Application Instructions for the Drug Distributor Accreditation

Direct questions to vawd@nabp.pharmacy or 847/391-4539

Before You Start

1. Review the criteria to confirm the program meets your facility's needs and the facility's ability to comply with criterion.
2. Review the Policy and Procedures (P&P) Assessment to confirm your facility is able to demonstrate compliance with the criteria through its P&P submission and the on-site survey.
3. Review the Drug Distributor Accreditation Frequently Asked Questions in the Help section.
4. Know whether your facility is subject to additional unique requirements. In the Help Section, select "Drug Distributor Accreditation" then "Are there unique requirements for non-traditional business models? "In the program criteria, select "Virtual Manufacturers and Wholesale Distributors."

Application Submission Guidelines

1. Only the initial application and document submission are completed online. After an application has been submitted, subsequent documentation needed during the application process must be provided electronically by sending an email to vawd@nabp.pharmacy or a flash drive to NABP at the following address:
   ATTN: Drug Distributor Accreditation
   National Association of Boards of Pharmacy
   1600 Feehanville Drive
   Mt Prospect, IL 60056
2. An application, once submitted, can only be refunded for services not yet performed.
3. An application, once submitted, can incur administrative fees for added processing needed to further an application.
4. An application that is not submitted and paid within 60 days is considered inactive and will be permanently removed.
5. An application is required for each facility seeking accreditation and is location specific.
6. Facilities can use a consultant to assist in the application process. However, NABP will not engage directly with a consultant contacting NABP on behalf of a client or accept documents submitted by a consultant on behalf of a client.
7. An application cannot be submitted by a facility that does not complete the Application Questionnaire and agree to its current ability to sign the program Letter of Agreement.

Progressing Through the Application

1. To save information in the application, select the "Save" or "Next Page" buttons. Once selected, the information cannot be changed. Correction requests must be sent to cvaccreditation@nabp.pharmacy prior to advancing.
2. Users can log out and resume at the last point of completion.
3. Prior to final submission, a verification page is displayed. If an error is discovered, contact cvaccreditation@nabp.pharmacy and describe the needed change(s).

4. Print the verification page for your facility's records. Your facility will not be able to access the application after it has been submitted.
5. Notify vawd@nabp.pharmacy within 48 hours if changes to the submitted information are needed after the application has been submitted.

Completing the Application

User Account

A user account is required to complete and submit an initial application. An individual employed by the applicant facility (ie, cannot be acting on behalf of, under contract to, or consulting for the facility) must establish the account; the same individual is subsequently responsible for the application's completion and contents. This person may use his or her login to complete multiple applications and may steward future applications for the company.

Information page

- A **Legal Business Name** (LBN) is used by a company to file its tax return and is the name on the business's articles of incorporation.
- A **Doing Business as Name** (DBA or "fictitious name" or "trade name") is the name used by the company to conduct business that is different from the LBN. These names are typically registered with the state, county, or local municipality with a clear connection between the LBN and DBA.
- The **website URL** provided is the web page used by the facility to display the program Seal if accredited.
- The **physical address** is the commercial (non-residential) location of the applicant reflected on its state licenses and business registration.

Ownership Information page

The **Contact Person** must be employed by the applicant (*ie*, cannot be acting on behalf of, under contract to, or consulting for the facility) and will be contacted by NABP for all activities needed to advance the application towards accreditation and to maintain the facility's accreditation if approved.

Designated Representative page

- The **Designated Representative** (DR) oversees day-to-day operations and is often the warehouse manager.
- The **Designated Representative Supervisor** (DRS) must be the person to whom the DR reports and must be aware of the facility's daily operations.

Facility Information page

The Contact completing the application must know about facility operations.
Executive Officers page

Included **Executive Officers** are responsible for facility operations.

Major Investor page

Major investors include silent partners, venture capitalists, and any person, partnership, or corporation that directly or indirectly owns greater than 10% ownership equity, controlling interest, or voting interest in the applicant facility.

Supplemental Documents page

- Required documents are provided with the application using the "Upload Files" option.
- Documents provided with the application must be named to correspond with the request (*eg*, Business Model Description, License List, etc).

i. **Business Model Description**
A written description that provides:

- Type of operation (eg, wholesale distributer, third-party logistics provider, manufacturer, reverse distributer, repackager, etc)
- A narrative explanation of facility operations (eg, our facility purchases prescription drugs and devices from manufacturers and primary wholesale distributors that are then sold to pharmacies; our facility takes possession of a customer's bulk product for repackaging to smaller units that is returned to them)
- Any specialty and/or unique services offered (eg, sample distribution, compounding, providing drugs for clinical trials, etc)
- Estimated number of products distributed per day
- Types of customers to whom products are distributed (eg, pharmacies, hospitals, practitioners, etc)
- Types of prescription products offered (ie, human, veterinarian, or both)
- Types of prescription dosage forms used (eg, oral, injectable, topical, etc)
- A list of the storage requirements for distributed products as defined in the United States Pharmacopeia (USP) Chapter <659> Packaging and Storage Requirements (eg, Controlled Room Temperature (CRT) requirement 68°F to 77°F used for oral dosage products; refrigerated range 36°F to 46°F used for injectable vaccines and insulin)

ii. **List of Ownership information**
A vertical and horizontal organizational chart from the ultimate parent company to the applicant incorporating all affiliate businesses. Include for each:

- Legal business name
- Doing business as name
- Corporate address
- Type of ownership
  - Sole proprietorship (include sole proprietor's full name and home address)
  - Partnership (include full name of each individual and the home address of the individuals)
  - Corporation (include name and title of each corporate officer and director; name of the state of incorporation)
  - Limited liability company (include name of each member, manager, and state in which the limited liability company was organized)

ii. **License list in Microsoft Excel format (use provided template)**
Only include licenses for the applicant facility. List all pending licenses.

