WHOLESALE DISTRIBUTOR INSPECTION REPORT

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
(617) 973-0800
(617) 973-0988 TTY

DATE(S) OF INSPECTION:				INSPECTION #:							
BUSINESS NAME (DBA):											
STREET ADDRESS:											
CITY / STATE / ZIP:											
DESIGNATED REPRESENTATIVE (REP):											
REP. YEARS AT BUSINESS:											
REP. TELEPHONE:											
REP. FAX:											
REP EMAIL:											
WHOLESALER PERMIT #:											
PERMIT EXPIRATION:											
DEA REG. NUMBER:											
DEA REG. EXPIRATION:											
OPERATING HOURS:	MON		TUE		WED		THU		FRI		
	SAT				SUN						
# OF YEARS AT CURRENT BUSINESS ADDRESS:											
STATES SHIPPING INTO:											
AVG. ORDERS SHIPPED DAILY:											
GENERAL DESCRIPTION OF DISTRIBUTION ACTIVITIES:											
BUSINESS MEMBERS PRESENT FOR INSPECTION AND ROLE:											

Item #	Requirement	Y/N/N/A	Comment
A	**LAWS/REGULATIONS**		
1	Are systems in place for ongoing monitoring of state and federal laws/regulations for changes?		
2	Are resources and related training in place for staff to apply the changes in laws/regulations into current practices?		
3	Are the most stringent laws/regulations followed between the host state, the state being shipped into, and federal requirements, where applicable, and including DSCSA?		
4	If the above functions are performed at a different location, who is the primary contact?		
5	Does the applicant have any open or pending regulatory actions pertaining to the distribution of drugs or operation of the facility?		
B	**REPORTING AND NOTIFICATIONS**		
6	Who is responsible at this facility for making suspect product determinations? (NA if Virtual)		
7	Has the facility received any requests for verification of suspect product from FDA?		
8	Has any suspect product been identified by the facility (defined by DSCSA as counterfeit, diverted, stolen, intentionally adulterated, part of a fraudulent transaction)?		
9	Has suspect product been investigated?		
10	Has any product been determined to be illegitimate?		
11	Was the determination made in coordination with the manufacturer?		
12	Was it reported to FDA and to anyone to whom the product was shipped (if applicable), within 24 hours?		
13	• Has a termination notification taken place in consultation with FDA? *NOTE: Mark NA if they have no illegitimate product.*		
14	Have any illegitimate product notifications been **received** from FDA or from trading partners?		
15	Was a corresponding suspect product investigation conducted?		
16	Did the facility have any of the illegitimate product indicated in the notification in stock?		
17	If so, was it moved to quarantine and a sample kept?		
18	Was the FDA notified within 24 hours?		
19	Did they receive, transfer or distribute any of the product indicated in the notice?		
20	If so, did they notify applicable trading partners within 24 hours?		
21	Has any other prescription drug or device (not defined as illegitimate product under the DSCSA such as APIs, blood components, IV products, etc.) been identified which is counterfeit, diverted, misbranded, adulterated or tampered with, part of a fraudulent transaction, or otherwise unlawful?		
22	Was it reported outside the facility? To whom? *Review reports.*		

