

Per Rule §15-5-4.7. renewal applications must be RECEIVED in our office by June 15th in order to allow time to process by June 30th. If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expired, the license is expired. Renewal applications received after June shall require the payment of a late fee in the amount of \$150.00 in addition to the renewal fee. Renewal applications not received by the first day of August each year shall require the payment of a reinstatement fee of \$250.00 in addition to the renewal fee.

West Virginia Board of Pharmacy

1207 Quarrier St. 4th Floor

Charleston, WV 25301

APPLICATION FOR LICENSE AS A MANUFACTURER

(Includes Traditional Manufacturer, Virtual Manufacturer, and 503B Compounding Manufacturer)

(W.Va. Code § 30-5-25)

July 1, 2026 to June 30, 2028

Legal Name: _____

DBA Name: _____

Physical Address: _____

Mailing Address: (Check box if same as Physical address)

City _____ County _____ State _____ Zip _____

License # MR Email Address: _____ DEA# _____ Phone # _____

Type of Application (Must Select ONE):

New License: Relocation (change of physical address): Change of Ownership: Renewal:

Has this facility had a change of physical address and/or name? YES NO

Expiration Date:

Have you done business within the state of West Virginia, even on one occasion, since your expiration date? YES NO N/A

If YES, please ATTACH an explanation of the extent of business done since your license expired.

If renewing while your license is still active, please select N/A.

Business Information:

NABP e-Profile ID: _____ (If you do not have a NABP e-profile ID, please input N/A.)

Are you required to be licensed by your home state? YES NO

If YES, please **ATTACH** a copy of home state license.

List all other states in which this facility is licensed: _____

Doing Business As (select one): Individual Partnership Corporation

ATTACH a list of current owners, partners, or corporate officers and titles.

ATTACH a list of products to be manufactured, packaged, or repackaged.

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FDA:

Are you licensed/registered by the FDA? YES NO NOT REQUIRED* Virtual Manufacturer*

IF NO, STOP HERE! Per Rule §15-5-4.5, "Each applicant for a manufacturer permit must be authorized to operate as a manufacturer with the Federal Food and Drug Administration, and must supply proof of that authorization along with its application."

If YES, are you registered as: Manufacturer or 503b Outsourcing Facility

If Manufacturer, Please **ATTACH** a copy of your current FDA registration.

If Manufacturer and required to be inspected by FDA, Please **ATTACH** a copy of FDA inspection within the last 5 years. Please also **ATTACH** a copy of any FDA 483 or warning letters associated with that inspection and responses.

If 503b Outsourcing Facility, Please **ATTACH** a copy of your current FDA registration, please ATTACH a copy of FDA inspection within the last 5 years. Also, **ATTACH** a copy of any FDA 483 or warning letter associated with that inspection and responses. Also **ATTACH** a copy of the Sterile Compounding Policy and Procedure Manual for your facility. **(If 503b additional fee is required for sterile compounding permit)**

*If Not Required and/or Virtual Manufacturer, please **ATTACH** proof from the FDA that you are not required to be registered and inspected by the FDA.
*

INSPECTION:

Are you required to be inspected by your home state? YES NO

If YES, Please **ATTACH** a copy of the most recent inspection performed by your home state (NOTE: Must be within the last 2 years).

CONTROLLED SUBSTANCES:

If handling Controlled Substances, an additional fee for the Controlled Substance Handling Permit is required.

Do you handle Controlled Substances? YES NO

IF YES, MUST Circle applicable drug schedules: C-I C-II C-III C-IV C-V

PLEASE ATTACH current copy of DEA Registration Certificate.

Name of person authorized to sign for controlled substances _____

Sterile Products:

Do you produce sterile products? YES NO

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PHARMACIST-IN-CHARGE/PERSON-IN-CHARGE:

Pharmacist-In-Charge _____ RPh# _____ Phone _____

Address _____ City _____

State _____ Zip _____ County _____

NOTE: If a pharmacist is not employed, give the following information on person in charge:

Chief Science Officer/Person-In-Charge _____ Phone _____

Address _____

City _____ State _____ Zip _____ County _____

<u>New Application:</u>		
<u>FEES (check all applicable):</u>		
New Permit	<input type="checkbox"/>	\$500.00
Controlled Substance Handling Permit	<input type="checkbox"/>	\$50.00
Sterile Compounding Pharmacy Permit (503b ONLY)	<input type="checkbox"/>	\$100.00
Total Fees to be paid with this Application (by check or money order):		

<u>Renewal/Relocation/Change of Ownership:</u>		
<u>FEES (check all applicable):</u>		
Renewal/Relocation/Change of Ownership	<input type="checkbox"/>	\$1000.00
Controlled Substance Handling Permit	<input type="checkbox"/>	\$100.00
Sterile Compounding Pharmacy Permit (503b ONLY)	<input type="checkbox"/>	\$200.00
Total Fees to be paid with this Application (by check or money order):		

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CERTIFICATION:

By checking this box, I hereby certify that the answers given in this application are true and correct to the best of my knowledge. I understand that approval of this application will only extend to those products listed and that the products and personnel approved thereby are not subject to change except upon approval by the Board of Pharmacy of a new application.

By checking this box, I understand that every application for a manufacturer permit shall be accompanied by the required fee. I understand that I must attach copies of all documents that are noted as required (if applicable) throughout this application. Furthermore, I understand that failure to complete this application completely and accurately and to attach the required documents may result in denial of this application. All fees associated with this application are non-refundable.

Name of Person Completing this Application: _____

Direct Phone Number of Person Completing this Application: _____

Email Address of Person Completing this Application: _____

Signature of Person Completing this Application:

Title:

Date: