process of receiving, investigating and the final disposition of complaints.

(7) The department and local health departments shall coordinate inspections, complaint investigations, and enforcement activities on regulated entities where there is joint responsibility and as specified in the Environmental Service Delivery Plan.

R305-10-8. Local Health Department Environmental Emergency Response.

(1) Each local health department shall participate in environmental emergency preparedness efforts, including:

(a) identifying local health department roles and responsibilities in emergency response;

(b) establishing partnerships with volunteers, emergency response agencies, and other community organizations involved in emergency response;

(c) cooperating with the Department of Environmental Quality in fulfilling responsibilities associated with Emergency Support Functions;

(d) maintaining an all hazards response plan;

(e) maintaining a continuity of operations plan that shall include employee notification, lines of authority and succession, and prioritized local health department functions; and

(f) testing public health preparedness through participation in Department coordinated response drills and exercises.

R305-10-9. General Performance Standards for Local Health Department Laboratory Services.

(1) Each local health department shall ensure that laboratories used to analyze environmental samples have the necessary certification to conduct the applicable tests.

KEY: administrative procedures, local health departments
Date of Enactment or Last Substantive Amendment: 2021
Authorizing, and Implemented or Interpreted Law: 19-1-201; 26A-1-106(4)

NOTICE OF PROPOSED RULE		
TYPE OF RULE: Amendment		
Utah Admin. Code Ref (R no.):	**R384-415**	**Filing No. 53257**

Agency Information

1. Department:	Health	
Agency:	Disease Control and Prevention, Health Promotion	
Building:	Cannon Health Building	
Street address:	288 N 1460 W	
City, state:	Salt Lake City, UT 84116	
Mailing address:	PO Box 142106	
City, state, zip:	Salt Lake City, UT 84114-2106	
Contact person(s):		
Name:	**Phone:**	**Email:**
Braden Ainsworth	801-538-6187	tobaccorulescomments@utah.gov
Christy Cushing	801-538-6260	tobaccorulescomments@utah.gov

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R384-415. Electronic Cigarette Substance Standards

3. Purpose of the new rule or reason for the change:

These changes revise this rule to align with changes in Section 26-57-103, which became effective 07/01/2020. The changes are needed due to the passage of H.B. 23 during the 2020 General Session, requiring the Department of Health (Department) to establish labeling; nicotine content; packaging; and product quality standards for manufacturer sealed electronic cigarette substances. Between July and September 2020, the Department consulted with representatives from local health departments and members of the public to establish the language for this rule amendment.

4. Summary of the new rule or change:

This rule amendment to Rule R384-415 revises this rule to align with definition changes throughout the Utah Code. In addition, the rule amendment establishes labeling; nicotine content; packaging; and product quality standards and requirements for retailers that sell manufacturer sealed electronic cigarette substances.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

Enactment of this rule amendment is not expected to have any fiscal costs to the state budget, as existing allocated resources can cover an increase for Quit Line cessation services.

There are costs to Utahns who use electronic cigarettes, especially to those who use them now during the COVID-19 pandemic.

An electronic cigarette with a higher concentration of nicotine has a greater likelihood of being more addictive. Utahns who are addicted to nicotine products and want to quit are more likely to need tobacco cessation services to be able to quit successfully. Currently, tobacco cessation services are provided by the Utah Department of Health through the state tobacco quit line and through quit services covered by health insurance plans. The continued sale of addictive products results in higher cost to the state tobacco quit line and health insurance companies to cover treatment for nicotine dependence.

In 2018, 13.3% of Utah's Medicaid recipients used electronic cigarettes. Reducing the nicotine content in

electronic cigarettes sold in Utah could reduce electronic cigarette use among this population and subsequently decrease nicotine dependence treatment and healthcare expenditures for Medicaid clients, both in the short and long term. The Utah Medicaid program currently spends an estimated $125,900,000 each year to treat tobacco-related diseases.