Item #	Requirement	Y/N/N/A	Comment
B	**REPORTING AND NOTIFICATIONS**		
23	Has any theft, pilferage, or unexplained excessive loss of any prescription drug been identified?		
24	If it involved a controlled substance, was it reported to DEA?		
25	Was it reported to any other agency outside the facility?		
26	If criminal activity involving inventory is suspected, does reporting to outside agencies happen within 3 days?		
C	**FACILITY LICENSES/PERMITS/REGISTRATIONS**		
27	Is there any substantial change to the customer base and/or state licenses since the last information was provided to NABP?		
28	Is the business licensed in all applicable jurisdictions where prescription products are distributed? (or received from, for reverse distributors).		
29	Review at least three customer profiles and compare addresses to licenses? Is there a license for each state in which the customer resides?		
30	Are domicile state licenses displayed, and other state licenses available for review?		
31	Does the facility hold federal and state controlled substance licenses appropriate to their controlled substance activity? Observe the licenses to ensure they are valid.		
32	If repackager, does facility hold appropriate Food and Drug Administration (FDA) registration?		
33	Are adequate systems in place for maintaining current licenses?		
34	Are sufficient systems in place to prevent prescription products from being shipped into states (or received from states for reverse distributors) where the applicant does not hold a license?		
35	If any of the above is done at a different location, who is the primary contact?		
D	**POLICIES & PROCEDURES AND RECORD RETENTION**		
36	Are the policies and procedures site specific? .		
37	each owned by an individual or department for updating and implementation?		
38	reviewed routinely to ensure they stay current?		
39	Is the most current P&P being followed?		
40	Are adequate systems, processes, facilities, and employee training in place to facilitate the collection and archiving of all records associated with a wholesale distributor as required by law/regulation?		
41	Does the system include adjustments to audits?		
42	Does the system include records of destruction?		
43	Does the system include DEA records (controlled substance product movement and inventories)?		

Item #	Requirement	Y/N/N/A	Comment
D	**POLICIES & PROCEDURES AND RECORD RETENTION**		
44	Are suspect product investigations, illegitimate product determinations and product tracing information (Transaction Information, Transaction History, Transaction Statement) archived for at least 6 years?		
45	Are pedigree records archived?		
E	**PERSONNEL**		
46	Is the designated representative physically present at the applicant facility during normal business hours (except for customary leave times), and actively involved in the management of overall distribution operations?		
47	Are job applicants required to complete adequate application/resumes? Do they include contact information, previous employment, references, education, etc?		
48	Is application information confirmed with relevant parties, and the confirmations documented?		
49	Are criminal background checks conducted on “key” employees with access to drugs/devices?		
50	Do new employees receive adequate training related to:		
51	the general operations/systems of the facility?		
52	critical operations related to their assigned task?		
53	operational safety?		
54	Do employees receive continued training in critical operations? How often?		
55	Is training documented?		
56	Are job appraisals/performance reviews and disciplinary actions performed and documented?		
F	**IT SECURITY**		
57	Are computers password protected?		
58	Are passwords required to be changed at least every 90 days?		
59	Are systematic processes in place to prevent employees from accessing data/systems unrelated to their job critical task?		
60	Are purchases, sales, shipments, and inventory-adjustment data files audit controlled?		
61	How often is data backed-up?		
62	Is backup data stored off-site?		
63	Do other entities (corporate, related divisions, or other companies) have access to computer data?		
G	**AUTHORIZED TRADING PARTNER – SOURCES/VENDORS**		
64	Does applicant determine that each new vendor holds appropriate licenses/permits/registrations for the level of service it’s providing?		
65	Does the applicant verify these directly with the appropriate state and federal agencies (including FDA) prior to engaging in purchasing?		

Item #	Requirement	Y/N/N/A	Comment
G	**AUTHORIZED TRADING PARTNER – SOURCES/VENDORS**		
66	Does applicant re-verify vendors' licenses/permits/registrations directly with the appropriate state and federal agencies at least annually (including FDA)?		
67	Are there any vendors (non-manufacturer) from whom the facility has purchased prescription drugs and devices that are NOT on the most recent submitted vendor list? .		
68	Has the facility purchased prescription drugs and devices from a non-manufacturer vendor who subsequently exhibited suspect activity (unusually low price, prescription labels on bottles, worn labeling, shortage drugs with questionable procurement history, etc.) or were unable/unwilling to supply complete transaction information, or provided questionable transaction history (pedigree if prior to 1/1/15), in the last 3 years?		
69	Do you still purchase products from the vendors identified above?		
70	Are prescription drugs and devices purchased from wholesalers or repackagers that did not purchase those items directly from the manufacturer?		
71	• If yes, are any due diligence activities conducted with each trading partner?		
72	Does the facility have processes in place to ensure trading partners provide prescription drugs that were legitimately obtained from each previous owner?		
73	Does the facility ensure that prescription drugs and devices purchased from trading partners were not previously distributed to: (1) pharmacies; (2) healthcare entities; or, (3) in violation of contracts for "own use" or other restrictions limited by Group Purchasing Contracts or Federal Purchasing Programs, such as 340B.		
74	Does the facility purchase (or sell/broker for Virtuals) API (bulk active pharmaceutical ingredients)?		
75	Do they determine that the supplier of the API is legitimate?		
76	Do they determine the legitimacy of the supplier's **sources** of API?		
77	Do they determine that the API is legitimate?		
H	**AUTHORIZED TRADING PARTNER - CUSTOMERS**		
78	Does applicant determine that each new customer holds appropriate licenses/permits/registrations for the level of service it's providing?		
79	Does applicant verify customers' licenses directly with the appropriate state and federal agencies (including FDA)?		
80	Does applicant have adequate processes in place for monitoring purchase activity of customers and identifying ordering patterns that suggest criminal activity related to controlled substances?		
81	Was a suspicious order monitoring report available to observe?		
I	**QUALITY PROGRAM**		
82	Is a quality assurance/improvement program in place that addresses areas of critical operations?		
83	Is information collected as part of the program used to track trends and improve processes?		

