

Secretary of the State File Number

6421

Regulation of the

Department of Consumer Protection
Concerning

Sale of Nonlegend Drugs in Vending Machines

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

Posted to the Connecticut eRegulations System on **November 7, 2024**

EFFECTIVE DATE

November 7, 2024

Approved by the Attorney General on

July 30, 2024

Approved by the Legislation Regulation Review Committee on

October 22, 2024

Electronic copy with agency head certification statement electronically submitted to and received by the Office of the Secretary of the State on

November 4, 2024

Form ICM-ECOPY (NEW 6/2015)
State of Connecticut
Secretary of the State



IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES
This form should be used only for regulations first noticed *on and after March 23, 2015*.

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the
Department of Consumer Protection
Concerning
Sale of Nonlegend Drugs in Vending Machines

Approved by the Legislative Regulation Review Committee: **October 22, 2024**

eRegulations System Tracking Number: **PR2023-052**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto
set my hand on **November 4, 2024**.

A handwritten signature in blue ink that reads "Julianne Avallone".

Julianne Avallone

Legal Director

Department of Consumer Protection

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 provided 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 same meaning [given to this term by Section] as provided in section 20-571 of the Connecticut General Statutes;

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

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

(i) “Nonlegend drug” has the same meaning as provided 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 provided in section [Section] 20-571 of the Connecticut General Statutes; [and]

[(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 allow a person 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 by a nonlegend drug permittee in a manner accessible only to employees of the nonlegend drug permittee 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 from retail display upon expiration.

(e) A nonlegend drug permittee shall, upon receiving a nonlegend product from a wholesaler or another nonlegend drug permittee, and prior to offering any nonlegend products for sale, inspect the expiration date of each nonlegend product offered for sale by authorized employees of such nonlegend drug permittee to ensure such product is not expired.

(f) A nonlegend drug permittee shall not sell or dispense at retail a recalled nonlegend product.

(g) It is the responsibility of each nonlegend drug permittee to prevent the retail 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 retail sale are subject to any such 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 not later than forty-eight hours after 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 retail sale.

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

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

(l) All records required to be maintained under 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 retail 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 retail sale of any nonlegend product that is commercially known or visually evident to be damaged, adulterated, misbranded, or expired is prohibited.

(o) 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, in a form and manner prescribed by the commissioner, at least thirty days prior to such transfer. 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. [Sale of nonlegend drugs in vending machines] 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) 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, products requiring age verification or proof of identity or subject to a quantity limitation.

(e) 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.

(f) 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 not later than forty-eight hours after a request from the department.

(g) Vending machines shall be in good working order. Should a machine become inoperable, the vending machine registrant shall, not later than twenty-four hours after 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 is commercially reasonable. If the vending machine does not return to operation on or before the seventh calendar day after the vending machine registrant is 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) Vending machine 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 became inoperable;

(6) Contents of the vending machine;

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

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

(9) Whether 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.

(h) Each vending machine registrant shall maintain a record of each 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 not later than one business day after a request for such information from the department.

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

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

(k) Any vending machine containing a nonlegend product shall be protected from the elements through internal systems or an 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.

(l) 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 not later than five calendar days after such relocation. When a vending machine is relocated to the exterior of an authorized premises or another location on such premises where the climate or other elements may impact the vending machine or nonlegend products therein, the vending machine registrant shall request authorization from the department prior to such relocation. Such a request for authorization shall be submitted to the department, in 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 provide a description of quality controls to ensure the protection of the vending machine and the nonlegend products contained therein.

(m) In the event that a vending machine has been tampered with or otherwise damaged, or the vending machine's contents have been forcibly removed, stolen or otherwise compromised, the vending machine registrant shall notify the department not later than twenty-four hours after discovering the event. Not later than five days after 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, the vending machine registrant shall evaluate nonlegend products remaining within the vending machine to determine if the nonlegend products are adulterated or are damaged products. If any such nonlegend product is adulterated or is a damaged product, the vending machine registrant shall not offer such product for sale and such product shall be immediately removed from the vending machine.

