

State of Connecticut
Department of Consumer Protection
Policies and Procedures
concerning
Opioid Warning Labels - November 2023
Effective November 10, 2023

These policies and procedures effectuate the intent of Public Act No. 23-100 of the 2023 Regular Session. Said Public Act requires the Department to enact policies and procedures which set forth placement and appearance requirements for the warning label placed on controlled substances. Notwithstanding any notice and comment period, these policies and procedures are effective as of the date set forth above pursuant to the above-cited Public Act. These policies and procedures will be followed by proposed regulations adding sections 20-636-1 et seq to the Regulations of Connecticut State Agencies.

Section 1.

(a) Definitions. As used in this section:

- (1) “Container” means the receptacle that holds the prescription medication, labeled with information required by federal and state law for dispensing;
- (2) “Controlled substance” shall have the same meaning as in section 21a-240 of the general statutes;
- (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:0.6, Y:1, K:0, and with a decimal value of 16738048;
- (4) “Opioid drug” shall have the same meaning as in section 20-14o of the general statutes;
- (5) “Packaging” means the bag, box, wrapping, or other material used to contain or enclose the container for delivery to a patient;
- (6) “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.

(b) Dimensions. The label or sticker shall be:

- (1) Round and no less than one and one-quarter inch in diameter; and
- (2) Fluorescent orange in color with black text.

(c) Warning Statement.

- (1) Each label or sticker shall contain:

- (i) 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; and
 - (ii) 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.
 - (2) The text and the graphic prescribed in subdivision (c)(1) of this section shall be clearly legible and unobscured.
 - (3) 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 of this subsection.
- (d) Placement. A label or sticker shall be directly on or affixed to outer surface of the container or packaging in a manner that:
- (1) Is legible, unobscured, prominently placed and conspicuous so that it is readily visible to the patient; and
 - (2) Does not: (i) obstruct the opening of the container or packaging; (ii) impede the delivery of the controlled substance; or (iii) obscure any information on the prescription label affixed to the container or packaging that is required by federal and state law.