

**National Association of Boards of Pharmacy® (NABP®) 1600 Feehanville Drive**

**Mount Prospect, Illinois 60056**

**Website:**

***[www.nabp.pharmacy/programs/drug-distributor](http://www.nabp.pharmacy/programs/drug-distributor)***

**Email:** [**VAWD@nabp.pharmacy**](mailto:vawd@nabp.pharmacy)

**Phone: 847/391-4539**

**Drug Distributor Accreditation**POLICY AND PROCEDURE ASSESSMENT

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| **APPLICANT INFORMATION** | | | | | | | | |
| **Applicant’s Legal Business Name** | | | **Doing Business As (DBA) Name – If applicable** | | | | | **Date** |
|  | | |  | | | | |  |
| **Applicant’s Physical Address of Facility** | | **Any other businesses handling prescription drugs at this facility?** | **Contact Person for Drug Distributor Accreditation** | | | | | |
|  | | **Yes  No** | **Name** | | | **Telephone Number** | | **Email Address** |
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| **Type of Application** | | | **Does your facility take possession of the drugs you own?** | | | **Is the facility’s drug storage area air conditioned?** | | |
| **New Applicant  Reaccreditation  Other** | | | **Yes  No** | | | **Yes  No  N/A** | | |
| **Type of Facility: (Check All That Apply)** | | | | | | | | |
| **WD - Wholesale Distributor** | **3PL - Third-Party Logistics Provider** | | | **RD - Reverse Distributor** | | | | |
| **MFR - Manufacturer** | **503B - Outsourcing Facility1** | | |  | **SD - Sample Distributor** | | **VD - Virtual Distributor** | |
| **AD - API Distributor** | **DD - Device Distributor**  **1 503Bs sourcing DSCSA-defined products are subject to DSCSA requirements for incoming product .** | | | **RPKG - Repackager2**  **2 Repackagers taking ownership of DSCSA-defined products are subject to DSCSA requirements.** | **VET - Veterinary Prescription**  **Drugs** | | **Other (Describe)** | |
| **GENERAL COMMENTS** | | | | | | | | |
| |  | | --- | | **Reviewer Comments:** |   **Applicant Comments:** | | | | | | | | |
| **INSTRUCTIONS** | | | | | | | | |
| **IMPORTANT NOTE: Save this document to your computer using Microsoft Word. Complete it electronically and submit the final Word version of the document and referenced policies and procedures (P&Ps) back to** [**VAWD@nabp.pharmacy**](mailto:VAWD@nabp.pharmacy)**. Handwritten assessments are not acceptable. PDF assessments are not acceptable.**  Familiarize yourself with this *Policy & Procedure Assessment* prior to completion. Contact [VAWD@nabp.pharmacy](mailto:VAWD@nabp.pharmacy) or 847/391-4539 with any questions.  **Instructions to ALL Applicants**   1. P&P List: Using the “P&P Index” located at the back of this document, create a list of all shared P&Ps indicating which locations use the P&P. 2. Functional List: Using the “Off-Site Functions List” template located at back of this document, create a list of all functions performed off site that are essential to your business and relative to the purpose of brokering, shipping, and receiving prescription drugs and devices. 3. Does Not Apply To: Focus points not applying to specific facility types are referenced in this column. Refer to the “Facility Type” listing above in “Applicant Information” for facility type abbreviations. 4. P&P Type: Indicate whether the P&P referenced is a “Shared” or a “Site-Specific” document. 5. P&P Name or Number: For all applicable “Focus Points,” insert the P&P name or number that corresponds to the electronic file containing the P&P. 6. P&P Page Number: Provide the page number within your P&P where the specific criterion can be found. 7. N/A: If a criterion does not apply to your business operation, type “N/A” in the P&P Name or Number column and then explain in the “Applicant Comments” section.   **ADDITIONAL Instructions to Those That DO NOT TAKE POSSESSION OF PRODUCT (“Virtual Distributors”)**   1. P&P Name or Number: For functions performed by your third-party logistics provider (3PL) or business partner, include in the place of the “P&P Name or Number” *the DBA name or number, as indicated on your Functional List, located on the final page of this document*. | | | | | | | | |

