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*Deputy Director*

**Disease Control and Prevention**  
Janae Duncan, M.P.A.  
*Division Director*

June 1, 2021

Dear Outlet Manager:

The Utah Department of Health filed to make change in proposed rule amendment R384-415, rule filing #53257, effective June 1, 2021. A copy of this current Administrative Rule R384-415 Electronic Cigarette Substance Standards is enclosed in this letter.

The current rule R384-415-1(4) requires that "Beginning on July 1, 2021, a person may only sell a manufacturer sealed electronic cigarette substance that is compliant with the established standards and requirements set forth in this rule." The rule establishes labeling, nicotine content, packaging, and product quality standards for manufacturer sealed electronic cigarette substances, or otherwise known as a sealed electronic cigarette pod or cartridge.

Effective July 1, 2021, a Utah tobacco retailer is prohibited from selling a manufacturer sealed electronic cigarette substance that do not meet the labeling requirements, and the prohibited sale requirements, including manufacturer sealed electronic cigarette substances that contain additives that create the impression that the product has a health benefit; that are associated with energy and vitality; that contain illegal or controlled substances as identified in Section 58-37-3; and additives having coloring properties for emissions. Retailers are prohibited from selling manufacturer sealed electronic cigarette substances with a nicotine concentration that is greater than 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine. Manufacturer sealed electronic cigarette substances sold must be sold in their original packaging and not repackaged. Any CBD non-manufacturer sealed electronic cigarette substances or e-liquids and manufacturer sealed electronic cigarette substances or cartridges/pods must be compliant with Title 4, Chapter 41, Part 1, Industrial Hemp and Section R68-26-5 and Section R68-33-5. Lastly, the product quality standards require retailers to only sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance that has received marketing authorization from the U.S. Food and Drug Administration (FDA) under their Premarket Tobacco Product Application process by when the FDA begins enforcing non-compliance of products without authorization.

Due to the passage of S.B. 1003 during the First Special Session on May 19, 2021, the Utah Department of Health is again proposing an amendment to the current rule R384-415 to align with changes in Title 26, Chapter 57, Section 103. On June 15, 2021, a copy of the proposed rule amendment to R384-415 will be published on the homepage of <https://utahtobaccolaws.org/>. New text is underlined and any deleted text is bracketed and struck through.

If the proposed rule amendment goes into effect as written, it would become effective on July 22, 2021. At that time, all the same current requirements of the rule would apply to manufacturer sealed electronic cigarette products, otherwise known as prefilled electronic cigarettes or disposables. A tobacco retailer would be prohibited from selling prefilled electronic cigarettes or disposables with a nicotine concentration that is greater than 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine.

In addition, the proposed rule amendment would prohibit a tobacco retailer from selling a manufacturer sealed electronic cigarette product, including cartridges, pods, and prefilled disposables with a nicotine concentration that is greater than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine, effective September 1, 2021. Lastly, a manufacturer or retailer may continue to sell electronic cigarette products if the product complies with all the requirements set forth in the proposed rule, the manufacturer submitted a timely Pre-Market Tobacco application or Substantial Equivalent application to the FDA by September 9, 2020, and the FDA has not issued a written marketing order.

Public comments on the proposed rule amendment to R384-415 Requirements to Sell Electronic Cigarette Products, filing #53559, will be accepted until 7/15/2021 and can be sent to [tobaccorulescomments@utah.gov](mailto:tobaccorulescomments@utah.gov). Please contact TPCP Policy Analyst Christy Cushing for questions at 801-538-6260 or [ccushing@utah.gov](mailto:ccushing@utah.gov).

Sincerely,



Braden Ainsworth  
Program Manager  
Tobacco Prevention and Control Program

**R384. Disease Control and Prevention, Health Promotion.**

**R384-415. Electronic Cigarette Substance Standards.**

**R384-415-1. Authority and Purpose.**

- (1) This rule is authorized by Section 26-57-103.
- (2) The purpose of this rule is to establish standards for labeling, nicotine content, packaging, and product quality for non-manufacturer sealed electronic cigarette substances and manufacturer sealed electronic cigarette substances for the regulation of selling electronic cigarette products.
- (3) A person may only sell a non-manufacturer sealed electronic cigarette substance that is compliant with the established standards and requirements set forth in this rule.
- (4) Beginning on July 1, 2021, a person may only sell a manufacturer sealed electronic cigarette substance that is compliant with the established standards and requirements set forth in this rule.
- (5) A product in compliance with this rule is not endorsed as safe.

