



Virginia Department of
Health Professions
Board of Pharmacy

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INSTRUCTIONS FOR COMPLETING THE APPLICATION FOR A CONTROLLED SUBSTANCE REGISTRATION

Applications are valid for one year from the date of receipt.

The required fee must accompany the original application and additional required documentation. Make a check or money order payable to “Treasurer of Virginia”. Fees are not refundable.

Acceptable signatures are hand-signed or via DocuSign.

Applications with no required fee may be sent to the Board via email.

APPLICATION TYPES AND APPLICABLE SECTIONS TO COMPLETE

New – Complete Sections B, C, D, E, and G – (additionally, Section H if EMS).

Change of Ownership – Complete sections B, C, D, F, and G.

Change of Location or Remodel – Complete sections B, C, D, and E.

Change to Drug Schedules – Complete sections B, C, and D

Change of Tradename – Complete sections B, C, and D.

Change of Responsible Party and/or Supervising Practitioner – Complete sections B, C, and D

Reinstatement – Complete sections B, C, D, E, and G

Change to EMS Designated Locations – Complete sections B, C, D, and H

DESCRIPTIONS OF ACTIVITY TYPES

Alternate Delivery – This activity is for facilities that receive patient specific drugs shipped or delivered to them for subsequent patient pickup or administration.

Ambulatory Surgery Center and Outpatient Clinic – These activities are for clinics that are requesting a CSR for a common stock of drug to be used for several providers in patient settings.

Government Official – This activity is for government entities that are requesting a CSR to obtain a stock of drug required in their work. An example of this would be canine trainers in police departments or animal control officers.

Researcher – This activity is for persons who conduct research under a protocol that requires a stock of drug to be used in their research. Additionally, this may include physicians who dispense only research drugs.

Animal Shelter or Pound – This activity is for public or privately owned animal shelters seeking a stock of certain Schedule VI drugs to treat communicable diseases and drug stock for euthanasia of domestic animals under the protocol issued by the State Veterinarian.

Hospital – This activity is for hospitals without in-house pharmacies.

Teaching Institution – This activity is for academic institutions that are requesting a stock of drugs to be used for student instruction.

Warehouser, Wholesale Distributor, Third Party Logistics Provider, Manufacturer – These activities are for a Virginia facility of the same title that will be handling, stocking, and distributing Schedule II-V drugs. Out of state entities with the same license title are **not** required to have this registration.

Drug Dispensing Device – This activity is for pharmacies applying for a Controlled Substance Registration to place an automated drug dispensing device or remote dispensing device in an authorized location.

Telemedicine – This activity is for an entity where a patient may receive telemedicine services and be prescribed a Schedule II-V drug, but the patient is not in the physical presence of a practitioner who maintains a DEA registration.

Analytic Laboratory – This activity is for analytic laboratories that will be performing analysis on Schedule II-VI drugs or marijuana.

EMS Agency – This activity is for EMS agencies registered under VDH Office of Emergency Management

Naloxone Dispensing – This activity is for entities that will be dispensing naloxone injectable with a syringe by persons authorized by DBHDS. **No fee is required for this type.

Crisis Stabilization – This activity is for entities that provide crisis stabilization services, licensed by DBHDS, and do not intend to have a pharmacy operate an automated dispensing device or remote dispensing device for the drug stock. If all drugs are maintained in this automated system, the pharmacy must apply for the CSR.

Correctional Facility – This activity is for state and private correctional facilities that have a medical clinic.

ADDITIONAL DOCUMENTATION AND REQUIREMENTS FOR EACH ACTIVITY:

Alternate Delivery:

- Submit a description of business practice and why this registration is needed. Include examples of the drugs intended to be received at this location.
- Supervising Practitioner must be someone licensed in Virginia who is authorized to prescribe or may be a pharmacist.
- Responsible Party must be a person licensed to administer drugs such as a nurse or, for this activity type, a pharmacy technician. The responsible party should be present regularly at the location.
- A pharmacist or prescriber must be present at all times when the site is open unless prior approval is given in limited circumstances.
- Only Schedule VI drugs are permitted to be delivered via alternate delivery aside from a few limited Schedule III injectable drugs. Check Schedule III and/or Schedule VI only if your location will receive these patient-specific dispensed drugs. Do not check any other schedules on the application.

Ambulatory Surgery Centers and Outpatient Clinics

- Submit a description of business practice and why this registration is needed.
- Supervising Practitioner must be someone licensed in Virginia who is authorized to prescribe. For this activity, this person is often the medical director.
- Responsible Party must be a person licensed to administer drugs, such as a nurse. The responsible party should be present regularly at the location.

