NABP
National Association of Boards of Pharmacy

# Application Guide

## General Guidance Prior to Completing the Application

- Google Chrome is the preferred internet browser. If you experience login issues, please clear your browser cache and cookies and try again.
- If difficulties are encountered, please contact 847-391-4539 or email the applicable program or service:
    - Verified Pharmacy Program: vpp@nabp.pharmacy
    - Supply Chain Inspection: sci@nabp.pharmacy
    - DMEPOS Pharmacy Accreditation: dmepos@napb.pharmacy
    - Community Pharmacy Accreditation: community@nabp.pharmacy
    - Drug Distributor Accreditation: vawd@nabp.pharmacy
    - OTC Medical Device Distributor Accreditation: vdip@nabp.pharmacy
    - Digital Pharmacy Accreditation: vipps@nabp.pharmacy
    - Specialty Pharmacy Accreditation: specialty@nabp.pharmacy
    - Compounding Pharmacy Accreditation: compounding@napb.pharmacy
    - Home Infusion Therapy Accreditation: homeinfusion@nabp.pharmacy
- The Username is the email provided to create an account.
- To save the information on a page, the page must be filled out completely, then press save or next.
- Please note that some states may have additional requirements beyond the inspection and/or accreditation requirements. For the most recent information regarding state licensure or other requirements, please contact the state boards directly.
    - Participating in inspection services or accreditation programs does not guarantee achieving licensure for a particular state.
    - It is important to determine the state's requirements for licensure.
    - State by state contact information can be found here: https://nabp.pharmacy/boards-of-pharmacy/.

- The contact (or authorized representative) accessing this account and application for completion and submission on behalf of the applicant organization (AO) must be an AO employee.
    - The authorized representative cannot be a consultant or temporary employee for the AO.
    - Only full and part-time employees of the AO can be listed on the application.

- The authorized representative accessing this application holds primary responsibility for communications in connection with this application.

- While certain fields within the business e-Profile are optional, NABP recommends providing as much detail as possible. Doing so helps ensure NABP and its member boards have the most accurate and up-to-date information related to your business location.
- The information needed to create and maintain the business e-Profile helps to:
  - Streamline the licensure or registration process by providing verified data to pharmacy regulators (such as state boards of pharmacy) to assist when making licensure determinations.
  - Accurately identify your business location
  - Ensure any data previously provided to NABP for the facility (name or a license number), is correctly maintained in your facility e-Profile
  - Keep your facility e-Profile updated
  - Minimize multiple requests for the same data
- Information to be maintained is outlined in the sections below.

- Applicants must provide related information and materials requested by NABP and within NABP timelines.
- NABP strongly recommends designating an authorized representative who will provide accurate, thorough, and timely responses to application requests and any other NABP correspondence.

