

Collection Receptacle Mobile Inspection Form

The 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.

Pharmacy Collection Receptacle

General Questions		Yes	No	Advised
1	Does the authorized collector have written operating procedures for the collection receptacle? [Section 20-576a-2(c)]			
2	Does the authorized collector participate in take-back events, as defined in 21 CFR 1317.65, within the interior of the same building in which the authorized collector's collection receptacle is located? [Section 20-576a-2(e)]			
3	Does the authorized collector participate in mail-back programs, as outlined in 21 CFR 1317.70, whereby the authorized collector receives drugs returned to it via mail? [Section 20-576a-2(f)]			
4	Does the authorized collector dispose of its inventory or stock of drugs in the collection receptacle? [Section 20-576a-2(g)]			
5	Does the authorized collector maintain the confidentiality of ultimate users that utilize the collection receptacle? [Section 20-576a-2(h)]			
6	Do employees, including authorized employees, of the authorized collector handle, count, sort, or inventory any drugs brought by ultimate users for deposit in the collection receptacle? [Section 20-576a-2(i)]			
7	Are all records required by Sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies kept on the premises of the authorized collector? [Section 20-576a-2(k)]			
8	Are all records required by Sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies maintained current and separate from other business records in such form as to be readily available for inspection and copying by the Commissioner of Consumer Protection at reasonable times? [Section 20-576a-2(k)]			

9	Does the authorized collector maintain all records required by Sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies for a period of no less than three years? [Section 20-576a-2(k)]			
10	Does the authorized collector permit the Commissioner of Consumer Protection to enter and inspect its premises and collection receptacles, and audit its records and written operating procedures, at reasonable times and in a reasonable manner? [Section 20-576a-2(j)]			
11	Is the authorized collector aware that when it intends to discontinue its use of the collection receptacle it shall notify the Director of Drug Control in writing thirty days prior to discontinuing collection activities? [Section 20-576a-2(1)]			

Requirements		Yes	No	Advised
1	Is the collection receptacle lockable? [Section 20-576a-3(a)]			
2	Is the collection receptacle sturdy? [Section 20-576a-3(a)]			
3	Is the collection receptacle securely fixed within the authorized collector's registered location? [Section 20-576a-3(a)]			
4	Does the collection receptacle have a one-way access point to allow ultimate users to deposit drugs? [Section 20-576a-3(a)]			
5	Does the collection receptacle have two locking mechanisms for access to the collection receptacle's inner liner with different keys for operating such locks for simultaneous use by two different authorized employees? [Section 20-576a-3(b)]			
6	Are the different keys for operating the two locking mechanisms for access to the collection receptacle's inner liner maintained in a secure location?			
7	Does the collection receptacle's one-way access point have a locking mechanism to prevent the acceptance of drugs when the pharmacy is closed or the collection receptacle's inner liner is full? [Section 20-576a-3(b)]			
8	Is the key for operating the locking mechanism for the collection receptacle's one-way access point maintained separate from the different keys for operating the two locking mechanisms for access to the collection receptacle's inner liner?			

Signage		Yes	No	Advised
1	Does the collection receptacle bear a sign for the types of drugs permitted for deposit? [Section 20-576a-3(g)(1)]			

2	Does the collection receptacle bear a sign for prohibited items? [Section 20-576a-3(g)(2)]			
3	Does the collection receptacle bear a sign that no drugs intended for return are to be left in the vicinity of the collection receptacle at any time? [Section 20-576a-3(g)(3)]			

Security		Yes	No	Advised
1	Is the collection receptacle at least five feet away from waste or trash receptacles located in public areas? [Section 20-576a-3(h)]			
2	Is the collection receptacle located in the immediate proximity of a designated area where controlled drugs are stored and at which an authorized employee is present? [Section 20-576a-3(d)]			
3	Is the collection receptacle visible to authorized employees? [Section 20-576a-3(d)]			
4	Does the collection receptacle only accept drugs when the authorized collector is open for business and an authorized employee is present? [Section 20-576a-3(e)]			
5	Is the collection receptacle secured pursuant to the procedures required by Section 20-576-18 of the Regulations of Connecticut State Agencies when the pharmacy is closed? [Section 20-576a-3(f)]			
6	Is the collection receptacle locked to prevent ultimate users from depositing any drugs when the drug fill level of the collection receptacle's rigid container has reached a point where overfill is imminent? [Section 20-576a-3(c)]			
7	Are the collection receptacle's locks kept in good working order with keys removed therefrom? [Section 20-576a-3(b)]			
8	Are keys to the collection receptacle's locks left in a location accessible to anyone other than specifically authorized employees? [Section 20-576a-3(b)]			
9	Are all of the collection receptacle's access points and the sealing of collection receptacle's inner liners continuously monitored by video camera with a minimum of fourteen days of information storage? [Section 20-576a-3(i)]			
10	Is all stored video of the collection receptacle made available upon request of the Commissioner not later than forty-eight hours after such request? [Section 20-576a-3(i)]			
11	Does the authorized collector when aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information retain an unaltered copy of the recording until the investigation or proceeding is closed or the person or entity conducting the investigation or proceeding notifies the authorized collector that it is not necessary to retain the recording? [Section 20-576a-3(i)]			