The Utah state quit line budget is approximately $1,000,000 annually and all the tobacco cessation services provided is free and confidential for users. The average state cost for treating nicotine dependence using the Utah quit line ranges between $273 - $300 per user. The Utah youth tobacco cessation program "My Life My Quit" (for both vaping and smoking), offered by the Utah tobacco quit line for individuals between the ages of 13 - 17, cost per user (counseling calls, text messaging, email support) is $273. The Utah adult cessation program provided by the Utah tobacco quit line, cost per user (counseling calls, text messaging, email support, NRT) is $300.

In Utah, an estimated 30,000 youth currently use electronic cigarette products (12.4%). 44.5% of U.S. adolescents who vape are seriously interested in quitting, and 24.9% tried to quit in the past year (Smith, 2020). To offer tobacco cessation services to 44.5% of Utah youth who vape (13,350) would cost Utah an estimated $3,600,000. To offer tobacco cessation services to 50% of young adults who vape (ages 18 - 34) (~55,000) would cost Utah an estimated $16,600,000.

Effective 07/01/2021, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 5% nicotine by weight per container, or exceeding a 59mg/mL concentration of nicotine; and effective 01/01/2022, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 3% nicotine by weight per container, or exceeding a 36mg/mL concentration of nicotine. An electronic cigarette substance with a higher concentration of nicotine has a greater likelihood of being more addictive, being that "the amount of nicotine delivered and the way in which it is delivered influences the addictiveness of a tobacco product" (Eaton DL et al., 2018; HHS, 2010b). Reducing the nicotine content in electronic cigarette substances sold in Utah can aid in preventing youth and adult initiation of electronic cigarette products among Utahans who do not already smoke or vape. Electronic cigarette use is more popular among Utah youth than all other tobacco products combined, therefore limiting youth access to highly addictive electronic cigarette products is critical for preventing a new epidemic of nicotine addiction.

A study of youth and young adults ages 13 - 24 argues that those who have ever used e-cigarettes are five times more likely to contract COVID-19 than those who do not use tobacco products. Dual users of cigarettes and e-cigarettes are nearly seven times more likely to contract the respiratory disease (Gaiha, S. M, et al., 2020).

B) Local governments:

Enactment of this rule amendment is not expected to have any fiscal impact on local governments, 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 this amended rule.

C) Small businesses ("small business" means a business employing 1-49 persons)**:**

This rule amendment may result in a direct cost to small businesses that employ fewer than 50 employees and choose to sell manufacturer sealed electronic cigarette substances. This 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, and 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 the Department 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. The Department 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, or the number of small businesses that sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than 3% by weight per container or exceed 36 mg/ml concentration of nicotine. Approximately 168 small business tobacco retailers, or approximately 12% choose to not sell electronic cigarette substances and these businesses will not be affected by this rule amendment.

The proposed rule amendment labeling; packaging; and product quality standards and requirements for retailers that sell manufacturer sealed electronic cigarette substances are effective 07/01/2021. Whereas regarding nicotine content, effective 07/01/2021, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 5% nicotine by weight per container, or exceeding a 59mg/mL concentration of nicotine; and effective 01/01/2022, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 3% nicotine by weight per container, or exceeding a 36mg/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. The additional six months' notice of the nicotine content limit from 5% nicotine by weight per container, or 59mg/mL concentration of nicotine to equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine may reduce the direct fiscal cost impact on tobacco retailers. The additional six months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette substances with a nicotine concentration higher than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine to sell their current inventory of manufacturer sealed electronic cigarette substance with a nicotine concentration of 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine and avoid restocking these products before 01/01/2022.

According to Statista's E-cigarette market share in the United States in 2020, by brand, 09/04/2020 report, five electronic cigarette manufacturer brands account for 97% of the U.S. market share: Juul (42%), Vuse (36%), blu (9%), Logic (8%) and Njoy (2%). Some of these electronic cigarette brands sell products with a nicotine concentration that is more than 3% nicotine by weight or 36mg/ml concentration of nicotine. Nevertheless, all these brands also offer electronic cigarette products with less than a 3% nicotine by weight per container or 36 mg/ml concentration of nicotine. Utah tobacco retailers that sell manufacturer sealed electronic cigarette substances (or prefilled pods or cartridges) will continue to have the option to sell manufacturer sealed electronic cigarette substances with a nicotine concentration equal to or less than 5% nicotine by weight per container, or that do not exceed a 59mg/mL concentration of nicotine until 01/01/2022, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette substances with a nicotine concentration equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine. As indicated, the five electronic cigarette manufacturer brands listed above all offer manufacturer sealed electronic cigarette substances that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement.