| **EXAMPLE** | | | | | | |
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| **FOCUS POINT** | **Does Not Apply To** | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Quarantine, Disposition, Returns, and Disposal**  May be included in P&Ps for product returns and destructions |  |  |  |  |  |  |
| Process for determining product to be in quarantine |  | Shared | **SOP.QT.002.V4 – Product Quarantine** | **5** |  |  |
| Process for ensuring the safety, identity, strength, quality, and purity of prescription products to be returned to vendors, active stock, destroyed, or held for Food and Drug Administration (FDA) |  | Site-Specific | **SOP.QT.001.V2 – Returned Product Integrity Assessment** | **3-4** |  |  |
| Process for creating documentation showing that proper conditions were maintained and that these documents were provided to the manufacturer or wholesale distributor to which products are returned |  | Site-Specific | **SOP.QT.011.V6 – Shipping Product Returns** | **8** |  |  |

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| **APPLICANT’S POLICY & PROCEDURE INFORMATION** |

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| **Licensing and Compliance with Laws/Regulations** |  |  |  |  |  |  |
| Process for determining requirement for licensure in a state |  | Choose an item. |  |  |  |  |
| Process for obtaining and maintaining current licenses and DEA registrations (if applicable) in all relevant jurisdictions |  | Choose an item. |  |  |  |  |
| Process for ensuring compliance with federal, state, and local laws/regulations in the host state and each state to which prescription drugs and/or devices are shipped as required |  | Choose an item. |  |  |  |  |
| Process for ensuring the annual reporting by prescription drug wholesale distributor facilities to FDA | DD, MFR, RD, 3PL, RPKG, 503B, VET | Choose an item. |  |  |  |  |
| Process for ensuring the annual reporting to FDA by third-party logistic provider facilities | AD, DD, MFR, RD, RPKG, SD, VD, WD, 503B | Choose an item. |  |  |  |  |
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| **Operations** |  |  |  |  |  |  |
| Pre-employment process for ensuring all personnel who have access to the operation and handling of prescription drugs and/or devices, or directly supervise those who do, meet the following qualifications prior to their association, employment, or contract: |  | Choose an item. |  |  |  |  |
| * Local and national criminal background checks |  | Choose an item. |  |  |  |  |
| * Initial toxicology screening |  | Choose an item. |  |  |  |  |
| * Appropriate education, experience, and minimum qualifications for the specific duties of the position |  | Choose an item. |  |  |  |  |
| Process for ensuring the title, duties, and qualifications of responsible persons and persons in charge, including facility managers or designated representatives, are documented and updated as needed |  | Choose an item. |  |  |  |  |
| Ongoing process for ensuring all personnel who have access to the operation and handling of prescription drugs and/or devices, or directly supervise those who do, undergo the following regularly (as defined) after employment: |  | Choose an item. |  |  |  |  |
| * For-cause local and national criminal background checks |  | Choose an item. |  |  |  |  |
| * For-cause toxicology screening |  | Choose an item. |  |  |  |  |
| * Documented training of all personnel necessary to remain current on changes |  | Choose an item. |  |  |  |  |
| Process describing how the facility manager or designated representative duties are covered in their absence |  | Choose an item. |  |  |  |  |
| Process for ensuring that proper document controls are in place, including processes for proper version control, effective dates, and change history, and ensuring that only the most current version is available for use |  | Choose an item. |  |  |  |  |
| Process for a formalized, thorough, and documented quality assurance program that monitors critical areas of operations for product receipt, storage, and distribution activities (eg, inventory control and accuracy, shortages/overages/damages, investigations, complaints, employee safety) |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Housekeeping** |  |  |  |  |  |  |
| Custodial process provides general requirements, including documented, scheduled cleaning tasks, approved cleaning agents, etc | VD, RD | Choose an item. |  |  |  |  |
| Pest control process provides general requirements, including documented monthly inspections, use of EPA-approved pesticides, and maintenance of safety data sheets | VD, RD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Security**  May be addressed in separate P&Ps |  |  |  |  |  |  |
| Process describing the facility’s security alarm system |  | Choose an item. |  |  |  |  |
| * Alarms process for handling alarm activation during off hours; and |  | Choose an item. |  |  |  |  |
| * Description of how access is controlled |  | Choose an item. |  |  |  |  |
| Process for ensuring visitors are escorted at all times (this should also apply to housekeeping and pest control vendors) *(Recommended for Virtuals)* |  | Choose an item. |  |  |  |  |
| Process for ensuring only task-critical employees are allowed in the prescription drug and/or device storage and processing area, including the controlled substances cage | VD | Choose an item. |  |  |  |  |
| Process for ensuring restrictions against food/drink, purses, coats, etc, in drug storage and processing areas are enforced | VD | Choose an item. |  |  |  |  |
| Process for monitoring trash to prevent diversion of prescription drugs and devices (prevention of prescription drugs and devices being hidden in refuse and retrieved afterward) | VD | Choose an item. |  |  |  |  |