## Business Detail Acronyms/Definitions

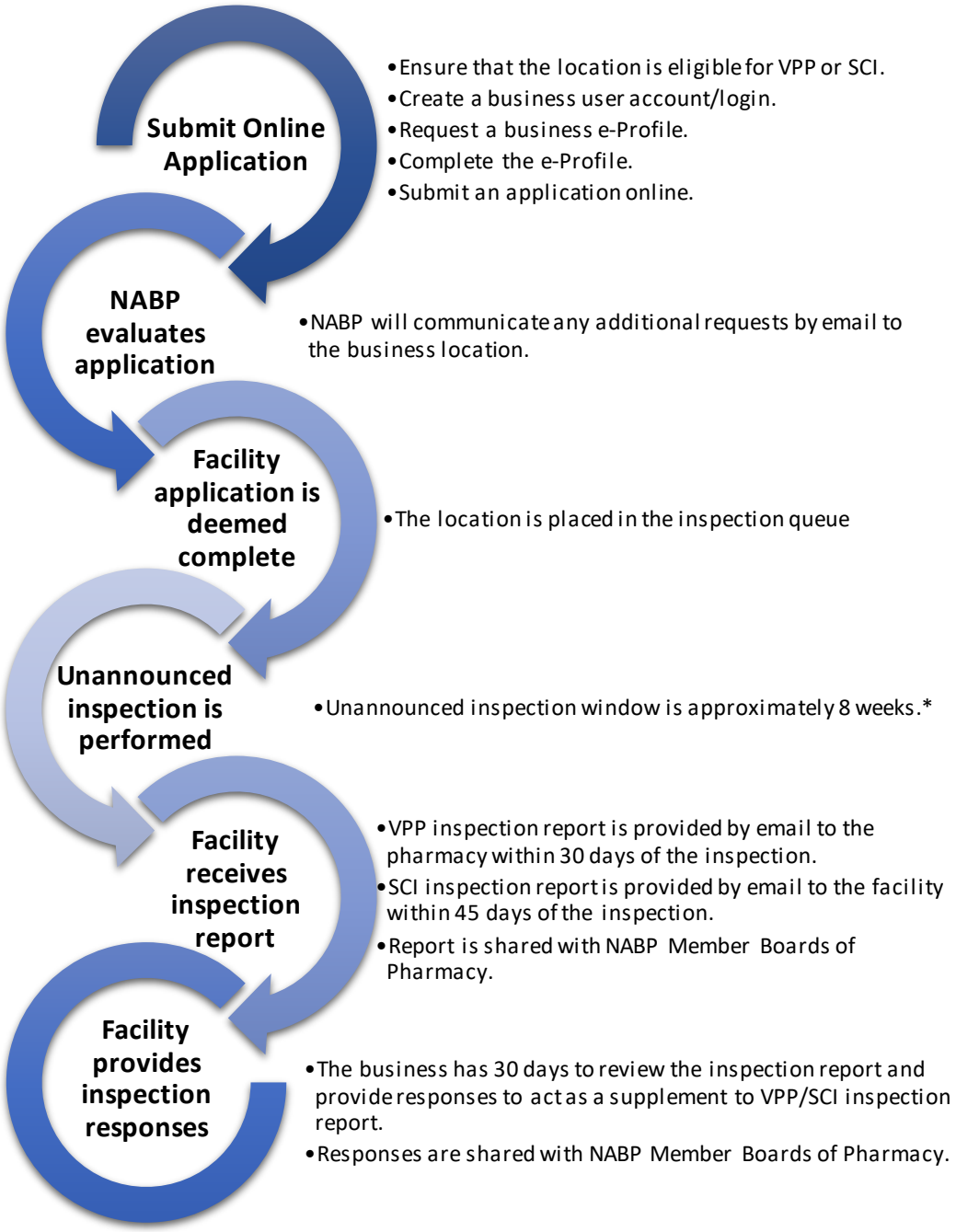
- **Legal Business Name (LBN):** the name under which the business files its tax returns with the Internal Revenue Service (IRS) or the name included on the business' articles of incorporation.
- **Doing Business As (DBA):** the name the company uses that is different from the **LBN**. Also known as fictitious name.
- **Address:** The physical location of the facility.
- **Formerly Known As (FKA):** other names the company has used in the past. Please list any previous **DBAs** and **FKAs**.
- **Store number:** If applicable, please list.
- **FEIN (Tax ID):** the nine-digit federal employer identification number issued by the IRS. If your business does not have an FEIN, select ☑ No FEIN Number.

- **NPI**: the 10-digit National Provider Identifier issued by the Centers for Medicare and Medicaid Services. This field is not applicable to all business models; if this does not apply to your business, select ☑ No NPI Number.
- **NCPDP Number:** the seven-digit number issued to the pharmacy by the National Council for Prescription Drug Programs. This field is not applicable to all business models; if this does not apply to your business, select ☑ No NCPDP Number.

## Other Terms

- **Mail Order**: a pharmacy that runs a large-scale mail order operation which predominantly dispenses using automation.
- **Central Fill/Shared Services/Central Processing**: a pharmacy/facility that designates any portion of the prescription processing or dispensing to another location.
- **Nuclear Pharmacy/Radiopharmaceutical**: This designation includes the compounding of radiopharmaceuticals.
    - NOTE: additional questions will be asked of the nuclear pharmacy and any nonnuclear activities performed at the same location later in the application. For VPP, if you have additional nonnuclear activities at your pharmacy, additional inspection fees will likely apply.
- **Outsourcing Facility**: a facility registered Food and Drug Administration (FDA) as an outsourcing facility (list of registered outsourcing facilities can be found here: https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities).
    - NOTE: neither VPP nor SCI inspect for compliance with current good manufacturing practices (cGMPs). VPP performs an inspection to determine compliance with USP <795> and <797> standards, as applicable.

# Verified Pharmacy Program and Supply Chain Inspection Services: Process Overview




*Note: This time frame for inspection is an estimate and is subject to change pending inclement weather, a significant number of facility black-out dates, or other unforeseen circumstances.

# Accreditation Programs: Process Overview




- Ensure that the location is eligible for the applicable accreditation program.
- Create a business user account/login.
- Request a business e-Profile.
- Complete the business e-Profile.
- Submit an application online.

- NABP will communicate any additional requests by email to the business location.
- Accreditation programs may require comprehensive reviews of your location's policies and procedures which may necessitate multiple rounds of compliance reviews.

- Certain programs, including DMEPOS, perform an unannounced onsite survey.
- Other programs, including Digital Pharmacy Accreditation and Drug Distributor Accreditation, schedule the onsite survey in coordination with the applicant facility.

- The onsite survey evaluates a facility's compliance with applicable laws and regulations, as well as accreditation program standards.
- Surveys may occur in a single day (up to eight hours at the facility) or extend multiple days, depending on the program and onsite findings.

