

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

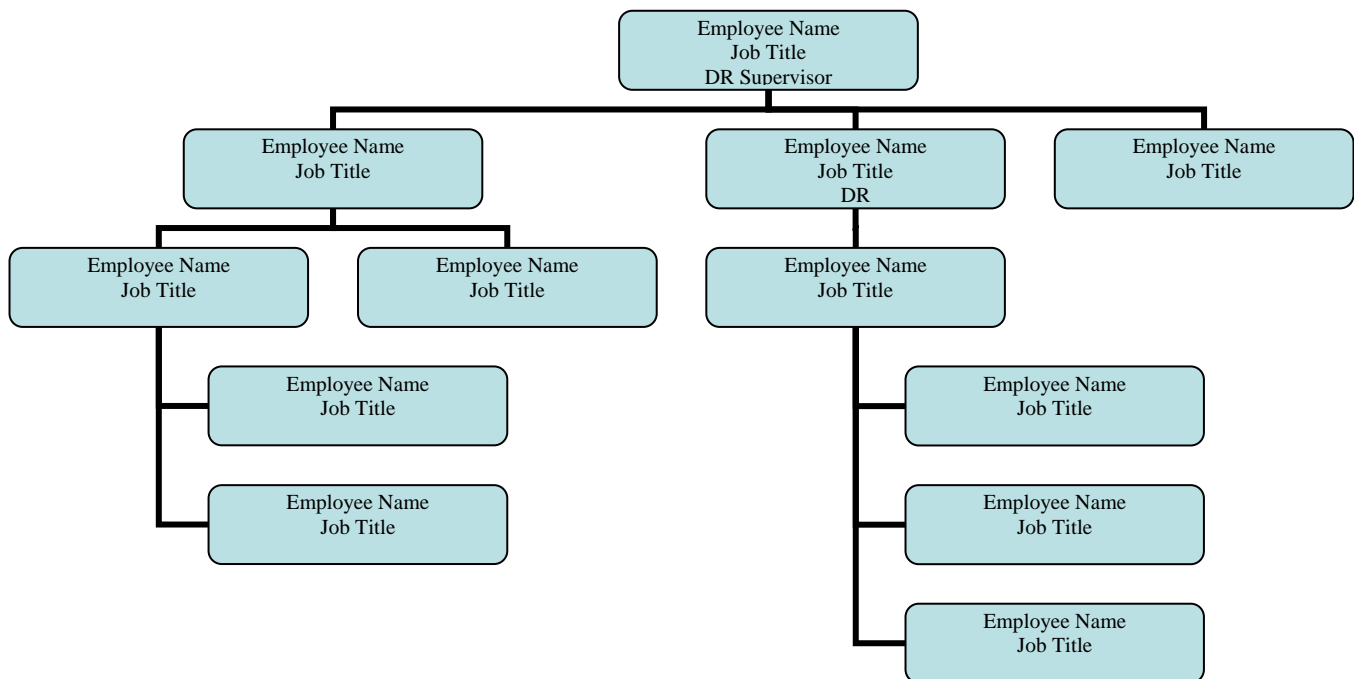
Important Information:

1. **Applications MUST be submitted online.**
2. **We strongly encourage that the application, survey, annual participation, and background check fees be paid by credit card (MasterCard, Visa, or American Express) at time of submission of the online application.**
3. **Payments sent via mail must be received at NABP within 14 days from submission of the application.**
4. **ALL required supplemental documentation and copies of actual policies and procedures (P&Ps) as set forth in the 2009 VAWD P&P Guidance Checklist must be provided to NABP within 90 days from application submission date or the application may be cancelled.**
5. **We will review P&Ps only upon receiving and confirming ALL supplemental documentation is acceptable.**
 - **Refer to No. 11 below for instructions on submitting P&Ps. An example of acceptable P&P format is included in the 2009 VAWD P&P Guidance Checklist, which will be provided upon receipt of application and fees.**
6. **We will schedule an on-site survey only upon receiving and confirming ALL P&Ps are compliant with VAWD criteria.**
7. **Cancelled or withdrawn applications are subject to administrative fees.**

The VAWD accreditation process begins with completing the online application. The following instructions are included to help the applicant provide the correct information.