| Information technology (IT) security process that covers the key elements of IT security, including secure login, off-site backup, firewalls, timeouts, and password security |  | Choose an item. |  |  |  |  |
| Process for separating and securing all aspects of the wholesale distributor’s operation when the wholesale distributor’s facilities are co-located with another business authorized to purchase prescription drugs and/or devices |  | Choose an item. |  |  |  |  |
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| **Drug Supply Chain Security Act (DSCSA) Requirement: Authorized Trading Partners (section 582 of the FD&C Act)**  **and**  **Vendor and Customer Validation (applies to all applicants, including those that do and those that do not fall under DSCSA requirements)** |  |  |  |  |  |  |
| Regular validation of the identity of each entity seeking to engage in the distribution of prescription drugs or devices with the applicant. This includes all sources from which drugs and/or devices are purchased or received and all entities to which drugs or devices are sold or shipped. |  | Choose an item. |  |  |  |  |
| * Initial and ongoing license validations of all entities engaged in the distribution of prescription drugs and/or devices with the applicant conducted directly with federal and state regulatory agencies with jurisdiction over such trading partner or other entity (all licenses of sources/vendors and “ship-to” entities/customers must be in good standing) |  | Choose an item. |  |  |  |  |
| * Initial and ongoing validation that all wholesale distributors engaged in the distribution of prescription drugs with the applicant have reported to FDA | AD, DD, RD, SD, VET, 3PL,  503B as applicable | Choose an item. |  |  |  |  |
| * Initial and ongoing validation that all 3PLs engaged in the distribution of prescription drugs with the applicant have reported to FDA | AD, DD, RD, SD, VET, 3PL,  503B as applicable | Choose an item. |  |  |  |  |
| Criteria for denying business with any entity, including all vendors (sources) and customers (recipients) seeking to engage in the distribution of prescription drugs with the applicant |  | Choose an item. |  |  |  |  |
| Process for determining that each trading partner engaged in a transaction involving a product with the applicant is authorized, consistent with section 582 of the Act, as applicable | AD, DD, RD, SD, VET, 3PL, RPKG as applicable,  503B as applicable | Choose an item. |  |  |  |  |
| Process for establishing the legitimacy of prescription drugs and/or devices purchased or received from wholesale distributor and repackager sources which purchase such prescription drugs and/or devices exclusively from the manufacturer | AD, RD, SD, 3PL, RPKG as applicable,  503B as applicable | Choose an item. |  |  |  |  |
| Process for establishing the legitimacy of prescription drugs and/or devices purchased or received from wholesale distributor and repackager sources that do not purchase such prescription drugs and/or devices exclusively from the manufacturer: | AD, RD, SD, 3PL, RPKG as applicable,  503B as applicable | Choose an item. |  |  |  |  |
| * Regularly establishing the legitimacy of any such entity’s sources of prescription drugs and devices | AD, RD, SD, 3PL, RPKG as applicable,  503B as applicable | Choose an item. |  |  |  |  |
| * Regularly establishing that prescription drugs and devices from any such entity were legitimately obtained and further distributed by each previous owner before being obtained by the entity and resold or shipped to the applicant and not previously distributed to pharmacies, health care entities, or under special restricted pricing contracts, such as 340B, own-use, and closed-door pharmacy/long-term care including when the pharmacy, health care entity, etc has a wholesale distributor license | AD, RD, SD, 3PL, RPKG as applicable,  503B as applicable | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **DSCSA Requirement: Product Tracing under Section 582 of the FD&C Act** |  |  |  |  |  |  |
| Process to achieve and maintain compliance with the product tracing requirements under section 582 of the FD&C Act for transactions involving product and the exchange of transaction data (transaction information (TI), transaction history (TH), and a transaction statement (TS)), consistent with [FDA’s November 2014 Draft Guidance for Industry,](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424895.pdf) entitled “DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information” | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process for retaining transaction data for no less than six years after the transaction, consistent with section 582 of the FD&C Act | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process to identify “products” as defined under section 581(13) of the FD&C Act; once defined as a product, the exchange of transaction data applies | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process to identify “transactions” as defined under section 581 (24) of the FD&C Act; once defined as a transaction, the exchange of transaction data applies | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process to ensure that the transaction information (TI) contains the following information, as applicable, consistent with section 581 (26) of the FD&C Act: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Proprietary or established name or names of the product; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Strength and dosage form of the product; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * National Drug Code number of the product; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Container size; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Number of containers; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Lot number of the product; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Date of the transaction; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Date of the shipment, if more than 24 hours after the date of the transaction; and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Business name and address of the person from whom and to whom ownership is being transferred. