

2015 HB0415 – 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).

R384-415-3 General Labeling

The retailer shall ensure that a container holding refillable e-liquid offered for sale to the consumer conforms to the following labeling standards:

1. the **label is smear resistant**; and
2. the label clearly displays:
 - a. the **nicotine content in mg/mL** or percent by volume which meets requirements of Section R384-415-7;
 - b. the **manufacturer name** (this is not the brand but the actual manufacturer);
 - c. the **batch/lot number** (This may be on the label ~or~ laser etched on bottle);
 - d. the **ingredients**, as required in Section R384-415-4 and Section R384-415-9;
 - e. a **tamper-evident warning**, which meets the requirements of Section R384-415-5; and
 - f. a **safety warning**, which meets the requirements of Section R384-415-6.

Note: after-market warning labels are permitted and are being designed for items e & f above. However, all other information **must** be contained on the label or it is not permitted to be sold in Utah. Please see next sections which outline the details required under items a-f above.



Utah R384-415 Regulations

Enforcement effective July 1, 2016

R384-415-4 Labeling of Ingredients

The retailer shall ensure that:

1. An ingredient of refillable e-liquid is listed on the label of the container holding refillable e-liquid
2. An artificial coloring ingredient is listed on the label using the classification system that best applies. Classification systems include:
 - a. Food, Drug, and Cosmetic color designation and number;
 - b. Drug and Cosmetic color designation and number; or
 - c. The generic straight color name, if the artificial color is not classified under the systems found in sections (a) and (b) above.
3. An ingredient included in the manufacturer's proprietary mixture of flavorings is exempt from being listed on the label by name.
4. 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 refillable e-liquid displays a tamper-evident warning alerting the consumer to the tamper-evident feature of the packaging
 - a. The warning may be printed directly upon the manufacturer's product label or may be an after-market label affixed securely to the bottle so long as it aligns with sections 2 and 3 below.
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
3. lists the type of tamper-evident feature used with the product.

R384-415-6 Labeling of Safety Warning

1. The retailer shall ensure that refillable e-liquid offered for sale to the consumer features a prominent safety warning stating explicitly that “*Nicotine is addictive and poisonous. Keep away from children and pets*”.
2. The safety warning **must**:
 - a. Occupy at least **20 percent of the largest panel** of the container and any additional immediate packaging (*this is bottle size, not label size*);
 - b. Be in capitalized letters;
 - c. Have a font size that occupies the maximum amount of the area described in Subsection (a) above
 - d. Use the Helvetica, Arial, or Univers font; and
 - e. Use either a black font on a white background or a white font on a black background.

R384-415-7 Nicotine Content

1. The nicotine content for refillable e-liquid is limited to 360 mg per container, and may not exceed 24mg/mL (or 2.4%) concentration (see below chart).
2. The nicotine level for refillable e-liquid is limited to a 10% variation in mg/mL above the content level indicated on the label.
3. Refillable e-liquid labeled 0 mg/mL or 0% by volume contains no nicotine.

Bottle Size	Max Nicotine Content per container	Max Nicotine mg/ml
10	360	24
15	360	24
20	360	18
30	360	12
50	360	7.2
60	360	6
120	360	3
180	360	2
240	360	1.5

R384-415-8 Packaging

The retailer shall ensure that the packaging of refillable e-liquid intended for sale to a consumer;

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

R384-415-9 Product Quality

1. The retailer shall ensure that an ingredient in refillable e-liquid 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 refillable e-liquid that contains:
 - a. vitamins or other additives that create the impression that e-liquid 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 e-liquid 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 refillable e-liquid is compliant with Section R384-415-7 (generally this will be a testing certification)
 - b. the packaging of a refillable e-liquid bottle is child-resistant; and
 - c. an ingredient used in refillable e-liquid meets the appropriate standard found in Section R384-415-9.
2. The retailer shall have a system in place to trace production of refillable e-liquid 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. The retailer shall ensure that documents produced through batch tracing provide evidence in support of the refillable e-liquid transaction statement.
3. The retailer shall 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 refillable e-liquid product. Retailers shall provide these documents to the enforcing agency within 5 working days of a request.



Utah R384-415 Regulations

Enforcement effective July 1, 2016

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.

