

Summary

On October 8, 2019, Governor Steve Bullock directed the Montana Department of Public Health and Human Services (DPHHS) to implement emergency administrative rules to temporarily prohibit the sale of flavored e-cigarettes.

DPHHS announced on Friday, December 13, 2019 its notice of intent to begin enforcing Emergency Rules that temporarily restrict the sale of flavored e-cigarette products in Montana. Enforcement of the Emergency Rules begins on Wednesday, December 18, 2019 at 1:00 pm. The Department's intent is to enforce the rules for a period of 120 days from this date ending April 15, 2020.

Link to the emergency rules: <https://dphhs.mt.gov/administrativerules>

Information About the Montana Temporary Restriction, Emergency Rules, New FDA Guidance

What are emergency rules?

Emergency rules allow the Department to respond to rapidly-developing public health crisis. They are adopted in circumstances where there is an imminent threat to public health, safety, or welfare. The rules are temporary.

When will these emergency rules be effective?

DPHHS announced on Friday, December 13, 2019 its notice of intent to begin enforcing Emergency Rules that temporarily restrict the sale of flavored e-cigarette products in Montana. Enforcement of the Emergency Rules begins on Wednesday, December 18, 2019 at 1:00 pm. The Department's intent is to enforce the rules for a period of 120 days from this date ending April 15, 2020.

What do the emergency rules restrict?

The emergency rules apply to all flavored e-cigarette/vaping products.

Do the rules apply to flavoring sold separately or as part of a Do-It-Yourself (DIY) kit?

The temporary restriction on the sale of flavored vaping products applies to any flavoring component, with or without nicotine, that is intended to be used in a vaping device. Under the rules, a flavoring component intended to be used in vaping device cannot be sold as part of a DIY kit. The emergency rules provide that a vaping product includes "a vapor cartridge **or other container** that may contain nicotine or THC in a solution or other form **that is intended to be used with or in an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device.**"

Does this emergency rule impact medical marijuana?

The rule impacts all flavored vaping products, regardless of whether they include THC, nicotine, CBD or other substances.

How does this impact Tribes?

The emergency rules will not apply to the Tribal reservations in the state. The Tribes in Montana are sovereign nations, which have their own authorities to implement policies to protect the health of their communities. DPHHS would highly recommend the Tribes adopt similar policies as well.

Does this apply to online sales as well?

Yes, for any vapor products intended for delivery to a person living in Montana.

Under what authority is the department putting these rules in place?

State law (2-4-303) reads that emergency rules may be adopted only in circumstances that truly and clearly constitute an existing imminent peril to the public health, safety, or welfare that cannot be averted or remedied by any other administrative act.

How will the emergency rules be enforced?

DPHHS and the local health departments have authority to enforce this measure and will enforce it in the same way current tobacco protections such as the Clean Indoor Air Act are enforced. Inspections of retailers and citizen complaints will be used to monitor compliance with the rules.

How does the new FDA guidance on unauthorized flavored cartridge-based e-cigarettes affect the emergency rules?

Montana's emergency rules temporarily restrict the sale of all flavored vaping products (other than tobacco and marijuana flavor), including the flavor of menthol. The emergency rules apply to both closed (i.e. pre-filled cartridge or pod-based systems) and open systems. The FDA guidance prioritizes enforcement against closed cartridge/pod-based flavored vaping products. Enforcement will apply to all flavors in these closed systems except for tobacco and menthol flavors. Flavoring sold in open vaping systems (e.g., tanks and mods) are not prioritized under the FDA guidance and, therefore, not likely to be subject to enforcement. The FDA has indicated enforcement of the guidance will not take effect until 30 days from the publication of the notice of their [guidance in the Federal Register](#). Montana's emergency rules are more comprehensive than the FDA guidance in that the rules apply with equal force to closed and open systems and cover the flavor of menthol. The emergency rules will remain in effect until April 15, 2020.

Information for Retailers

What action is required of retailers?

Because this is a temporary restriction, retailers at this time are not being asked to destroy products. However, retailers must discontinue sales of flavored e-cigarette/vaping products upon the rule going into effect on December 18, 2019.