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process to ensure that the transaction history (TH) contains the following information, consistent with section 581 (25) of the FD&C Act: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process to ensure that the transaction statement (TS) contains the following information, consistent with section 581 (27) of the FD&C Act:  A statement, in paper or electronic form, that the entity transferring ownership in a transaction: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Is authorized as required under DSCSA; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Received the product from a person that is authorized as required under DSCSA; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Received transaction information (TI) and a transaction statement (TS) from the prior owner of the product, as required under the law; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Did not knowingly ship a suspect or illegitimate product; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Had systems and processes in place to comply with validation requirements under the law; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Did not knowingly provide false transaction information (TI); and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Did not knowingly alter the transaction history (TH). | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| If a direct purchase statement is used per 582 (c)(1)(A)(ii) of the FD&C Act, then a wholesale distributor must include: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * A process for ensuring that a direct purchase statement is used only for those products purchased directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Process that ensures a wholesale distributor or a repackager does not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history (TH), transaction information (TI), and a transaction statement (TS), consistent with section 582 of the FD&C Act. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Inbound Prescription Drugs/Devices and Receiving** |  |  |  |  |  |  |
| Processes for examining inbound prescription drugs and devices to ensure containers and labeling are not suspected of being damaged, adulterated, misbranded, counterfeited, diverted, tampered with, or are otherwise unlawful or unfit for distribution | VD | Choose an item. |  |  |  |  |
| * Ensure prescription drugs and devices whose sealed outer and/or secondary containers have been opened/used are identified, quarantined, and properly disposed of; | VD | Choose an item. |  |  |  |  |
| * Verify that prescription drugs and devices match shipping receipts (prescription drug and device/shipper validation); | VD | Choose an item. |  |  |  |  |
| * Include visual inspections of prescription drugs and devices; and | VD | Choose an item. |  |  |  |  |
| * Include plan of action for when suspect prescriptiondrugs and/or medical devices are identified, including quarantining product. | VD | Choose an item. |  |  |  |  |
| Process for maintaining the security of controlled substances during receiving | DD, VD | Choose an item. |  |  |  |  |
| Process for handling temperature-sensitive products*:* | RD, VD | Choose an item. |  |  |  |  |
| * Process for ensuring products were shipped under appropriate storage conditions; and | RD, VD | Choose an item. |  |  |  |  |
| * Process for transporting products to an appropriate storage area (eg, refrigerated/frozen storage) within an allowable time frame (USP requires less than four hours for receipt and shipping processes). | RD, VD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Verification**  **(Section 582 of the FD&C Act)** |  |  |  |  |  |  |
| **Suspect Product Definition (Section 581 (21) of the FD&C Act)**  The term *Suspect Product* means a product for which there is reason to believe that such product:   1. is potentially counterfeit, diverted, or stolen; 2. is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; 3. is potentially the subject of a fraudulent transaction; or 4. appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Processes to assist in the timely identification of suspect product in accordance with the above definition of suspect product, which: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * include specific measures for detecting suspect product based on “*Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Chain*” and “*Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product is a Suspect Product as Soon as Practicable*” contained in [FDA’s December 2016 Final Guidance for Industry,](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf) entitled “Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry;” | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * ensure such measures incorporate regular vigilance and awareness to identify suspicious activity or potential supply chain threats; and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * ensure such measures incorporate specific due diligence activities including, but not limited to, establishing compliance with licensure and reporting requirements, as applicable which are regularly performed when conducting business with trading partners. