

**Wholesaler of Drugs, Medical Devices, and/or Cosmetics Mobile Inspection Form**

The State of Connecticut Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

**Wholesaler of Durable Medical Equipment (DME) Compliance, Opening, and Relocation Inspection Form**

**Durable Medical Equipment (DME) Questions**

		Yes	No	Advised
1	Did the wholesaler provide a list of officers, directors, managers, and other persons in charge of wholesale durable medical equipment distribution, storage, and handling, including a description of their duties and a summary of their qualifications?			
2	Have wholesaler personnel been provided with appropriate education and/or experience to assume responsibility for the positions related to compliance with registration requirements?			
3	Are all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed of suitable size and construction to facilitate cleaning, maintenance, and proper			
4	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate lighting?			
5	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate ventilation?			

6	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate temperature?			
7	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate sanitation?			
8	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate humidity?			
9	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate space?			
10	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate equipment?			
11	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have storage areas designed to provide adequate security conditions?			
12	Do all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed have a quarantine area for storage of durable medical equipment that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened?			
13	Are all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed maintained in a clean and orderly condition?			

14	Are all facilities at which durable medical equipment is stored, warehoused, handled, offered, marketed, or displayed free from infestation by insects, rodents, birds, or vermin of any kind?			
15	15. Is the wholesaler's facility secure against any unauthorized entry?			
16	Is access from outside of the wholesaler's premises kept to a minimum and well controlled?			
17	Is the perimeter of the wholesaler's facility well-lighted?			
18	Is entry into areas where the wholesaler holds durable medical equipment limited to authorized personnel only?			
19	Is the wholesaler's facility equipped with an alarm system to detect entry after business hours?			
20	Is the wholesaler's facility equipped with a security system that will provide suitable protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records?			
21	Does the wholesaler store all durable medical equipment at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such durable medical equipment?			
22	Are storage requirements established for all durable medical equipment stored by the wholesaler?			

23	Does the wholesaler hold durable medical equipment at "controlled" room temperature, as defined in an official compendium, to help ensure that each durable medical equipment's identity, strength, quality, and purity is not adversely affected?			
24	Does the wholesaler undertake the appropriate measures to ensure that durable medical equipment is stored under conditions of proper temperature and humidity?			
25	Does the wholesaler adequately document temperature and humidity?			
26	Does the wholesaler, upon receipt, visibly examine each outside shipping container for identity?			
27	Does the wholesaler, upon receipt, visibly examine each outside shipping container to prevent the acceptance of contaminated durable medical equipment that is otherwise unfit for distribution?			
28	Does the wholesaler carefully inspect each outgoing shipment for identity of the durable medical equipment?			
29	Does the wholesaler carefully inspect each outgoing shipment to ensure that there is no delivery of durable medical equipment that has been damaged in storage or held under improper conditions?			
30	Does the wholesaler quarantine and physically separate durable medical equipment that is outdated, damaged, deteriorated, misbranded, or adulterated from other durable medical equipment until they are destroyed or returned to the supplier?			

31	Does the wholesaler quarantine and physically separate durable medical equipment whose immediate containers have been identified as opened or used from other durable medical equipment until they are either destroyed or returned to the supplier?			
32	Does the wholesaler quarantine and physically separate durable medical equipment whose sealed outer containers have been identified as opened or used from other durable medical equipment until they are either destroyed or returned to the supplier?			
33	Does the wholesaler quarantine and physically separate durable medical equipment whose sealed secondary containers have been identified as opened or used from other durable medical equipment until they are either destroyed or returned to the supplier?			
34	Has the wholesaler experienced any situations in which the conditions under which durable medical equipment was returned cast doubt on the durable medical equipment's safety, identity, strength, quality, or purity?			
35	Did the wholesaler handle the durable medical equipment appropriately when the conditions under which the durable medical equipment was returned cast doubt on its safety, identity, strength, quality, or purity?			
36	Do the inventory and record of receipt, distribution, and other disposition bear the name and principal address of the seller or transferror?			
37	Do the inventory and record of receipt, distribution, and other disposition bear the address of the location from which durable medical equipment was shipped or in the case of distribution the name and address of the purchaser?			

38	Do the inventory and record of receipt, distribution, and other disposition bear the identity of durable medical equipment received and distributed or disposed of?			
39	Do the inventory and record of receipt, distribution, and other disposition bear the quantity of durable medical equipment received and distributed or disposed of?			
40	Do the inventory and record of receipt, distribution, and other disposition bear the dates of receipt and distribution or other disposition of durable medical equipment?			
41 & 42	Where does the wholesaler keep the inventories and records of all transactions regarding the receipt and distribution or other disposition of products?			
	Inspection site			
	Immediately retrievable by computer or other electronic means			
	Central location apart from inspection site and not electronically retrievable			
	Other			
	Are the wholesaler's records of all transactions regarding the receipt and distribution or other disposition of durable medical equipment kept at either the <b>inspection site or immediately retrieved by computer or other electronic means</b> readily available for authorized inspection during the retention period?			
	Are the wholesaler's records of all transactions regarding the receipt and distribution or other disposition of durable medical equipment kept at a <b>central location apart from the inspection site and not electronically retrievable</b> made available for inspection within two working days of a request by an authorized official of a Federal, State, or local agency during the retention period?			
	43	Does the wholesaler make inventories and records available for inspection and photocopying by authorized Federal, State, or local officials for three years following the disposition of durable medical equipment?		

44	Does the wholesaler have a written procedure in which the oldest stock or durable medical equipment product is distributed first?			
45	Does the wholesaler have a written procedure for handling durable medical equipment recalls and durable medical equipment withdrawals due to the U.S. Food and Drug Administration or other Federal, State, or local law enforcement, or government agency, voluntary action by the manufacturer?			
46	Does the wholesaler have a written procedure to ensure that the wholesaler prepare for, protect against, and handle any crisis that affects security or operation in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency?			
47	Does the wholesaler have a written procedure to ensure that any outdated durable medical equipment is segregated from other durable medical equipment and either returned to the manufacturer or destroyed?			
<b>Additional Comments</b>				
<b>Yes    No</b>				
1	Does the inspecting agent have any additional comments with respect to this wholesaler inspection?			