**R384-415-2. Definitions.**

As used in this rule:

- (1) "Child resistant" means the same as the term "special packaging" is defined in 16 C.F.R 1700.1(a)(4) and is tested in accordance with the method described in 16 C.F.R. 1700.20.
- (2) "Department" means the Utah Department of Health.
- (3) "Electronic cigarette" means the same as that term is defined in Section 76-10-101.
- (4) "Electronic cigarette product" means the same as that term is defined in Section 76-10-101.
- (5) "Electronic cigarette substance" means the same as that term is defined in Section 76-10-101.
- (6) "Local health department" means the same as that term is defined in Subsection 26A-1-102(5).
- (7) "Industrial hemp product" means the same as that term defined is in Section 4-41-102.
- (8) "Manufacture" means the same as that term is defined in Section 26-57-102.
- (9) "Manufacturer" means the same as that term is defined in Section 26-57-102.
- (10) "Manufacturer sealed electronic cigarette substance" means the same as that term defined is in Section 26-57-102.
- (11) "Mg/mL" means milligrams per milliliter, a ratio for measuring an ingredient, in liquid form, where accuracy is measured in milligrams per milliliter, or a percentage equivalent.
- (12) "Nicotine" means the same as that term is defined in Section 76-10-101.
- (13) "Non-manufacturer sealed electronic cigarette substance" means:
  - (a) an electronic cigarette substance that is not a manufacturer sealed electronic cigarette substance; and
  - (b) an electronic cigarette substance container the electronic cigarette manufacturer does intend for a consumer to open or refill.
- (14) "Package" or "packaging" means a pack, box, carton, or container of any kind, or if no other container, any wrapping, in which an electronic cigarette substance or a manufacturer sealed electronic cigarette substance is offered for sale, sold, or otherwise distributed to consumers.
- (15) "Permit" means the same as that term is defined in Section 26-62-101.
- (16) "Retailer" means any person who sells, offers for sale, exchanges, or offers to exchange for any form of consideration, an non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance to a consumer. This definition is without regard to the quantity of an non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance sold, offered for sale, exchanged, or offered for exchange.
- (17) "Transaction statement" means a statement, in paper or electronic form, which the manufacturer transferring ownership of the product certifies that the non-manufacturer sealed electronic cigarette substance or the manufacturer sealed electronic cigarette substance is in compliance with the standards in this rule.

**R384-415-3. Labeling.**

- (1) The retailer shall ensure that nicotine containing non-manufacturer sealed electronic cigarette substance or manufacturer sealed electronic cigarette substance offered for sale to the consumer features on the product package label the required safety warning stating "WARNING: This product contains nicotine. Nicotine is an addictive chemical."
- (2) Consistent with 21 C.F.R. 1143.3, the safety warning statements required in Subsection (1), the required safety warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:
  - (a) be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;
  - (b) be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;
  - (c) be printed in conspicuous and legible Helvetica bold or Arial bold type, or other sans serif fonts, and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;
  - (d) be capitalized and punctuated as indicated in Subsection (1); and
  - (e) be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(3) The retailer shall ensure that a non-manufacturer sealed electronic cigarette substance marketed as nicotine-free and offered for sale to the consumer features a safety warning stating "WARNING: Keep away from children and pets."

(4) The safety warning statements required in Subsection (3), the required safety warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(a) be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(b) be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(c) be printed in conspicuous and legible Helvetica bold or Arial bold type, or other sans serif fonts, and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, consistent with the other printed material on the package;

(d) be capitalized and punctuated as indicated in Subsection (3); and

(e) be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(5) A retailer will not be in violation of this section for packaging that:

(a) contains a health warning;

(b) is supplied to the retailer by the electronic cigarette substance manufacturer, importer, or distributor, who has the required state, local, or tobacco tax license or permit, if applicable; and

(c) is not altered by the retailer in a way that is material to the requirements of this section.

(6) A non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance package that would otherwise be required to bear the safety warning in Subsection (1) or (3) but is too small or otherwise unable to accommodate a safety warning label with sufficient space to bear such information is exempt from compliance with the requirement provided that:

(a) the information and specifications required in Subsection (1) and (3) appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information; or

(b) appear on a tag otherwise firmly and permanently affixed to the non-manufacturer sealed electronic-cigarette substance package or the manufacturer sealed electronic cigarette substance package.

(7) In the case of Subsection (6)(a) or (b), the carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

(8) The retailer shall ensure that an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette substance is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp and Section R68-26-5, unless:

(a) an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance marketed as containing nicotine and offered for sale or an industrial hemp product that is a manufacturer sealed electronic cigarette substance marketed as containing nicotine and offered for sale is in compliance with the safety warning requirements in Subsection (1) and (2); or

(b) an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance marketed as nicotine-free and offered for sale is exempt from the safety warning requirements in Subsection (3) and (4); if the product is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp and Section R68-26-5.