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| A process for making timely suspect product determinations | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Upon making a determination that a product in the possession or control of the applicant is a suspect product, or upon receiving a request for verification from FDA that has made a determination that a product within the possession or control of the applicant is a suspect product, processes for: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * quarantining suspect product within the possession or control of the applicant from product intended for distribution until such product is cleared or dispositioned; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * promptly conducting an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, including:   + validating any applicable transaction history (TH) and transaction information (TI) in the possession of the applicant; and   + otherwise investigating to determine whether the product is an illegitimate product; and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * promptly notifying FDA, if applicable, when the applicant determines that a suspect product is not an illegitimate product so that such product may be further distributed. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| **Illegitimate Product Definition (Section 581 (8) of the FD&C Act)**  The term *Illegitimate Product* means a product for which credible evidence shows that such product:   1. is counterfeit, diverted, or stolen; 2. is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; 3. is the subject of a fraudulent transaction; or 4. appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| A process for making illegitimate product determinations in coordination with the manufacturer | AD, DD, Mfr, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Upon determining, in coordination with the manufacturer, that a product in the possession or control of the applicant is an illegitimate product, processes for: | AD, DD,Mfr, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * quarantining illegitimate product within the possession or control of the applicant from product intended for distribution until such product is dispositioned; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * the disposition of illegitimate product within the possession or control of the applicant; | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * taking reasonable and appropriate steps to assist a trading partner in dispositioning an illegitimate product not in the possession or control of the applicant; and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * retaining a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or FDA (or other appropriate federal or state official) upon request by the manufacturer or FDA (or other appropriate federal or state official), as necessary and appropriate. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Upon determining that a product in the possession or control of applicant is an illegitimate product, processes for: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * notifying FDA of the illegitimate product determination no later than 24 hours after making the illegitimate product determination using Form FDA 3911 and incorporating guidance for illegitimate product notifications contained in [FDA’s December 2016 Final Guidance for Industry](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf), entitled “Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry;” and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * notifying all immediate trading partners that the applicant has reason to believe may have received the illegitimate product, within 24 hours of making the determination. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| Upon the receipt of a notification from FDA or a trading partner that a determination has been made that a product is an illegitimate product, processes for: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * identifying all illegitimate product subject to the illegitimate product notification that is in the possession or control of applicant, including any product that is subsequently received; and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * performing the activities described for suspect product determinations. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| A process for determining, in consultation with FDA, that an illegitimate product notification is no longer necessary, including: | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * the termination of illegitimate product notifications using FDA Form 3911 and incorporating guidance for terminating illegitimate product notifications contained in [FDA’s December 2016 Final Guidance for Industry](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf), entitled “Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry;” and | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * prompt notification to immediate trading partners that received illegitimate product notifications from the applicant that the illegitimate product notification has been terminated. | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| A process to respond to all verification requests (allows for the use of a secure electronic database developed by the applicant or a secure electronic database developed or operated by another entity to meet the verification requirements, but does not relieve the applicant of the requirement to respond to verification requests). | AD, DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Temperature Standards** |  |  |  |  |  |  |
| Process for ensuring drugs and devices are stored at temperature standards according to the drug and device labeling or United States Pharmacopeia (USP) standards. The most common temperature labeling requirements, although not all inclusive, are: | RD, VD | Choose an item. |  |  |  |  |
| * + Freezer -13° to 14° F | RD, VD | Choose an item. |  |  |  |  |
| * + Controlled Cold Temperature (CCT) 36° to 46° F | RD, VD | Choose an item. |  |  |  |  |
| * + Controlled Room Temperature (CRT) 68° to 77°F     - Excursions allowed from 59° to 86°F, provided the mean kinetic temperature does not exceed 77°F | RD, VD | Choose an item. |  |  |  |  |
