

[B-](2)(a) [An individual] a person whose interpreter [f] or transliterator certificate has been suspended or revoked for unlawful or unprofessional conduct may apply for reinstatement to the Board.

(b) The Board may:

(i) require the applicant for reinstatement to complete the procedure for certification; or

(ii) [may,] upon consultation with the advisory board, designate the areas of the application process in which the applicant [shall] will be reviewed.

KEY: certification, interpreters [f], transliterators

Date of Enactment or Last Substantive Amendment: [January 2,] 2015

Notice of Continuation: September 9, 2014

Authorizing, and Implemented or Interpreted Law: 53A-24-103; 53A-1-401(3); 53A-26a-201; 53A-26a-202; 53A-26a-303 through 53A-26a-305

Health, Disease Control and Prevention, Health Promotion R384-415 Electronic-Cigarette Substance Standards

NOTICE OF PROPOSED RULE

(New Rule)

DAR FILE NO.: 39797

FILED: 10/01/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: During the 2015 General Session, the state legislature passed a new statute, Section 26-57-103 (H.B. 415) authorizing the Utah Department of Health to set standards for electronic-cigarette substances.

SUMMARY OF THE RULE OR CHANGE: The proposed rule seeks to regulate electronic-cigarette substances at the point of sale between the retailer and the consumer. The regulation takes the form of standards for: 1) labeling; 2) nicotine content; 3) packaging; and 4) product quality. As stated in Section 26-57-103, the sale of electronic-cigarette substances that fail to meet these standards will be prohibited. The purpose of enacting regulatory standards for these products is to attempt to limit the increased number of nicotine related poisonings in the state. Labeling standards seek to better communicate product information and nicotine toxicity to the consumers. Standards for nicotine content set a limit for the concentration of nicotine in an electronic-cigarette substance, and a maximum for variation from the labelled concentration. Packaging standards are intended to make child entry and tampering to the product more difficult. Product quality standards prescribe requirements for ingredients used in electronic-cigarette substances. The rule

also features recordkeeping provisions that will aid retailers in proving compliance to the aforementioned standards.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Section 26-57-103 and Subsection 59-14-803(5)

ANTICIPATED COST OR SAVINGS TO:

♦ **THE STATE BUDGET:** The state health department will incur costs from the implementation of this rule. The state health department will need to utilize a contract with their media partners to distribute the information of the rule to effected persons. The state health department will be responsible for funding the compliance checks of local health departments to enforce this rule. As no additional funding was provided to the department as a part of the authority to create the rule, the state health department will need to divide the funds used for tobacco retail compliance-checks with the compliance checks for this rule. As such, it will cost the state health department approximately \$172,800 of the Tobacco Prevention and Control Programs budget to cover the cost of enforcing the rule. Calculating savings to state government is difficult, but there are departments that may experience savings as a result of this rule. It is hoped that the Utah Poison Control Center will see a decrease in the number of poison control calls related to electronic-cigarette substances. Though exact figures are not available, it is estimated that the cost of receiving a poison control call is \$65 and the number of electronic-cigarette related poison control calls in 2014 was 131, and therefore cost the state \$8,515. It is unlikely that the standards in the rule will eliminate these calls to poison control centers, but a decrease would mean savings for the state. There may also be savings to the Utah Medicaid program. Poisonings among Medicaid covered individuals would increase medical bills. It has been estimated that the medical costs associated with a single poisoning is \$15,000 for in-hospital treatment and \$3,000 for an emergency room visit. Though the health department cannot determine the number of electronic-cigarette related poisoning among Medicaid patients (and thus the total savings), it is expected that that there would be some savings to Medicaid through enforcing the rule.

♦ **LOCAL GOVERNMENTS:** The state health department will be responsible for funding the compliance checks of local health departments to enforce the rule; therefore state funds become a part of the local health department's budget. As no additional funding was provided to the department as a part of the authority to create the rule, local health departments will need to divide the funds used for tobacco retail compliance checks with the compliance checks for this rule. As such, it will cost local health departments approximately \$172,800 to enforce the standards of the rule. However, local health departments may impose fines for non-compliance, which could offset some of these costs. The state health department does not expect that there will be any savings to local government budgets. It is anticipated that the rule will only interact with local government in the context of ensuring compliance. Therefore savings will only occur at the local government level if there are fines imposed by a local

government entity and that revenue exceeds the cost of enforcement. At this time, the health department cannot predict these amounts.