Item #	Requirement	Y/N/N/A	Comment
I	**QUALITY PROGRAM**		
84	Are **product** complaint files maintained locally (Complaints from customers about the product integrity, not delivery times, etc.)?		
85	Do any of the product complaints investigation result in a determination that the product is a "suspect" or "illegitimate" product?		
86	If so, what actions were taken as a result of the determination?.		
J	**RECALLS**		
87	If a specific item is subject to a recall, is there a way to identify all the customers to whom the product has been distributed?		
88	Are recall records maintained and reports made to FDA/manufacturer when required by the recall notice?		
89	Do employees demonstrate adequate knowledge of processes and proper techniques for complying with all classes of recalls?		
90	Are recalled products immediately removed from stock and placed in quarantine when required by the recall notice? (NA for Virtuals)		
K	**CRISIS OPERATIONS**		
91	Are adequate processes in place to ensure security, product integrity, and maintenance of critical records during emergency conditions?		
92	Does staff receive training related to crisis operations?		
93	Are adequate processes in place, and is staff properly trained to conduct after-action assessment of prescription products to ensure products' integrity was not compromised due to the crisis? (NA for Virtuals)		
94	Is sufficient power back-up in place (such as a generator) for use during emergency conditions? (NA for Virtuals)		
95	If components of crisis operation procedures are outsourced (such as security or climate controlled off-site storage facilities), are contracts/formal agreements in place guaranteeing the availability of the services at time of a crisis. (NA for Virtuals)		
L	**COMMON CARRIER** (NA for Virtuals)		
96	Does the facility use its own fleet and drivers to deliver prescription products?		
97	Does the facility use any couriers or common carriers to deliver prescription products?		
98	For couriers/common carriers, are processes in place to ensure security of products while the items are in their care?		
99	Are adequate processes in place for monitoring trends related to all prescription product losses while in-transit?		
100	reporting losses and trends to the carrier?		
101	discontinuing business with a carrier if trending determines a pattern of unresolved losses?		
102	investigating losses in coordination with the carrier?		
103	reporting trends of in-transit losses to law enforcement agency(s)?		