| * Process to maintain an electromechanical or electronic recording and monitoring system that operates continuously (24/7/365) in all prescription drug/device storage areas. The system must provide recorded data (recording) as well as the real-time alarm status of excursions (monitoring) on a continuous (24/7/365) basis | RD, VD | Choose an item. |  |  |  |  |
| * Temperature monitoring equipment calibration frequency should be at least annually or according to manufacturer recommendation (time frame must be specified if using manufacturer recommendation) | RD, VD | Choose an item. |  |  |  |  |
| * 24/7/365 plan of action when temperature or humidity excursions occur, including drug and device assessment | RD, VD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Humidity Standards** |  |  |  |  |  |  |
| Processes for monitoring humidity to ensure all prescription drugs and devices are stored according to the product labeling | RD, VD | Choose an item. |  |  |  |  |
| * Monitoring and recording all areas 24/7/365; and | RD, VD | Choose an item. |  |  |  |  |
| * Humidity monitoring equipment calibration frequency should be at least annually or according to manufacturer recommendation (time frame must be specified if using manufacturer recommendation) | RD, VD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Inventory Controls** |  |  |  |  |  |  |
| Process for identifying unusual prescription drug/device orders, including unusual ordering patterns and amounts, and payments that identify potential diversion or criminal activity. For controlled substances, this process must include how suspicious order quantities are determined and adhered to by the applicant. | RD | Choose an item. |  |  |  |  |
| Process for identifying, recording, and reporting losses, thefts, or otherwise missing prescription drugs and devices |  | Choose an item. |  |  |  |  |
| * Inventory/cycle count schedule; |  | Choose an item. |  |  |  |  |
| * Correcting all errors, inaccuracies, or other adjustments in prescription drug and device inventories; |  | Choose an item. |  |  |  |  |
| * Inventory adjustments with approval by authorized personnel; |  | Choose an item. |  |  |  |  |
| * Protection against unauthorized access to computers or electronic records for purposes of concealing theft or diversion activities; |  | Choose an item. |  |  |  |  |
| * Conducting internal investigations of inventory discrepancies to detect losses/thefts and other possible criminal activity; and |  | Choose an item. |  |  |  |  |
| * In-transit losses/thefts investigated with carrier and trended for evaluation of carrier’s continued service. |  | Choose an item. |  |  |  |  |
| Process for import and/or export when applicable |  | Choose an item. |  |  |  |  |
| * Import process must include FDA clearance | RD | Choose an item. |  |  |  |  |
| * Receipt of a valid certificate of analysis for active pharmaceutical ingredients (APIs) | DD, RD | Choose an item. |  |  |  |  |
| Process for reporting identified criminal activities with regard to prescription drug and device inventory to the state agencies that licensed the facility (eg, the board of pharmacy), FDA, and Drug Enforcement Administration (DEA) (if applicable) in accordance with state and federal laws within three business days of suspecting criminal activity (if DSCSA-related, it must be reported within 24 hours to FDA, per the Verification Focus Point above). |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **FOCUS POINT** | **Does Not Apply To** | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Shipping / Outbound** |  |  |  |  |  |  |
| Process for ensuring the oldest approved stock or short-dated drugs and devices are distributed first | RD, VD | Choose an item. |  |  |  |  |
| Process for ensuring the identity of the drugs and/or devices in each outgoing shipment and that the drug and/or device has not been damaged or held under improper conditions while at the applicant’s facility (prior to shipping) | RD | Choose an item. |  |  |  |  |
| Process for maintaining proper temperature controls in shipments of temperature-sensitive drugs and/or devices labeled as refrigerated, frozen, do not freeze, etc (note that virtual distributors must provide these specifications to the appropriate 3PL for distribution of temperature-sensitive products) | RD | Choose an item. |  |  |  |  |
| * Use of validated shipping containers that include temperature and time-in-transit parameters (ie, container and shipping materials are validated to hold required temperature storage for the duration of shipment), **or** | RD | Choose an item. |  |  |  |  |
| * Use of temperature indicators that will provide shipment acceptability to the customer (must include customer instructions for indicator use and indicator(s) must be used for both hot and cold temperature seasons/geographical areas). | RD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Recalls** |  |  |  |  |  |  |
| Process for handling recalls and voluntary and written withdrawals of drugs and devices |  | Choose an item. |  |  |  |  |
| * Drug or device is removed from active inventory and quarantined; and | VD | Choose an item. |  |  |  |  |
| * Handling returned drugs and devices including screening returns against a list of recent recalled drugs and devices | VD | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Quarantine, Disposition, Returns, and Disposal**  May be included in P&Ps for drug and device returns and destructions  (note that Virtual Distributors (as the product owner) must have a procedure in place that provides 3PL guidance for handling of all types of quarantined products, eg, damaged, temperature-deviated, outdated/short-dated, suspect/illegitimate, otherwise unfit for distribution) |  |  |  |  |  |  |
| Process for determining and documenting drugs and devices to be quarantined (due to temperature excursions or quality hold, damaged, , otherwise unfit for distribution, etc) | RD | Choose an item. |  |  |  |  |