♦ **SMALL BUSINESSES:** The state health department anticipates that there will be costs to small businesses that sell or manufacture electronic-cigarette substances. Representatives from the electronic-cigarette industry have estimated that for rule compliance a small specialty-business would need to invest approximately \$13,000 to \$470,000 to their operations during the first year of rule enforcement. Because the number of small specialty-businesses is unknown, the health department cannot estimate cost to the industry as a whole. However, the wide range in the cost estimate perhaps reflects the large variability in product quality that exists in the industry. Much of the responsibility to comply with the rule will fall on manufacturers who sell to Utah retailers, as it is the manufacturer who has control over labeling, nicotine content, packaging, and product quality. Industry representatives estimate that the rule will cost a small manufacturer approximately \$13,000 to \$340,000 during the first year of enforcement. Because the number of small manufacturers is unknown, we cannot estimate the cost to the industry as a whole. Also, much of this cost is reported as lost sales through the restriction of nicotine content. Therefore the industry cost estimate is based on the assumption that consumers would not purchase an alternative product if their selection was restricted. The manufacturer would also face non-fiscal costs. Prescribing manufacturer labeling requirements may be perceived as an infringement of the manufacturer's freedom of speech. Also, the manufacturer may face a perceived infringement on their intellectual property if product information is requested by the enforcing agency. The small specialty-retailer will also face costs because of the rule. The small specialty-retailer may experience a loss in business because of the restrictions placed on the nicotine content. Industry representatives have estimated that the rule will cost a small specialty-retailer approximately \$22,000 to \$470,000 during the first year of enforcement. Because the number of small specialty-businesses is unknown, the health department cannot estimate the cost to the industry as a whole. Also, the industry cost estimate is based on the assumption that consumers would not purchase an alternative product if their selection of nicotine content was restricted. The small specialty-retailer may also experience enforcement costs through fines imposed on them by local health departments. The schedule of these fines would be decided upon by local health departments once the rule has been implemented, and as such the potential cost is unknown. Local health departments also have the authority to report violations and request that the state tax commission revoke the license of a non-compliant business. Revocation of a tobacco license would equate to a loss in business, but it is expected that with an adequate period to prepare for enforcement this event would be rare. The small specialty-retailer may incur some small costs to educate staff on compliance with the rule. It is not possible to predict these costs due to varying circumstances, but to reduce this burden the state and local health department will provide support. It is expected that

small general-retailers will incur little cost through the enforcement of the rule. General retailers typically sell manufacturer-sealed electronic-cigarette substances, which are exempt from the rule. General retailers may experience some cost through educating staff on the rule or through incurring local enforcement fines. However, because the number of small general-retailers who sell these products is unknown, the health department cannot estimate the total cost they will incur. The state health department anticipates little non-fiscal costs to the retailer; except for in the rare event that a local health department exercises their authority to seize goods they have determined to be a danger to public health.

♦ **PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES:** The state health department anticipates that there will be costs and savings to the public. Those who purchase electronic-cigarette substances may experience a monetary cost as retailers increase their prices to afford compliance. With the available data it is not possible to predict the potential price increase. Consumers may also perceive the restrictions of nicotine content as a nuisance or an infringement of their personal liberties, or both. Major savings to the public will come from preventing poisonings. The average medical bill associated with a poisoning is approximately \$15,000 for inpatient treatment and \$3,000 in emergency room fees. The cost of a poisoning in terms of lost productivity is approximately \$2,600 per poisoning if the victim is hospitalized. It is difficult to estimate a population level saving; however, it could be sizable when considering there were 131 electronic-cigarette related poison control calls in 2014. There may also be savings to the public over time. Long-term studies may show that electronic-cigarettes are significantly detrimental to health. Placing safety warnings on electronic-cigarette substances may dissuade use and therefore prevent illness and medical costs in the future. However, without the result of these long-term studies, the reality of this situation is unknown. There is evidence that suggests that electronic-cigarettes among youth may be connected to using traditional tobacco. If this is the case, the provisions of the rule may reduce future tobacco related medical costs. The Centers for Disease Control and Prevention has estimated that in Utah, residents as a whole experience \$542,000,000 annually because of tobacco products. General retailers may experience some cost through educating staff on the rule or through incurring local enforcement fines. However, because the number of general retailers who sell these products is unknown, we cannot estimate the total cost they will incur.