- A report outlining the findings of the onsite survey will be sent to the facility within 30-60 days of the onsite visit.
- The report may or may not require a response within 30 days. Once NABP receives the response, it will be evaluated for compliance with program standards.

- Once the applicant business has submitted a complete and satisfactory application, supporting documents, policies and procedures, and successfully completed an onsite survey with post-survey remediation, if required, the application process will be summarized in a recommendation for accreditation and sent for final approval to the accreditation committee. This review (to determine if accreditation is to be awarded) typically takes between one to two weeks.

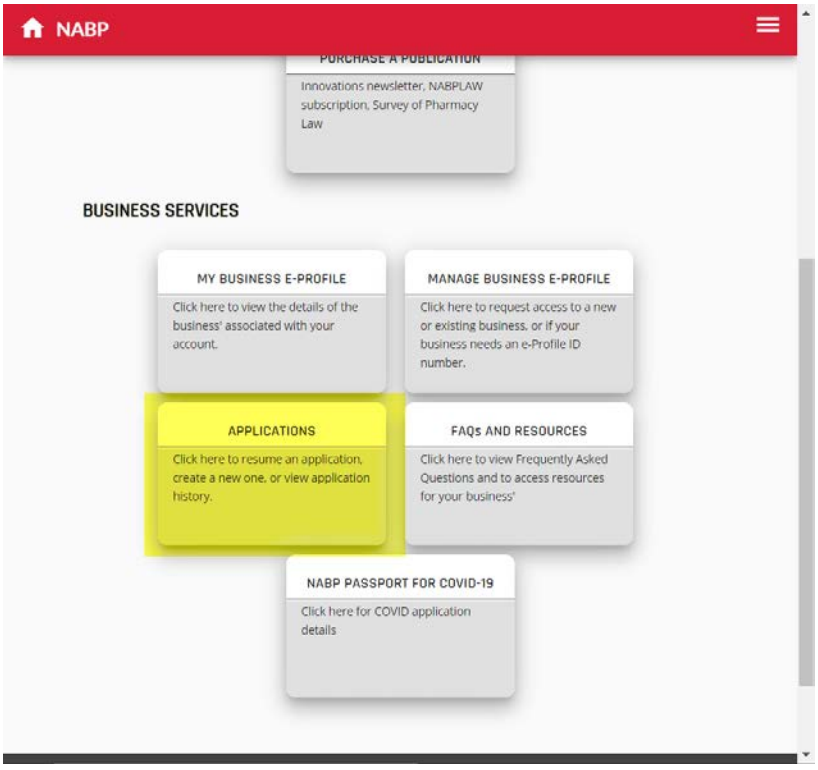
## Applications

- **Before starting an application, a business e-Profile must be created and completed. If you have not already done so, please reference the documents Creating a Business e-Profile and Completing a Business e-Profile prior to starting an application.**

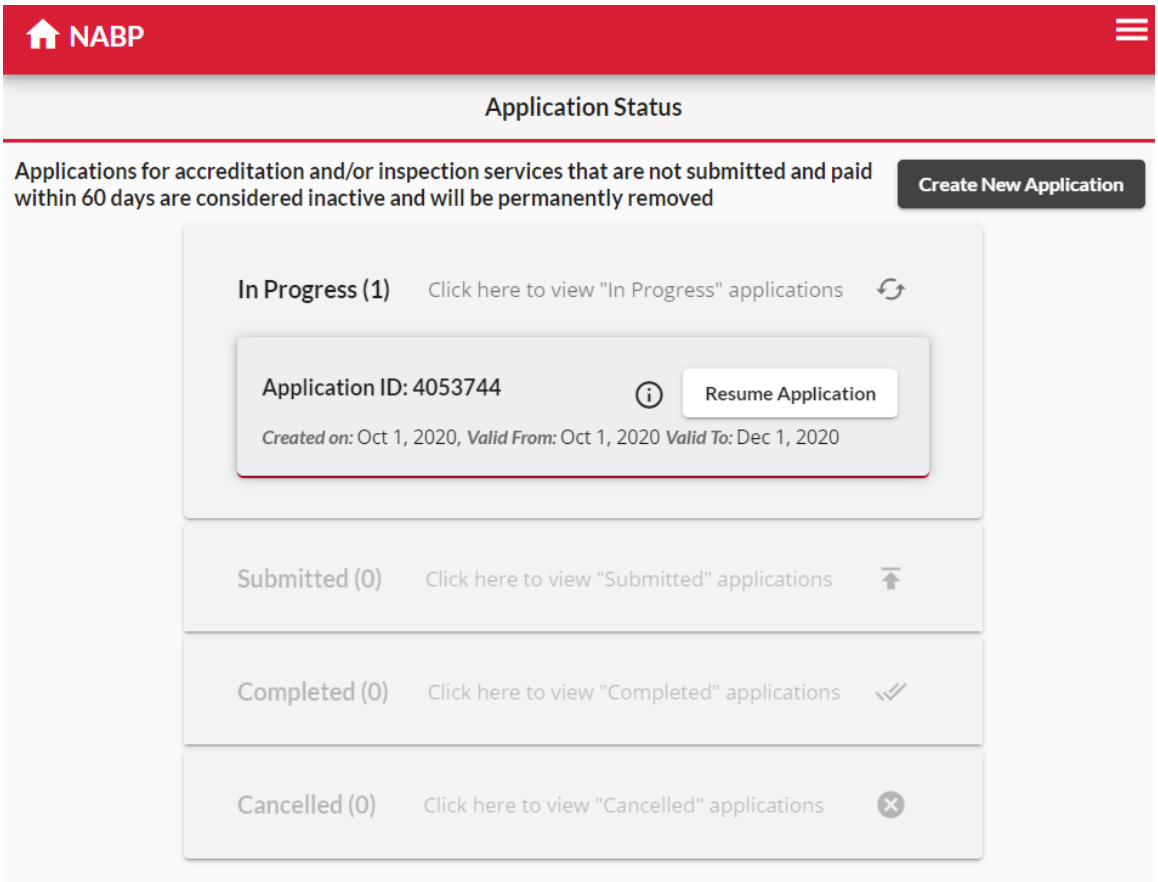
- The Applications page is where a user can:

