

**NOTICE OF CHANGE IN PROPOSED RULE**

Utah Admin. Code Ref (R no.):

R384-415

Filing No. 53257

**Agency Information**

<b>1. Department:</b>	Health	
<b>Agency:</b>	Disease Control and Prevention, Health Promotion	
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Please address questions regarding information on this notice to the agency.		

**General Information**

<b>2. Rule or section catchline:</b>	
R384-415. Electronic Cigarette Substance Standards	
<b>3. Change in Proposed Rule:</b>	
Changes FILING Name, Publication date of prior filing:	R384-415. Electronic Cigarette Substance Standards, published 01/15/2021
<b>4. Reason for this change:</b>	
Utah Department of Health (UDOH) reviewed and evaluated the comments received between January 15, 2021, and February 15, 2021, and seeks to incorporate the following four changes to the original rule filing.	
<b>5. Summary of this change:</b>	
There are four changes in this change in proposed rule (CPR). First is eliminating the requirement for nicotine-free labeling on manufacturer sealed electronic cigarette substances in Subsections R384-415-3(3) and R384-415-3(8)(b), second is correcting a reference error in Subsection R384-415-3(6), third is clarifying the prohibition language in Subsection R384-415-4(2), and fourth is eliminating the 3% or 36mg/mL manufacturer sealed electronic cigarette substance nicotine content requirements in Subsection R384-415-5(1)(b). (EDITOR'S NOTE: The original proposed amendment upon which this CPR was based was published in the January 15, 2021, issue of the Utah State Bulletin, on page 20. Underlining in the rule below indicates text that has been added since the publication of the proposed rule mentioned above; strike-out indicates text that has been deleted. You must view the CPR and the proposed amendment together to understand all of the changes that will be enforceable should the agency make this rule effective.)	

**Fiscal Information**

<b>6. Aggregate anticipated cost or savings to:</b>
<b>A) State budget:</b>
Enactment of this CPR is not expected to have any fiscal costs to the state budget. Manufacturer sealed electronic cigarette substances should have been excluded from the nicotine free labeling, as the federal law only mandates child-resistant packaging for containers that are meant to be refilled or that are able to be opened by an adult; therefore, a manufacturer sealed container is exempt from the Poison Prevention Packaging Act of 1970.
<b>B) Local government:</b>
Enactment of this CPR is not expected to have any fiscal impact on the local government budgets, as local health departments will continue to conduct retail observations and investigations in accordance with respective state tobacco control laws, state administrative rules, and local health department regulations using existing allocated resources to enforce the amended rule.
<b>C) Small businesses ("small business" means a business employing 1-49 persons):</b>
Enactment of this CPR may result in a direct cost to small businesses that employ fewer than 50 employees and choose to sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine.
The rule amendment may result in a direct fiscal cost to small businesses that primarily rely on the sale of tobacco products

(retail tobacco specialty businesses) and operate under the North American Industry Classification System (NAICS) codes of 453991, 424940. Other small businesses that sell manufacturer sealed electronic cigarette substances among other products they choose to sell include (445120) convenience stores, (447110) gas stations with convenience stores, (445110) supermarkets and other grocery stores, (452319) general merchandise and discount stores, (447190) other gasoline stations, (453991) tobacco stores, (424940) tobacco product merchant wholesalers, (453220) gift, novelty, and souvenir stores, (721110) hotels, (813410) civic and social organizations. A review of UDOH combined local health department tobacco retail compliance check logs for fiscal year 2020 and cross-referenced with Utah Department of Workforce Services (DWS) Firm Find Data, shows that there are approximately 1,175 small businesses that sell some type of electronic cigarette substances in Utah, or approximately 88% of Utah tobacco retailers.

UDOH does not know how many of these 1,175 small businesses sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine. Only tobacco retailers that currently sell manufacturer sealed electronic cigarette substances with a higher nicotine concentration may experience a direct fiscal impact.

**D) Non-small businesses** ("non-small business" means a business employing 50 or more persons):

Enactment of this CPR may result in a direct cost to non-small businesses that employ more than 50 employees and choose to sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine.

The rule amendment may result in a direct fiscal cost to non-small businesses that sell manufacturer sealed electronic cigarette substances among other products they choose to sell include (445120) convenience stores, (447110) gas stations with convenience stores, (445110) supermarkets and other grocery stores, (452319) general merchandise and discount stores, (447190) other gasoline stations, and (453220) gift, novelty, and souvenir stores. A review of UDOH combined local health department tobacco retail compliance check logs for fiscal year 2020 and cross-referenced with Utah Department of Workforce Services (DWS) Firm Find Data, shows that there are approximately 208 non-small businesses that sell some type of electronic cigarette substances in Utah, or approximately 12% of Utah tobacco retailers.

UDOH does not know how many of these 208 non-small businesses sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine. Only tobacco retailers that currently sell manufacturer sealed electronic cigarette substances with a higher nicotine concentration may experience a direct fiscal impact.

**E) Persons other than small businesses, non-small businesses, or state or local government entities** ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an **agency**):

Enactment of this CPR may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine and individuals who work for small businesses or non-small businesses that sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine.

The indirect costs or indirect benefits to persons is unknown and difficult to determine, as the potential impact on consumers is unknown as they could choose to vape manufacturer sealed electronic cigarette substances with a lower nicotine concentration, or they may choose to quit using manufacturer sealed electronic cigarettes because of enactment of this CPR.

Likewise, the indirect costs or indirect benefits to persons employed at tobacco retail businesses is unknown and it is difficult to determine the impact on individual tobacco retail employees, who may be employed at either small businesses or non-small businesses which could be impacted as already indicated in 5C. and 5D above, because of enactment of this CPR.

**F) Compliance costs for affected persons:**

Enactment of this CPR may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine and individuals who work for small businesses or non-small businesses that sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than either 5% by weight per container or exceed 59 mg/ml concentration of nicotine.

**G) Regulatory Impact Summary Table** (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table			
Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0

<b>Total Fiscal Cost</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Fiscal Benefits</b>			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
<b>Total Fiscal Benefits</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Net Fiscal Benefits</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

**H) Department head approval of regulatory impact analysis:**  
The Executive Director of the Department of Health, Richard G. Saunders, has reviewed and approved this fiscal analysis.

**7. A) Comments by the department head on the fiscal impact the rule may have on businesses:**  
The fiscal impact of this CPR is inestimable because retailers have the option to sell manufacturer sealed electronic cigarette substances with nicotine concentrations equal to or less than 5% by weight per container or 59 mg/ml concentration of nicotine.

**B) Name and title of department head commenting on the fiscal impacts:**  
Richard G. Saunders, Executive Director

**Citation Information**

**8. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):**  
Subsection 26-57-103(2)

**Public Notice Information**

**10. The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

**A) Comments will be accepted until (mm/dd/yyyy):** 04/14/2021

**11. This rule change MAY become effective on (mm/dd/yyyy):** 04/21/2021

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 11, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

**Agency Authorization Information**

<b>Agency head or designee, and title:</b>	Richard G. Saunders, Executive Director	<b>Date (mm/dd/yyyy):</b>	02/25/2021
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**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 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 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 [~~or a 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 [(2)](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 [or an industrial hemp product that is a 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 ~~ensure that~~ 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[:

~~(i)] to 5% nicotine by weight per container, or does not exceed a 59mg/mL concentration of nicotine, effective July 1, 2021 [; and~~

~~(ii) to 3% nicotine by weight per container, or does not exceed a 36mg/mL concentration of nicotine, effective January 1, 2022].~~

**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**

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