Government Official

- Submit a protocol that specifically names the controlled substances to be used and provides details as to the intended use of these controlled substances within the work.
- Provide documentation showing competence (curriculum vitae, education credentials, professional licensure, training) to use the controlled substances within the scope of this activity.
- A Supervising Practitioner is not required.
- Responsible Party must be the trained individual who is demonstrating competence in the use of the controlled substances.

Researcher

- If applying as a physician who intends to dispense Schedule II-VI drugs only to patients under a research protocol, the name of the physician shall be entered in the “Name of Business Entity” field.
- Submit the research protocol that details the names of drugs to be used and provide details as to the intended use of these controlled substances within the work.
- Provide documentation showing competence (curriculum vitae, education credentials, professional licensure, training) to use the controlled substances within the scope of this activity.
- Schedule I must be approved by DEA before Board approval. A copy of the DEA registration must be sent to the Board for the Virginia controlled substance registration to be updated to reflect Schedule I.
- Leave the section for Supervising Practitioner blank.
- Responsible Party must be the person who is demonstrating competence in the use of the controlled substances.

Animal Shelter or Pound

- Submit a description of business practice and why this registration is needed.
- Supervising Practitioner must be a licensed Veterinarian.
- Responsible Party should be present regularly at the shelter and trained in euthanasia if stocking drugs for that purpose. Proof of training must be submitted along with the application.

Hospital

- Submit a description of business practice and why this registration is needed.
- Supervising Practitioner must be a pharmacist.
- Responsible Party must be a person licensed to administer drugs, such as a nurse. The responsible party should be present regularly at the location.

Teaching Institution

- Submit a description of business practice and why this registration is needed. Include the drugs intended to be stocked at this location.
- Supervising Practitioner must be someone licensed in Virginia who is authorized to prescribe or may be a pharmacist.
- Responsible Party must be a person licensed to administer drugs, such as a pharmacist or nurse. The responsible party should be present regularly at the location.

Warehouser, Wholesale Distributor, Third Party Logistics Provider, and Manufacturer

- The Supervising Practitioner section may be left blank.
- The Responsible Party must be an individual responsible for storage and security of drugs.

Drug Dispensing Device

- The entity name must be the name of the pharmacy providing drugs to the device and overseeing the audits.
- The address is the location where the device is being placed.
- Supervising Practitioner is the pharmacist at the pharmacy providing services.
- Responsible Party is a person authorized by law to administer drugs, such as a nurse who is present regularly at the location.

Telemedicine

- Submit a description of business practice and why this registration is needed.
- Supervising Practitioner must be a prescriber.
- Responsible Party is a prescriber, nurse, pharmacist, or other person authorized in § 54.1-3408 to administer.
- There is no inspection required for this activity type.

Analytic Laboratory

- Submit the description of business practice that details the names of controlled substances to be tested.
- Provide documentation showing competence (curriculum vitae, education credentials, professional licensure, training) to use the controlled substances within the scope of this activity.
- Supervising Practitioner section may be left blank.
- Responsible Party must be the person who is demonstrating competence in the use of the controlled substances.

EMS

- Submit a description of business practice and why this registration is needed. Include the drugs intended to be stocked and distributed at this location.
- Supervising Practitioner must be the Operational Medical Director.
- Responsible Party must be a person licensed to administer the drugs, such as a paramedic. The responsible party should be present regularly at the location.
- Attach a list of designated locations where drugs are intended to be delivered, if applicable. The list must include the name, physical address, and contact phone number for each. Please read and sign the attestation in section H.

Naloxone Dispensing

- Submit a description of business practice and why this registration is needed.
- Supervising Practitioner section may be left blank.

- Responsible Party shall be a nurse, prescriber, pharmacist, or other person authorized by DBHDS to train individuals on the administration of injectable naloxone and proper disposal of a hypodermic needle or syringe.
- No inspection or fee is required.

Crisis Stabilization

- Submit a description of business practice and why this registration is needed.
- An example of a qualifying Supervising Practitioner is a prescriber.
- Responsible Party is a person licensed to administer drugs, such as a nurse. The responsible party should be present regularly at the location.
- Only check this box and apply for this registration if the facility will be ordering and stocking its own drugs that are not kept in an automated dispensing device or remote dispensing device.

Correctional Facility

- Submit a description of business practices and why this registration is needed.
- Supervising Practitioner must be a prescriber or pharmacist.
- Responsible Party is a person licensed to administer drugs, such as a nurse. The responsible party should be present regularly at this location.