1. The VAWD application includes a list of VAWD criteria for which the National Association of Boards of Pharmacy® (NABP®) requires documentation demonstrating compliance. NABP reviews the submitted documents and specifically looks for certain policies and procedures believed by NABP to be essential to meeting the intent of the VAWD criteria. You will be notified, via e-mail, if NABP finds any of the submitted materials unacceptable or in need of clarification. When requested, please send mocked-up forms with fictitious information so that the data demonstrates how the form is actually used. Do not send blank forms. Completed forms help NABP interpret how a form is actually used.
2. Authorization and release forms for background checking must be completed and signed by the individual whose criminal and financial background must be checked. Contact VAWD staff for more information about the forms and fees. Applicable background checks must be completed prior to any awarding of accreditation.
3. Legal Business Name is the name that will appear on the listing of VAWD-accredited facilities that NABP maintains.
4. Web site URL (if any) must be the Internet address for the wholesale distributor's (WD) home page.
5. Contact person will complete the application form, and will coordinate responses and revisions to policies and procedures, if necessary, and will schedule on-site surveys and will coordinate the annual renewal of accreditation.
6. Designated Representative (DR) oversees the day-to-day operations of the WD facility. In most facilities, the DR is the warehouse manager.

7. Ownership information applies to any for-profit or not-for-profit legal entity that owns or contracts for the WD's services. It is the ultimate controlling or parent company.
8. Executive Officers apply to officers, directors, and other persons who are in charge of the operations of the WD facility.
9. Major Investors include silent partners, venture capitalists, and any person, partnership, or corporation who directly or indirectly owns greater than 10% equity position in the ownership or controlling interest of the WD organization and/or greater than 10% voting interest in such organization.
10. **Ensure all supplemental documentation listed below is submitted.**
 - a. Proof of surety bond in an amount of at least \$100,000 (examples of acceptable proof include evidence of insurance, a statement showing that funds have been deposited in a trust account or financial institution, or an irrevocable letter of credit). If your facility has a state license that requires a surety bond, and the amount is at least \$100,000, with the beneficiary being the state board of pharmacy, a copy of this surety bond is acceptable.
 - b. Copy of **general** and **product** liability certificate of insurance (certificate must indicate date of issuance and expiration, and type and amount of coverage). Both general and product must be covered in the policy. If the certificate is held under the corporate name and location, it must state the coverage includes all subsidiaries or specifically state the name and address of the facility.
 - c. Organizational chart (see example) that includes the following information:
 - i. Warehouse operations management, including names & job titles.
 - ii. Warehouse staff, including names & job titles.
 - iii. Administrative staff whose duties include vendor and/or customer verification, product ordering, or are involved with controlling the movement of prescription drugs.
 - iv. DR and DR Supervisor must be appropriately charted



- d. Graphical layout of the WD facility.
- e. Brief description of the security alarm system. In addition, **if your facility has a freezer/cooler area, please describe how it is tied-in with your security alarm system.**
- f. DR resume, including 10-year working history and educational background.
- g. Copies of inspection reports and notices. 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 the fact.
 - i. State inspection report
 - ii. Drug Enforcement Administration (DEA) inspection notice
- h. Copy of the lease agreement, property deed, or other document evidencing rightful ownership or possession of the property. If the physical address of the facility applying for VAWD is not included on the document please submit a copy of most recent tax bill or current utility bill that includes the facility address.
- i. Current list of licenses on an Excel (xls) file (see example) that include the following:
 - i. State WD and controlled substance license, & DEA registration, including any pending state license applications
 - ii. License numbers
 - iii. Type of License
 - iv. Date license acquired
 - v. Expiration date
 - vi. DR license number, date acquired, & expiration date (California and Florida licensees only)

Example:

State 1	License Number	Type of License	Date License Acquired	Expiration Date
State 2	License Number	Type of License	Date License Acquired	Expiration Date
DEA	License Number	Type of License	Date License Acquired	Expiration Date
CA	License Number	DR License	Date License Acquired	Expiration Date
FL	License Number	DR License	Date License Acquired	Expiration Date

- j. Current list of customers, including city and state, on an Excel (xls) file. Information must be separated by row and column; see example below.
 - i. Customers – businesses to whom applicant is selling and/or shipping prescription drug products

Example:

Customer Name 1	City	State
Customer Name 2	City	State
Customer Name 3	City	State

- k. Current list of vendors, including city and state, on an Excel (xls) file. Information must be separated by row and column; see example below.

