WHOLESALE DISTRIBUTOR APPLICATION INSTRUCTIONS

- Complete the attached Maryland Board of Pharmacy's **Application for Wholesale Distributor Permit**. Be sure to check the box for the relevant application type (New, Renewal, Ownership Change, Relocation, or Reinstatement).

> **NOTE:** The Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act (Md. Code Ann., Health Occ. § 12–6C–01 *et seq*.) requires a wholesale distributor to hold a permit issued by the Maryland Board of Pharmacy ("Board") before engaging in wholesale distribution of prescription drugs or devices into or within the State. For further details, please review the Act and the relevant Board regulations located in COMAR 10.34.22.01 – 08.

- Submit the completed application with all attachments and a check made payable to the Maryland Board of Pharmacy in the appropriate amount to:

Maryland Board of Pharmacy, PO BOX 2024, Baltimore, MD 21203-2024.

- Applications sent overnight or through priority mail must be addressed to the appropriate lockbox and sent to:

Wells Fargo Bank, Attn: State of MD – Board of Pharmacy, Lockbox 2024
7175 Columbia Gateway Drive, Columbia, MD 21046

- The application process must be completed within one year from submission of the initial application. Applicants failing to complete the process within one year will be required to submit a new application. Fees paid for applications that have expired will not be refunded or credited.
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- The application fee is a non-refundable, administrative fee.

- For **IN-STATE APPLICANTS**, the Board may not issue a Wholesale Distributor Permit unless the Board or its designee conducts a physical inspection of the applicant's place of business, including any facility owned or operated by the applicant.

- For **OUT-OF-STATE APPLICANTS**, the Board may not issue a wholesale distributor permit unless the applicant is accredited by a Board-recognized accrediting program or eligible for reciprocity. **Current Board-recognized accrediting programs are: VAWD** (Verified-Accredited Wholesale Distributors), **The Joint Commission**, **ACHC** (Accreditation Commission for Home Care) and **CHAP** (Community Health Accreditation Program), **BOC** (Board of Certification/Accreditation) and **NCDQA QAS** (Nationally Coalition for Drug Quality & Security. – refer to page 3

- Out-of-state applicants for a Wholesale Distributor Permit may be eligible for reciprocity if they are located in a state with requirements that are substantially equivalent to Maryland's wholesale distributor requirements, including requirements for pedigree, routine inspections, security measures, and a prohibition against operating in a residence. Reciprocal applicants must submit a copy of an inspection report issued by an agency in the state of residence completed within the previous two years, but they need not be accredited. **Current reciprocal states include Arizona; California (devices only); Colorado; Florida; Georgia; Idaho; Illinois; Indiana; Kentucky; Nebraska; Nevada; Ohio; Oklahoma (human drugs only); Oregon; Washington; and Wyoming.*; New York and South Carolina***

Revised 03/12/2024

NOTE: On November 23, 2013 the Drug Supply Chain Security Act (DSCSA) was signed into federal law which outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed. Among the changes the law prohibits states from licensing Third Party Logistics (3PL's) providers as Distributors. Third Party Logistic providers are not required to obtain/renew Maryland permits.

NOTE: 503(b) FDA registered Outsourcing Facilities are do not complete this application, please use the Manufacturer's application

NOTE: Please allow two to four weeks for the Board to process your completed application.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore MD 21215-2299
Phone: 410-764-4755
Fax: 410-358-6207
www.dhmh.maryland.gov/pharmacy

APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

APPLICATION TYPE				
☐ **New Application** **Fee: $1,750.00**	☐ **New Ownership** **Fee: $1,750.00**	☐ **Renewal** **Fee: $1,750.00**	☐ **Relocation** **Fee: $1,750.00**	☐ **Reinstatement** **Fee: $3,250.00**

Proposed date for ownership or relocation change: _____

1. APPLICANT INFORMATION	
A. Name of Applicant: ***(name in which company is doing business)***	
Permit Number *(if applicable)*:	

B. Facility Address *(physical location of establishment which should be reflected on all sales invoices and shipping documents)*:							
Street Address:						**Suite #:**	
City:		**State:**		**Zip Code:**			
Telephone #:				**Fax #:**			
Web Site:			**Email Address:**				
Federal Tax ID #:							

C. Type of Business (check all that apply):		
☐ Sole Proprietorship	☐ Partnership	☐ C Corporation
☐ S Corporation	☐ LLC	☐ Other (please explain):

