

Application Instructions for the Verified-Accredited Wholesale Distributors® (VAWD®)



Completing the Online Application

General Guidance Prior to Completing the Application

- The online application is for new VAWD applications only.
- Do not complete the online application if your facility has a previous application that was canceled by NABP within the most-recent 180 days for non-compliance with the VAWD criteria. Contact vawd@nabp.pharmacy for special instructions.
- Canceled or withdrawn applications are subject to [handling fees](#). Applications that are in-process may incur [administrative fees](#).
- Select the “Save” or “Next Page” buttons to save information in the application. Once the “Save” or “Next Page” button has been pressed, the information entered on that page cannot be changed. If a correction is needed, please contact NABP at cvaccreditation@nabp.pharmacy prior to moving forward in the application.
- Users may log out and resume filling out the application at the point of the last submitted entry.
- Prior to final submission, a verification page for application review will display. Applicants are unable to make changes to this page. However, should any errors be discovered, contact cvaccreditation@nabp.pharmacy and describe the needed change(s). NABP recommends printing this page for your records.
- You will no longer be able to access an application once it has been submitted to NABP.
- Applications for accreditation that are not submitted and paid within 60 days are considered inactive and will be permanently removed.
- If during the accreditation process any information submitted on the VAWD application changes, NABP must be notified in writing within 48 hours. Submit changes via email to VAWD@nabp.pharmacy.

If you have questions about completing the VAWD application, please email VAWD@nabp.pharmacy.

Application Completion

Create NABP User Account Page

- The NABP VAWD application requires the applicant to create a User Account. It is strongly recommended that the person completing the application is the individual who will serve as the facility’s primary contact during the accreditation process. This person may use his or her login to complete multiple applications and will be the steward of future applications for that company. Should the wholesale distributor (WD) wish to change the person charged with submitting the applications, please contact NABP at VAWD@nabp.pharmacy.



Wholesale Distributor Information Page

- The **Legal Business Name** is the name under which the company files its tax returns with the Internal Revenue Service (IRS) or the name included on the business's articles of incorporation.
- The **Doing Business As Name** (otherwise known as "fictitious name" or "trade name") is the name that the company uses that is different than the Legal Business Name. Typically, the Doing Business As Name is registered with the state, county, or local municipality, and the registration clearly connects the Doing Business As Name with the Legal Business Name.
- The **Website URL** (if any) must be the Internet address for the WD's home page and is the site address that will be used to display the VAWD seal upon accreditation.
- The **Physical Address of the WD Establishment** is the commercial, non-residential location of the facility applying for VAWD accreditation and must be the same address used on the WD's state licenses.

Ownership Information Page

The **Contact Person** is responsible for the following:

- Submitting the facility's application, supplemental documentation, and P&Ps
- Remediating any deficiencies discovered during documentation, P&P reviews, and the on-site survey
- Scheduling on-site surveys
- Coordinating the annual accreditation renewal

While not required, NABP strongly recommends that the contact person also have a working knowledge of the facility's P&Ps (and if applicable, how the P&Ps are shared across VAWD-accredited facilities) and the authority to make any necessary P&P revisions. This can help ensure a smooth process.

Designated Representative Page

- The **Designated Representative** (DR) oversees the day-to-day operations of the applicant facility. In most facilities, the DR is the warehouse manager.
- The **DR Supervisor** should be at least one level above the DR and the person to whom the DR reports. The DR supervisor must be actively involved in, and aware of, the daily operations of the distribution facility.

Facility Information Page

Completion requires knowledge of facility operations.

Executive Officers Page

The Executive Officers field refers to officers, directors, and other persons who are in charge of the operations of the applicant facility.

Major Investor Page

Major Investors include silent partners, venture capitalists, and any person, partnership, or corporation who directly or indirectly owns greater than 10% equity in the ownership or controlling interest of the WD organization and/or greater than 10% voting interest in the organization.

Supplemental Documents Page

Completing the VAWD application requires the applicant to:

1. Submit supplemental documents which facilitate an understanding of the applicant's business.
2. Submit P&Ps which demonstrate compliance with the VAWD criteria.



All required documentation must be provided to NABP with the application or the application may be canceled. NABP recommends that supplemental documents be submitted using the online application's "Upload Files" option. (**Note:** This option is not available for all documents. The application will prompt you for eligible documents.)

NABP only accepts supplemental documents utilizing the "Upload Files" option during application submission. Documents not submitted with the online application must be submitted via email or standard mail. Whenever possible, items sent via standard mail should be submitted on a CD-ROM or USB flash drive.

