DISTRIBUTOR ACCREDITATION INELIGIBILITY MATRIX

Drug Distributor Accreditation & OTC Medical Device Distributor Accreditation

Facilities engaged in the below activities are ineligible to pursue distributor accreditation.

If an X appears by your facility type and your facility performs the corresponding activity, it is ineligible to pursue Drug Distributor Accreditation or OTC Medical Device Distributor Accreditation.

This Distributor Accreditation Ineligibility Matrix (DAIM) applies to all new applicants for accreditation.
It is subject to change by NABP without notice at any time, in our sole discretion.
The current, applicable version of this DAIM will be posted on the NABP website, and you should review the DAIM.
Your continued participation in the process of application after a posted change in the DAIM will constitute your acceptance of and agreement to such changes.
In addition, NABP reserves the right to consider each facility's circumstances individually, without reference to others.

Activities *("Drugs" are prescription drugs; "Devices" are prescription devices and diagnostic OTC medical devices pursuant to a prescription)*	**Wholesale Distributors**	**Reverse Distributor**	**3PL**	**503B** *(does not purchase finished drugs for compounding)*	**503B** *(purchases finished drugs for use in compounding)*	**Prescription medical device distributor** *(no drugs or convenience kits with drugs)*	**Prescription medical device distributor** *(convenience kits with drugs)*	**Repackager** *(Does not take ownership)*	**Repackager** *(Takes ownership)*	**Veterinary Drug Distributor** *(distributes no human drugs)*	**Veterinary Drug Distributor** *(distributes human drugs)*	**Samples Distributor**	**API Distributor/ Repackager**	**Investigational Drug Distributors**	**Manufacturers**	**Virtual Distributor**	**Virtual Manufacturers**	**OTC Medical Device Distributor**
Not licensed in all jurisdictions where required	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Does not have a state licensed/registered Designated Representative where required	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Not **operational** for prescription drugs or prescription devices	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Not **operational** for OTC Medical diagnostic devices																		X
Unable to demonstrate during the inspection facility processes related to purchasing, receiving, storing, handling, selling, and/or shipping prescription drugs or prescription devices	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Co-locating applicant and pharmacy without adequate physical separation to secure drugs and devices	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X
Co-locating applicant and reverse distributor without adequate physical separation to secure drugs and devices	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Co-locating wholesale distributor and pharmacy without separate accounts to distinguish drug and device purchases made by the two entities	X															X		X
Distributing adulterated, misbranded, diverted, counterfeit, or illegitimate prescription drugs and devices	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Distributing for an unaccredited (NABP) wholesale distributor not purchasing directly from an FDA registered manufacturer			X															
Buying from an unaccredited (NABP) wholesale distributor who has not purchased directly from an FDA registered manufacturer																X		
Distributing for and/or sourcing from an unregistered FDA manufacturer			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Distributing unapproved compounding kits	X		X	X	X		X		X	X	X	X	X		X	X		
Distributing unapproved drugs and/or devices	X		X	X	X	X	X		X	X	X	X	X		X	X	X	X
Manufacturing, acquiring, purchasing, receiving, storing, selling, offering, or distributing drugs that are not listed with FDA as required	X		X			X	X	X	X	X	X	X	X		X	X	X	
Manufacturing, acquiring, purchasing, receiving, storing, selling, offering, or distributing a prescription device that is not listed with FDA	X		X			X	X	X	X	X	X	X	X		X	X	X	
Located in a private residence	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Not storing contolled substances in accordance with DEA security requirements	X	X	X	X	X		X	X	X	X	X	X	X	X	X		X	
Pattern of repeated noncompliance with DEA biennial inventory, recordkeeping, and/or inventory management requirements	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	
Operating in a facility not of suitable size and construction to facilitate cleaning, maintenance, and proper distribution operations	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
Subject to disciplinary proceedings contrary to section 8.2 of the program **Terms and Conditions**	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Unwilling to install and maintain a continuously operating electronic temperature/humidity recording and monitoring system	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Unwilling to modify a business model that currently includes pharmacies in the supply chain	X		X		X	X	X		X		X		X	X		X	X	X
Unwilling to modify environmental controls to comply with regulatory and manufacturer label requirements (may require installing proper HVAC controls)	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Unwilling to obtain documented rationale for number and location of temperature/humidity probes	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Wholesaling 503B compounded products	X			X	X											X	X	
Unwilling to provide policies and procedures following a request by NABP	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Unwilling to provide records requested by NABP to evidence compliance with certain provisions of law, rule, or program standards	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Unwilling to modify a business model that currently includes purchases not from a manufacturer or a WD that purchased from a manufacturer																		X

Please Note:

- When seeking licensure in states requiring either NABP accreditation or an active accreditation application, facilities must consider the time required for inspection completion and a decision by NABP whether the facility is eligible to pursue accreditation.
- All regulators may not accept a Supply Chain Inspection to satisfy requirements. If this is a needed outcome for an applicant, it is suggested affirmative written confirmation from the regulator is obtained before submitting an application.
- This Distributor Accreditation Ineligibility Matrix applies to all new applicants for accreditation.
- Facilities must be operational for 30 days before completing an inspection.