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

This rule amendment 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. 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 the Department combined local health department tobacco retail compliance check logs for fiscal year 2020 and cross-referenced with 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. The Department 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, or the number of non-small businesses that sell manufacturer sealed electronic cigarette substances with nicotine concentrations higher than 3% by weight per container or exceed 36 mg/ml concentration of nicotine. Approximately 164 non-small business tobacco retailers, or approximately 9.6%, choose to not sell any electronic cigarette substances and these businesses will not be affected by this rule amendment.

The proposed rule amendment labeling; packaging; and product quality standards and requirements for retailers that sell manufacturer sealed electronic cigarette substances are effective 07/01/2021. Whereas regarding nicotine content, effective 07/01/2021, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 5% nicotine by weight per container, or exceeding a 59mg/mL concentration of nicotine; and effective 01/01/2022, this rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette substance from selling a manufacturer sealed electronic cigarette substance with a nicotine concentration higher than 3% nicotine by weight per container, or exceeding a 36mg/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. The additional six months' notice of the nicotine content limit from 5% nicotine by weight per container, or 59mg/mL concentration of nicotine to equal to or less than 3% nicotine by weight per container, or that do not exceed

a 36mg/mL concentration of nicotine may reduce the direct fiscal cost impact on tobacco retailers. The additional six months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette substances with a nicotine concentration higher than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine to sell their current inventory of manufacturer sealed electronic cigarette substance with a nicotine concentration of 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine and avoid restocking these products before 01/01/2022.

According to Statista's E-cigarette market share in the United States in 2020, by brand, 09/04/2020 report, five electronic cigarette manufacturer brands account for 97% of the U.S. market share: Juul (42%), Vuse (36%), blu (9%), Logic (8%) and Njoy (2%). Some of these electronic cigarette brands sell products with a nicotine concentration that is more than 3% nicotine by weight or 36mg/ml concentration of nicotine. Nevertheless, all these brands also offer electronic cigarette products with less than a 3% nicotine by weight per container or 36 mg/ml concentration of nicotine. Utah tobacco retailers that sell manufacturer sealed electronic cigarette substances (or prefilled pods or cartridges) will continue to have the option to sell manufacturer sealed electronic cigarette substances with a nicotine concentration equal to or less than 5% nicotine by weight per container, or that do not exceed a 59mg/mL concentration of nicotine until 01/01/2022, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette substances with a nicotine concentration equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine. As indicated, the five electronic cigarette manufacturer brands listed above all offer manufacturer sealed electronic cigarette substances that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement.

E) Persons other than small businesses, non-small businesses, 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***)**:**

This rule amendment to Rule R384-415 may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy electronic cigarette substances and individuals who work for small businesses or non-small businesses that sell electronic cigarette substances. The indirect costs or indirect benefits to persons is unknows and difficult to determine, as the potential impact on consumers is unknown as they could choose to vape electronic cigarettes with a lower nicotine concentration, or they may choose to quit using electronic cigarettes as a result of enactment of this rule amendment. 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, as a result of enactment of this rule amendment.

F) Compliance costs for affected persons:

This rule amendment to Rule R384-415 may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy electronic cigarette substances and individuals who work for small businesses or non-small businesses that sell electronic cigarette substances.

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
Total Fiscal Cost	**$0**	**$0**	**$0**
Fiscal Benefits			
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
Total Fiscal Benefits	**$0**	**$0**	**$0**
Net Fiscal Benefits	**$0**	**$0**	**$0**

H) Department head approval of regulatory impact analysis:

The Interim Executive Director of Department of Health, Richard G. Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:
After conducting a thorough analysis, it was determined that this proposed rule amendment will not result in a fiscal impact to businesses is inestimable because retailers have the option to sell this product.
B) Name and title of department head commenting on the fiscal impacts:
Richard G. Saunders, Interim Executive Director

Citation Information

7. 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

9. 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:	02/15/2021

10. This rule change MAY become effective on:	2/22/2021
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 10, 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

Agency head or designee, and title:	Richard G. Saunders, Interim Executive Director	**Date:**	12/17/2020

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[~~ and Subsection 59-14-803(5)~~].