Do I have to make any changes to in-store advertisements?

The regulation of tobacco product advertising is regulated by Title 16, Chapter 10 of the Montana Code Annotated and under the purview of the Department of Revenue. Accordingly, these emergency rules do not affect advertising.

What happens if I violate the rules?

A person who violates any provision of the rules can be charged with a misdemeanor punishable by a term of imprisonment not to exceed 6 months and a fine of up to \$500. Each day in violation of the rules is a separate offense. DPHHS or a county attorney can also sue an individual or business to abate or restrain activity in violation of the rules, and costs and fees related to that action awarded.

Who has the authority to enforce the rules?

DPHHS and the local health departments have authority to enforce this measure and will enforce it the same way current tobacco protections such as the Clean Indoor Air Act are enforced. Inspections of retailers and citizen complaints will be used to monitor compliance with the rules.

The Health Risks to Youth

Why are flavored e-cigarettes being restricted?

Protecting the health, safety, and well-being of Montanans and young people is of paramount importance.

E-cigarette use is an epidemic among Montana youth. The dramatic increase in use of e-cigarettes, or vaping, by youth is driven in large part by flavored e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. E-cigarettes are now the most commonly used tobacco product among high school students. The 2019 Montana Youth Risk Behavior Survey showed nearly a third (30%) of Montana high school students currently use e-cigarettes and more than half (58%) have tried them. Approximately 43,000 Montana youth between ages 12 and 18 have tried vaping products and 22,000 Montana youth are currently using vaping products. Between 2017 and 2019, the percentage of Montana high school students using these products frequently (on 20 or more of the past 30 days) has increased by 243% and daily use has increased by 263%.

There has been a recent and alarming outbreak of vaping-associated pulmonary illness (VAPI) in multiple states. As of Dec. 12, this outbreak includes over 2,400 confirmed and probable cases and 52 deaths linked to e-cigarette use in 48 states and 1 U.S. territory. Montana has seven confirmed cases. People are using an array of products and no one product, brand or substance has been linked to all the cases.

Information About Flavored Electronic Cigarette Products

What are some of the risks to youth from e-cigarette use?

Youth are uniquely at-risk for long lasting effects of nicotine exposure because the brain continues to develop until age 25. Nicotine exposure during adolescence harms the part of the brain that controls attention, learning, mood and impulse control. Nicotine, in any form, is unsafe for youth. Nicotine is highly addictive and can prime the brain for addiction other drugs in the future. Research indicates that youth who use e-cigarettes are four times more likely to become cigarette smokers, and the CDC states the surge in e-cigs has erased past progress in reducing youth tobacco use.

Are e-cigarettes regulated?

Not currently. E-cigarettes came under the purview of the FDA in 2009 but the FDA has consistently pushed back enforcement of these regulations. After public health groups sued this year, a U.S. District Court ordered that these regulations must be enforced no later than May 12, 2020.

Are e-cigarettes less harmful than regular cigarettes?

Youth who start using tobacco and nicotine products before their brains are fully developed are at a greater risk of addiction to other drugs. While some flavorings may be “generally recognized as safe” for food consumption, they have not been proven safe for inhalation. Some of the other chemicals in e-liquids and in the aerosol from e-cigarettes are known to cause cancer in humans. Heavy metals such as lead and cadmium that have been found in e-cigarette aerosol can cause respiratory distress and disease. The FDA has never approved these devices for tobacco cessation.

You’re restricting flavored vaping products. Does that mean it is safe to use unflavored vaping products?

No. The Surgeon General, the CDC and DPHHS have issued recommendations that youth, young adults and pregnant women should not use these products and that adults currently using these products stop. The emergency rules regarding flavored vaping products are specifically focused on Montana youth.

What percentage of youth-initiated use of flavored e-cigarettes?

More than 3.6 million middle and high school students in the United States use e-cigarettes, accounting for about one-third of all U.S. e-cigarette users. E-cigarettes with kid-friendly flavors such as mint, mango, gummy bear and cotton candy are fueling this epidemic; 96% of 12 to 17-year-olds who initiated e-cigarette use started with a flavored product, and 70 percent report the flavors as the reason they use e-cigarettes (PATH Study, 2016-18). Teen smoking rates in the United States declined by more than 70 percent between 2000 and 2018, but the spike in e-cigarette use among youth threatens to undo a generation's worth of progress.