COMPLIANCE COSTS FOR AFFECTED PERSONS: The state health department has sought comment from representatives in the electronic-cigarette industry. It is estimated that an individual small-manufacturer will incur approximately \$13,000 to \$340,000 in compliance costs during the first year of rule enforcement. It is expected that the majority of these costs will come from redesigning labels, and sales lost through limiting nicotine content. Therefore this industry estimate is based on the assumption that the

consumer would not purchase an alternate product if their selection was restricted. The small-specialty retailer will also incur compliance costs. It is estimated that a single, small specialty-retailer will need to pay approximately \$22,000 to \$470,000 to comply with the rule. It is expected that the majority of these costs will come from sales lost through limiting nicotine content. Therefore this industry cost estimate is based on the assumption that the consumer would not purchase an alternate product if their selection was restricted. It is expected that general-retailers will incur little compliance cost, because the majority of the products they sell are exempt from the rule. The small portion of general retailers that will come under regulation may experience; 1) a negligible loss in sales; 2) some cost through educating staff; and 3) potential fines through local enforcement. However, because the number of general retailers who sell these products is unknown, the health department cannot estimate what individual compliance cost they will incur.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: This rule will have a fiscal impact on business. There is a wide variation in estimated costs provided by industry representatives. The high initial cost of compliance is most likely a reflection of the absence of regulation this industry has so far experienced.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

HEALTH
DISEASE CONTROL AND PREVENTION,
HEALTH PROMOTION
CANNON HEALTH BLDG
288 N 1460 W
SALT LAKE CITY, UT 84116-3231
or at the Division of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:

♦ Stephanie Saperstein by phone at 801-538-6430, or by Internet E-mail at stephaniesaperstein@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 11/16/2015

THIS RULE MAY BECOME EFFECTIVE ON: 11/23/2015

AUTHORIZED BY: Joseph Miner, MD, Executive Director

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) This rule establishes standards for labeling, nicotine content, packaging, and product quality for electronic-cigarette substances for the regulation of electronic-cigarettes.

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

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

R384-415-2. Definitions.

As used in this rule:

(1) "Artificial coloring" means the same as the term is defined in 21 C.F.R. 101.22(a)(4) (April 1, 2015) and as the term "color additive" is defined in 21 C.F.R. 70.3(f) (April 1, 2015).

(2) "Artificial flavoring" means the same as the term is defined in 21 C.F.R. 101.22(a)(1) (April 1, 2015).

(3) "Batch number" means the same as the term "lot number, control number, or batch number" is defined in 21 C.F.R. 210.3(b)(11) (April 1, 2015).

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

(5) "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).

(6) "Department" means the Utah Department of Health.

(7) "Electronic-cigarette" means the same as the term is defined in Subsections 26-38-2(1) and 59-14-802(2).

(8) "Electronic-cigarette Product" means the same as the term is defined in Subsection 59-14-802(3).

(9) "Electronic-cigarette substance" means the same as the term is defined in Subsection 59-14-802(4).

(10) "EP standards" means the standards established for medicines by the European Pharmacopeia, the European equivalent of the United States Pharmacopeia. The EP standards define requirements for the qualitative and quantitative composition of medicines, and the tests that are to be used on medicines, substances, and materials used in their production.

(11) "Generally Recognized As Safe" means an United States Food and Drug Administration designation that a substance added to food is generally recognized, by qualified experts, as having been adequately shown to be safe under the conditions of its intended use, as found in 21 C.F.R. 170.30 (April 1, 2015). Such a substance is exempted from the usual Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq. (2013).

(12) "Local health department" means the same as the term is defined in Subsection 26A-1-102(5).

(13) "Manufacture" means the same as the term is defined in Subsection 26-57-102(5).

(14) "Manufacturer" means the same as the term is defined in Subsection 26-57-102(6).

(15) "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.