Item #	Requirement	Y/N/N/A	Comment
M	**FACILITY**		
104	Is the facility of sufficient size, construction, and design to provide adequate lighting, separation of work areas, and storage/movement of product in an orderly and safe manner? (NA for Virtuals)		
105	Is the applicant located in a personal dwelling?		
106	Are restrictions enforced on food/drink and/or personal items (purses, backpacks, large coats) in the prescription processing and storage areas? (NA for Virtuals)		
107	Are housekeeping functions sufficient to ensure the facility is kept in a clean and well maintained manner at all times? Review supporting documentation for cleaning and sanitation schedules. (NA for Virtuals)		
108	Are there secure trash removal processes in place in order to deter or detect theft of prescription product, packaging and product labeling? (NA for Virtuals).		
109	Are pest control services sufficient to control against insects, birds, and vermin? (NA for Virtuals)		
N	**FACILITY SECURITY** (NA for Virtuals)		
110	Is the perimeter of the facility adequately secured and well lighted?		
111	Does the facility have a security system (contact alarms, motion detectors, glass break detectors, etc.) that adequately covers product storage areas including all entrances/exits or other openings (windows that open, skylights, roof access doors) during and after business hours?		
112	Are emergency exits equipped with an audible alarm or other means to detect opening during normal business hours?		
113	Are alarm codes and after-hours entry authorizations limited to only necessary management?		
114	Can the facility identify who accesses the facility after hours?		
115	Are visitors required to sign-in/sign-out?		
116	If there are contract services (housekeeping, pest control), have employees had background checks and are bonded?		
117	Are visitors escorted at all times they are in the facility?		
118	Is any area of the facility shared with another business?		
119	Identify and describe the other business.		
120	Are there prescription drug transactions between the applicant and the co-located business?		
121	Are adequate methods/systems/devices in place for separating out/securing all aspects of the applicant's operations, both physical and financial?		
122	Are systematic processes and equipment in place to limit entry into the prescription processing/storage area to only authorized task-critical employees?		
123	Are adequate security devices in place for securing bay doors?		
124	Are video surveillance methods in place? (Not required)		

Item #	Requirement	Y/N/N/A	Comment
N	**FACILITY SECURITY** (NA for Virtuals)		
125	Is the monitoring station secured?		
126	Who has access to the monitoring station and tapes/images?		
127	Are tapes/images retained?		
O	**IN-BOUND PRODUCT AND RECEIVING** (NA for Virtuals)		
128	**Do employees demonstrate proper knowledge and techniques related to:** Examination of the physical package, case, or tote for signs it has been opened, broken seal, damaged, leaking, repaired, or altered		
129	Examination of label on the package, case, or tote examined for shipping address, postmarks, shipping address cut out, other indications that the product came from an unexpected foreign entity or source		
130	Examination of the product for short dating, damage, leaking, broken seals, prescription labels or tape residue, missing package inserts or package inserts for different product		
131	Foreign labeling, altered information on product, smudged or difficult to read print, missing lot number/NDC or strength, worn labels, misspelled words, bubbling on surface of the label, color or format of label does not seem usual		
132	Doesn't match purchase order, packing slip discrepancies, order changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).		
133	If any of the above are detected, process for refusing the package, or moving to quarantine?		
134	Are the issues detected reported to management?		
135	Identifying temperature-sensitive items, and the method of ensuring that temperatures are maintained within label requirements upon receipt?		
136	Identifying controlled substances products and securing them upon receipt?		
137	Is the receipt of transaction data verified prior to receiving product into active stock (for those products for which it is required)?		
138	Returns – returns of prescription products are identified at receiving and moved to quarantine in a timely manner?		
139	Are received products entered into a computer database for tracking throughout the period applicable to inventory record requirements?		
P	**PRODUCT TRACING**		
140	Does the facility identify "products" (as defined under section 581(13) of the FD&C Act) requiring "Transaction" data?		
141	Does the facility purchase/receive (sell/broker if Virtual) prescription drugs that are NOT defined as "products" (so do NOT require transaction data)?		
142	Is transaction data received for all products for which transaction data is required.		
143	Is transaction data transmitted for all products for which transaction data is required.		