  1. Create new applications
  2. Edit applications that have not yet been submitted
  3. View submitted applications
  4. See completed and canceled applications

- Any applications associated with the business e-Profile or user account can be found on the homepage of the dashboard (click the home icon (NABP)to arrive at the homepage). Select APPLICATIONS to view existing applications or any that have been submitted.



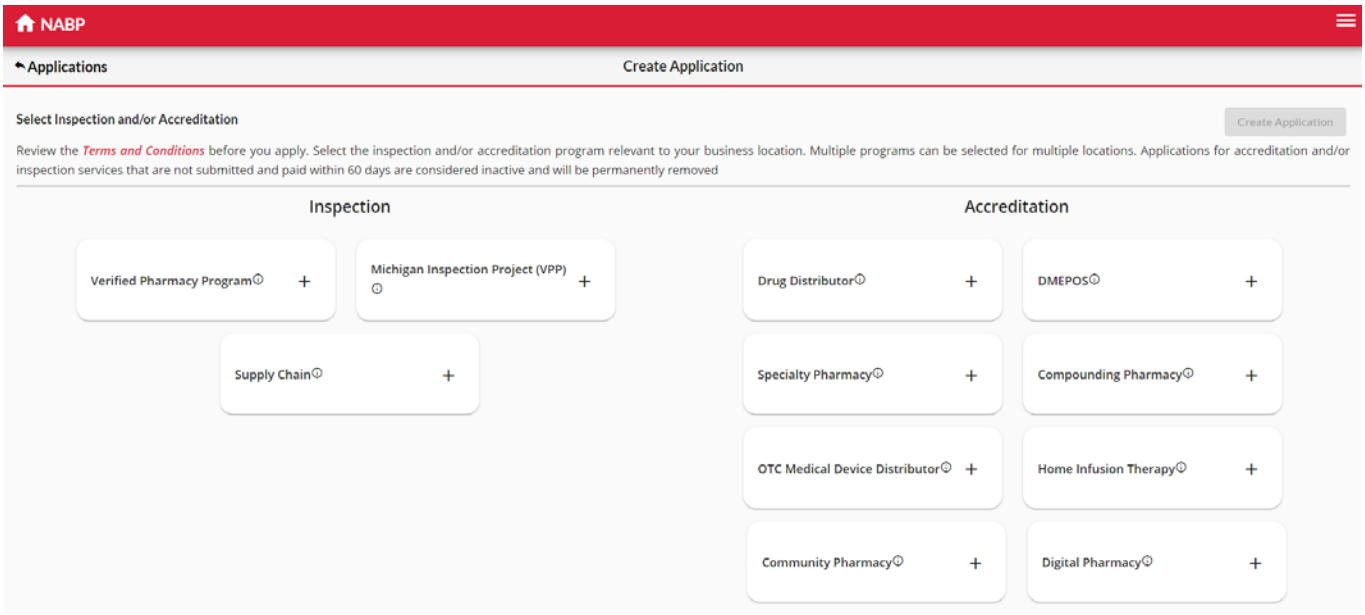

- Applications for accreditation programs and/or inspection services that are not submitted and paid within 60 days are considered inactive and will be permanently removed. There are four statuses associated with a given application(s): in progress, submitted, completed, and cancelled.



