

STATE OF CONNECTICUT
Regulation of
DEPARTMENT OF CONSUMER PROTECTION
concerning
Sale of Nonlegend Drugs in Vending Machines

Section 1. Section 20-576-1 of the Regulations of Connecticut State Agencies is amended to read as follows:

Sec. 20-576-1 Definitions

For the purpose of sections 20-576-1 through 20-576-53, inclusive, of the Regulations of Connecticut State Agencies, the following terms shall have the meanings indicated:

(a) “Adulterated” has the same meaning as prescribed in section 21a-105 of the Connecticut General Statutes;

(b) “Commission” means the Commission of Pharmacy;

(c) “Commissioner” means the Commissioner of Consumer Protection or his or her authorized representative;

(d) “Damaged product” means nonlegend products that have been exposed to conditions that the packaging is intended to prevent, or stored in a manner contrary to the manufacturer’s recommendations;

[(b)](e) “Department” means the Department of Consumer Protection;

[(c)](f) “Legend drug” has the meaning given to this term by Section 20-571 of the Connecticut General Statutes;

(g) “Misbranded” has the same meaning as prescribed in section 21a-106 of the Connecticut General Statutes;

(h) “Nonlegend device” has the same meaning as prescribed in section 20-571 of the Connecticut General Statutes;

(i) “Nonlegend drug” has the same meaning as prescribed in section 20-571 of the Connecticut General Statutes;

(j) “Nonlegend drug permittee” means the holder of a permit to sell nonlegend drugs pursuant to section 20-624 of the Connecticut General Statutes;

(k) “Nonlegend product” means a nonlegend drug or a nonlegend device;

[(d)](l) "Prescribing practitioner" has the [meaning given to this term by] same meaning as prescribed in section [Section] 20-571 of the Connecticut General Statutes;

[(e)](m) "Prescription department" means that area within a pharmacy where drugs are compounded and dispensed pursuant to the order of a prescribing practitioner[.];

(n) "Service" means nonlegend product handling within a vending machine and the maintenance, mechanical services or repairs made to vending machines that result in a person able to access the interior of the vending machine containing nonlegend drugs;

(o) "Vending machine" means any automated mechanical device operated by a vending machine registrant from which nonlegend products are dispensed to a consumer;

(p) "Vending machine registrant" means a nonlegend drug permittee that holds an active vending machine registration pursuant to section 20-623 of the Connecticut General Statutes; and

(q) "Wholesaler" means a person issued a certificate of registration in accordance with section 21a-70 (b) of the Connecticut General Statutes.

Sec. 2. The Regulations of Connecticut State Agencies are amended by adding section 20-576-30a as follows:

(NEW) Sec. 20-576-30a. Sale of Nonlegend Drugs

(a) A nonlegend drug permittee shall only purchase nonlegend drugs from a wholesaler or another nonlegend drug permittee.

(b) A nonlegend drug permittee shall ensure all nonlegend products purchased from a wholesaler or other nonlegend drug permittee are labeled for individual sale in accordance with the requirements of the federal Food and Drug Administration or successor agency.

(c) A nonlegend product, the sale of which is subject to quantity limitation, proof of identification, age verification, or other restriction pursuant to federal or state law, shall be stored and maintained in manner accessible only to employees prior to purchase.

(d) It is the sole responsibility of each nonlegend drug permittee to ensure that all nonlegend products are not expired, and to take reasonable steps to ensure expired nonlegend products are promptly removed upon expiration.

(e) Upon receiving a nonlegend product from a wholesaler or another nonlegend drug permittee, and prior to offering any nonlegend products for sale, the expiration date of each nonlegend product offered for sale shall be inspected to ensure that it is not expired.

(f) Under no circumstance may a recalled nonlegend product be sold or dispensed from a vending machine.

(g) It is the sole responsibility of each nonlegend drug permittee to take reasonable steps to prevent the sale of any nonlegend product that has been subject to a recall for any reason by the manufacturer, the federal government or the state of Connecticut.