D. Legal Name (if different from Applicant Name):	
State of Incorporation:	
Date of Incorporation:	

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E. Parent Companies *(include any and all companies that have direct or indirect control over the applicant)*

F. Resident Agent (*attach Resident Agent Agreement, required for facilities not located in Maryland)*:					
Name:		**Title:**			
Street Address:				**Suite #:**	
City:		**State:**		**Zip Code:**	
Telephone #:		**Fax #:**			

2. FACILITY INFORMATION

A. Date of last inspection by a state agency, accreditation program, or FDA: *(attach most recent inspection report)*	

B. Accreditation program *(attach proof of accreditation as applicable to company operations)*:
☐ **VAWD** (Verified-Accredited Wholesale Distributors) - Prescription Drugs and/or Devices
☐ **The Joint Commission** - Durable Medical Equipment
☐ **ACHC** (Accreditation Commission for Home Care) - Oxygen
☐ **CHAP** (Community Health Accreditation Program) - Medical Gases other than oxygen
☐ **BOC** (Board of Certification/Accreditation)
☐ **NCDQS Qas** (National Coalition for Drug Quality & Security

C. DEA Registration #: *(attach copies of registration certificates)*		**Expiration Date:**	
Maryland CDS Registration # *(attach copies of registration certificates)*		**Expiration Date:**	

D. State and Federal permit/license/registration numbers *(Non-Resident applicants: Include a copy of the permit/license/registration in your state of residence)* *(attach additional pages if necessary)*:	
LICENSING BODY	**PERMIT / LICENSE / REGISTRATION NUMBER**

E. Facility ownership description *(attach certificate of occupancy)*:	
☐ OWN ☐ RENT	
1. Number of years in current facility:	
2. Name of Lessor (if applicable):	

F. Facility physical description *(see COMAR 10.34.22.03 and .06)*	
1. Square footage:	
2. Description of security and alarm systems:	
3. Description of temperature and humidity control monitoring:	

3. OPERATIONS			
A. Hours of Operation			
Sunday		Thursday	
Monday		Friday	
Tuesday		Saturday	
Wednesday			

B. Products distributed *(check all applicable boxes) (please send a list of the products distributed--do not send catalogs)*:

- ☐ **Drugs**
  - ☐ **Prescription**
  - ☐ **Non-prescription**
  - ☐ **Controlled Dangerous Substances (CDS)**
- ☐ **Medical Gasses**
- ☐ **Devices**
  - ☐ **Class I**
  - ☐ **Class II**
  - ☐ **Class III**

C. Import Activities *(list all countries of import for each facility listed on application)*:
If you import CDS, please attach DEA Form 357.

4. OWNERSHIP
Please include the following on a separate sheet:
1. Full name, title, date of birth, and business address for owner, sole proprietor, each partner, and/or each corporate director or officer;
2. Full name, title, date of birth, and business address for each manager of an LLC;
3. Full name, title, date of birth and business address for each shareholder owning 10% or more of the shares for a *non-publicly traded corporation*; and
4. Corporate name for a non-publicly traded corporation.

5. DISCIPLINARY ACTIONS	
Please include a separate sheet listing all disciplinary actions by federal or state agencies against the wholesale distributor, as well as any such actions against principals, owners, directors, or officers. Please include documentation of any corrective actions taken in response to any disciplinary actions and any final orders issued by any federal or state agencies. **Please only include information not previously disclosed to the Board.**	
Attachment included:	☐YES ☐NO

6. SURETY BOND	
Is a surety bond or other equivalent means of security attached?	☐ YES ☐ NO
☐ **Annual gross receipts in Maryland for previous tax year are less than $10,000,000 (please attach appropriate documentation)**	
☐ **Annual gross receipts in Maryland for previous tax year are $10,000,000 or more**	

Means of Security

(For further details on means of security, please review Md. Code Ann., Health Occ. § 12-6C-05(f) and COMAR 10.34.22.03.E.)

☐ Surety Bond

☐ Irrevocable Letter of Credit (LOC)

Documentation of sales in Maryland below $10,000,000 will be required if using a Surety Bond or LOC in the amount of $50,000. Documentation is either last year's tax records or a review of the company's sales by a Certified Public Accountant (CPA).