(16) "Natural flavoring" means the same as the term is defined in 21 C.F.R. 101.22(a)(3) (April 1, 2015).

(17) "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).

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

(19) "Pharmaceutical" means a compound manufactured for use as a medicinal drug.

(20) "Retailer" means any person who sells, offers for sale, or offers to exchange for any form of consideration, an electronic-cigarette substance to a consumer. This definition is without regard to the quantity of an electronic-cigarette substance sold, offered for sale, exchanged, or offered for exchange.

(21) "Retailing" means involvement in any of the activities listed in Subsection R384-415-2(20). This definition is without regard to the quantity of an electronic-cigarette substance sold, offered for sale, exchanged, or offered for exchange.

(22) "Straight color" means a color additive approved for human consumption in food and drugs as listed in 21 C.F.R. 73.1 through 21 C.F.R. 73.1991 (April 1, 2015), 21 C.F.R. 74.101 through 21 C.F.R. 74.1711 (April 1, 2015), and 21 C.F.R. 81.1 (April 1, 2015), and includes substances as are permitted by the specifications for such color.

(23) "Tamper-evident" means the packaging uses an indicator or barrier to entry that is distinctive by design, or must employ an identifying characteristic.

(24) "Transaction statement" means a statement, in paper or electronic form, which the manufacturer transferring ownership of the product certifies that the electronic-cigarette substance is in compliance with the standards in this rule.

(25) "USFDA Food Standards" means the United States Food and Drug Administration's common designation for standards of identity, standards of quality, and standards of fill of container promulgated under the Federal Food, Drug & Cosmetics Act, 21 U.S.C. Sec. 301 et seq. (2013) and as contained in 21 C.F.R. 130 through 21 C.F.R. 169 (April 1, 2015).

(26) "USP-NF standards" means the standards for drug products established by the United States Pharmacopeia and National Formulary. The USP-NF standards include standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements.

R384-415-3. General Labeling.

(1) The retailer shall ensure that a container holding an electronic-cigarette substance offered for sale to the consumer conforms to the following labeling standards:

- (a) the label is smear resistant; and
- (b) the label clearly displays:
 - (i) the nicotine content in mg/mL or percent by volume;
 - (ii) the manufacturer name;
 - (iii) the batch number;
 - (iv) the ingredients, as required in Section R384-415-4;
 - (v) a tamper-evident warning, which meets the requirements of Section R384-415-5; and
 - (vi) a safety warning, which meets the requirements of Section R384-415-6.

R384-415-4. Labeling of Ingredients.

- (1) The retailer shall ensure that:
 - (a) an ingredient of an electronic-cigarette substance is listed on the label of the container holding an electronic-cigarette substance, except as provided for in Subsection R384-415-4(1)(c) (i).

(b) An artificial coloring ingredient is listed on the label using the classification system that best applies. Classification systems include:

- (i) Food, Drug, and Cosmetic color designation and number;
 - (ii) Drug and Cosmetic color designation and number; or
 - (iii) the generic straight color name, if the artificial color is not classified under the systems found in Subsection R384-415-4(1)(b)(i) or Subsection R384-415-4(1)(b)(ii).
- (c)(i) An ingredient included in the manufacturer's proprietary mixture of flavorings is exempt from being listed on the label by name.
- (ii) An ingredient included in the manufacturer's proprietary mixture of flavorings is listed on the label under the generic term of artificial flavoring, natural flavoring, or both.

R384-415-5. Labeling of Tamper-Evident Warning.

- (1) The retailer shall ensure that the label of an electronic-cigarette substance displays a tamper-evident warning alerting the consumer to the tamper-evident feature of the packaging
- (2) The retailer shall ensure that the tamper-evident warning:
 - (a) is prominently displayed to consumers;
 - (b) is placed on the label so that it would be unaffected if the tamper-evidence feature is removed; and
 - (c) lists the type of tamper-evident feature used with the product.

R384-415-6. Labeling of Safety Warning.

