~~internal patient safety processes for specified problems. The reporting under this rule will also help the Department and health care providers to understand patterns of system failures in the health care delivery system and, where appropriate, to recommend statewide improvements to reduce the incidence of patient injuries. It limits access to identifiable health information that facilities report to the Department under this rule.~~

~~(2) This rule is authorized by Utah Code Subsections 26-1-30(2)(a), (b), (d), (e), and (g) and Section 26-3-8.~~

~~R380-210-2. Definitions.~~

~~"Adverse drug event" means any event involving a medication that causes or leads to patient harm, while the medication is in the control of the facility. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."~~

~~"Facility" means a general acute hospital, critical access hospital, ambulatory surgical center, psychiatric hospital, orthopedic hospital, rehabilitation hospital, chemical dependency/substance abuse hospital or chronic disease hospital as those terms are defined in Title 26, Chapter 21.~~

~~"Harm" means death or temporary or permanent impairment of body function or structure requiring intervention such as:~~

~~(1) a change in monitoring the patient's condition;~~

~~(2) a change in therapy; or~~

~~(3) active medical or surgical treatment.~~

~~R380-210-3. Patient Injury Identification.~~

~~(1) Each facility shall implement processes to effectively identify and report to the Department the incidence of all:~~

~~(a) adverse drug events.~~

~~(2) Reporting to the Department may occur through established, statewide, electronic health care facility reporting systems managed by the Department.~~

~~(3) The report shall include codes applicable to the event from the current International Classification of Diseases Clinical Modification (ICD-CM) diagnosis coding, including codes for external cause of injury (E-codes) and codes for place of occurrence.~~

~~R380-210-4. Patient Injury Reduction.~~

~~(1) Each facility shall implement processes that are effective in reducing the incidence of:~~

~~(a) adverse drug events.~~

~~R380-210-5. Confidentiality.~~

~~(1) Information that the Department holds under this rule is confidential under the provisions of Title 26, Chapter 3. Because of the public interest needs to foster health care systems improvements, the Department exercises its discretion under Section 26-3-8 and shall not release information collected under this rule to any person pursuant the provisions of Subsections 26-3-7(1) or (8).~~

~~(2) Information produced or collected by a facility is confidential and privileged under the provisions of Title 26, Chapter 25.~~

~~R380-210-6. Penalties.~~

~~As required by Section 63G-3-201(5): An entity that violates any provision of this rule may be assessed a civil money penalty not to exceed the sum of $5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6.~~

~~KEY: hospital, injury prevention, quality improvement, patient safety~~

~~Date of Enactment or Last Substantive Amendment: July 26, 2010~~

~~Notice of Continuation: September 13, 2016~~

~~Authorizing, and Implemented or Interpreted Law: 26-1-30(2)(a); 26-1-30(2)(b); 26-1-30(2)(d); 26-1-30(2)(e); 26-1-30(2)(g); 26-3-8~~|

NOTICE OF PROPOSED RULE		
TYPE OF RULE: Amendment		
Utah Admin. Code Ref (R no.):	**R384-415**	**Filing No. 53559**

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:

The proposed rule amendment to Rule R384-415 revises this rule to align with changes in Section 26-57-103, due to the passage of S.B. 1003 during the 2021 First Special Session. In addition, the Utah Department of Health (UDOH) seeks to incorporate the following additional changes related to the nicotine content in Subsection R384-415-5(1)(b), and the product quality requirements in Section R384-415-7 to address public comment concerns the UDOH received between March 15, 2021, and April 15, 2021.

4. Summary of the new rule or change:

The proposed rule amendment to Rule R384-415 revises this rule to align with changes to Section 26-57-103. These changes include replacing the word "standards" to "requirements to sell" in Section R384-415-1, adding the

new definition of manufacturer sealed electronic cigarette product to Section R384-415-2, and throughout the rule replacing the term "manufacturer sealed electronic cigarette substance" with the new definition of "manufacturer sealed electronic cigarette product."

In addition, regarding the nicotine content limit change in Subsection R384-415-5(1)(b), the proposed rule amendment would prohibit a tobacco retailer from selling a manufacturer sealed electronic cigarette product 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, allowing retailers two and a half months' time to anticipate the change, as it is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by September 1, 2021, in anticipation of the U.S. Food and Drug Administration's (FDA) prohibition of electronic nicotine delivery systems (ENDS) and other deemed products on the market without premarket authorization of the sale 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), that is anticipated to be effective September 9, 2021.

