State of Connecticut
Regulation of
Department of Consumer Protection
Concerning
Return of Prescription Drugs to Pharmacies

Section 1. The Regulations of Connecticut State Agencies are amended by adding 20-576a-1 to 20-576a-7, inclusive, as follows:

(NEW) Sec. 20-576a-1. Definitions

As used in sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies:

(a) "Authorized Collector" means a retail pharmacy authorized to handle controlled substances currently licensed pursuant to section 20-594 of the Connecticut General Statutes, with an active registration to be a collector of drugs for disposal by the United States Drug Enforcement Agency and the department ;

(b) "Authorized Employee" means an individual with an active license or registration that is: (1) a minimum of 18 years of age; and (2) employed by an authorized collector as a licensed pharmacist, pharmacist intern, or pharmacist technician pursuant to chapter 400j of the Connecticut General Statutes;

(c) "Collection Receptacle" means a secured receptacle into which unused or expired drugs, including controlled substances and legend and non-legend drugs, can be deposited by ultimate users. A collection receptacle shall have a removable inner liner and rigid container, and shall meet the requirements specified in 21 CFR 1317.60 and 21 CFR 1317.75 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies;

(d) "Commissioner" means the Commissioner of Consumer Protection or the commissioner's representative;

(e) "Controlled substance" means a drug, substance, or immediate precursor in schedules I to V, inclusive, of the Connecticut controlled substance scheduling regulations adopted pursuant to section 21a-243 of the Connecticut General Statutes;

(f) "Department" means the Department of Consumer Protection;

(g) "Drug" means "Drug" as defined in subsection (17) of section 21a-240 of the Connecticut General Statutes ;

(h) "Drug Control Division" means the division within the department responsible for overseeing the return of prescription drugs to pharmacies;

(i) "Inner Liner" means the removable liner within a collection receptacle that meets the requirements specified in 21 CFR 1317.60, that is used to collect drugs when placed in a collection receptacle;

(j) "Pharmacy" means "Pharmacy" as defined in subsection (3) of section 20-571(18) of the Connecticut General Statutes;

(k) "Prescription" means "Prescription" as defined in subsection (45) of section 21a-240 of the Connecticut General Statutes;

(*l*) "Reverse Distributor" means a wholesale distributor or its authorized third party logistics provider, as defined in Connecticut General Statutes section 21a-70, whether within or without the

boundaries of the state of Connecticut, who receives and destroys prescription medications, including controlled substances and legend and non-legend drugs, from an authorized collector which has an active registration by the United States Drug Enforcement Agency.

(m) "Rigid Container" means a container constructed of sturdy material used to hold the inner liner while in the collection receptacle and to transport the inner liner to the reverse distributor for destruction. Rigid containers are removable from the collection receptacle, are not reusable and shall be destroyed with the inner liner contained therein;

(n) "Third-party logistics provider" means "Third-party logistics provider" as defined in subsection (27) of section 20-571 of the Connecticut General Statutes; and

(o) "Ultimate User" means a person who has lawfully obtained, and who possesses, a controlled substance for their own use or for the use of a member of their household or for an animal owned by a member of their household, as defined in 21 U.S.C. 802 (27) or any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance.

(NEW) Sec. 20-576a-2. Authorized collector

(a) A pharmacy may operate a collection receptacle if they: (1) meet the requirements specified in 21 CFR Part 1307 and 21 CFR Part 1317; (2) meet the requirements set forth in sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies; and (3) register with the department as an authorized collector.

(b) An authorized collector applicant shall submit an application and all other required documentation on forms prescribed by the commissioner. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant has adequate facilities to properly carry on the business described in their application and that the applicant conforms to and is in compliance with federal and state requirements. Registrations shall be renewed annually on or before January 31.

(c) Prior to the issuance of a certificate of registration, the commissioner shall perform an initial inspection of the applicant's premises, collection receptacle and written operating procedures prior to the commencement of collection activities from ultimate users.

(d) The commissioner shall have the right to deny an authorized collector a certificate of registration if the commissioner determines that the issuance of such registration is inconsistent with the public interest, or may have a negative impact on public health and safety.

(e) An authorized collector shall not participate in a take back event, as defined in 21 CFR 1317.65, within the interior of the same building in which the authorized collector's collection receptacle is located.

(f) An authorized collector shall not participate in a mail back program as outlined in 21 CFR 1317.70, whereby the authorized collector receives drugs returned to it via mail.

(g) An authorized collector shall not dispose of its inventory or stock of drugs in the collection receptacle.

(h) An authorized collector shall maintain the confidentiality of ultimate users that utilize the collection receptacle.

