

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) Section 20-636-1. Definitions

- (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. Its decimal value is 16738048;
- (4) “Opioid drug” shall have the same meaning as in section 20-140 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.

(NEW) 20-636-2. Dimensions

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

(NEW) 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 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 Sections 20-636-2 and 20-636-3 of the Regulations of Connecticut State Agencies.

(NEW) 20-636-4. Placement

- (a) A label or sticker shall be:
 - (1) Directly on or firmly affixed to the outer surface of the container or packaging;
 - (2) Directly on or affixed to the container or packaging so that it is legible, unobscured, prominently placed and conspicuous so that it is readily visible to the patient; and
 - (3) Directly on or affixed on the container or packaging so that it 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.

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.