

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 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, 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.