| Process for identifying and handling short-dated/outdated drugs and/or devices that must be segregated from other drugs and devices (quarantined). This process must include at what point the short-dated products are removed from saleable inventory (eg, three months, 30 days). |  | Choose an item. |  |  |  |  |
| Process for determining and documenting drugs to be quarantined (recalled drugs and suspect product/illegitimate product) | RD | Choose an item. |  |  |  |  |
| Documented disposition of quarantined drugs and devices with rationale for returning it to active stock, disposal, return to manufacturer/distributor, etc | RD | Choose an item. |  |  |  |  |
| Process for accepting and distributing returned saleable product from a dispenser or repackager consistent with section 582 (c)(1)(B)(i)(I) of the FD&C Act | AD, DD, MFR, RD, RPKG as applicable, SD, 3PL, 503B | Choose an item. |  |  |  |  |
| **Drug and Device Destruction Process** |  | Choose an item. |  |  |  |  |
| * Documentation of products to be destroyed |  | Choose an item. |  |  |  |  |
| * Disposal must be witnessed and documented by a responsible member of the facility personnel |  | Choose an item. |  |  |  |  |
| * Certificate of destruction must be received from the destruction vendor/reverse distributor, if used |  | Choose an item. |  |  |  |  |
| * Inventory reconciliation (comparison of documentation of product sent for destruction with documentation of product destroyed to ensure all product is accounted for) |  | Choose an item. |  |  |  |  |
| Process for disposing of containers, labels, and packaging that contain drug and device information (Note: In some cases, packaging and labeling is disposed of with the drug or device. If so, explain in the Applicant Comments section below and the following bullets do not apply.) |  | Choose an item. |  |  |  |  |
| * Documentation of disposal (label accountability) and method of destruction used (eg, rendering packaging/labels unusable by marking, shredding, etc.) Process for destroying/defacing drug and device cartons, overwraps, package inserts, and packaging waste generated as part of regular operations to prevent its retrieval and use for counterfeiting or diversion | VD | Choose an item. |  |  |  |  |
| * Disposal witnessed by responsible member of facility personnel (eg, destruction of labels by repackager/relabeler) | VD | Choose an item. |  |  |  |  |
| * Certificate of destruction received from destruction vendor/reverse distributor, if used |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Records**  Compliance may be met through an all-inclusive document or in the individual operational documents. |  |  |  |  |  |  |
| A process to establish and maintain records related to the receipt, storage, wholesale distribution, and disposition of all prescription drugs and devices, including but not limited to, invoices, packing slips, shipping records, sales invoices, agreements, leases, deeds, and certificates of destruction. |  | Choose an item. |  |  |  |  |
| * Process for identification, storage, access, and protection of such records; |  | Choose an item. |  |  |  |  |
| * Process for making all records accessible for inspection within two business days of a request by an authorized official of a federal, state, or local law enforcement agency; and |  | Choose an item. |  |  |  |  |
| * Process for maintaining all records for a minimum of three years, unless otherwise required by the DSCSA (see below). |  | Choose an item. |  |  |  |  |
| A process to establish and maintain records for products, as defined by the DSCSA. This includes: |  | Choose an item. |  |  |  |  |
| * Records demonstrating that all trading partners are authorized; | DD, RD, RPKG as applicable, SD, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Transaction information (TI), transaction history (TH), and a transaction statement (TS) for each transaction, and the maintenance of such records for no less than six years after the date of the transaction; | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Records of a suspect product investigation and the maintenance of such records for no less than six years after the conclusion of the investigation; | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Requests for information from FDA or other appropriate state or federal official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product; | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Illegitimate product notifications and terminations; | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Records of illegitimate product dispositions for no less than six years after the conclusion of the disposition; and | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| * Records of the receipt and distribution of saleable product returned from a dispenser or repackager as well as return of nonsaleable product. | AD, DD, RPKG as applicable, VET, 3PL, 503B as applicable | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **FOCUS POINT** | **Does Not Apply To** | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Crisis Operations** |  |  |  |  |  |  |
| Process for operations during a disaster that affects the facility’s security or operation, including: |  | Choose an item. |  |  |  |  |
| * After-action assessment of drugs and devices to ensure their continued integrity; |  | Choose an item. |  |  |  |  |
| * Record preservation; |  | Choose an item. |  |  |  |  |
| * Drug and device management; | VD | Choose an item. |  |  |  |  |
| * Backup/outsourced resources (power, security, and storage); and |  | Choose an item. |  |  |  |  |
| * Reporting to NABP, DEA, and the state licensing agency when the facility is rendered inoperable for 10 or more days. |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |