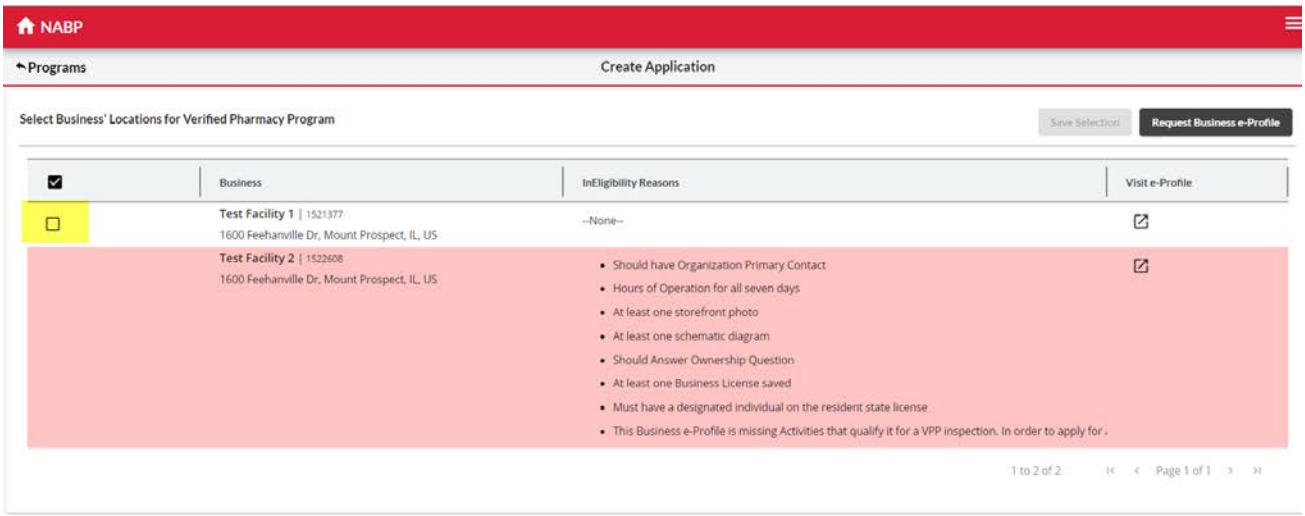

- The following information will be displayed for each application:
  - Status
  - Program (click the ⓘ icon on the page in the screenshot above to view the program type)
  - Application ID
  - Submitted Date
  - Valid From date
  - Valid To date
  - Completed Date
- To start an application, click Create New Application in the upper right-hand corner of the screen.
- A pop-up will appear with the following message:
  - Before starting an application, make sure the Business e-Profile(s) intended for applying is reviewed for the following information: up-to-date Business licenses, Staff licenses (if applicable to your business), primary contact information, hours of operation, storefront and schematic images/files, and ownership information. If you are applying for more than

one of our accreditation programs and/or inspection services at the same time, please contact industry@nabp.pharmacy for more information about potential discounts.

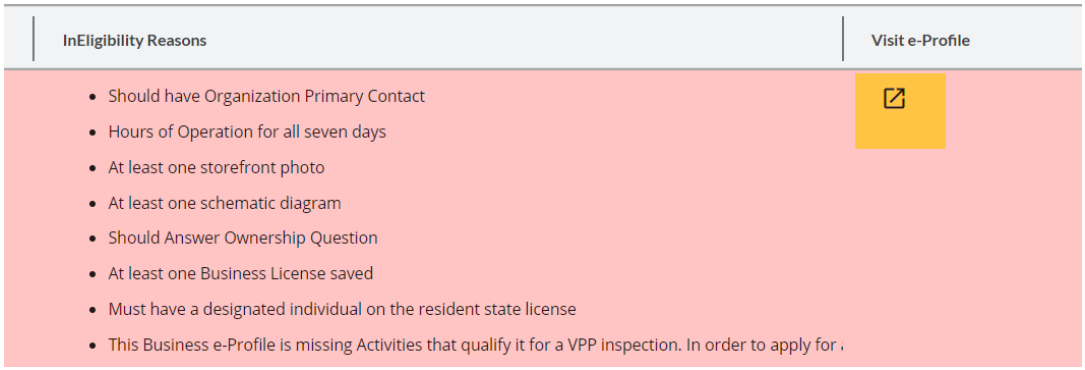
- Select Go to Application to proceed to the Create Application page.
    - If you need to return to the Business e-Profile to add more information, select Go to Business e-Profiles.