- Name the documents sent in accordance with what NABP has requested. For example, our request for a brief description of a business model should be named, "Business Model Description." For P&Ps, the file name should include both the document's number and name. For example, "P&P 45.3 – Temperature & Humidity Control."
- Email the documents as attachments to VAWD@nabp.pharmacy. In the subject line and body of the email, include the facility name, city, and state; **or**
- Mail a CD of the documents along with a copy of the application receipt page (issued following completion of the online application) via a land carrier to:

ATTN: VAWD
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mt Prospect, IL 60056

Documents should be gathered and submitted to NABP at one time rather than individually, whether submitted online, via email, or via traditional mail.

Application Documents Eligible for Upload

1. Description of the Business Model
 2. List of Ownership Information
 3. List of Licenses
 4. List of Customers
 5. List of Sources
 6. Policies and Procedures and P&P Assessment
- 1. A brief description of the business model.** Please provide a description of your business model to help NABP better understand the operations of the warehouse. This should include the following information, as applicable. You must include all information requested or explain its non-inclusion:
- The type of operation. Examples: wholesale distribution, third-party logistics provider, manufacturing, reverse distribution, repackaging, etc
 - Any specialty and/or unique services that are offered. Examples: sample distribution, compounding, providing drugs for clinical trials, etc
 - The estimated number of products distributed per day
 - The types of customers to whom products are distributed. Examples: pharmacies, hospitals, practitioners, etc
 - The types of prescription products that are offered (human, veterinarian, or both)
 - The types of prescription dosage forms that are used. Examples: oral, injectable, topical, etc
 - A list of the storage requirements for the products that are distributed, as defined in the United States Pharmacopeia (USP) Chapter <797>. Example: Controlled Room Temperature (CRT) refrigeration of 68°F to 77°F is used for most dosage forms of products such as vaccines and



insulin.

2. **A list of ownership information** that includes an organizational chart outlining the legal business entities from the ultimate parent company to, and including, the WD applicant. The organizational chart should include, as defined for the VAWD application, the legal business name, doing business as name, corporate address, and the type of ownership for each legal business entity on the organizational chart. Additionally, list the names of the owners of the legal entities, including:
 - If a sole proprietorship, the full name of the sole proprietor and the home address of the individual.
 - If a partnership, the full name of each individual and the home address of the individuals.
 - If a corporation, the name and title of each corporate officer and director and the name of the state of incorporation.
 - If a limited liability company, the name of each member, the name of each manager, and the name of the state in which the limited liability company was organized.

3. **A current list of licenses** that the facility holds (for example, state WD, state controlled substances, manufacturer, Food and Drug Administration (FDA) registration, Drug Enforcement Administration (DEA) registration, or other licenses relating to prescription products) in a Microsoft Excel (.xlsx) file that includes the following:
 - The state issuing the license
 - The name that appears on the license
 - License numbers
 - The type of license
 - The date the license was acquired
 - The expiration date of the license
 - The DR license number, the date acquired, and the expiration date (California and Florida licensees only)

The current list of licenses should only include licenses that are applicable to the WD applying and any **pending** licenses where an application has been or will be submitted, but not issued.

[Download the Current List of Licenses](#) template (Excel). This template is the required format for the list of licenses. Any other format will not be accepted.

4. **A current list of customers** that includes the city and state, whether the customer is a wholesale distributor or non-wholesale distributor, and the last date of sale to that customer. Using Excel, the information must be separated in rows and columns, be specific to the facility applying, and only include customers as NABP defines them (see template below).

***Customers* are only businesses to whom the applicant **sells** and/or **ships** prescription drug products and prescription devices.**

[Download the Current List of Customers](#) template (Excel). While this template does not have to be used, the information provided to NABP must be in the same format as shown in the template.

5. **A current list that includes all sources of prescription drugs and prescription devices.** Provide the source's city and state, whether or not it is a manufacturer, whether or not it is an affiliate business, the most recent date of conducting business with the source, and whether the source is active.



Using Excel, information must be separated in rows and columns, be specific to the facility applying, and should only include sources as NABP defines (see template below).

Applicant Facilities: Provide sources for the past 3 years.

Already-Accredited Facilities: Provide sources for the past year.

[Download the Current List of Sources](#) template (Excel). While this template does not have to be used, the information provided to NABP must be in the same format as shown in the template.

Sources are only businesses from whom the applicant buys and/or obtains prescription drug products and prescription devices.

6. Policies and Procedures

Applicants must complete the [VAWD P&P Assessment](#) and submit it with all referenced P&Ps. The P&P Assessment is a Microsoft Word document that enables an applicant to designate which of its organizational P&Ps fulfill the VAWD criteria. The document clearly lays out the P&Ps necessary to meet VAWD compliance requirements and enables the applicant to enter either the name or number and the page number for the P&P demonstrating compliance. The P&P Assessment also enables applicants utilizing shared P&Ps or that have business partners responsible for off-site processes relative to the VAWD criteria to provide a map of how their documents and processes are used and shared.