Important

Scroll down for what this means for retailers and manufacturers in Utah and any manufacturer located outside of Utah.

These regulations are final as of March 15th 2016. Regulations are subject to change with proper notice based on need or requirement as outlined by HB415.

Contact board@utsmokefree.org with any questions.



Utah R384-415 Regulations

Enforcement effective July 1, 2016

Manufacturers (in or out of Utah)

Labeling

- Bottle label meets warning label requirements of section “R384-415-6 Labeling of Safety Warning” *~or~* retailer agrees to affix after-market warning label meeting the size and language requirements.
 - After-market labels meeting size and language requirements will be provided to all UTSFA general members at limited or no cost where possible.
- A tamper-evident warning must be printed on the manufacturing label as outlined in section “R384-415-5 Labeling of Tamper-Evident Warning” *~or~* retailer agrees to affix after-market warning label meeting the size and language requirements. The tamper evident warning **must** remain on the bottle when the tamper evident seal is removed/broken.
 - After-market labels meeting size and language requirements will be provided to all UTSFA general retail members at limited or no cost where possible.
- Manufacturing label includes all information as outlined in sections “R384-415-4 Labeling of Ingredients” AND “R384-415-3 General Labeling”. This may **not** be added as an after-market label and must be printed directly on the primary manufacturing label.

Packaging

- All caps are certified child-resistant following the federal CPSC requirements of the The Child Nicotine Poisoning Prevention Act of 2015. The manufacturer **MUST** have certificates from the cap supplier showing alignment with the CNPPA regulations.
- All bottles contain either a heat shrink-wrap, breakaway ring or induction seal for the tamper evident seal.
- Unless the manufacturer can comply with **both** warning statements required, the heat shrink band may be removed at the retailer to allow after-market warnings to be applied. Heat shrink bands will then be replaced by the retailer at their own cost.
- The Batch/Lot number may be either printed directly on the label or laser etched directly on the bottle.

Batch tracing

Batch tracing of the products must be able to verify that:

- Batch data is maintained for a minimum of 2 years from the date of manufacture
- Raw ingredients meet requirements under section “R384-415-9 Product Quality”
- E-liquid batch has been tested with a 10% over labeled limit as outlined in section “R384-415-7 Nicotine Content”
- All ingredients used in the manufacturing of the particular product can be provided as part of the batch report following the requirements in section “R384-415-4 Labeling of Ingredients”

Note: If you are a Utah based manufacturer, it is expected that your products will meet 100% of all required labeling, packaging, nicotine content, product quality and record keeping requirements outlined above. However, the UTSFA is happy to also provide you with the Nicotine Warning label to be applied to the bottles sold to your Utah retail customers.

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Retailers

It is the accountability of every retail point of sale to ensure the e-liquid they sell meets 100% of the labeling, packaging and batching requirements. If the manufacturer is unable or unwilling to comply with all of the requirements, then you will be unable to offer their product for sale through your retail operation. If necessary, the UTSFA are happy to discuss the requirements with any manufacturer to ensure they understand all the regulations.

Each retailer must ensure every e-liquid manufacturer carried has the correct batch tracing program in place (and batch number on the bottle) should the health department request the data. They will provide retailers 5 business days to obtain batch data from the manufacturer but if you are unable to provide it, may result in financial penalties, inability to sell the product until proof of compliance can be verified, up to the loss of your retail sales permit. Batch information must be stored for a minimum of 2 years by the manufacturer.

After-market warning labels for the primary safety warning outlined in section "R384-415-6 Labeling of Safety Warning" and the tamper-evident warning outlined in section "R384-415-5 Labeling of Tamper-Evident Warning" will be provided to all UTSFA retail members at a reduced or no cost where possible. These labels may be affixed to the bottles after received from your supplier however the labels **must** remain on the bottle **and** unaffected by any tamper-evident features when removed by the customer. In some cases, removal of heat shrink bands may be necessary to allow the warnings to be included. If this occurs, the retailer must reapply new heat shrink bands to the product before stocking.

At this time, there are no regulations outlining the type of bottle to be used, only that the caps are certified child-resistant following the federal CPSC requirements of the The Child Nicotine Poisoning Prevention Act of 2015.

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