means any person or entity that provides durable medical equipment services or products and that currently bills or plans to bill a claim for reimbursement of services or products to a third party. **Source** A. Any supplier of durable medical equipment to a consumer in this state shall possess a durable medical equipment supplier license issued by the State Board of Pharmacy pursuant to the Oklahoma Durable Medical Equipment Licensing Act. **Source 2** Per communication with the Oklahoma Board of Pharmacy: Gemco Medical Asks: “We would like clarification regarding Section 5, which indicates the act does not apply to ”10. Suppliers of insulin infusion pumps and related supplies or services.” Does the term “related supplies or services” include glucose testing supplies such as Continuous Glucose Monitors (CGM), accessories, and other diabetic testing supplies?” Gary LaRue at the Oklahoma Board of Pharmacy Responds: “The Oklahoma State Board of Pharmacy (OSBP) interprets "Suppliers of insulin infusion pumps and related supplies or services" to include continuous glucose monitors, diabetic testing supplies, and accessories. These items would be exempt from requiring licensure as a DME Supplier.”

OR	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory.** (Back to Map) 689.005 Definitions. (8) “**Device**” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist. **Source** Nonprescription Drug Outlet - Class C (Medical Device, Equipment & Gas Drug Outlet) is any outlet that sells **medical devices** and/or medicinal gasses and over-the-counter medications to a consumer. **Source 2**
RI	**License required to distribute: Needles & Syringes.** (Back to Map) 6.3 Sale of Hypodermic Needles and Syringes in Licensed Pharmacies B. Hypodermic needles and syringes shall be sold only in licensed pharmacies. 1. Hypodermic needles and syringes shall be stored in the pharmacy. Access to hypodermic needles and syringes shall be by authorized pharmacy personnel only. **Source**
SC	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) (23) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label: "Caution: Federal law restricts this device for sale by or on the order of a _____", the blank to be filled with the word physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; or "Federal law prohibits dispensing without prescription"; or any products deemed to be a public health threat after notice and public hearing as designated by the board. **Source** E. Medical Gas/Legend Device Permit 1. A Medical Gas/Legend Device Permit is required for a facility to dispense medical gases and/or **legend devices** to a patient or a patient's agent on the order of a licensed practitioner. **Source 2**

TN	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological, Needles & Syringes.** (Back to Map) Section 63-10-204 - Definitions (11) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a person duly authorized; (16) "**Distributor**" means a person engaged in the distribution of drugs or devices; provided, that "distributor" does not include licensed wholesale distributors or licensed third-party logistics providers; **Source** (1) Every manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and **prescription devices** in this state, must be licensed by the Board in accordance with this chapter. **Source 2**
UT	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) R156-17b-617d. Class E Pharmacy Operating Standards– **Durable Medical Equipment**. (16) "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician." **Source**
VA	**License required to distribute: Insulin Pumps, Pump Supplies, CGM, Respiratory, Urological.** (Back to Map) "**Medical equipment supplier**" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation. **Source** The following classes of drugs and devices shall be controlled by Schedule VI:

	3. Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" or any **device** which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____." (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.) **Source 2**