

Application Supplemental Documentation

To avoid unnecessary delays, please take the time to thoroughly review the required documentation and gather the documents outlined below prior to starting the application process. This documentation is required for NABP's Supply Chain Inspection application.

Utilize the checklist below to prepare the supplemental documentation for your application:

<p>Business schematic diagram</p> <p>a. Make sure all key areas of the business are visible and clearly labeled. For example, please indicate areas dedicated to sterile compounding, if applicable to your business, and product storage areas identified by storage type (refrigerated, controlled room temperature, temperature probes, etc). Please also indicate areas dedicated to distribution, if applicable.</p>
<p>Photo of the business storefront</p> <p>a. Please ensure that the business name and entrance are visible.</p>
<p>All licenses held by the business (closed, inactive, pending, DEA, controlled substance, wholesale distributor, etc.)</p> <p>a. These can be added or updated individually in your business e-Profile or added via the license template provided in the e-Profile system.</p>
<p>Licenses and e-Profile IDs for licensed staff. Staff license requirements vary from program to program.</p> <p>a. For distributor programs (Drug Distributor, OTC Medical Device Distributor, or Supply Chain Inspection), a licensed designated representative is only required for wholesale distributors if the business is doing business in California or Florida.</p> <p>To avoid application delays, staff should update their license information in their individual e-Profiles prior to filling out the business application.</p>
<p>Ownership information, including names, addresses, and contact information for individual and company owners that have 5% or greater equity in the ownership or controlling interest of the organization and/or 5% or greater interest in the organization</p>
<p>Names and addresses of affiliate businesses, including any website to which the 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 contact information, such as a phone number or street address, with the business</p>
<p>If the business is in a shared services agreement or central fill arrangement, the names and addresses of the other locations will be requested.</p>

<p>List of the top drugs processed¹ or sold by the business, including dosage forms</p> <ol style="list-style-type: none"> a. Provide the top five non-compounded, top five nonsterile compounded, and top five sterile compounded drugs, as applicable.
<p>Average number of drug and/or device orders processed through the business per day</p>
<p>Square footage of the business</p>
<p>Policy and Procedure (P&P) Overview document</p> <ol style="list-style-type: none"> a. Download and complete the P&P Overview document found in NABP e-Profile . b. Gather all P&Ps referenced in the Overview document.
<p>List of the business' non-manufacturer prescription drug sources for the past three years</p> <ol style="list-style-type: none"> a. Source list instructions and a template are available in the e-Profile system.
<p>List of the customers for the past three years</p> <ol style="list-style-type: none"> a. Customer list instructions and a template are available in NABP e-Profile.
<p>Certification reports if sterile compounding</p> <p>Note: reports must be from within the last six months to request an inspection.</p> <p>Must include:</p> <ol style="list-style-type: none"> a. Primary engineering controls certification report b. Secondary engineering controls certification report c. Viable air testing report d. Viable surface testing report e. Technician notes f. Summary
<p>Scanned copies of the most recent state, federal, or third-party inspection reports and any responses provided by the business, if available</p> <ol style="list-style-type: none"> a. All documentation submitted must be free of any protected health information (PHI) or personally identifiable information (PII). If any PHI or PII is included, the application will be considered incomplete and the review will be delayed. <ol style="list-style-type: none"> i. Note: PHI and PII include, but are not limited to, patient names, prescription numbers, Social Security numbers, etc.
<p>Disciplinary action taken (or in process) within the last five years against the business, business owners, or licensed staff</p> <ol style="list-style-type: none"> a. Copies of disciplinary action (or other action taken against the business) will be requested in the following scenarios: <ol style="list-style-type: none"> i. FDA warning letters and/or FDA Form 483s ii. Pending discipline (any action that is not final or settled) iii. Civil penalties related to insurance fraud or billing practices iv. Criminal violations (other than minor traffic violations) that are under appeal b. All documentation submitted must be free of any PHI or PII. If any PHI or PII is included, the application will be considered incomplete and the review will be delayed. <ol style="list-style-type: none"> i. Note: PHI and PII include, but are not limited to, patient names, prescription numbers, Social Security numbers, etc.

¹ The term "process" recurs throughout the application. Processing may include, but is not limited to, drug and/or device orders that are sold, shipped, stored, distributed, and/or dispensed.