

Secretary of the State File Number

**6410**

Regulation of the  
**Department of Consumer Protection**  
Concerning

**Opioid Warning Labels**

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 **June 26, 2024**

EFFECTIVE DATE

**June 26, 2024**

Approved by the Attorney General on

**June 4, 2024**

Approved by the Legislation Regulation Review Committee on

**June 25, 2024**

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

**June 25, 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  
**Opioid Warning Labels**

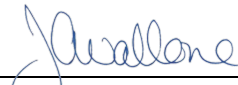
Approved by the Legislative Regulation Review Committee: **June 25, 2024**

eRegulations System Tracking Number: **PR2023-046**

**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 **June 25, 2024**.

  
\_\_\_\_\_  
Julianne Avallone  
Legal Director  
Department of Consumer Protection

**State of Connecticut**  
**Regulation of**  
**Department of Consumer Protection**  
**concerning**  
**Opioid Warning Labels**

**Section 1.** The Regulations of Connecticut State Agencies are amended by adding sections 20-636-1 to 20-636-4, inclusive, as follows:

**(NEW) Sec. 20-636-1. Definitions**

In addition to the defined terms set forth in section 20-571 of the Connecticut General Statutes, as used in this section and sections 20-636-2 to 20-636-4, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Container” means the receptacle that holds the legend drug, labeled with information required by federal and state law for dispensing;
- (2) “Controlled substance” means an opioid drug, as defined in section 20-14o of the Connecticut General Statutes, or a controlled substance in schedule II, III, IV or V;
- (3) “Fluorescent orange” means the hexadecimal color #ff6700 with RGB values of R:255, G:103, B:0, and CMYK values of C:0, M:60, Y:100, K:0;
- (4) “Packaging” means the bag, box, wrapping, or other material used to contain or enclose the container for delivery to a patient; and
- (5) “Label or sticker” means symbols, graphics or other information about the controlled substance, either directly on the container or packaging, or affixed to the container or packaging on separate material such as paper or film.

**(NEW) Sec. 20-636-2. Dimensions**

- (a) The label or sticker shall be round and no less than one and one-quarter inch in diameter.
- (b) The label or sticker shall be fluorescent orange in color with black text.

**(NEW) Sec. 20-636-3. Warning Statement**

- (a) Each label or sticker shall have a single black graphic of an equilateral triangle of no less than 0.67 inches per side, containing an exclamation point, of no less than 0.3 inches in height, inside the triangle.
- (b) Each label or sticker shall contain the following warning statement in black ink: "DANGER TO CHILDREN KEEP OUT OF REACH" in flat regular Arial or Calibri typeface and no less than eight-point font in size.
- (c) The text and the graphic on the label or sticker shall be clearly legible and unobscured.
- (d) A label or sticker exemplar shall be published on the Department’s internet website for use by pharmacies on all applicable packaging and containers and any pharmacy’s use of

such exact exemplar on applicable packaging and containers shall constitute compliance with the requirements set forth in this section and section 20-636-2 of the Regulations of Connecticut State Agencies.

**(NEW) Sec. 20-636-4. Placement**

A pharmacy shall ensure a label or sticker (1) is directly on, or firmly affixed to, the outer surface of the container or packaging, (2) is legible, unobscured, prominently placed and conspicuous so that it is readily visible to the patient; and (3) does not: (A) obstruct the opening of the container or packaging; (B) impede the delivery of the controlled substance; or (C) obscure any information on the prescription label affixed to the container or packaging that is required by federal and state law.

**Statement of Purpose:**

To promulgate regulations pursuant to Public Act 23-100 which set forth placement and appearance requirements of the warning label placed on controlled substances.

**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

**Opioid Warning Labels**eRegulations System Tracking Number **PR2023-046****I hereby certify the following:**

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities: **Public Act 23-100**

*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 **October 12, 2023**.

(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 **January 2, 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 **January 2, 2024**.

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **May 10, 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

May 10, 2024  
DATE

**OFFICE OF THE ATTORNEY GENERAL  
REGULATION CERTIFICATION**

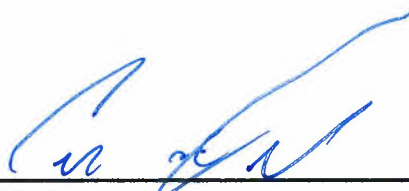
**Agency: Department of Consumer Protection**

***REGULATION NUMBER: PR2023-046***

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

**DATE: 6/4/2024**

**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

June 25, 2024

Agency: Department of Consumer Protection  
Description: Opioid Warning Labels  
LRRC Regulation Number: 2024-006A  
eRegulation Tracking Number: PR2023-046

The above-referenced regulation has been

### **Approved with Technical Corrections and Substitute Pages**

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 Opioid  
Warning Labels  
eRegulations System Tracking Number PR2023-046  
Legislative Regulation Review Committee Docket Number 2024-006A

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 June 25, 2024.

Said regulation is assigned Secretary of the State File Number 6410.

The effective date of this regulation is June 26, 2024.

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

Stephanie Thomas  
Secretary of the State  
June 26, 2024

By:

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