(h) A nonlegend drug permittee shall have a written policy that sets forth a process to respond to recalls, which shall include but not be limited to a review of nonlegend products to identify if any nonlegend products offered for sale are subject to the recall and a protocol to remove, return, destroy or sequester nonlegend products as applicable for each recall. The policy shall be electronically submitted to the department within forty-eight hours of a request from the department.

(i) Each nonlegend drug permittee shall maintain a record of all nonlegend products purchased from a wholesaler and other nonlegend drug permittees for individual sale.

(j) Each nonlegend drug permittee shall maintain a record of each received recall notice for all recalls.

(k) Each nonlegend drug permittee shall maintain a record of each nonlegend product that was returned, and denote on such record the reason for each return, including returns due to recall, damage, or other reason.

(l) All records required in this section and section 20-576-31 of the Regulations of Connecticut State Agencies shall be maintained for a minimum of three years.

(m) The sale of any nonlegend products without a permit to sell nonlegend drugs pursuant to section 20-624 of the Connecticut General Statutes is prohibited.

(n) The sale of any nonlegend product that is commercially known or visually evident to be damaged, adulterated, misbranded, expired or recalled is prohibited.

(o) A nonlegend product subject to any sale restriction pursuant to state or federal law shall not be contained in a vending machine. Such restricted products shall include, but not be limited to: age verification; proof of identity requirement; or quantity limitation.

(p) Neither a nonlegend drug permit, nor a vending machine registration, shall be transferable from one place to another, or from one vending machine to another without notice to the department, a form and manner prescribed by the commissioner, at least thirty days prior to such change. Neither a nonlegend drug permit, nor a vending machine registration, shall be transferable to another person.

Sec. 3. Section 20-576-31 of the Regulations of Connecticut State Agencies is amended to read as follows:

Sec. 20-576-31. Storage, Sale and Acquisition of Nonlegend Drugs in Vending Machines
[No nonlegend drug shall be sold or offered or exposed for sale or dispensed by any means in any type of vending machines.]

(a) A vending machine registrant shall only purchase nonlegend drugs from a wholesaler or another nonlegend drug permittee.

(b) A vending machine registrant shall ensure all nonlegend products purchased from a wholesaler or other nonlegend drug permittee are labeled for individual sale in accordance with the requirements of the federal Food and Drug Administration or successor agency.

(c) All nonlegend products sold in a vending machine shall be:

(1) Stored in accordance with manufacturer recommendations, including but not limited to temperature conditions; and

(2) Sold only in the manufacturer's clearly labeled, original, unbroken, tamper-proof and expiration-dated packaging.

(d) No expired nonlegend products shall be sold from a vending machine. Such products shall be removed by the vending machine registrant from the vending machine on or before the manufacturer's expiration date.

(e) A nonlegend drug permittee shall have a written policy to review expiration dates of nonlegend products contained in the vending machine at least monthly. The policy shall be made available to the Department upon request within forty-eight hours of the request.

(f) Vending machines shall be in good working order. Should a machine become inoperable, the vending machine registrant shall, within twenty-four hours of being made aware of the vending machine's inoperability, affix a sign indicating to consumers that the vending machine is not in working order. The vending machine registrant shall arrange for the vending machine to be serviced so that it can return to operation as soon as commercially possible. If the vending machine does not return to operation within seven calendar days of the vending machine registrant being made aware of the vending machine's inoperability, the vending machine registrant shall notify the department in a form and manner prescribed by the commissioner that the vending machine is inoperable and include the following information:

(1) Registration number;

(2) Serial number of the vending machine;

(3) Vending machine location;

(4) Date vending machine became inoperable;

(5) Date vending machine registrant was made aware that the vending machine was inoperable;

(6) Contents of the vending machine;

(7) A description of why the vending machine is inoperable;

(8) If any contents of the vending machine have been damaged or compromised as a result of the vending machine's inoperability;

(9) If and when the vending machine is expected to return to operation; and

(10) A contact name and the phone number for the company servicing the vending machine.