12	Do special hazards exist such as extremely large stock, exposed handling, or unusual vulnerability to loss, theft, diversion, or robbery where additional safeguards are required by the Commissioner? [Section 20-576a-3(j)]			
13	Does the authorized collector maintain the collection receptacle to prevent theft and unauthorized access of the collection receptacle or the collection receptacle's inner liner? [Section 20-576a-3(k)]			
14	Has the authorized collector had any loss, theft, serious damage, or destruction of the collection receptacle or its contents?			
15	Has the authorized collector reported any and all loss, theft, serious damage, or destruction of the collection receptacle or its contents within seventy-two hours of any such occurrence to the Director of the Drug Control Division? [Section 20-576a-3(l)]			

Inner Liners		Yes	No	Advised
1	Is access to the collection receptacle's inner liners restricted to employees of the authorized collector? [CFR 1317.60(b)]			
2	Do the collection receptacle's inner liners bear a permanent, unique identification number that enables the collection receptacle's inner liners to be tracked? [Section 20-576a-4(a) and CFR 1317.60(a)(5)]			
3	Do the collection receptacle's inner liners contain an absorbent material sufficient to prevent leakage of any drugs deposited in the collection receptacle? [Section 20-576a-4(b)]			
4	Are the collection receptacle's inner liners waterproof? [CFR 1317.60(a)(1)]			
5	Are the collection receptacle's inner liners tamper-evident? [CFR 1317.60(a)(1)]			
6	Are the collection receptacle's inner liners tear resistant? [CFR 1317.60(a)(1)]			
7	Are the collection receptacle's inner liners removable and sealable immediately upon removal without emptying or touching the contents? [CFR 1317.60(a)(2)]			
8	Are the contents of the collection receptacle's inner liners viewable from the outside when sealed? [CFR 1317.60(a)(3)]			
9	Do the collection receptacle's inner liners have the size of the collection receptacle's inner liner clearly marked on the outside of such liner (e.g. 5-gallon, 10-gallon, etc.)? [CFR 1317.60(a)(4)]			
10	Are the collection receptacle's inner liners placed in or a part of the collection receptacle's rigid container prior to use and placement inside the collection receptacle? [Section 20-576a-4(c)]			

11	Is the permanent unique identification number of the collection receptacle inner liner marked, in a clear and permanent manner, on the rigid container prior to placement inside the collection receptacle? [Section 20-576a-4(c)]			
12	Do the collection receptacle's inner liners remain inside the collection receptacle's rigid container from the point of placement in the collection receptacle to the time of destruction? [Section 20-576a-4(c)]			

Rigid Containers		Yes	No	Advised
1	Are the collection receptacle's rigid containers leak resistant? [Section 20-576a-4(c)]			
2	Do the collection receptacle's rigid containers have sealable openings? [Section 20-576a-4(c)]			

Disposal		Yes	No	Advised
1	Is or was the reverse distributor present and ready to receive the collection receptacle's inner liner? [Section 20-576a-5(a)(1)]			
2	Are or were two authorized employees present and performing the removal and replacement of the collection receptacle's rigid container and inner liner? [Section 20-576a-5(a)(2)]			
3	Is or was one of the two authorized employees present and performing the removal and replacement of the collection receptacle's rigid container and inner liner a Connecticut licensed pharmacist? [Section 20-576a-5(a)(2)]			
4	Is or was the collection receptacle's rigid container, including the collection receptacle's inner liner, removed from the collection receptacle together? [Section 20-576a-5(a)(3)]			
5	Is or was the collection receptacle's inner liner immediately sealed? [Section 20-576a-5(a)(3)]			
6	Is or was the collection receptacle's rigid container sealed at all openings with tamper-evident tape? [Section 20-576a-5(a)(4)]			
7	Does or did the collection receptacle's rigid container display the unique identification number of the collection receptacle's inner liner contained therein? [Section 20-576a-5(a)(4)]			
8	Does or did the collection receptacle's rigid container have any outer markings that indicate the nature of its contents? [Section 20-576a-5(a)(5)]			
9	Do or did the authorized employees present during the disposal record all required information and perform all actions necessary to record log entries pursuant to Section 20-576a-5 of the Regulations of Connecticut State Agencies? [Section 20-576a-5(a)(6)]			

