

VIRGINIA BOARD OF PHARMACY

CATEGORIES OF FACILITY LICENSURE

PHARMACY: This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. Federal law allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

NONRESIDENT PHARMACY: This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

MEDICAL EQUIPMENT SUPPLIER: This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

NONRESIDENT MEDICAL EQUIPMENT SUPPLIER: This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user.

NONRESIDENT WHOLESALE DISTRIBUTOR: This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors.

WAREHOUSER: This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements. This permit may be preferable to the wholesale distributor license for those entities which distribute prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user.

NON-RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs.

RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use.

CONTROLLED SUBSTANCES REGISTRATION (CSR): This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouse, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration to dispense naloxone without charge or compensation. An entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedule II through VI controlled substances may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

OUTSOURCING FACILITY: This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite, the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

NONRESIDENT OUTSOURCING FACILITY: This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices

into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

Practitioner of the Healing Arts to Sell Controlled Substance Facility Permit: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

* § 54.1-3455. Schedule VI.

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.
2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
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.)