Item #	Requirement	Y/N/N/A	Comment
P	**PRODUCT TRACING**		
144	Select a product from each of the vendors indicated in the surveyor notes above and examine transaction data (Transaction Information, Transaction History, Transaction Statement). List vendors in comments.		
145	Is the transaction data received and complete?		
146	Does the data trace back to the manufacturer (may include direct purchase statements)?		
147	Is data transmitted to all customers (surveyor view/verify all subsequent transactions)?		
148	Select a product from each vendor that the facility purchases from that is NOT on the list of vendors supplied to NABP (if applicable) and examine transaction data.		
Q	**TEMPERATURE** (NA for Virtuals)		
149	Does the facility have both heating and cooling (HVAC) for all product storage areas?		
150	Are processes and sufficient equipment in place for monitoring and recording temperature:		
151	at all times **(24/7/365)?**		
152	in the general prescription product receipt, storage, and shipping areas?		
153	in cold storage areas (refrigerators/freezers/cold rooms)?		
154	Are monitors/probes located sufficiently and in ample numbers to adequately cover all prescription products in processing/storage areas?		
155	Is monitoring equipment calibrated no less than annually or otherwise in compliance with its manufacturer's recommendations?		
156	Are records of temperature storage conditions maintained?		
157	Is the temperature in the main storage area within range set?		
158	Is the temperature in the refrigerated area(s) within range set?		
159	Is the temperature in the freezer(s) area within range set?		
160	Do employees demonstrate adequate knowledge and proper techniques related to:		
161	identifying temperature requirements for all products?		
162	following up when a temperature excursion occurs 24/7/365?		
R	**HUMIDITY** (NA for Virtuals)		
163	Does the facility handle products with specific humidity requirements or APIs?		
164	If so, are processes and sufficient equipment in place for monitoring humidity:		
165	at all times **(24/7/365)?**		
166	in the general prescription product receipt, storage, and shipping areas?		
167	are monitors/probes located sufficiently and in ample numbers to adequately cover all prescription products in processing/storage areas?		
168	Is monitoring equipment calibrated no less than annually or otherwise in compliance with its manufacturer's recommendations?		
169	Are records of humidity storage conditions maintained?		
170	Is the humidity in the drug storage areas within the range set?		
171	Do employees demonstrate adequate knowledge and proper techniques related to:		

Item #	Requirement	Y/N/N/A	Comment
R	**HUMIDITY** (NA for Virtuals)		
172	identifying humidity requirements for all products?		
173	following up when a humidity excursion occurs?		
S	**CONTROLLED SUBSTANCES** (NA for Virtuals)		
174	Are controlled substances stored in a Drug Enforcement Administration (DEA) approved cage/vault?		
175	Is the controlled substance cage/vault equipped to ensure entry is limited to only authorized personnel?		
176	How is access to the cage/vault monitored such as a log book, electronic record, etc.?		
177	Is there a visitor log maintained to document access by others (maintenance, inspections, etc.)?		
178	Are non-controlled substances stored within the DEA cage/vault?		
179	Are adequate processes in place for handling List I chemicals?		
180	Are periodic inventories performed and reconciled for **Schedule II** controlled substances?		
181	Are periodic inventories performed and reconciled for **Schedule III-Schedule V** controlled substances?		
182	Does the facility conduct a complete inventory of all controlled substances at least biennially?		
183	Are DEA 106 forms on file? Observe three to five reports.		
184	If so, does the number of reports, or the quantity of product reported as lost, indicate possible inadequate controls?		
185	Was appropriate internal follow-up conducted regarding the losses?		
186	Are patterns of losses evident in the reports?		
187	Is the facility operating under a DEA directive, either formal or informal, regarding the reporting of controlled substance purchases that are more restrictive than CFR requirements?		
T	**QUARANTINE** (NA for Virtuals)		
188	Are processes in place for segregating prescription drugs or devices:		
189	that have been returned?		
190	whose immediate container has been opened?		
191	that are out of date?		
192	that have been recalled?		
193	are determined to be suspect or illegitimate product		
194	any other prescription drug or device that may be damaged, counterfeit, contraband, adulterated, or misbranded, diverted, tampered with, or whose labeling is suspect?		
195	Are quarantined products segregated from other stock?		
196	If electronic, are processes adequate to ensure against quarantined products being commingled with saleable stock?		

