

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New) NOTICE OF PUBLIC HEARING ON
Rules I through III pertaining to) PROPOSED ADOPTION
flavored electronic smoking devices)

TO: All Concerned Persons

1. On July 16, 2020, at 3:00 p.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed adoption of the above-stated rules. Because there currently exists a state of emergency in Montana due to the public health crisis caused by the coronavirus, there will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: <https://mt-gov.zoom.us/j/91570526763>, meeting ID: 915 7052 6763;

(b) Dial by telephone +1 646 558 8656, meeting ID: 915 7052 6763; find your local number: <https://mt-gov.zoom.us/u/airGmYnn6>.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on July 10, 2020, to advise us of the nature of the accommodation that you need. Please contact Heidi Clark, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I DEFINITIONS As used in this subchapter, the following definitions apply:

(1) "Electronic smoking device" means any device that may be used to deliver any aerosolized or vaporized substance to the person inhaling from the device, including, but not limited to, an e-cigarette, e-cigar, e-pipe, vape pen, or e-hookah. An electronic smoking device includes any component, part, or accessory of the device, including, but not limited to, flavor enhancers, and also includes any substance that may be aerosolized or vaporized by such device, whether or not the substance contains nicotine. An electronic smoking device does not include drugs, devices, or combination products authorized for sale by the U.S. Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

(2) "Flavored electronic smoking device" means an electronic smoking device that imparts a taste or smell other than the taste or smell of tobacco. This

includes but is not limited to menthol, mint, wintergreen, chocolate, cocoa, vanilla, honey, or the taste or smell of any fruit, candy, dessert, alcoholic beverage, herb, or spice. An electronic smoking device shall be presumed to be a flavored electronic smoking device if a retailer, manufacturer, or a retailer or manufacturer's agent or employee has:

(a) made a public statement or claim that the product or device imparts a taste or smell other than the taste or smell of tobacco;

(b) used text and/or images on the electronic smoking device's labeling or packaging to explicitly or implicitly indicate that the electronic smoking device imparts a taste or smell other than tobacco; or

(c) taken action directed to consumers that would be reasonably expected to cause consumers to believe the electronic smoking device imparts a taste or smell other than tobacco.

(3) "Person" means a natural person, company, corporation, firm, partnership, organization, or other legal entity.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

NEW RULE II DISTRIBUTION OF FLAVORED ELECTRONIC SMOKING DEVICES (1) A person shall not sell, offer for sale (e.g., display on a retailer's physical premises that is accessible to the public), give, market, advertise, or otherwise distribute flavored electronic smoking devices to persons within this state.

(2) A person shall not transport within this state flavored electronic smoking devices intended for sale or distribution within this state by any person.

(3) These rules apply with equal force regardless of whether a retailer or reseller is physically located in this state or utilizes online or other remote sale methods that are intended to deliver flavored electronic smoking devices to this state.

(4) These rules do not apply to a "marijuana infused product" as defined under 50-46-302(13), MCA.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

NEW RULE III SEVERABILITY (1) If any rule or subsection of these rules, in whole or in part, is found to be invalid by a court of competent jurisdiction, such decision will not affect the validity of the remaining portion of these rules.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

4. Statement of Reasonable Necessity

The Department of Public Health and Human Services (department) is proposing adoption of these rules in response to the epidemic of youth e-cigarette or electronic smoking device use (vaping). The rules prohibit selling, offering for sale, marketing,

advertising, or otherwise distributing flavored electronic smoking devices to persons in Montana. This would thereby remove from Montana commerce the flavored electronic smoking devices that have been targeting youth users and inflicting grievous health effects on Montana's youth. The department is proposing these rules pursuant to its authority under 50-1-202, MCA, to adopt and enforce rules regarding conditions of public health importance.

The rate of youth usage of e-cigarettes has increased at an astronomical rate and shows no signs of abating. Both the United States Surgeon General and Food and Drug Administration (FDA) have declared youth vaping a national epidemic.¹ National youth vaping rates increased 78% from 2017 to 2018.² In 2019, more than one in four (27.5%) high schoolers were current vapers.³ The number of middle and high school students vaping rose from 3.6 million in 2018 to 5.4 million in 2019, representing an increase of about 1.8 million youth.⁴ The 2019 National Youth Tobacco Survey data show that 34.2% of current high school vaping users and 18.0% of current middle school vaping users use electronic smoking devices on 20 days or more per month and the Monitoring the Future Study found that in 2019, 11.7% of high school seniors vape nearly daily, suggesting that more users are becoming dependent on these products.⁵

Montana historically has ranked above the national average in youth vaping rates. In 2019, 58.3% of high school-aged youth reported ever trying vaping, 30.2% reported vaping in the past month, and 12.7% reported frequent use (at least 20 days in the prior 30-day period). Legislative efforts such as adding vapor products to the Youth Access to Tobacco Products Control Act (Mont. Code Ann. § 16-11-301 et seq.) seem to have failed to check youth vaping growth in the state. An estimated 22,500 Montana middle and high schoolers are currently vaping.⁶ Additionally, the rate of high school students reporting frequent vaping has grown 243% since 2017.⁷