- i. Vendors – businesses from whom applicant is buying and/or obtaining prescription drug products

Example:

Vendor Name 1	City	State
Vendor Name 2	City	State
Vendor Name 3	City	State

- l. If your facility has Authorized Distributor of Record (ADR) status for all manufacturers, submit proof of ADR status (ie, copies of written agreement with the manufacturer).
- m. DR Photo Submission Form must be scanned in color and e-mailed to NABP (only required for DR, and only if the facility has or in the process of applying for an Indiana or North Dakota license).
 - i. Download the DR Photo Form from the VAWD Web page.
- n. Kroll Background Check Release Forms for:
 - i. DR
 - ii. DR’s supervisor
 - iii. Owners/principals with greater than 10% ownership interest
 - iv. Download the Kroll Background Check Release Form from the VAWD Web page.

11. Ensure all required Policies and Procedures listed below are submitted

- 1. Structure of policies and procedures
- 2. Licensing
- 3. Housekeeping
- 4. Temperature and humidity controls
- 5. Personnel
- 6. Security
- 7. Inventory controls
- 8. Controlled substances
- 9. Records
- 10. Vendors and customer authentication
- 11. Product authentication – inbound
- 12. Product authentication – outbound
- 13. Product authentication – returned products
- 14. Reverse distributor drug returns
- 15. Recall
- 16. Crisis operations
- 17. Quarantined product
- a. Copies of **actual** P&Ps (drafts NOT accepted) evidencing compliance as set forth in the *VAWD P&P Guidance Checklist*. P&Ps not submitted in accordance with the *VAWD P&P Guidance Checklist* will delay processing the application.

(While working on your P&Ps to comply with the VAWD criteria, also provide a list of all your facilities that share the same P&Ps. Any facility-specific P&Ps should also be identified. At minimum, the list should include the following information:

 - o Name of the facility
 - o Complete address

- VAWD # (if applicable)

(If any of the processes are performed at your corporate office, provide a list of those processes and identify it on the checklist)

- b. P&P must be in an acceptable format including:
 - i. Title and P&P number on each one
 - ii. Appropriate signatures **must** be in one of these formats:
 - a. Actual signature on each page of the P&Ps
 - b. Electronic signature on each page of the P&Ps
 - c. Signature statement indicating all P&Ps are approved
- c. *P&P Guidance Checklist* must be completed and submitted along with copies of the actual P&Ps.
 - i. The checklist will allow you to type your answers on each page; however, you cannot save this document. You must print the document and scan it into a new file.
- d. To help expedite the application process we **strongly** encourage the following:
 - i. Submit P&P as Microsoft Word files
 - ii. Include an Index
 - iii. Submit each P&P as an individual file. See below for an example of how to best name the P&P files

Document Submission:

1. All documents should be submitted together at one time rather than individually.
2. To expedite the application process, documents should be uploaded electronically as individual files during the online application process.
3. When uploading electronic documents please select the appropriate title of the document in the drop-down menu.
4. Alternatively, the documents may be submitted by one of the following methods, however, this separation of materials may result in processing delays

- a. E-mailing the documents (**as attachments**) to vawd@nabp.net
- b. Mailing a CD of the documents along with a copy of the 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

- c. When e-mailing or sending the documents via CD-ROM, please include appropriate identifying information about the pharmacy and name the documents according to the examples below:

Example 1: For Supplemental Document #c, name electronic file document as “Organizational Chart”

Example 2: For Policy and Procedure, name electronic file and label paper document as “P&P 45.3 - Temperature & Humidity Control”