(2) The[~~is~~] purpose of this rule is to establish[~~es~~] 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[~~s~~] 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.

[~~(3) This rule does not apply to a manufacturer sealed electronic cigarette substance.~~]

[~~(4)~~](5) A product in compliance with this rule is not endorsed as safe.

R384-415-2. Definitions.

As used in this rule:

[~~(1) "Business" means any sole proprietorship, partnership, joint venture, corporation, association, or other entity formed for profit or non-profit purposes.~~]

[~~(2)~~](1) "Child resistant" means the same as the term "special packaging" is defined in 16 C.F.R 1700.1(a)(4) [~~(January 1, 2015)~~]and is tested in accordance with the method described in 16 C.F.R. 1700.20[~~ (January 1, 2015)~~].

[~~(3)~~](2) "Department" means the Utah Department of Health.

[~~(4)~~](3) "Electronic[-] cigarette" means the same as that[~~the~~] term is defined in [~~Subs~~]Section[~~s 26-38-2(1) and 59-14-802(2)~~] 76-10-101.

[~~(5)~~](4) "Electronic[-] cigarette [~~P~~]product" means the same as that[~~the~~] term is defined in [~~Subs~~]Section [~~59-14-802(3)~~]76-10-101.

[~~(6)~~](5) "Electronic[-] cigarette substance" means the same as that[~~the~~] term is defined in [~~Subs~~]Section [~~59-14-802(4)~~]76-10-101.

[~~(7)~~](6) "Local health department" means the same as that[~~the~~] 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[~~the~~] term is defined in [~~Subs~~]Section 26-57-102[~~(5)~~].

(9) "Manufacturer" means the same as that[~~the~~] term is defined in [~~Subs~~]Section 26-57-102[~~(6)~~].

(10) "Manufacturer sealed electronic cigarette substance" means the same as that term defined is in Section 26-57-102.

[~~(10)~~](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.

[~~(11) "Nicotine" means the same as the term is defined in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 387(12) (2013).~~]

[~~(12) "Manufacturer sealed electronic cigarette substance" means the same as the term defined is in Subsection 26-57-102(6).~~]

(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.

[~~(13)~~](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.

[~~(14)~~](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.

[~~(15) "Retailing" means involvement in any of the activities listed in Subsection R384-415-2(14). This definition is without regard to the quantity of an electronic cigarette substance sold, offered for sale, exchanged, or offered for exchange.~~]

[~~(16)~~](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.

[~~(2)~~](3) The retailer shall ensure that a[~~n~~] 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.

[~~(3) The retailer shall ensure that the required safety warning appear directly on the package and must be visible underneath any cellophane or other clear wrapping as follows:~~

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

~~(b) is capitalized and punctuated as indicated in Subsection (1) or (2) of this Section;~~

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

~~(d) uses a conspicuous and legible Helvetica, Arial, or other san serif font;~~

~~(e) uses either a black font on a white background or a white font on a black background; and~~

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

[~~(4)~~](5) A retailer [~~of an electronic cigarette substance~~]will not be in violation of this [~~S~~]section [~~when~~]for packaging that:

(a) contains a health warning;

(b) is supplied to the retailer by [~~a~~]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 [~~S~~]section.

[~~(5)~~](6) A[~~n~~] 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) [~~of this Section~~]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 [~~(2)~~](3) [~~of this Section~~]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 [~~packaged~~]electronic[-]

cigarette substance package or the manufacturer sealed electronic cigarette substance package.

[~~(c)~~](7) In the case of Subsection [~~(5)~~](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[~~n~~] non-manufacturer sealed electronic[-] cigarette substance or a manufacturer sealed electronic cigarette substance[~~to the public~~] that is labeled [~~to the public~~]as containing:

(a) additives that create the impression that a[~~n~~] 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 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; Section R68-26-5; and Section R68-33-5.