Please note, the Surety Bond/LOC must list the facility's address

☐ Proof of General and Product Liability Insurance

7. DESIGNATED REPRESENTATIVE/DIRECT SUPERVISOR
Please complete and attach Attachment 1 – Designated Representative and Attachment 2 – Direct Supervisor of Designated Representative.

8. SIGNATURE
By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in a Maryland wholesale distributor permit may be revoked if any assertion made in this application is found to be false.

Signature of Applicant:	

Business Telephone #:		**Business Fax #:**	
Name and Title:			

9. LIST OF DESIGNEE		
If applicable, list the names of person and/or entity that you authorize the Board to release information about your application:		
Name of Organization	**Name of Person**	**Title**

10. APPLICATION CHECKLIST		
Application Fee ($1,750 or $3,250)	☐YES	☐NO
Resident Agent Agreement (if applicable)	☐YES	☐NO
Most Recent Inspection Report	☐YES	☐NO
Proof of Accreditation (if applicable)	☐YES	☐NO
Copies of DEA & Maryland CDS Registration Certificates	☐YES	☐NO
Copy of Permit from State of Residence (if applicable)	☐YES	☐NO
Copy of Lease or Deed	☐YES	☐NO
DEA Form 357 (if applicable)	☐YES	☐NO
Ownership Information	☐YES	☐NO
Surety Bond (or other similar security)	☐YES	☐NO
Proof of Annual Gross Receipts (if applicable)	☐YES	☐NO
Evidence of General/Product Liability Insurance	☐YES	☐NO
Attachment 1 – Designated Representative	☐YES	☐NO
Attachment 2 – Immediate Supervisor of Designated Rep.	☐YES	☐NO

CRIMINAL BACKGROUND CHECK

Required for Designated Representative and Immediate Supervisor of Designated Representative:

Maryland law requires the state background results be provided by the State of residence and the Federal results be provided by a state or federal agency.

Below is the process in order to obtain the needed background checks.

To obtain the state results:

The State followed by "background check" (ex.: *Maryland Background Check*) would be searched online. The results would provide the process for obtaining that state's background check

To obtain the federal results:

There are currently two options regarding the Federal background check.

- Submit background cards for the Federal level checks to the State of Maryland for processing, the federal check will be processed by Maryland CJIS (http://www.dpscs.state.md.us/publicservs/bgchecks.shtml)

Or

- Submit the federal background check directly to the FBI (http://www.fbi.gov/about-us/cjis/background-checks)

Please note: Third party background results are not accepted

APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

ATTACHMENT 1

DESIGNATED REPRESENTATIVE

Place a recent photograph in this space

Attach a photograph showing your face, with a three quarter view. The photograph **must be recent and in good condition.**

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

I certify that this is a photograph of me taken within the previous 180 days of submitting this application.	
Signature:	

1. IDENTIFICATION					
First Name:					
Middle / Maiden Name:					
Last Name:					
Street Address:					
City:		**State:**		**Zip:**	
Work Phone:					
Date of Birth:		**Place of Birth:**			
Email Address:					

2. PLACES OF RESIDENCE
Complete the following table with your places of residence for the previous seven (7) years.

Dates(s)	Address	City, State, Zip

3. EMPLOYMENT INFORMATION

Complete the following table with your places of employment for the previous seven (7) years.

Employer Name	Job Title	Date of Hire	Date of Termination	Address	City, State, Zip

4. PERSONAL ATTESTATION QUESTIONS

Initial each statement to indicate your understanding and agreement to abide by the requirements of a designated representative for a wholesale distributor:

____	**Employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping related to prescription drugs.**
____	**Employed by the applicant full time in a managerial level position.**
____	**Actively involved in, and aware of, the daily operation of the wholesale distributor.**
____	**Physically present, except for an authorized absence such as sick or vacation leave, at the facility of the applicant during regular business hours.**
____	**Serving as a designated representative for only one applicant at a time, or for two or more members of an affiliated group as defined in §1504 of the Internal Revenue Code.**
____	**Does not have any convictions for a violation of any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.**
____	**Does not have any convictions for a felony under federal, state, or local laws.**