**National Association of Boards of Pharmacy® (NABP®) 1600 Feehanville Drive**

**Mount Prospect, Illinois 60056**

**Website:**

***[www.nabp.pharmacy/programs/drug-distributor](http://www.nabp.pharmacy/programs/drug-distributor)***

**Email:** [**VAWD@nabp.pharmacy**](mailto:VAWD@nabp.pharmacy)

**Phone: 847/391-4539**

**Drug Distributor Accreditation**POLICY & PROCEDURE ASSESSMENT

**P&P Index**

For facilities that **share** policies and procedures (P&Ps), list all P&Ps. Place an “X” in the appropriate column to indicate which facility(ies) uses the P&P.

|  |  |  |  |  |  |  |  |  |
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|  | | | Enter the applicable facility location in the column header. If additional columns are needed type over  the “example” facility names. | | | | | |
| **P&P Name** | **P&P Number** | **File Name of Document**  **Sent to NABP** | **[Example] ABC pharmaceutical Nashville, TN** | **[Example] ABC pharmaceutical Chicago, IL** | **[Example] ABC Pharma**  **dba 123 Distr**  **New York, Ny** | **[facility name]** | **[facility name]** | **[facility name]** |
|  |  |  |
| **[Example]** Receiving | SOP 123 | SOP123.doc | X |  | X |  |  |  |
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**Email:** [**VAWD@nabp.pharmacy**](mailto:vawd@nabp.pharmacy)

**Phone: 847/391-4539**

**Drug Distributor Accreditation**

POLICY & PROCEDURE ASSESSMENT

**Off-site functions List**

Provide the requested information for *all* functions performed off site that are essential to your business and relative to the purpose of brokering, shipping, and receiving prescription drugs and devices.

List: Third-Party Logistics Providers (3PLs), “Other” Business Partners, and Intracompany Contributors

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Function Performed** | **Relationship Type** | **Legal Business Name (LBN)** | **Doing Business As Name (DBA)** | **Complete Address** |
| 1 | [Example] Stock, Pick, and Ship | 3PL | Zeta Pharmaceutical Shipping, Inc | Zeta Ships | 555 Abraham Way  Island Lake, WI 66652 |
| 2 | [Example] License Verification | "Other" Bus Partner | Anika Data Services | Anika Data Services | 538 Lakeland Ave  San Antonio, MI 58399 |
| 3 | [Example] State Licensing | Corporate Parent | Alpha Company, LLC | Alpha Company, LLC | 3535 Score Rd  Fish Creek, TX 85622 |
| 4 | [Example] Stock | Same Co/Other Location | Alpha Company, LLC | Alpha Company, LLC | 962 Washington Creek  Park Place, NY 68568 |
| 5 |  | Choose an item. |  |  |  |
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