R384-415-5. Nicotine Content.

(1) The retailer shall be prohibited from selling a[~~n~~] non-manufacturer sealed electronic[-] cigarette substance or a manufacturer sealed electronic cigarette substance to the consumer [~~that~~]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[~~and~~] 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[~~n~~] 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.

[~~When the United States Food and Drug Administration instituting its process to approve electronic cigarettes, the retailer shall only sell an electronic cigarette substance that has been approved for regulatory sale by the United States Food and Drug Administration through a Pre-Market Tobacco application or Substantial Equivalent application.~~]

(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[~~s~~] transaction statements or manufacturer sealed electronic cigarette substance transaction statements to the Department or the local health department within 14 calendar[~~five working~~] 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;

[~~(a)~~](b) the nicotine content of a[~~n~~] 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);

[~~(b)~~](c) the packaging standards are compliant with Section R384-415-6[~~of an electronic cigarette substance is child-resistant~~]; and

[~~(c)~~](d) the product quality standards are compliant with Section R384-415-7[~~An electronic cigarette substance that has been approved for regulatory sale by the United States Food and Drug Administration through a Pre-Market Tobacco application or Substantial Equivalent application~~].

(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[~~5 working~~] 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.

[~~(1) The Department may enforce and seek penalties for the violation of public health rules including, the standards for electronic cigarettes set forth in this rule as prescribed in Sections 26-23-1 through 26-23-10.~~

~~(2) A local health department may enforce and seek penalties for the violation of the standards for electronic cigarettes set forth in this rule. A local health department shall have authority to enforce and seek penalties for violations of public health law including this rule as is found in Sections 26-23-1 through 26-23-10, 26A-1-108, 26A-1-114(1) and 26A-1-123.~~

~~(3) The Department or local health department is responsible to make a determination as to if a person holding a Utah State Tax Commission license to sell electronic cigarettes has violated the standards of this rule. If the Department or local health department makes such a determination it shall notify the Utah State Tax Commission to revoke the person's license as provided in Subsection 59-14-803(5).~~

~~(4) Administrative or civil enforcement of this rule by the Department or local health departments does not preclude criminal enforcement by a law enforcement agency and prosecution of any violation of the standards in this rule that can constitute a criminal offense under state law.~~]

KEY: electronic cigarettes, nicotine, standards, Electronic Cigarette Regulation Act
Date of Enactment or Last Substantive Amendment: [~~December 1, 2019~~]2021
Authorizing, and Implemented or Interpreted Law: 26-57-103[~~; 59-14-803(5)~~]

NOTICE OF PROPOSED RULE		
TYPE OF RULE: Amendment		
Utah Admin. Code Ref (R no.):	**R414-505-6**	**Filing No. 53270**

Agency Information

1. Department:	Health
Agency:	Health Care Financing, Coverage and Reimbursement Policy
Building:	Cannon Health Building
Street address:	288 N 1460 W
Mailing address:	PO Box 143102
City, state, zip:	Salt Lake City, UT 84114-3102
Contact person(s):	

Name:	**Phone:**	**Email:**
Craig Devashrayee	801-538-6641	cdevashrayee@utah.gov

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R414-505-6. Intergovernmental Transfer (IGT) Certification

3. Purpose of the new rule or reason for the change:

The purpose of this change is to implement a submission requirement for non-state governmental entities (NSGEs) to obtain annual IGT certification.

4. Summary of the new rule or change:

This amendment includes a deadline for NSGEs to submit their annual IGT certification, using the annual IGT certification form.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There is no impact to the state budget as this change only specifies a time requirement for NSGEs to obtain IGT certification. It neither affects member services nor provider reimbursement.

B) Local governments:

There is no impact on local governments as this change only specifies a time requirement for NSGEs to obtain IGT certification. It neither affects member services nor provider reimbursement.

C) Small businesses ("small business" means a business employing 1-49 persons)**:**

There is no impact on small businesses as this change only specifies a time requirement for NSGEs to obtain IGT certification. It neither affects member services nor provider reimbursement.