5. ADDITIONAL QUESTIONS	
If you answer "YES" to any question, please provide a detailed explanation (attach additional pages if necessary) and supporting documentation. Failure to provide complete and correct information may result in delay, or denial, of your wholesale distributer application.	
1. Have you been in involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund)?	☐YES ☐NO
2. Have you been in involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund) that has been named a party in a lawsuit?	☐YES ☐NO
3. Have you been the subject of any proceeding for the revocation of any professional or business license or any criminal violation? If yes, provide the details of the nature and disposition of the proceeding.	☐YES ☐NO
4. Have you been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs? If yes, provide the details and any documentation regarding the event.	☐YES ☐NO
5. Have you been found guilty of any misdemeanor or felony offense (regardless of whether adjudication of the guilt was withheld, you pled guilty or nolo contendere or whether the criminal conviction is under appeal) as an adult?**	☐YES ☐NO
6. Do you have a criminal conviction currently under appeal at the time of this application? If yes, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal) should accompany this application.	☐YES ☐NO

***** Nolo contendere- A plea in a criminal case which has a similar legal effect as pleading guilty. The defendant does not admit or deny the charges, but a fine or sentence may be imposed based on this plea.***

SIGNATURE: Designated Representative			
By signing this application, I solemnly affirm under the penalties of perjury that the contents of this section (Section VII) are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of a Designated Representative under the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution.. I understand that in the Wholesale Distributor Permit issued pursuant to this application may be revoked if any assertion made in this application is found to be false.			
Name:			
Date of Birth: *(must be minimum 21 y/o)*		**Place of Birth:**	
Telephone #:		**Fax #:**	

Signature:	

Date:	

APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

ATTACHMENT 2
IMMEDIATE SUPERVISOR OF DESIGNATED REPRESENTATIVE

Place a recent photograph in this space

Attach a photograph showing your face, with a three quarter view. The photograph **must be recent and in good condition.**

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

I certify that this is a photograph of me taken within the previous 180 days of submitting this application.	
Signature:	

1. IDENTIFICATION					
First Name:					
Middle / Maiden Name:					
Last Name:					
Street Address:					
City:		**State:**		**Zip:**	
Work Phone:					
Date of Birth:		**Place of Birth:**			
Email Address:					

2. PLACES OF RESIDENCE
Complete the following table with your places of residence for the previous seven (7) years.

	Dates(s)	Address	City, State, Zip
	3. EMPLOYMENT INFORMATION		

Complete the following table with your places of employment for the previous seven (7) years.

Employer Name	Job Title	Date of Hire	Date of Termination	Address	City, State, Zip

4. PERSONAL ATTESTATION QUESTIONS

Initial each statement to indicate your understanding and agreement to abide by the requirements of a designated representative for a wholesale distributor:

____	**Employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping related to prescription drugs.**
____	**Employed by the applicant full time in a managerial level position.**
____	**Actively involved in, and aware of, the daily operation of the wholesale distributor.**
____	**Does not have any convictions for a violation of any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.**
____	**Does not have any convictions for a felony under federal, state, or local laws.**

5. ADDITIONAL QUESTIONS

If you answer "YES" to any question, please provide a detailed explanation (attach additional pages if necessary) and supporting documentation. Failure to provide complete and correct information may result in delay, or denial, of your wholesale distributer application.

1. Have you been in involved with or have any investments in any business (es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund)?	☐YES ☐NO
2. Have you been in involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund) that has been named a party in a lawsuit?	☐YES ☐NO
3. Have you been the subject of any proceeding for the revocation of any professional or business license or any criminal violation? If yes, provide the details of the nature and disposition of the proceeding.	☐YES ☐NO

4. Have you been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs? If yes, provide the details and any documentation regarding the event.	☐YES ☐NO
5. Have you been found guilty of any misdemeanor or felony offense (regardless of whether adjudication of the guilt was withheld, you pled guilty or nolo contendere or whether the criminal conviction is under appeal) as an adult?**	☐YES ☐NO
6. Do you have a criminal conviction currently under appeal at the time of this application? If yes, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal) should accompany this application.	☐YES ☐NO

***** Nolo contendere- A plea in a criminal case which has a similar legal effect as pleading guilty. The defendant does not admit or deny the charges, but a fine or sentence may be imposed based on this plea.***

SIGNATURE: Immediate Supervisor of the Designated Representative			
By signing this application, I solemnly affirm under the penalties of perjury that the contents of this section (Section VII) of the application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of a Designated Representative under the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution.. I understand that in the Maryland Wholesale Distributor Permit issued pursuant to this application may be revoked if any assertion made in this application is found to be false.			
Name:			
Date of Birth: ***(must be minimum 21 y/o)***		**Place of Birth:**	
Telephone #:		**Fax #:**	

Signature:	

Date:	