(g) Each vending machine registrant shall maintain a record of any service. Such record shall include the date the vending machine was serviced, the company servicing the vending machine and the purpose of the service, and shall be either:

(1) Affixed to the interior of the vending machine, in a manner visible from the exterior of the vending machine; or

(2) Maintained electronically in a manner that the vending machine registrant can provide the records required pursuant to this subsection within one business day of a request for such information from the Department of Consumer Protection.

(h) The vending machine shall be securely constructed and weigh a minimum of seven hundred and fifty pounds or be physically affixed to the building.

(i) Vending machines shall be mechanically serviced at least once per year to ensure proper operation.

(j) Any vending machine containing a nonlegend product shall be protected from the elements through internal systems or external enclosure which shall be:

(1) Weather-tight;

(2) Well-ventilated;

(3) Moisture-controlled;

(4) Well-lit;

(5) Protected from direct sunlight; and

(6) Capable of maintaining storage conditions consistent with the manufacturer's recommendations for each nonlegend product at all times.

(k) When a vending machine is relocated inside the authorized premises of a vending machine registrant, the vending machine registrant shall notify the department in writing within five calendar days of such relocation. A vending machine registrant shall request authorization from the department prior to relocating a vending machine to the exterior of an authorized premises or other location on such premises where the climate or other elements may impact the vending machine or nonlegend products therein. A request for authorization shall be submitted to the department, a form and manner prescribed by the commissioner, at least thirty days prior to such proposed relocation and shall describe the reason for the request and a description of quality controls to ensure the protection of the vending machine and the nonlegend products contained therein.

(l) In the event that the machine has been tampered with or otherwise damaged, or if the machine's contents have been forcibly removed, stolen or otherwise compromised, the vending machine registrant shall notify the Department within twenty-four hours of discovering the event. Within five days of discovering the event, the vending machine registrant shall submit a written description of the event, including, but not limited to, steps taken by the vending machine registrant to resolve the event and prevent such occurrences from happening again. During such five day period, a vending machine registrant shall evaluate nonlegend products remaining within the vending machine to determine if the nonlegend products are adulterated or damaged products. If such nonlegend product is an adulterated or damaged product, the vending machine registrant shall not offer such product for sale and such product shall be immediately removed from the vending machine.

(m) The Department may inspect vending machines and the contents thereof. The department's inspection may include, but is not limited to the following:

(1) Verifying the owner of the vending machine has the required registration and permit pursuant to section 20-623 of the Connecticut General Statutes;

(2) Verifying that the vending machine:

- (i) Is located where indicated on the registration;
- (ii) Is in good working order;
- (iii) Contains required notices and signage;
- (iv) Has been serviced in accordance with subsection (j) above;
- (v) Is protected from the elements in accordance with subsection (c) above;
and
- (vi) Contains products are not expired, subject to a recall, tampered evident, damaged or prohibited for sale within a vending machine.

(n) If the vending machine registrant decides to permanently remove the vending machine from nonlegend product service, the vending machine registrant shall notify the department in writing no less than five calendar days before nonlegend products will permanently cease to be offered at the vending. A sign shall be affixed to the vending machine informing customers of the last date of nonlegend product service for the vending machine not less than five calendar days before the vending machine will cease offering nonlegend products. All nonlegend products must be removed from the vending machine by 11:59 p.m. of the last day of operation for the vending machine. If such vending machine exclusively offered nonlegend products, the vending machine registrant shall ensure a sign remains affixed to the vending machine, at all times when such machine is accessible to consumers, indicating that the machine is no longer operational.

Statement of Purpose:

To promulgate regulations that set forth nonlegend product vending machine requirements pursuant to Public Act 23-52.