#### **R384-415-4. Prohibited Sales.**

(1) The retailer shall be prohibited from selling a non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance that is labeled as containing:

(a) additives that create the impression that a non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance has a health benefit;

(b) additives that are associated with energy and vitality;

(c) illegal or controlled substances as identified in Section 58-37-3; and

(d) additives having coloring properties for emissions.

(2) The retailer shall be prohibited from selling an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette substance unless it is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp; Section R68-26-5; and Section R68-33-5.

#### **R384-415-5. Nicotine Content.**

(1) The retailer shall be prohibited from selling a non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette substance to the consumer if the product is not compliant with the following:

(a) the nicotine concentration for a non-manufacturer sealed electronic cigarette substance is limited to 360 mg nicotine per container, or does not exceed a 24mg/mL concentration of nicotine; and

(b) the nicotine concentration for a manufacturer sealed electronic cigarette substance is limited to 5% nicotine by weight per container, or does not exceed a 59mg/mL concentration of nicotine, effective July 1, 2021.

NOTHING ABOUT  
36 mg SEPTEMBER

**R384-415-6. Packaging.**

(1) The retailer shall ensure that the packaging of a non-manufacturer sealed electronic cigarette substance intended for sale to a consumer is certified as child resistant, and compliant with federal standards and law concerning child nicotine poisoning prevention.

(2) The retailer shall sell non-manufacturer sealed electronic cigarette substances and manufacturer sealed electronic cigarette substances in the product's original packaging.

(3) The retailer shall be prohibited from repackaging or dispensing any non-manufacturer sealed electronic cigarette substance or any manufacturer sealed electronic cigarette substance for retail sale.

(4) The retailer shall be prohibited from refilling a manufacturer sealed electronic cigarette substance that is not intended to be opened by a retailer or a consumer.

(5) The retailer shall ensure that an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette substance is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp; and Rule R68-26.

**R384-415-7. Product Quality.**

(1) No manufacturer or retailer shall sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance unless the product complies with each of the relevant electronic cigarette product standards established by the U.S. Food and Drug Administration under 21 U.S.C. 387g(3).

(2) Notwithstanding Subsection (3), after September 9, 2021, no manufacturer or retailer shall sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance unless the product has received marketing authorization from the U.S. Food and Drug Administration (FDA) under 21 U.S.C. 387j(c)(1)(A)(i), 21 U.S.C. 387j(a)(2)(A)(i), or 21 U.S.C. 387j(a)(2)(A)(ii).

(3) This section will take effect on the date that manufacturers are required to secure marketing orders from the FDA to continue marketing their products in the United States. Any delays in enforcement efforts by FDA due to litigation will not impact the effective date of this section.

**R384-415-8. Record Keeping and Testing.**

(1) The retailer shall provide the non-manufacturer sealed electronic cigarette substance transaction statements or manufacturer sealed electronic cigarette substance transaction statements to the Department or the local health department within 14 calendar days of a request. The retailer shall ensure that the transaction statement includes manufacturer certifications that:

(a) the labeling standards are compliant with Section R384-415-3;

(b) the nicotine content of a non-manufacturer sealed electronic cigarette substance is compliant with Subsection R384-415-5(1)(a) and the nicotine content of a manufacturer sealed electronic cigarette substance is compliant with Subsection R384-415-5(1)(b);

(c) the packaging standards are compliant with Section R384-415-6; and

(d) the product quality standards are compliant with Section R384-415-7.

(2) The retailer shall provide evidence that supports the documents described in Subsection R384-415-8(1) to the Department or the local health department within 14 calendar days of a request.

(3) The retailer shall have access to the documents described in Subsections R384-415-8(1) and R384-415-8(2) for a period of two years after the retailer purchases the non-manufacturer sealed electronic cigarette substance or the manufacturer sealed electronic cigarette substance.

**R384-415-9. Enforcement.**

(1) In enforcing or seeking penalties of any violation as set forth in this rule or Section 26-57-103, the Department and local health departments shall comply with the enforcement requirement in Title 26, Chapter 62, Part 3, Enforcement.

**KEY: electronic cigarettes, nicotine, standards, Electronic Cigarette Regulation Act**

**Date of Enactment or Last Substantive Amendment: 2021**

**Notice of Continuation: December 8, 2020**

**Authorizing, and Implemented or Interpreted Law: 26-57-103**