54 N.J.R. 88(a)

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RULE ADOPTIONS

Reporter
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Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF PHARMACY

Administrative Code Citation

Adopted Amendment: N.J.A.C. 13:39-7.12

Text

Opioid Warning Label

Proposed: April 5, 2021, at 53 N.J.R. 497(a).

Adopted: June 30, 2021, by the State Board of Pharmacy, Linda Witzal, R.Ph., President.

Filed: December 6, 2021, as R.2022 d.004, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-15.1 and 45:14-47; and P.L. 2019, c. 162.

Effective Date: January 3, 2022.

Expiration Date: March 1, 2024.

Summary of Public Comments and Agency Reponses:

The official comment period ended June 4, 2021. The Board of Pharmacy (Board) received comments from:

1. Elise M. Barry, MS, CFRE, Chief Executive Officer, on behalf of the New Jersey Pharmacists Association;

2. Jeenu Philip, R.Ph. Director, Pharmacy Affairs, Walgreens Co.; and

3. John Holub, Executive Director, New Jersey Council of Chain Drugs Stores.

1. COMMENT: One commenter, recognizing the extent of the opioid crisis and the efforts to educate patients on the use of opioids, suggested that the proposal include an exemption from the requirement to add a warning label on prescriptions filled for hospice patients receiving care at home or in non-institutional settings (outside an institution which is covered in the proposal). The commenter stated that pharmacists have expressed concern that these critically ill patients should not be presented with any deterrent to taking the medication legitimately prescribed to manage their pain or condition.

RESPONSE: N.J.S.A. 24:21-17 requires all pharmacists dispensing an opioid medication to affix to the container in which such opioid medication is sold or dispensed, a warning label or sticker describing the risks associated with opioid medications. The law exempts a pharmacist in an institutional pharmacy, as that term is defined at N.J.A.C. 13:39-9.2. The rules must be consistent with statutory requirements, and, therefore, the Board cannot change those exemptions as the commenter suggested.

2. COMMENT: Two commenters recommended that the Board amend the warning label color, font, and location requirements at N.J.A.C. 13:39-7.12(e)2. Although the commenters expressed support for the intent behind the regulation, they believe the objective can be satisfied through less stringent means and with greater flexibility.

One of the commenters believes some of the specifics of the proposed language to be onerous, and potentially costly to pharmacies, as some of the requirements do not align with states that have existing requirements regarding an opioid warning label. In addition, this commenter contended that having broader requirements also reduces the Board potentially needing to entertain future waiver requests on this issue. This commenter requested that the Board consider the fact there are a few states that have implemented similar requirements, though, some vary in specifics.

The second commenter, urging greater flexibility, noted that none of the five states with the warning label requirement explicitly address font size. In addition, this commenter noted that California allows the warning to be imprinted on the cap. The commenter noted that in New Hampshire, the warning label is orange and allowed on the cap or prescription vial in "easily legible font," and Utah allows the warning to be affixed to either the "lid" or "container." This commenter stated that five states currently have opioid warning label requirements, and all five states provide greater flexibility than what is being proposed in New Jersey.

The first commenter, urging flexibility, requested that the Board amend the warning label color, font, and location requirements to allow for easier matching with other existing states' requirements by either expanding the color options or eliminating the color requirement, eliminating specific location requirements, and eliminating specific font requirements, while still meeting the legislative intent. Specifically, the commenter suggested amending N.J.A.C. 13:39-7.12(e)2 as follows (additions in bold; deletions in strikethrough):

"2. The warning label or sticker must be:

i. Red**, orange** or yellow in color;

ii. Printed with a font

size between 10- and 12-point font that is printor block-based (that is, not cursive) and such that the font and lettering shall be easily and clearly readable; and

iii. iv. Placed on the side, not the bottom or top, of the bottle or box that contains the prescription label.

Alternatively, the commenter suggested the following amendments (additions in bold; deletions in strikethrough):

"2. The warning label or sticker must be:

i. Red or yellow in color;

ii. Printed with a font
size between 10- and 12-point font that is printor block-based (that is, not cursive) and such that the font and lettering shall be easily and clearly readable; and

iii. iv. Placed on the side, not the bottom or top, of the bottle or box that contains the prescription label.

The other commenter urging flexibility requested that the Board amend N.J.A.C. 13:39-7.12(e)2 as follows (additions in bold; deletions in strikethrough):

2. The warning label or sticker must be:

i. Red, **orange** or yellow in color;

ii. Written in black color text;

iii. Printed with

a font size between 10- and 12-point font that is printor block-based (that is, not cursive) such that the font and lettering shall be **an** easily **legible font that is** and clearly readable; and

iv. Placed on the

side, not the bottom or top, of the bottle or box **cap or container** that contains the prescription label.

The commenters believe that these requested changes will provide the needed flexibility for its member companies and does not believe these changes diminish the impact or intent of the law.

RESPONSE: N.J.SA. 24:21-17 requires the Board to specify, by rule, the location on the medication container where the warning label or sticker shall be affixed, the font and format of any language to be included on the warning label or sticker, and the specific language to be included on the warning label or sticker, which, at a minimum, shall indicate that the medication in the container is an opioid and that opioid medications carry a risk of addiction and overdose. In addition, the law specifies that, unless otherwise provided by rules or regulations promulgated by the Board, the label or sticker shall be red in color with the text printed in black. When the Board proposed its rules, it took into consideration the existing requirements of other states, as well as its statutory mandate.

The Board agrees with the commenters' suggestion to expand the color options for the label. Upon adoption, the Board will change the section to add orange as an acceptable color for the label. In addition, to provide more flexibility and to also establish an objective regulatory standard for the regulated

community to follow, upon adoption, the Board will change the font size, such that it is a minimum of 10-point font. By specifying a minimum readable font size, the Board is fulfilling the statutory requirement of regulating the font and providing flexibility to the regulated community to comply with the section. With respect to the location, the Board understands the desire to provide pharmacists with the flexibility to use the available space on a container. The Board also believes that it is important that the warning label be prominently placed such that it is visible to the patient. Therefore, upon adoption, the Board will change the rule to allow the label to be placed on the cap, but not the bottom of a bottle or box. Additional public notice of these changes is not necessary because the amendments do not impose any additional burdens and do not change the effect of this rule, so as to destroy the value of the original notice.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendment is governed by N.J.S.A. 45:14-40 et seq., and there are no Federal laws or standards applicable to the adopted amendment.

Full text of the adopted amendments follow (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

[page=89] SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.12 Labeling

(a)-(d) (No change.)

(e) In addition to the requirements set forth in this section, when a pharmacist dispenses a prescription for an opioid medication, the pharmacist shall affix, to the container, a warning label or sticker such that the label or sticker shall:

1. Contain the warning, "Opioid Risk of Addiction and Overdose." Punctuation and layout of the warning may be determined by the permitted pharmacy.

2. The warning label or sticker must be:

i. Red ***, orange,*** or yellow in color;

ii. Written in black color text;

iii. Printed with a font size *[between]* ***of at least*** 10-*[and 12-]* point font that is print- or block-based (that is, not cursive) such that the font and lettering shall be easily and clearly readable; and

iv. Placed on the side, not the bottom *[or top]*, of the bottle or box that contains the prescription label ***, or on the cap of the bottle***.