Lastly, the proposed amendments in Section R384-415-7 are consistent in aligning with federal law requirements, and removes the 09/09/2021 date, as the FDA published a perspective in February 2021 noting their progress reviewing electronic cigarette product Premarket Tobacco Product Applications (PMTA), mentioning they may need additional time beyond the 09/09/2021 date to complete this process. On May 20, 2021, the FDA published an updated perspective, posting lists identifying over 6,000,000 products where a premarket application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

Enactment of this proposed 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 product 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 UDOH 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 of 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), provided 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.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (UDOH suspects this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence).

As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types." 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). As a result of enactment of this proposed rule amendment, to hypothetically provide tobacco cessation services to 44.5% of Utah youth who vape (13,350) would cost Utah an estimated $3,600,000. To hypothetically provide tobacco cessation services to 50% of young adults who vape (ages 18-34) (~55,000) would cost Utah an estimated $16,600,000.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product with a nicotine concentration higher than 3% nicotine by weight per container, or exceeding a 36mg/mL concentration of nicotine. An electronic cigarette product 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 products 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 product 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.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have no fiscal impact to the state budget.

B) Local governments:

Enactment of this proposed 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 the amended rule.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have no fiscal impact to the local governments, and the FDA published a perspective dated 05/20/2021 identifies over 6,000,000 products where a PMTA application was submitted to the FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

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

The proposed 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 products. The proposed 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 products 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 products 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 products 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 products and these businesses will not be affected by this rule amendment.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product 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 products with a higher nicotine concentration may experience a direct fiscal impact.

The two and a half 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 two and a half months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette products 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 products 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 09/01/2021. It is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by 09/01/2021 in anticipation of the FDA's prohibition of ENDS and other deemed products on the market without premarket authorization of the sale of 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), that is anticipated to be effective 09/09/2021.

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. Since August 2019, disposable prefilled electronic cigarettes that have risen in popularity. A variety of disposable prefilled electronic cigarettes brands offer their products with nicotine concentrations equal to or less than 3% nicotine by weight per container or 36 mg/mL concentration of nicotine, including Puff Bar, Dinner Lady, Zaero Vape, Cali Bar, and Twst Disposable. Utah tobacco retailers that sell manufacturer sealed electronic cigarette products will continue to have the option to sell manufacturer sealed electronic cigarette products 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 09/01/2021, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette products 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 products that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement and there are also several popular disposable prefilled electronic cigarette brands that offer their products with nicotine concentrations that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine requirement.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (UDOH suspects this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence). As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types."

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact on small businesses that sell manufacturer-sealed electronic cigarette products, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule amendment and are pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete. FDA published a perspective dated 05/20/2021, that identifies over 6,000,000 products where a PMTA application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

The indirect costs to small businesses are unknown and difficult to determine, as the potential impact is unknown. UDOH does not know how many of these 1,175 small businesses choose to sell manufacturer sealed electronic cigarette products with nicotine concentrations higher than 3% by weight per container or exceed 36 mg/mL concentration of nicotine.

Similarly removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to small businesses, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

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

The 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 products. The rule amendment may result in a direct fiscal cost to non-small businesses that sell manufacturer sealed electronic cigarette products 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 DWS Firm Find Data, shows that there are approximately 208 non-small businesses that sell some type of electronic cigarette products 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 products with nicotine concentrations higher 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 products and these businesses will not be affected by this rule amendment.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product 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 products with a higher nicotine concentration may experience a direct fiscal impact.

The two and a half 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 two and a half months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette products 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 products 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 09/01/2021. It is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by 09/01/2021 in anticipation of the FDA's prohibition of ENDS and other deemed products on the market without premarket authorization of the sale of un 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), that is anticipated to be effective 09/09/2021.

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. Since August 2019, disposable prefilled electronic cigarettes have risen in popularity. A variety of disposable prefilled electronic cigarettes brands offer their products with nicotine concentrations equal to or less than 3% nicotine by weight per container or 36 mg/mL concentration of nicotine, including Puff Bar, Dinner Lady, Zaero Vape, Cali Bar, and Twst Disposable. Utah tobacco retailers that sell manufacturer sealed electronic cigarette products will continue to have the option to sell manufacturer sealed electronic cigarette products 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 09/01/2021, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette products 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 products that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement and there are also several popular disposable prefilled electronic cigarette brands that offer their products with nicotine concentrations that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine requirement.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (we suspect this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence). As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types."

