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 sq. (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 sq. (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~~ [20] 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~~ [360] 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, [and compliant with federal standards and law concerning child nicotine poisoning prevention];

(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~~ [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)[(a)] The retailer shall ~~maintain~~ [have access to] 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.

[(b) the retailer shall provide the documents described in Subsections R384-415-10(1) and R384-415-10-(2) to the Department or the local health department within 5 working days of a request.]

R384-415-11. Enforcement.

(1) The ~~department~~ [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~~ [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~~ [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~~ [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:
Notice of Continuation:

Authorizing, and Implemented of Interpreted Law: Section 26-57-103 and Subsection 59-14-803(5)