

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.

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* medical devices
4. Schedule VI sterile water or saline used in the operation and cleaning of medical devices
5. 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.

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.

LIMITED-USE WHOLESALE DISTRIBUTOR: This license is a "carve-out" of a regular wholesale distributor restricted to those entities that only wholesale distribute medical gases, and in which the Board may waive some of the requirements of regulation. The Board typically waives some of the requirements for information required on initial application and some requirements related to the responsible party as well as some physical standards.

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, 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 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 without the need to obtain a permit as a humane society.

HUMANE SOCIETIES: This permit is a limited permit which, in conjunction with a controlled substances registration, authorizes a non-government entity to purchase and possess any drug approved by the State Veterinarian for **the sole purpose of euthanasia** of sick, unwanted, injured, or homeless domestic pets and animals at the location of the permitted facility. The person signing the application as the responsible party must have proper certification of training by a licensed veterinarian. Neither this permit, nor the CSR, authorizes a humane society to purchase or possess other prescription drugs for use in the treatment of animals. This permit is not needed for an animal shelter which is owned and operated by a government agency, but the CSR is most likely still needed if prescription drugs are to be used for restraint or capture.

* § 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.)