- (1) The retailer shall ensure that an electronic-cigarette substance offered for sale to the consumer features a safety warning stating "nicotine is addictive and poisonous. Keep away from children and pets".
- (2) The retailer shall ensure that the safety warning:
 - (a) occupies at least 30 percent of the largest panel of the container and any additional immediate packaging;
 - (b) is in capitalized letters;
 - (c) has a font size that occupies the maximum amount of the area described in Subsection R384-415-6(2)(a);
 - (d) uses the Helvetica, Arial, or Univers font; and
 - (e) uses either a black font on a white background or a white font on a black background.

R384-415-7. Nicotine Content.

- (1) The retailer shall comply with the following nicotine content standards regarding an electronic-cigarette substance sold to the consumer:
 - (a) The nicotine content for an electronic-cigarette substance is limited to 240 mg per container, and does not exceed a 24mg/mL concentration.
 - (b) The nicotine level for an electronic-cigarette substance is limited to a 10% variation in mg/mL, above the content level indicated on the label.
 - (c) An electronic-cigarette substance labeled 0 mg/mL or 0% by volume contains no nicotine.

R384-415-8. Packaging.

- (1) The retailer shall ensure that the packaging of an electronic-cigarette substance intended for sale to a consumer:

- (a) is certified as child resistant;
- (b) does not leak at the time of sale; and
- (c) utilizes a tamper-evident feature by means of one or more of the following:
 - (i) a bubble pack;
 - (ii) a heat shrink band;
 - (iii) a breakable cap; or
 - (iv) an inner-seal.

R384-415-9. Product Quality.

(1) The retailer shall ensure that an ingredient in an electronic-cigarette substance is compliant with either USP-NF standards, EP standards, USFDA Food Standards, or is Generally Recognized As Safe at the time of sale.

(2) The retailer shall be prohibited from selling an electronic-cigarette substance that contains:

- (a) vitamins or other additives that create the impression that an electronic-cigarette substance has a health benefit or presents reduced health risks;
- (b) pharmaceuticals;
- (c) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- (d) illegal or controlled substances as identified in Section 58-37-3; and
- (e) additives having coloring properties for emissions.

R384-415-10. Record Keeping and Testing.

(1) The retailer shall provide the electronic-cigarette substances transaction statement to the department or the local health department within five working days of a request. The retailer shall ensure that the transaction statement includes manufacturer certifications that:

- (a) the nicotine content of an electronic-cigarette substance is compliant with Section R384-415-7;
- (b) the packaging of an electronic cigarette-substance is child-resistant; and
- (c) an ingredient used in an electronic-cigarette substance meets the appropriate standard found in Section R384-415-9.

(2)(a) The retailer shall have a system in place to trace production of an electronic-cigarette substance through the labeled batch number to the ingredients used in manufacturing.

(b) The retailer shall provide documents produced from batch tracing to the enforcing agency within five working days of a request.

(c) The retailer shall ensure that documents produced through batch tracing provide evidence in support of the electronic-cigarette substances transaction statement.

(3) The retailer shall maintain the documents described in Subsections R384-415-10(1) and R384-415-10(2) for a period of two years after the retailer purchases the electronic-cigarette substance.

R384-415-11. 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 Last Substantive Amendment: 2015

Authorizing, and Implemented or Interpreted Law: 26-57-103; 59-14-803(5)

Health, Health Care Financing, Coverage and Reimbursement Policy R414-1-5 Incorporations by Reference

NOTICE OF PROPOSED RULE
(Amendment)
DAR FILE NO.: 39800
FILED: 10/01/2015

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: Subsection 26-18-3(2)(a) requires the Medicaid program to implement policy through administrative rules. The department, in order to draw down federal funds, must have an approved state plan with the Centers for Medicare and Medicaid Services (CMS). The purpose of this change, therefore, is to incorporate the most current Medicaid state plan by reference and to implement by rule ongoing Medicaid policy described in the various Medicaid provider manuals.

SUMMARY OF THE RULE OR CHANGE: The department incorporates by reference the Utah Medicaid State Plan and approved State Plan Amendments (SPAs) to 10/01/2015. Specifically, the department incorporates by reference the following: SPA 15-0002-UT Inpatient Hospital Services, which removes duplicative details for Utah specific diagnosis related groups, removes prior authorization requirements that already exist, and removes provisions of the Superior System Waiver based on consultation with CMS; SPA 15-0019-UT Reimbursement for Dental Services and Dentures, which updates the effective date of rates for dental services and