- The Create Application page lists all inspection services and accreditation programs offered by NABP: Verified Pharmacy Program, Supply Chain Inspection, Michigan Inspection Project (VPP), Drug Distributor Accreditation, DMEPOS Accreditation, Specialty Pharmacy Accreditation, Compounding Pharmacy Accreditation, OTC Medical Device Distributor Accreditation, Home Infusion Therapy Accreditation, Community Pharmacy Accreditation, and Digital Pharmacy Accreditation.
- To select a service or program, click the + icon to the right of the program name.
    - The user should see the following screen:




- In the example above, there are two business locations, Test Facility 1 and Test Facility 2. Test Facility 1 is eligible for the program selected. To proceed to the application for Test Facility 1, select the box to the left of the business information (highlighted above), click Save Selection, Create Application, and proceed to the next bullet. In the case of Test Facility 2, this business e-Profile is not eligible as denoted by the red highlight, and needs the following information entered within the business e-Profile:




- Depending on the application of the program/service selected, certain questions will be asked. There are, however, universal questions asked on every application. Here are some of the universal application questions:
  - ***NOTE: this is <u>not</u> an exhaustive list of questions/information requested in a given application. There are sub-questions not included in the list below. For example, if the user indicates that the business location engages in compounding, the following information will be requested: type of compounding (sterile, non-sterile, patient-specific, etc), top five compounds dispensed by volume, estimated volume by units sold, etc. If the user answers Yes to any of the disciplinary questions, the following***

***information will be requested: who/what was disciplined, state/agency/entity taking action, and date of action.***

- ***Some of the information requested in the application will be prepopulated with the information from the business e-Profile. During navigation of the prepopulated pages, the information contained on each page should be verified for accuracy. All other pages which are not prepopulated require responses in all applicable fields.***

- **Disciplinary questions:**
  - This entire section pertains to discipline or other action, including ongoing investigations, taken (or in process) within the last five years related to the practice of pharmacy or any other healthcare profession, or the manufacture, dispensing, or distribution of drugs, controlled substances, or devices, unless it was already provided to or reviewed by NABP.
  - Please provide the information below for: Facility owner(s), the Facility (including all DBA and FKA-affiliated businesses), Designated Representative/Warehouse Manager, Pharmacist-In-Charge (PIC) (Resident/Non-resident if applicable), and Compliance Contact.
    - Are any of the above entities currently under investigation or the subject of any pending administrative or civil complaint(s) or criminal charge(s) by any regulatory agency or governmental authority for any reason other than minor traffic violations? Are there any pending malpractice claims, civil claims, or lawsuits in connection with drugs/devices?
    - Have any of the above entities ever been enjoined, disciplined, sanctioned, fined, punished, or the subject of judgment or final decree of action by a court, administrative tribunal, or regulatory agency for violation of a federal or state law or regulation relating to the operation of a pharmacy, the practice of pharmacy, or other laws related to drugs or devices?
    - Have any of the above entities ever entered a settlement or plea agreement with a court, administrative tribunal, or regulatory agency relating to the operation of a pharmacy, the practice of pharmacy, or other laws related to drugs or devices?

- Have any of the above entities ever had an initial or renewal application denied for a license, permit, or registration in any jurisdiction related to drugs/devices?
- Have any of the above entities ever settled any malpractice claims, civil claims, or lawsuits in connection with drugs/devices?
- Have any of the above entities ever been assessed civil or criminal penalties related to fraud or billing practices?
- Have any of the above entities ever been listed on the Office of Inspector General (OIG) Exclusion List, disqualified from participation by CMS, or denied payment or reimbursement or been disciplined by any federal regulatory agency (such as CMS) or state regulatory agency for violations of or non-compliance with applicable laws, regulations, or requirements?
- Have any of the above entities ever been denied or had a provider number revoked, suspended, or rescinded by CMS or other federal or state regulatory agency for violations of or non-compliance with applicable laws, regulations, or requirements?
- Have any of the above entities ever been charged with or convicted of any criminal violation other than a minor traffic violation? (If a criminal conviction is under appeal, please attach a copy of the notice of appeal of the criminal offense and, within 15 days after the disposition of the appeal, attach a copy of the final written order of disposition.)

- **Universal Questions**
  - Is this facility's address a personal residence?
    - ***If the answer to this question is Yes, the business location is ineligible for ALL programs/services.***
  - Does the business own/operate a single location only?
  - Are products (drugs/devices physically onsite at this location?
  - What is the average number of drug/device orders which are sold or shipped through this facility per day?
  - What are the names of the top five drugs/devices sold or processed through this facility by volume (units processed)?