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

(2) Verifying that the vending machine:

(A) Is located where indicated on the registration;

(B) Is in good working order;

(C) Contains required notices and signage;

(D) Has been serviced in accordance with subsection (j) of this section;

(E) Is protected from the elements in accordance with subsection (k) of this section; and

(F) Contains products that are not (i) expired, (ii) subject to a recall, (iii) showing evidence of being tampered with, (iv) damaged, or (v) prohibited for sale within a vending machine.

(o) If the vending machine registrant decides to permanently cease offering nonlegend products at a vending machine, the vending machine registrant shall notify the department in writing not less than five calendar days before nonlegend products will permanently cease to be offered at the vending machine. A sign shall be affixed to the vending machine informing customers of the last date of offering nonlegend products at the vending machine not less than five calendar days before the vending machine will cease offering nonlegend products. All nonlegend products shall be removed from the vending machine by 11:59 p.m. of the last day of offering such products at 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 pursuant to Section 20-576 of the general statutes related to the practice of pharmacy and the business of retailing drugs and devices. These regulations address the new authorization of nonlegend products sold through a vending machine permitted under Public Act 23-52. These regulations clarify how nonlegend drugs must be maintained and imposes requirements to ensure public health and safety.

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION**Department of Consumer Protection**

Proposed Regulation Concerning

Sale of Nonlegend Drugs in Vending MachineseRegulations System Tracking Number **PR2023-015****I hereby certify the following:**

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities: **Public Act 23-52 and CGA Sec. 20-576**

For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.

(2) As permitted by Section 4-168(h) of the *Connecticut General Statutes*, the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on **n/a**.

For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)

(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on **January 19, 2024**.

(4) *(Complete one)* No public hearing held or was required to be held. **OR** One or more public hearings were held on: **n/a**.

(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on **March 20, 2024**.

(6) *(Complete one)* No comments were received. **OR** Comments were received and the agency posted the statements specified in subdivisions (1) and (2) of CGS Section 4-168(e) to the eRegulations System website on **March 20, 2024**.

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **July 29, 2024**.

(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, **the final regulation shall be effective**

(Check one and complete as applicable)

When posted to the eRegulations System website by the Secretary of the State.

OR On _____

(Date must be a specific calendar date not less than 11 days after submission to the Secretary of the State)

SIGNED


(Head of Board, Agency or Commission,
or duly authorized deputy)

Legal Director
OFFICIAL TITLE

July 29, 2024
DATE

**OFFICE OF THE ATTORNEY GENERAL
REGULATION CERTIFICATION**

Agency: Department of Consumer Protection

REGULATION NUMBER: PR2023-052

This Regulation is hereby APPROVED by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: 7/30/2024

Signed: _____


Sean Kehoe

Associate Attorney General

Chief of the Division of Government Affairs

Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator John Kissel
Senate Chair



Representative Lucy Dathan
House Chair

Official Record of Committee Action

October 22, 2024

Agency: Department of Consumer Protection
Description: Sale of Nonlegend Drugs in Vending Machines
LRRC Regulation Number: 2024-013A
eRegulation Tracking Number: PR2023-052

The above-referenced regulation has been

Approved with Technical Corrections

by the Legislative Regulation Review Committee in accordance
with CGS Section 4-170.

Catherine M. Thomas
Committee Administrator



State of Connecticut
Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Consumer Protection concerning Sale of
Nonlegend Drugs in Vending Machines
eRegulations System Tracking Number PR2023-052
Legislative Regulation Review Committee Docket Number 2024-013A

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4-172 on November 4, 2024.

Said regulation is assigned Secretary of the State File Number 6421.

The effective date of this regulation is November 7, 2024.

A handwritten signature in blue ink, appearing to read "Stephanie Thomas".

Stephanie Thomas
Secretary of the State
November 7, 2024

By:

/s/ Christopher R. Drake
Christopher R. Drake
Director, Business Services
Division