(i) No employees, including authorized employees, of an authorized collector shall handle, count, sort, or inventory any drugs brought by ultimate users for deposit in the collection receptacle.

(j) Authorized collectors shall permit the commissioner to enter and inspect their premises and collection receptacles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner.

(k) All records required by sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies shall be kept on the premises of the registrant and maintained current and

separate from other business records in such form as to be readily available for inspection and copying by the authorized representative at reasonable times. The records shall be maintained by the authorized collector for a period of three (3) years.

(*l*) Any authorized collector that intends to discontinue its use of a collection receptacle shall notify the Director of Drug Control in writing 30 days prior to discontinuing collection activities. Upon the termination of operation, the authorized collector shall dispose of the inner liner and rigid container by following the procedure for disposal of inner liners and rigid containers outlined in section 20-576a-5 of the Regulations of Connecticut State Agencies, and remove the collection receptacle from the prescription department area.

(NEW) Sec. 20-576a-3. Collection receptacles

(a) Collection receptacles shall be lockable, sturdy, and securely fixed within the authorized collector's registered location, and have a one-way access point to allow ultimate users to deposit drugs.

(b) The collection receptacle shall have two locking mechanisms for access to the inner liner, and these locking mechanisms shall have different keys for operating the locks for simultaneous use by two different authorized employees. The one-way access point shall have a locking mechanism to prevent the acceptance of drugs when the pharmacy is closed or the inner liner is full. Locks shall be kept in good working order with keys removed there from. Keys to the locks shall not be left in a location accessible to other than specifically authorized employees.

(c) If it is necessary to unlock the collection receptacle and view the contents of the rigid container in order to determine the drug fill level and avoid overfill, two authorized employees shall perform this check, at an interval determined by the authorized collector, and one such authorized employee shall be a Connecticut licensed pharmacist. If the drug fill level of the rigid container has reached a point where overfill is imminent, the collection receptacle shall be locked to prevent ultimate users from depositing any drugs. Then the authorized collector shall commence disposal of the rigid container within forty-eight hours pursuant to section 20-576a-5 of the Regulations of the Connecticut State Agencies. The date of the rigid container check, the names of the authorized employees performing the check and the approximate drug fill level of the rigid container shall be entered in the record log maintained by the authorized collector.

(d) The collection receptacle shall be located in the immediate proximity of a designated area where controlled substances are stored and at which an authorized employee is present and the collection receptacle is visible to such authorized employee.

(e) The collection receptacle may only accept drugs when the authorized collector is open for business and an authorized employee is present.

(f) The collection receptacle shall be secured pursuant to the procedures required by section 20-576-18 of the Regulations of Connecticut State Agencies when the pharmacy is closed.

(g) The outside of each collection receptacle shall prominently display a sign indicating: (1) the types of drugs permitted for deposit; (2) the prohibited items; and (3) that no drugs intended for return are to be left in the vicinity of the collection receptacle at any time.

(h) Waste or trash receptacles located in public areas shall not be within 5 feet of a collection receptacle.

(i) All of the collection receptacle access points and the sealing of inner liners shall be continuously monitored by video camera with a minimum of 14 days of information storage. All stored video of the collection receptacle shall be available upon request of the commissioner within 48 hours. If an authorized collector is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the authorized collector shall retain an unaltered copy of the recording until the investigation or

proceeding is closed or the entity conducting the investigation or proceeding notifies the authorized collector that it is not necessary to retain the recording.

(j) Requirements for minimum security and safeguard standards for collection receptacles may be determined for each authorized collector by the commissioner after consideration of the protection offered from an overall standpoint in instances wherein other security measures provided exceed those specifically stated. If the authorized collector has provided other safeguards that can be regarded as an adequate substitute for some element of protection required of such authorized collector, such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, or unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the commissioner.

(k) An authorized collector shall maintain collection receptacles to prevent theft and unauthorized access of the collection receptacle or inner liner.

(*l*) Any loss, theft, serious damage or destruction of a collection receptacle or its contents must be reported by an authorized collector within 72 hours of any such occurrence to the director of the drug control division.

(NEW) Sec. 20-576a-4. Inner liners and rigid containers

(a) All inner liners shall have a permanent unique identification number, and the authorized collector shall track and maintain a record log of all inner liners used in the collection receptacle.

(b) All inner liners shall contain an absorbent material sufficient to prevent leakage of any drugs deposited in a collection receptacle.

(c) All inner liners shall be placed in or a part of a rigid container prior to use and placement inside a collection receptacle. Prior to placement inside a collection receptacle, the permanent unique identification number of the inner liner shall be marked, in a clear and permanent manner, on the rigid container. The inner liner shall remain inside the rigid container from the point of placement in the collection receptacle to the time of destruction. Rigid containers shall be leak resistant, and have sealable openings.

