

**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 shall either be received by the department in conjunction with a new wholesale or distributor registration application, or as an amendment to an existing wholesale or 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 documentation required by the commissioner 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 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 who 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

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department may seize such rigid container.

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

(Effective July 8, 2019)