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APPLICATION FOR A CONTROLLED SUBSTANCE REGISTRATION

**** A Controlled Substances Registration is not required for an individual prescriber to be authorized to prescribe and administer Schedule II-V drugs. This registration is for facilities only and physicians dispensing only research drugs to patients under a protocol.****

SECTION A - Check appropriate box(es):

- | | | | |
|--|--------------------|---|--------|
| ☐ New | \$180 | ☐ Change to Drug Schedules | No Fee |
| ☐ Change of Ownership | \$125 | ☐ Change of Tradename | No Fee |
| ☐ Change of Location | \$435 | ☐ Change of Responsible Party | No Fee |
| ☐ Remodel | \$435 | ☐ Change of Supervising Practitioner | No Fee |
| ☐ Reinstatement | Call Board for Fee | ☐ Change to EMS Designated Locations | No Fee |

If reinstatement, is it due to: ☐ Lapse of Permit or ☐ Suspension or Revocation of a Permit

SECTION B - Check the appropriate box(es) to describe the ACTIVITY TYPE:

- | | | | |
|--|--|---|--|
| ☐ Alternate Delivery Site | ☐ EMS Agency | ☐ Outpatient Clinic | ☐ Warehouser |
| ☐ Ambulatory Surgery Center | ☐ Government Official | ☐ Teaching Institute | ☐ Wholesale Distributor |
| ☐ Analytic Laboratory | ☐ Hospital | ☐ Telemedicine | ☐ Correctional Facility |
| ☐ Animal Shelter or Pound | ☐ Manufacturer | ☐ Researcher | ☐ Crisis Stabilization |
| ☐ Drug Dispensing Device | ☐ Naloxone Dispensing | ☐ Third Party Logistics Provider | |

SECTION C - Check the appropriate box(es) for the Controlled Substance Schedules requested:

- ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐ Marijuana

SECTION D - ALL APPLICANTS

Name of Business Entity		Virginia CSR number (if applicable) 0220-	
Street Address		Federal Employer Identification Number (FEIN)	
City		State	Zip Code

RESPONSIBLE PARTY INFORMATION

Name of Responsible Party		Email Address of Responsible Party	
Type of Professional License to administer drugs (if applicable)		Professional License Number of Responsible Party (if applicable)	
Signature of Responsible Party		Date	Telephone Number

SUPERVISING PRACTITIONER INFORMATION

Name of Supervising Practitioner (if applicable) ¹			Email Address of Supervising Practitioner		
Street Address			Telephone Number		
City	State	Zip Code	Professional License Number		
Signature of Supervising Practitioner			Date	DEA Number of Supervising Practitioner	

SECTION E – INSPECTION

Contact information to schedule an inspection	Expected Opening, Moving, or Remodel Completion Date	Requested Inspection Date
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A 14-day notice is required for scheduling an inspection. Drugs may not be stocked before inspection and approval. An inspector will call or email before the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party or supervising practitioner should contact the Board at pharmbd@dhp.virginia.gov to inquire.

*** An inspection is not required if only applying for telemedicine or naloxone dispensing activities ***

SECTION F – CHANGE OF OWNERSHIP

Previous Name of Legal Owner
Effective Date of Change of Ownership

SECTION G – NEW REGISTRATION & CHANGE OF OWNERSHIP

OWNERSHIP TYPE—check one: Corporation ☐ Partnership ☐ Individual ☐ Other ☐		
Name of ownership entity or individual:		
Street Address:		Phone No.
City:	State :	Zip Code:
State(s) of incorporation:		

Please list any partner or partners, member or members (owners) and, if a corporation, then the corporate officers and directors - Attach a separate sheet if needed.

Name:	_____	Title:	_____
Mailing Address:	_____		

SECTION H – EMS DESIGNATED LOCATION ATTESTATION

An EMS applicant who will have designated locations they intend to deliver Schedule II-VI controlled substances to under their registration must attach a list of such designated locations and include the name, physical address, and contact phone number for each. Please indicate if you are adding or removing the listed designated locations. **Additionally, the responsible party must sign the attestation below.** **Note:** Any additions to the designated locations require an application and shall be submitted to the Board in advance of delivering Schedule II-VI controlled substances to that location.

_____	_____
Signature of EMS Responsible Party	Date
As the responsible party, I hereby attest that each designated location listed on the document(s) included with this application complies with the storage and security requirements of 18VAC110-20-710.	