- ***Processing, here and throughout the application, may include, but is not limited to, drug/device orders which are sold shipped, stored, distributed, and/or dispensed.***

- Compliance contact name
- Has this facility been fully operational in all of its activities for at least 30 days?
  - ***If the answer to this question is No, the facility is ineligible for the following programs: VPP, DMEPOS, Community, Specialty, and Digital Pharmacy Accreditation.***
- Has your facility been inspected by its resident state regulatory authority (or entity that issued its license)?
- Were you referred to NABP by a state or other entity?
  - If so, what state(s) and/or entity referred you (eg, NABP Compounding Pharmacy Accreditation)?
- Will your business location be undergoing an address change within the next six months?
  - ***If applying for an accreditation program or inspection service, it is advised to apply <u>after</u> the relocation. If the user proceeds with an application for either Drug Distributor Accreditation, OTC Medical Device Distributor Accreditation, or Verified Pharmacy Program, the application will be canceled once the facility's address has changed.***
- Does your facility engage in distribution?
- Have you provided all licenses and registrations relevant to your facility via the facility's business e-Profile (eg, pharmacy license, DEA registration, wholesale distributor, nonresident licenses)?
- What is the square footage of the facility?
- Does your organization advertise or solicit business via the internet or email?
- Does your business have a website?
- Does your facility accept prescriptions from doctors who write prescriptions based on online patient evaluation forms or questionnaires?
- Source List:
  - The user will be asked to provide a current list of sources from which the busines location buys and/or obtains prescription drugs and devices. For third-party logistics providers, sources are entities the location contracts with to store and ship prescription drugs

and/or devices. For all pharmacy accreditation programs, the user will be asked to provide all sources of OTC drugs and/or devices. For OTC Medical Device Distributor Accreditation applicants, sources include businesses from which the location buys and/or obtains medical devices, including blood glucose test strips, which may be sold over-the-counter to patients without a prescription.

- For NEW APPLICANTS, provide all sources for the most-recent three years.
- For NABP ACCREDITED facilities, provide all sources for the most-recent twelve months.
    - The source list will request:
        - Source name
        - Country (if not US)
        - City
        - State
        - Type of source (Manufacturer, Repackager/Relabeler, Wholesale Distributor, Outsourcing Facility (503B), Pharmacy, and/or Other
        - Is the Source an Affiliate as defined by DSCSA?
            - DSCSA definition of affiliate can be found here: https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm376829.htm.
        - Most recent date of conducting busines with the source
        - Is the source considered "Active" by your facility?
            - Active means the facility still has an open account with the source and can purchase from them.

- All programs/services, *except DMEPOS,* will be asked the following questions:
    - What type(s) of drugs/devices does your facility sell or process?
    - Are all the drugs/devices distributed under the wholesale license also purchased under that license?
    - Does your facility perform compounding (non-nuclear, non-radioactive)?
- All programs/services, *except DMEPOS, Community, Specialty, Digital Pharmacy Accreditation, and Home Infusion Therapy,* will be asked the following question:
    - Does your facility handle or process hazardous drugs?

- All programs/services, *except DMEPOS, Supply Chain Inspection, Drug Distributor Accreditation, and OTC Medical Device Distributor Accreditation,* will be asked the following questions:
    - Are there any affiliate businesses to this facility? An "affiliate," in this context, includes without limitation, any website to which your business website links, as well as other entities that share or have shared in the past 12 months a common ownership or common principals, management, pharmacist-in-charge, or shared contact information such as a phone number or street address with your business.
    - Do you dispense nuclear drugs or radiopharmaceuticals?
    - Do you compound radiopharmaceuticals?
- All programs/services, *except Supply Chain Inspection, Drug Distributor Accreditation, and OTC Medical Device Distributor Accreditation*, will be asked the following:
    - Is this facility in a shared services agreement or central fill arrangement (ie, the facility performs or receives services by another facility under common ownership or another business entity)?
- If the application is for Specialty, the following information will be requested:
    - Please select the disease states for which you are seeking Specialty Accreditation.
    - How many total prescriptions do all facilities included in your application dispense per year?
        - The user can select from the following:
            - Less than 20,000 prescription dispensed per year
            - Between 20,000-99,999 prescriptions dispensed per year
            - 100,000 or more prescriptions dispensed per year
        - Depending on the answer to this question, the pricing for the Specialty Accreditation application may change. For the most up-to-date pricing information, visit the Specialty page on the NABP website: https://nabp.pharmacy/programs/specialty/.
- If the application is for DMEPOS, the following information will be requested:
    - Please select the product categories for which you are seeking DMEPOS accreditation (Products, Services and Supplies).
    - Does this facility have a Medicare Supplier Billing Number?
    - Has this facility had more than 10 customers for which there are billed prescriptions? (Note: Prescriptions do not need to be for Medicare customers)