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact on small businesses that sell manufacturer-sealed electronic cigarette products, as these retailers may be allowed to continue to sell product pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete. FDA published a perspective dated 05/20/2021, that identifies over 6,000,000 products where a PMTA application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

The indirect costs to non-small businesses are unknown and difficult to determine, as the potential impact is unknown. UDOH does not know how many of these 208 non-small businesses choose to sell manufacturer sealed electronic cigarette products with nicotine concentrations higher 3% by weight per container or exceed 36 mg/mL concentration of nicotine. Similarly removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to non-small businesses, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

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***)**:**

The proposed 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 products and individuals who work for small businesses or non-small businesses that sell electronic

cigarette products. 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 electronic cigarettes with a lower nicotine concentration, or they may choose to quit using electronic cigarettes as a result of enactment of this proposed 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 above, as a result of enactment of this proposed rule amendment.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to persons, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

F) Compliance costs for affected persons:

The 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 products and individuals who work for small businesses or non-small businesses that sell electronic cigarette products.

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 Executive Director of the 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:

The proposed rule amendment may result in a direct cost to businesses that sell manufacturer sealed electronic cigarette products and to businesses that primarily rely on the sale of tobacco products.

B) Name and title of department head commenting on the fiscal impacts:

Richard G. Saunders, 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:	07/15/2021

10. This rule change MAY become effective on:	07/22/2021

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, Executive Director	**Date:**	06/01/2021

R384. Disease Control and Prevention, Health Promotion.
R384-415. Requirements to Sell Electronic Cigarette Products [~~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 requirements to sell an electronic cigarette product regarding[~~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 an [~~non-manufacturer sealed~~]electronic cigarette substance, that is not a 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 product[~~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 is 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 is 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) "Manufacturer sealed electronic cigarette product" means the same as that term is defined in Section 26-57-102.

[~~(12)~~](13) "Nicotine" means the same as that term is defined in Section 76-10-101.

[~~(13)~~](14) "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)~~](15) "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 product[~~substance~~] is offered for sale, sold, or otherwise distributed to consumers.

[~~(15)~~](16) "Permit" means the same as that term is defined in Section 26-62-101.

[~~(16)~~](17) "Retailer" means any person who sells, offers for sale, exchanges, or offers to exchange for any form of consideration, a[~~n~~] non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette product[~~substance~~] to a consumer. This definition is without regard to the quantity of a[~~n~~] non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette product[~~substance~~] sold, offered for sale, exchanged, or offered for exchange.

[~~(17)~~](18) "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 product[~~substance~~] is in compliance with the requirements[~~standards~~] in this rule.

R384-415-3. Labeling.

(1) The retailer shall ensure that a nicotine containing non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 product[~~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 September 1, 2021.

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 products[~~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 product[~~substance~~] for retail sale.

(4) The retailer shall be prohibited from refilling a manufacturer sealed electronic cigarette product[~~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 product[~~substance~~] is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp; and Rule R68-26.

R384-415-7. Product Quality.

(1) Consistent with 21 U.S.C 387j, n[~~N~~]o 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) N[~~otwithstanding Subsection (3), after September 9, 2021, n~~]o 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) and related FDA regulations, policies, or actions.

(3) A manufacturer or retailer will not be in violation of Subsection (2) and may continue to sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance if:

(a) the manufacturer or retailer only sells, offers for sale, or distributes an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance that is compliant with the requirements set forth in this rule;

(b) the manufacturer submitted a timely Pre-Market Tobacco application or Substantial Equivalent application to the FDA by September 9, 2020, verified by being listed on the FDA's website as a deemed new tobacco product with timely application; and

(c) the FDA has not issued a written marketing order and therefore the product's Pre-Market Tobacco application or Substantial Equivalent application is pending review by the FDA.

[~~(3)~~](4) 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 product[~~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 requirements[~~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 product[~~substance~~] is compliant with Subsection R384-415-5(1)(b);

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

(d) the product quality requirements[~~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 product[~~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 Product and Nicotine Product Regulation Act
Date of Enactment or Last Substantive Amendment: [~~June 1,~~] 2021
Notice of Continuation: December 8, 2020
Authorizing, and Implemented or Interpreted Law: 26-57-103

NOTICE OF PROPOSED RULE		
TYPE OF RULE: New		
Utah Admin. Code Ref (R no.):	**R429-1**	**Filing No. 53439**

Agency Information

1. Department:	Health	
Agency:	Patient Safety Program	
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Please address questions regarding information on this notice to the agency.		