Information About the National Outbreak

The ongoing national outbreak of vaping associated pulmonary illness has led to even more concern and questions. As of Dec. 12, this outbreak includes over 2,400 confirmed and probable cases and 52 deaths linked to e-cigarette use in 48 states and 1 U.S. territory. More than half of the cases involve patients under age 25. Montana has seven confirmed cases.

Until more information is known, CDC and DPHHS are advising people not to use any type of e-cigarette product. Additionally, anyone who uses e-cigarette products should not buy them off the street and should not modify these products or add any substances that are not intended by the manufacturer.

What are the symptoms to watch for?

Based on reports from several states, patients have reported the following: respiratory symptoms (cough, shortness of breath, chest pain) gastrointestinal symptoms (nausea, vomiting, abdominal pain, diarrhea) or non-specific symptoms (fatigue, fever, or abdominal pain.) Some patients reported that their symptoms developed over a few days, while others have reported that their symptoms developed over several weeks. All patients reported history of using e-cigarette, or vaping, products and no consistent evidence of an infectious cause has been discovered.

Resources Available to Help Montanans Quit All Tobacco Products

Montana Tobacco Quit Line

Call 1-800-QUIT-NOW (1-800-784-8669)

- For all Montanans and ALL types of tobacco (smokeless, cigarettes, e-cigarettes etc.)
- FREE Nicotine Replacement Therapy (NRT), Reduced-cost prescription medication, FREE Quit Coaching, FREE Personalized Quit Plan
- Or, go to www.quitnowmontana.com

Specialized programs

My Life, My Quit is a new youth program for ages 12-17 who want to quit all forms of tobacco including vaping that provides FREE coaching through text, chat, or phone. CONFIDENTIAL enrollment and coaching, coaches specially trained to work with teens and youth, and on-line enrollment is offered. Text (or call) “Start My Quit” to 1-855-891-9989 or visit mylifemyquit.com.

American Indian Commercial Tobacco Quit Line

- American Indian Coach that provides culturally appropriate cessation services, distinguishing between commercial and traditional tobacco, and FREE NRT. Call 1-855-372- 0037 or enter through 1-800-QUIT NOW and ask for an American Indian coach.

Quit Now Montana Pregnancy Program

- Call 1-800-QUIT-NOW (1-800-784-8669)
- FREE personal female quit coach, cash incentives, and FREE NRT-when approved by doctor.

Additional resources:

- **E-cigarettes and Youth: What Parents Need to Know:** https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/OSH-E-Cigarettes-and-Youth-What-Parents-Need-to-Know-20190327-508.pdf
- **Get the facts about electronic cigarettes, their health effects and the risks of using e-cigarettes.** https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm
- **2018 Surgeon General Report officially declaring e-cig use among youth in the US an epidemic.**

What are the current stats of use by Montana youth?

The dramatic increase in use of e-cigarettes, or vaping, by youth is driven in large part by flavored e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. E- cigarettes are now the most commonly used tobacco product among high school students.

The 2019 Montana Youth Risk Behavior Survey showed nearly a third (30%) of Montana high school students currently use e-cigarettes and more than half (58%) have tried them.

13% of high school students report *frequently* (on 20 or more of the past 30 days) using e- cigarettes. This is a **243%** increase from 2017.

9% of high school students report *daily* use of e-cigarettes. This is a **263%** increase from 2017.

28% of middle school (grades 7-8) students report having tried e-cigarettes.

16% of middle school (grades 7-8) students report *currently* (at least once in the past 30 days) using e-cigarettes.

American Indian youth stats

66% of American Indian high school students report having tried an e-cigarette.

28% of American Indian high school students report *currently* (at least once in the past 30 days) using e-cigarettes.

7% of American Indian high school students report *frequently* (on 20 or more of the past 30 days) using e-cigarettes.

4% of American Indian high school students report *daily* use of e-cigarettes.