Item #	Requirement	Y/N/N/A	Comment
T	**QUARANTINE** (NA for Virtuals)		
197	If manual, are sufficient physical barriers and signage present to prevent commingling?		
198	Are adequate processes present to ensure security of quarantined controlled substances?		
199	Is there a segregated quarantine area in the refrigerator and freezer (if applicable)?		
200	Do employees performing quality checks on quarantined product being considered for placement into saleable stock (such as returns) demonstrate knowledge of processes and proper techniques?		
201	Record decisive factors used for vetting of product before returning to stock.		
202	Is there a record, evidence, or signed statement from the customer returning the item that indicates the products were stored under conditions to preserve product integrity (that includes transportation conditions for temperature sensitive items)		
203	Are adequate records maintained for documenting the quality checks of quarantined product that is returned to stock?		
204	Are returned products checked against list of recalled products?		
205	Is a perpetual inventory maintained for all prescription products in quarantine?		
206	**Are processes for destroying out-of-date or damaged products sufficient?**		
207	If in-house, are disposals/destructions witnessed by an appropriately authorized person?		
208	If an outside vendor is used for destroying prescription products, what is the company name?		
209	Does the applicant require proof of destruction records to be returned from the destruction agency?		
210	Are records verifying destruction or product returned to the vendor maintained?		
211	Do employees demonstrate adequate knowledge of processes and proper techniques for disposing of containers, labels, and packaging containing critical prescription product information to ensure that the items cannot be reused?		
212	For repackagers or relabelers, are records of disposal/destruction of containers, labels, and packaging maintained?		
213	**Suspect Product** is kept in quarantine until dispositioned (destroyed, returned, held for analysis) or cleared for distribution?		
214	**Illegitimate product** is kept in quarantine until dispositioned		
215	Sample is retained for analysis, if appropriate or requested by manufacturer or FDA?		
216	*Review an illegitimate product notification sent to the FDA by the facility (if applicable), and audit on-hand quantity and disposition records against quantity indicated in the notification.* Did the records and on-hand quantity match the quantity in the illegitimate product notification to FDA?		

Item #	Requirement	Y/N/N/A	Comment
U	**INVENTORY** (NA for Virtuals)		
217	Do employees demonstrate adequate knowledge of processes and proper techniques related to: monitoring prescription products for first-in, first-out/expiration dates?		
218	identifying and moving to quarantine, products that while in stock at the facility:		
219	have become out-of-date?		
220	have had their packaging opened?		
221	have possibly been subjected to temperature/humidity excursions?		
222	have become suspected of being adulterated/misbranded/or the integrity of which might otherwise have been compromised?		
223	Are cycle counts used to identify product shortages/losses?		
224	How often are cycle counts performed?		
225	Who has authority to adjust inventories related to inventory discrepancies?		
226	Does that person sign off on all adjustment records?		
227	Are inventory adjustment records archived for three years?		
V	**ORDER FULFILLMENT AND SHIPPING** (NA for Virtuals)		
228	Do employees demonstrate adequate knowledge of processes and proper techniques for filling customers' orders with accuracy and without jeopardizing the integrity of products?		
229	Do employees demonstrate adequate knowledge of processes and proper techniques for verifying and preparing orders for shipment?		
230	ensuring the integrity of products (including maintaining temperature/humidity requirements) is not jeopardized while being staged/held in the shipping department?		
231	prevent theft of prescription products while in the shipping area and during shipment?		
232	ensuring that the integrity of products requiring refrigeration/freezing is maintained during shipment?		
233	Are the shipping containers validated for maintaining appropriate temperature for the duration of shipment or other means to verify temperature?		
234	Does the facility have testing data from the manufacturer or supplier of the packaging that indicates appropriate performance under the temperature extremes of the destinations to which products are shipped?		
235	Does the facility perform its own testing during both hot and cold temperature extremes of the destinations to which products are shipped?		
236	Does the facility utilize temperature indicators or devices?		
237	Does the facility monitor weather/temperatures at the destinations and use to alter deliveries, if necessary?		

Observations

Plan of Correction:

Inspection Completion
Exit Interview
Plan of Correction (POC) Issued: ☐ Yes ☐ No Plan of correction for all findings due within 15 business days. POC Due: _____

Investigator Signatures	
Investigator:	
Date:	
Investigator:	
Date:	
Investigator:	
Date:	
Investigator:	
Date:	