- State issuing the license
- Entity issuing the registration (eg, DEA)
- Name that appears on the license
- License number
- Type of license
- Date the license was acquired
- Expiration date of the license
- DR license number, the date acquired, and the expiration date (California and Florida licensees only)

iii. **Customer list in a Microsoft Excel format (use provided template)**

Customers are businesses to whom the applicant sells and/or ships prescription drugs and prescription devices.
Third-party logistics provider customers are businesses to whom the applicant ships prescription drugs and prescription devices.

- Customer name
- Customer city
- Customer state
- Customer country (if outside the US)
- Whether the customer is a wholesale distributor or non-wholesale distributor
- Last date of sale or shipment to that customer

iv. **Source list in a Microsoft Excel format (use provided template)**

Sources are businesses from whom the applicant buys and/or obtains prescription drugs and prescription devices.
Third-party logistics provider sources are businesses the applicant contracts with to store and ship prescription drugs and prescription devices.

- Source name
- Source city
- Source state
- Source country (if outside the US)
- Whether or not the source is a manufacturer
- Whether or not the source is an affiliate business
- Most recent date of conducting business with the source
- Whether the source is active

v. **P&P Assessment (use Microsoft Word template provided)**
Applicants use the P&P Assessment to designate which of its operational policies and procedures (P&Ps) demonstrate written compliance with program criteria. Complete the Assessment by providing the policy and/or procedure's name and the information's location in the document that is to be reviewed. The policy and/or procedure name used in the Assessment must correspond to the submitted document.

The P&P Assessment also provides guidance to non-wholesale distributor business models seeking Drug Distributor Accreditation. All "Do Not Apply" designations should be used as a guideline. It is important that a facility assess whether certain items apply based on its operations, and when necessary, provide the requested information.

An incomplete and/or inaccurate P&P Assessment submission will prolong the application process and may jeopardize a facility's active application status.

vi. **Policies and Procedures (submit as Microsoft Word documents)**
Applicants must provide the P&Ps referenced in the Assessment. Submitted P&Ps must adequately demonstrate how a facility conducts business and make it possible for NABP to determine a facility's written compliance with Drug Distributor Accreditation criteria. The P&Ps must be descriptive and explain steps taken at the applicant facility; broad statements like "will conduct business according to state and federal requirements" or "according to DSCSA requirements" unaccompanied by specific details explaining how the facility will accomplish these functions are unacceptable. Also unacceptable are P&Ps that simply restate the Drug Distributor Accreditation criteria.

- Template procedures that do not reflect a facility's operations are not acceptable. As required by 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.
- Each employee must be trained on the P&Ps applicable to the function(s) they perform. The training must be documented and conducted by qualified individuals on a continual basis and with sufficient frequency to ensure the employee remains familiar with the procedural requirements applicable to them.
- Consultants advising on the manufacture, processing, packing, or holding of drug products must have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications and the type of service they provide. Applicants and accredited facilities are responsible for the content and implementation of their P&Ps and correspondence with NABP.
- P&Ps not submitted in accordance with program requirements will prolong the application process and may jeopardize a facility's active application status. P&Ps will be reviewed only after NABP confirms that all supplemental documentation is acceptable.

Supplemental Documents That May be Requested Following Application Submission

To facilitate a thorough understanding of the applicant's business, NABP may find it necessary to request documentation in addition to what the applicant has initially submitted. These documents are to be submitted only if a specific request is made by NABP. The following list does not represent all possible documents that can be requested.

i. **Organizational chart**
- Include warehouse operations management with names, job titles, and the number of staff reporting to the manager

- Include administrative staff performing vendor and/or customer verification, product ordering, or involved in dictating prescription drug movement

ii. DR's resume that includes a 10-year work history and educational background

iii. **Security System Description**
A general description of the following. Details will be reviewed during the on-site survey.

- Alarm company used
- Confirmation all possible entry into the facility is alarmed
- Camera usage
- Cooler and freezer temperature monitors that are part of the alarm system

iv. **Heating, Ventilation, and Air-conditioning (HVAC) System Description**
- Indicate if the facility is air conditioned and provide a brief description of the system.
- Include a description of the equipment utilized for temperature and humidity monitoring and recording
- Provide total square footage of the facility and the square footage utilized for drug storage and handling

v. **State Inspection Report Copies**
If a facility has not been inspected; or is unable to obtain a copy of the inspection report from the appropriate agency, an attestation stating this must be submitted.

vi. **Proof of Property Ownership or Possession**
Provide a document showing the applicant name and facility address to evidence rightful ownership or possession of the property. Documents that meet this requirement may include:

- Current lease agreement
- Property deed
- Current tax bill
- Current utility bill

Payment

Payment is required at time of application. Bank card payments can be made online when submitting the application; if mailing a certified check, cashier's check, money order, or company check, send payment within 14 days of application submission to:

ATTN: Drug Distributor Accreditation
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mt Prospect, IL 60056

Disclaimer

NABP reserves the right to share information with its member boards of pharmacy or appropriate regulatory or law enforcement authorities.