



Utah Department of Health – Proposed Rule R384-415

2015 HB 415 – Regulation of Electronic Cigarettes

- Requires a Tobacco or Electronic Cigarette license from the State Tax Commission to sell or distribute an electronic cigarette product
- Provides updated definitions for electronic cigarette products
 - Electronic cigarette includes the device, components and accessories
 - Electronic cigarette substance means any substance used or intended for use in an electronic cigarette
 - Electronic cigarette product is an umbrella term that includes both “Electronic Cigarette” and “Electronic cigarette substance”
- **Requires that the Utah Department of Health to regulate labeling, nicotine content, packaging and product quality standards for an electronic cigarette substance. Standards must be completed by January 1 2016 and will be effective July 1 2016.**
- Local health departments retain the ability to regulate manufacturing according to current/future ordinances
- Exempts all “manufacturer sealed electronic cigarette substances” (pre-filled cartridges not intended for multiple use applications).

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 sale of e-liquid that fail to meet these standards will be prohibited. The regulation takes the form of standards for:

- 1) labeling;
- 2) nicotine content;
- 3) packaging; and
- 4) product quality.

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.

Labeling Requirements - R384-514-(3,4,5,6)

All e-liquid sold or manufactured in Utah must abide by the following labeling standards:

- the label is smear resistant; and
- the label clearly displays:
 - the nicotine content in mg/mL or percent by volume;
 - the manufacturer name;
 - the batch number;
 - the ingredients; and
 - an ingredient that is included in the manufacturers proprietary mixture of flavorings is exempt from being listed by name on the label;
 - an ingredient that is included in the manufacturers proprietary mixture of flavorings is listed on the label under the generic term of artificial or natural flavoring;
 - An artificial coloring ingredient is listed on the label using the classification system that best applies. Classification systems include:
 - Food, Drug, and Cosmetic color designation and number;
 - Drug and Cosmetic color designation and number; or
 - 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).
 - A warning alerting the consumer to the tamper-resistant feature of the package.
 - The warning is prominently displayed to consumers (not to be included in the safety warning area);
 - The warning is placed so that it would be unaffected if the tamper-evidence feature is removed;
 - The warning lists the type of tamper-evident feature used with the product.
- Refillable e-liquid sold features a safety warning stating “*nicotine is addictive and a poison. Keep away from children and pets*”. The safety warning must:
 - Occupy 30 percent of the bottle label;
 - is in capitalized letters;
 - has a font size that occupies the maximum amount of the warning label size;
 - uses the Helvetica, Arial, or Univers font; and
 - uses a black font on a white background or white font on a black background.



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Nicotine Content Requirements – R384-415-7

- The nicotine content for e-liquid is limited to 240 mg per container, and does not exceed a 24mg/mL concentration
- The nicotine level is limited to a 10% variation in mg/mL above the content indicated on the label.
- An electronic-cigarette substance labeled 0 mg/mL contains no nicotine.

Bottle size	Max Nicotine Content	Nicotine mg/ml allowed
10	240	24
15	240	16
20	240	12
25	240	9.6
30	240	8
50	240	4.8
60	240	4
120	240	2

Packaging Requirements R384-514-8

- E-liquid sold in Utah is certified as child resistant (through compliance with Federal code 16 C.F.R 1700.15(b));
- Does not leak at the time of sale; and
- is tamper-resistant by utilizing one or more of the following:
 - a bubble pack;
 - a heat shrink band;
 - a breakable cap; or
 - an inner-seal (over the mouth of the bottle).



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Product Quality Requirements - R384-514-9

- E-liquid ingredients shall be compliant with USP-NF standards, EP Standards, USFDA grade standards, or is Generally Recognized As Safe at the time of sale.
- Prohibited electronic-cigarette substance ingredients include:
 - vitamins or other additives that create the impression that an electronic-cigarette substance has a health benefit or presents reduced health risks;
 - pharmaceuticals;
 - caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
 - illegal or controlled substances as listed in Utah Code Section 58-27-4 or in 21 U.S. Code 13.811; and
 - additives having coloring properties for emissions;

Record Keeping and Testing Requirements R384-514-10

1. The retailer shall provide the electronic-cigarette substances transaction statement to the department or the local health department within two working days of a request. The transaction statement includes manufacturer certifications that:
 - a. the nicotine content of an electronic-cigarette substance is compliant with Section R384-415-4;
 - b. the container of an electronic cigarette-substance is child-resistant as found in Section R384-415-5(1)(a); and
 - c. an ingredient used in an electronic-cigarette substance meets the appropriate standard found in Section R384-415-6(1).
2. 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.
 - a. The retailer shall provide documents produced from batch tracing to the enforcing agency within five working days of a request.
 - b. As a part of the documents produced through batch tracing the retailer shall provide evidence in support of the electronic-cigarette substances transaction statement.
3. Retailers shall maintain the documents described in section (1) and (2) for a period of two years after the purchase or sale of the product.



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Enforcement R384-514-11

- 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 Utah Code Sections 26-23-1 through 26-23-10.
- 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 Utah Code Sections 26-23-1 through 26-23-10, 26A-1-108, 26A-1-114(1) and 26A-1-123.
- The Department or Local Health Department is responsible to make a determination as to when a person holding a 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 Tax Commission to revoke the person's license as provided in Utah Code Section 59-14-803(5).
- 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.