The submission of copies of operational P&Ps evidencing compliance, as set forth in the P&P Assessment, are required. Submitted P&Ps must adequately demonstrate how a facility conducts business and must make it possible for NABP to determine the facility's compliance with VAWD criteria. The P&Ps must be descriptive and explain actual steps taken at the applicant facility. Broad statements such as "will conduct business according to state and federal requirements" or "according to DSCSA requirements" are not acceptable unless accompanied by the specific details explaining how the facility meets the referenced requirements. Also unacceptable are P&Ps that simply restate the VAWD criteria.

1. Template procedures are not acceptable and will be immediately rejected as they are not drafted to or indicative of actual processes performed at the applicant's facility(ies). As required in state and federal regulations, P&Ps must be designed to assure the identity, strength, quality, and purity of drug products during holding and distribution. They must be written to facilitate the sequential execution of production and process control functions; and, must be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.
2. Each employee shall be trained on the P&Ps applicable to the function(s) they perform. Such training must be documented and conducted by qualified individuals on a continual basis and with sufficient frequency to ensure that the employee remains familiar with the procedural requirements applicable to them.
3. Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications and the type of service they provide. Applicants and VAWD-accredited facilities are responsible for the content and implementation of its P&Ps and correspondence with NABP.



P&Ps not submitted in accordance with program requirements and/or without a completed P&P Assessment will delay processing the application. P&Ps will be reviewed only after NABP confirms that all supplemental documentation is acceptable.

[Download the VAWD P&P Assessment](#)

Supplemental Documents That May Be Required at a Later Date

NABP may find it necessary to request documentation in addition to what the applicant has initially submitted. The request is intended to facilitate a thorough understanding of the applicant's business. These documents are to be submitted only if a specific request is made by NABP.

1. Organizational Chart
2. DR's Résumé
3. Description of the Security Alarm System
4. Description of the Environmental System
5. State Inspection Reports
6. Facility Ownership Documents

1. **An organizational chart** that includes the following information:
 - Warehouse operations management, including names and job titles
 - Warehouse staff, including names and job titles, or the number of staff under each manager
 - Administrative staff whose duties include vendor and/or customer verification, product ordering, or who are involved with controlling the movement of prescription drugs
 - The DR and DR supervisor must be appropriately charted

[Download the organizational chart example](#) (Microsoft Word) for help creating your chart. This Word file can be used as a template when creating an organizational chart.

2. **The DR's résumé**, including a 10-year work history and educational background.
3. **A brief description of the security alarm system.** Please provide a general description of the security alarm system to help NABP better understand the security in place. This should include the following information:
 - The alarm company used
 - Confirmation that all possible entry into the facility is alarmed. Potential access points are doors, windows, skylights, etc
 - Any cameras
 - Any cooler and freezer temperature monitors that are part of the alarm system

Please note that the above-requested information should be general. Specific details such as the locations of sensors and cameras will be checked during the on-site VAWD survey.

4. **Indicate if the facility is air conditioned and provide a brief description of the heating, ventilation, and air conditioning (HVAC) system (for WDs with product on its premises).** Include a description of the HVAC equipment utilized for temperature and humidity monitoring and recording as well as the total square footage of the facility and the square footage utilized for drug storage and handling.
5. **Copies of state inspection report.** In the event your facility has not been inspected, or you are unable to obtain a copy of the inspection report from the appropriate agency, you must submit a written attestation of this fact.



- 6. Copy of a document evidencing the rightful ownership or possession of the property.** This document must show the actual address of the facility applying for VAWD accreditation. Documents that meet this requirement include one of the following:
- A current lease agreement
 - A property deed
 - A current tax bill
 - A current utility bill

Payment

NABP recommends that the application, survey, and annual participation, be paid via credit card (MasterCard, Visa, or American Express) at the time the application is submitted. If a credit card is not available, a prepaid debit/credit card, available for purchase at any banking institution, may be used to pay the VAWD fees. Payment in the form of a certified check, cashier's check, money order, or company check may also be sent via mail; NABP must receive such payments within 14 days of the application submission.

Mail checks to:

ATTN: VAWD
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mt Prospect, IL 60056

Canceled or withdrawn applications are subject to administrative fees.

Disclaimer

Please note that NABP reserves the right to share information with its member boards of pharmacy or appropriate regulatory or law enforcement authorities concerning the status of an applicant's accreditation application and/or any denial of accreditation.