        - ***If the answer to this question is No, the business location is ineligible for DMEPOS.***
- If the application is for Home Infusion Therapy Accreditation, the following questions will be asked:
    - Are Home Infusion Therapy professional services provided in a patient's home?
- If the application is for Supply Chain Inspection, Drug Distributor Accreditation, and/or OTC Medical Device Distributor Accreditation, the following information will be requested:
    - Designated representative name, email, phone number, and address.
    - Does your facility distribute into any jurisdictions where it does not hold a license/registration/permit to do so?
    - Are the distribution operations air conditioned?
    - How long has this operation been at this location?
    - How many employees work at this facility?
    - Has the business been inspected by its applicable state regulatory agency or its agent (or is there a future inspection planned/scheduled)?
    - What is the date this facility was last inspected by the DEA?
    - Has the facility reported to FDA as a wholesale distributor?
    - Has the facility reported to FDA as a 3PL?
    - Has your business location reported all state licenses, including nonresident, to FDA?
    - Has the facility registered with FDA as a manufacturer or repackager?
    - Are there any affiliate businesses to the facility?
    - Are there other locations where services related to the facility are performed (eg, storage, distribution center)?
    - Please provide a vertical and horizontal organizational chart from the ultimate parent company to the applicant incorporating all affiliate businesses. Please include the applicant entity, any doing business as entities, company addresses, and executive officers. The definition of affiliates can be found here: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.
    - Do you distribute through a third-party logistics provider (3PL)?
    - Does this facility export or ship prescription drugs/devices internationally?
    - Are other businesses handling prescription drugs or prescription devices at this facility?
    - Customer List:

        - Please provide a current list of customers your business supplies prescription drugs and/or devices to:
            - Customer name
            - City
            - State
            - Type of customer (pharmacy, practitioner, hospital, wholesale distributor, repackager, manufacturer, 3PL, outsourcing facility, or other)
            - Does this customer export?
            - Does the customer report to the FDA database?
            - Is this customer appropriately licensed?
            - Is the customer an affiliate as defined by DSCSA?
            - Date of last sale
- If the application is for Drug Distributor Accreditation and/or OTC Medical Device Distributor Accreditation, the following information will be requested:
    - Designated representative supervisor's name, email, phone number, and address.
    - Does the designated representative supervisor serve in this position for more than one distributor?

**Additional Information related to VPP**

- State inspection
    - If there was a letter sent from your board of pharmacy, please make sure to click the appropriate program option.

    NOTE: the Verified Pharmacy Program does not conduct partial inspections. If a pharmacy performs an activity (including but not limited to nonsterile compounding, sterile compounding, or nuclear activities) the inspection must include such activities.
    - To apply for VPP, the pharmacy must be fully operational for at least 30 days. If compounding, the pharmacy must also have been compounding preparations for at least 30 days prior to applying. If compounding, and pharmacy is remodeling its compounding facility, pharmacy must be fully operational and compounding in the new facility for at least 30 days before applying for VPP.
    - Once NABP has received a VPP application, an unannounced inspection of the pharmacy may occur at any time.

- If the pharmacy is a sterile compounding facility and needs an inspection due to the Texas Class E-S license requirement, please indicate so and select one of the following options:
    a) Option A: uniform VPP inspection form: recommended if the pharmacy holds or plans to hold licenses in other states.
    b) Option B: Texas Class E-S-specific inspection form: recommended if the pharmacy does not qualify for VPP or only holds nonresident licensure in the state of Texas.
    - Both inspections types are accepted by the Texas Board of Pharmacy and include the collection of the compounded sterile preparation during the onsite unannounced inspection.

      NOTE: if you are seeking, or plan to seek, licensure in Texas and the facility is a sterile compounding pharmacy, it is important to indicate so in the application.

- If during the application evaluation process any information submitted on the VPP application changes, NABP must be notified in writing within 48 hours. Submit changes via email to VPP@nabp.pharmacy.

## Consulting services

- I understand that NABP does not provide consultative services for completing the VPP application.

## Attestation and Agreement

- The Organization will need to read and agree to the Attestation and Agreement once the application has been completed and before submitting payment.

  NOTE: the person applying must be authorized to agree to the Attestation and Agreement on behalf of the Organization.

- All the requested information and documentation provided on the application and must be accurate, truthful, and complete before the application can be submitted. Any missing, incomplete or inaccurate information provided will result in the delay of the processing of the application.

## Payment

- The Payment page will display the total application fee. The application fee is based on the types of activities and attributes applicable to the pharmacy. Visit the Programs Page of the NABP website for more information on pricing: https://nabp.pharmacy/programs/.
    - Payments must be made by credit card or check.
    - Once the Pay & Submit button has been clicked, the application will be submitted, and a confirmation page will be displayed after the payment has been processed.
    - An email confirming the submission of the application will be sent to the email address provided.

## Incomplete Applications

- Applications not submitted within 60 days of application creation will be deleted. All information saved in the incomplete application will be deleted. To submit an application, a new application will need to be created if the previous version expired as NABP is unable to restore the deleted application.
- Applicants who submit an application without all necessary information applicable will be contacted by NABP with a request to submit the remaining information within 30 days. If the missing information is not provided within this time frame, the application will be canceled. Any refunds will be issued in accordance with the applicable program's refund policy. To navigate to the applicable program/service refund policy, visit the NABP Programs Page: https://nabp.pharmacy/programs/.
- Cancelled or withdrawn applications are subject to handling fees. See the applicable program or service refund policy on the NABP website.