(d) All inner liners used in collection receptacles shall meet the requirements of 21 CFR Part 1317.60 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies.

(NEW) Sec. 20-576a-5. Disposal

(a) To dispose of the inner liners and rigid containers: (1) the reverse distributor must be present and ready to receive the inner liner; (2) two authorized employees must be present and performing the removal and replacement of the rigid container and inner liner, and one such authorized employee shall be a Connecticut licensed pharmacist; (3) the rigid container, including the inner liner, shall be removed from the collection receptacle together and the inner liner shall be immediately sealed and replaced with a new rigid container and inner liner; (4) the rigid container shall then be sealed at all openings with tamper evident tape and display the unique identification number of the inner liner contained therein;(5) the rigid container shall not have any outer markings that would indicate the nature of its contents; (6) the authorized employees present during the disposal shall record all required information and perform necessary to record log entries pursuant to section 20-576a-4 of the Regulations of Connecticut State Agencies; (7) the authorized employees shall deliver the sealed rigid container that contains the sealed inner liner to a registered reverse distributor for destruction who shall sign the authorized collector's log book; and (8) the entire process shall be monitored and recorded by video camera(s), pursuant to section 20-576a-3(k) of the Regulations of Connecticut

State Agencies.

(b) An authorized employee shall record the following information for each transaction in record logs: (1) the date that the new inner liner and rigid container were placed in the collection receptacle; (2) the inner liner unique identification number; (3) the date that the numbered inner liner and rigid container was taken and sealed from the collection receptacle; (4) the names and signatures of the two authorized employees that witnessed and performed both the removal and replacement of the inner liner and rigid container; (5) date of transfer or delivery to the reverse distributor; and (6) the name, license number, and address of the reverse distributor. Inner liner and rigid container record logs are to be maintained by the authorized collector for three years and shall be available for inspection upon request by the department.

(c) Any materials deposited in the collection receptacle and captured in the inner liner shall not be removed, counted, sorted or otherwise handled.

(d) Upon placing a new inner liner and rigid container into a collection receptacle, the inner liner is presumed to contain prescription medications, including controlled substances, legend and non-legend drugs and shall be disposed of as per 21 CFR Part 1317 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies. Inner liners and rigid containers shall not be reused in a collection receptacle.

(e) No on site destruction of any rigid container, inner liner or its contents is permitted by the authorized collector or at its premises.

(f) The reverse distributor may designate a third party logistics provider or a federal Drug Enforcement Agency authorized common or contract carrier as per 21 U.S.C. 822 and 21 CFR 1317.15 to serve as an authorized representative of the reverse distributor.

(g) Law enforcement authorities may accept delivery of the sealed rigid container that contains the sealed inner in the same manner as a reverse distributor as set forth in sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies. Law enforcement authorities are permitted to destroy the sealed inner liner and rigid container pursuant to their department procedures and policies. Law enforcement authorities are not required by this regulation or any other Connecticut law to participate in the collection and disposal of returned drugs to pharmacies.

Sec. 20-576a-6. Reverse distributors

(a) No reverse distributor shall operate as such until it has registered with the department, which registration shall be renewed annually on or before January 31.

(b) A reverse distributor application for registration must either be received by the department in conjunction with a new wholesale distributor registration application, or as an amendment to an existing wholesale distributor registration held by the reverse distributor applicant pursuant to Section 21a-70 of the Connecticut General Statutes.

(c) Upon annual renewal the reverse distributor shall provide information related to the amount of drugs destroyed and any additional information required by the department.

(d) A reverse distributor applicant shall submit an application and all other required documentation on forms prescribed by the commissioner. No registration shall be approved under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant has adequate facilities and apparatus to properly carry on the business described in their application and that the applicant conforms to and is in compliance with federal and state requirements, including 21 CFR Part 1317 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies.

(e) The commissioner shall have the right to deny a reverse distributor registration if the commissioner determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider, among others, the factors

enumerated in section 21a-70(c) of the Connecticut General Statutes and any potential negative impact on public health and safety.

(f) A reverse distributor shall maintain record logs, which contain the following information for each transaction: (1) the name and address of the authorized collector from whom the reverse distributor collected the rigid container; (2) the date of collection of the rigid container from the authorized collector; (3) the date of delivery of the rigid container to the reverse distributor or the date the reverse distributor obtained possession of the rigid container; (4) the inner liner unique identification number marked on the outside of the rigid container; (5) the destruction date of each rigid container and its contents; and (6) the names of the reverse distributor employees or representatives that performed each function.