10	Do or did the authorized employees provide the collection receptacle's sealed rigid container that contains the collection receptacle's sealed inner liner to the registered reverse distributor for destruction? [Section 20-576a-5(a)(7)]			
11	Does or did the reverse distributor sign the authorized collector's log book? [Section 20-576a-5(a)(7)]			
12	Is or was the entire collection receptacle disposal process monitored and recorded by video camera pursuant to Section 20-576a-3 of the Regulations of Connecticut State Agencies? [Section 20-576a-5(a)(8)]			
13	Are or were any materials deposited in the collection receptacle and captured in the collection receptacle's inner liner removed, counted, sorted, or otherwise handled? [Section 20-576a-5(c)]			
14	Is or was the collection receptacle's inner liner presumed to contain prescription medications, including controlled drugs and legend and non-legend drugs and disposed of in accordance with 21 CFR 1317 and Sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies? [Section 20-576a-5(d)]			
15	Is or was the ON-SITE destruction of any of the collection receptacle's rigid container, collection receptacle's inner liner, or the collection receptacle's contents permitted BY the authorized collector? [Section 20-576a-5(e)]			
16	Is or was the ON-SITE destruction of any of the collection receptacle's rigid container, collection receptacle's inner liner, or the collection receptacle's contents permitted AT the authorized collector's premises? [Section 20-576a-5(e)]			

Overfill Log		Yes	No	Advised
1	Does the "Receptacle Overfill Record Log" bear the date of each check of the collection receptacle's rigid container? [Section 20-576a-3(c)]			
2	Does the "Receptacle Overfill Record Log" bear the approximate drug fill level of the collection receptacle's rigid container for each check of the collection receptacle's rigid container? [Section 20-576a-3(c)]			
3	Does the "Receptacle Overfill Record Log" bear the two names of the authorized employees performing each check of the collection receptacle's rigid container, one of which shall be a Connecticut licensed pharmacist? [Section 20-576a-3(c)]			

Disposal Log		Yes	No	Advised
1	Does the "Disposal Transaction Record Log" bear the date on which the collection receptacle's new inner liner and rigid container are placed in the collection receptacle? [Section 20-576a-5(b)(1)]			

2	Does the "Disposal Transaction Record Log" bear the unique identification number of the collection receptacle's inner liner? [Section 20-576a-5(b)(2)]			
3	Does the "Disposal Transaction Record Log" bear the date on which the collection receptacle's numbered inner liner and rigid container was taken and sealed from the collection receptacle and provided to the reverse distributor? [Section 20-576a-5(b)(3)]			
4	Does the "Disposal Transaction Record Log" bear the names and signatures of the two authorized employees who witnessed and performed both the removal and replacement of the collection receptacle's inner liner and rigid container? [Section 20-576a-5(b)(4)]			
5	Is or was one of the two authorized employees who witnessed and performed both the removal and replacement of the collection receptacle's inner liner and rigid container a Connecticut licensed pharmacist? [Section 20-576a-5(a)(2)]			
6	Does the "Disposal Transaction Record Log" bear the name, registration number, and address of the reverse distributor? [Section 20-576a-5(b)(5)]			

Inner Liner Log		Yes	No	Advised
1	Does the authorized collector track and maintain a record log to track the collection receptacle's inner liners used in the collection receptacle along with the unique identification number of each of the collection receptacle's inner liners? [Section 20-576a-4(a)]			
2	Does the authorized collector make the collection receptacle's inner liner and rigid container record logs available for inspection upon request by the Department of Consumer Protection? [Section 20-576a-5(b)(5)]			
3	Does the authorized collector maintain the collection receptacle's inner liner and rigid container record logs for three years? [Section 20-576a-5(b)(5)]			

Additional Comments		Yes	No	Advised
1	Does the inspecting agent have any additional comments with respect to this authorized collector inspection?			

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