(g) A reverse distributor shall not open or unseal, or otherwise tamper with a rigid container prior to destruction unless ordered to do so by the commissioner.

(h) Two employees of the reverse distributor shall witness the destruction of the rigid container and its contents, participate in completion of the logs, and each shall enter their names and signatures to the record log. Record logs shall be maintained by the reverse distributor for three years and copies shall be made available to the department for inspection upon request.

(i) Reverse distributors shall operate in compliance with applicable federal, state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing.

(j) Reverse distributors shall permit the commissioner, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures upon request of the drug control division. Upon reasonable suspicion by the department of tampering or adulteration of a rigid container in the possession of a reverse distributor the department may seize such rigid container.

(k) Any loss, theft, serious damage or destruction of an inner liner or rigid container must be reported by a reverse distributor within 72 hours of any such occurrence to the director of the Drug Control Division.

(NEW) Sec. 20-576a-7. Grounds for discipline

(a) The commissioner may suspend, revoke or refuse to renew a registration of an authorized collector or reverse distributor, place conditions on such registration, issue a letter of reprimand, or take other actions permitted by statute or regulation, including sections 20-579, 21a-8 and 21a-70 of the Connecticut General Statutes. Failure to renew a registration in a timely manner is not a violation for purposes of this section. Any of the following shall be sufficient cause for such action:

(1) Furnishing of false or fraudulent information in any application or other document filed with the department;

(2) Any criminal conviction of the authorized collector or reverse distributor under any federal or state statute concerning drugs;

(3) Any civil action under any federal or state statute, or regulation or local ordinance relating to the applicant's, licensee's or registrant's profession, or involving drugs, medical devices or fraudulent practices;

(4) Failure to maintain effective controls against diversion, theft or loss of controlled substances or other materials placed in the collection receptacles. This applies to both authorized collectors while the rigid container is in the collection receptacle and to reverse distributors after receiving the rigid container from the authorized collector;

(5) Discipline by, or a pending disciplinary action or unresolved complaint, with regard to any professional license or registration of any federal, state or local government;

(6) Failure to keep and maintain accurate records as required by sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies;

(7) Denial, suspension or revocation of a license or registration, or the denial of a renewal of a license or registration, by any federal, state or local government or a foreign jurisdiction;

(8) False, misleading or deceptive representations to the public or the commissioner;

(9) Involvement in a fraudulent or deceitful practice or transaction;

(10) Performance of incompetent or negligent work;

(11) Failure to maintain the entire collection receptacle or pharmacy area in which it is located in a clean, orderly and working condition;

(12) Failure to cooperate or give information to the department, local law enforcement authorities or any other enforcement agency upon any matter arising out of conduct by or at an authorized collector or a reverse distributor;

(13) Failure to comply with any provision of sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies; or

(14) A violation of a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction.

(b) Before denying, suspending, revoking or refusing to renew a registration, the commissioner shall afford the applicant an opportunity for hearing in accordance with the provisions of chapter 54 of the Connecticut General Statutes.

(c) No authorized collector or reverse distributor whose registration has been revoked may make an application for a registration under sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of such revocation.

(d) A registrant may at any time voluntarily surrender its certificate of registration for any or all for any of the following reasons: (1) As an indication of their good faith in desiring to remedy any incorrect or unlawful practices or (2) as a voluntary act arising out of their desire to terminate prescribing or handling of controlled substances in any or all schedules. Any such voluntary surrender shall constitute authority for the commissioner or their authorized agent to terminate and revoke any registration without a hearing or any other proceeding.

(e) If an authorized collector’s or reverse distributor’s registration is suspended, revoked, voluntarily surrendered, or is not renewed, the commissioner shall not be prohibited from suspending, revoking or imposing other penalties permitted by the Regulations of Connecticut State Agencies and Titles 20 and 21a, including sections 20-579, 21a-8 and 21a-70 of the Connecticut General Statutes, on any such underlying license or registration associated with the authorized collector, authorized employee or reverse distributor.

Statement of Purpose

(A) Purpose: Pursuant to Connecticut General Statutes Section 20-576a (2017 Public Act No. 109), this proposed new regulation provides guidelines for the safe collection and handling of unused prescription drugs that are returned to licensed Connecticut pharmacies by the public.
(B) Summary: This regulation requires participating pharmacies and disposal locations to be registered annually with the commissioner of Consumer Protection, reinforces compliance with federal regulations, and establishes requirements for the collection methods and handling methods at pharmacies as well as for the transportation and destruction of materials collected by disposal locations.
(C) Legal Effects: This is a new regulation that does not impact any state or local laws or regulations.