Youth vaping presents a condition of public health importance in Montana because it exposes youth to numerous adverse health effects. According to the Surgeon General, "E-cigarette use poses a significant and avoidable health risk to young people in the United States. Besides increasing the possibility of addiction and long-term harm to brain development and respiratory health, e-cigarette use is associated with the use of other tobacco products that can do even more damage to the body."⁸ Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development; the brain keeps developing until about age 25. In particular, nicotine use can harm the parts of the adolescent brain responsible for attention, learning, mood, and impulse control.⁹ Nicotine can also prime the brain for addiction to other drugs."¹⁰ Because of these risks, the Surgeon General has concluded that, "The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."¹¹

The effect of nicotine on developing brains may prime not just nicotine addiction, but greater vulnerability to addiction to other drugs as well. Research indicates that nicotine exposure occurring as a result of vaping may induce epigenetic changes that sensitize the brain to other drugs and prime it for future substance abuse.¹² A

meta-analysis of 21 prior studies also revealed that young people who vaped were also 3.5 times more likely to use marijuana.¹³

Differentiating between nicotine-containing products and non-nicotine-containing products could create difficulties enforcing a flavored e-cigarette rule. It is difficult to determine whether a product contains nicotine. Some e-cigarettes that have been marketed as non-nicotine-containing products have been found to contain nicotine.¹⁴ While manufacturers sometimes label nicotine content on their product, the labeling is not always accurate. A rule that excludes non-nicotine-containing products would give further incentive to manufacturers to mislabel the nicotine content of a product.

Additionally, non-nicotine-containing e-cigarettes pose their own risks to children's health. While e-cigarette aerosol contains fewer chemicals and toxins compared to cigarette smoke, it can still contain harmful and potentially harmful chemicals, including formaldehyde, acrolein, volatile organic compounds like toluene, tobacco-specific nitrosamines, and metals like nickel and lead.¹⁵

Flavorings in e-cigarettes may pose unique harms. According to the Surgeon General while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown and some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.¹⁶ According to the FDA, "Flavorings that are safe for use in food may become toxic when these chemicals are heated and inhaled. Some have been shown to be harmful to the lungs."¹⁷ There are over 15,000 flavors available on the marketplace and none of them have been reviewed by the FDA.¹⁸

Including non-nicotine-containing products will protect children from misleading manufacturer claims and potentially harmful chemicals.

Vaping has been shown to increase the likelihood of smoking cigarettes among young people, raising concerns that e-cigarettes are acting as an entry to nicotine products that may lead to use of more dangerous products such as combustible tobacco. According to a study published in 2019, youths nationwide are four times more likely to try cigarettes and three times more likely to currently use cigarettes if they previously vaped. The study also estimated that vaping is likely responsible for 22% of new ever cigarette use (trying a cigarette) and 15% of current cigarette use for the same group. Researchers estimate that this translates to over 43,000 current youth cigarette smokers who might not have become smokers without e-cigarettes.¹⁹ The National Academies of Science, Engineering and Medicine (NASEM) released a comprehensive report concluding that there was substantial evidence that vaping increases risk of ever using cigarettes among youth and young adults.²⁰

In proposing these rules to address the epidemic of youth vaping and the harms such products inherently pose to youth, the department was guided by data strongly indicating that flavors are a top reason behind youth initiation of vaping. Youth cite flavors as a top reason for vaping. Of youth e-cigarette users, 70.3% say they use

e-cigarettes "because they come in flavors I like."²¹ In addition, the FDA found that 97% of current youth e-cigarette users age 12 to 17 reported that they had used a flavored e-cigarette in the past month.²² E-cigarettes are available in a multitude of flavors, many of which are similar to candy, including flavors such as Cotton Candy, Slammin Pink Watermelon, Strawberry Rolls, and Cherry Skittles. Many of these products are also packaged in a manner that appeal to youth by closely resembling the packaging of candy.

The proposed rules are reasonably necessary to address the epidemic of youth vaping and its associated adverse health effects identified above, which represent a public health emergency and condition of public health importance in Montana. The proposed rules are designed to remove a primary pathway to youth initiation of e-cigarette use by preventing the sale of flavored e-cigarettes in Montana to reduce the number of youth who use e-cigarettes and their exposure to the harms inherent with the use of such products.

5. Small Business Impact Statement

Pursuant to 2-4-111, MCA, the department has analyzed whether the proposed rules will significantly and directly impact small businesses. As set forth below, the department has concluded the rules will significantly and directly impact small businesses who sell flavored e-cigarettes.

The businesses that must comply with this rule are any retailers or distributors who sell or distribute e-cigarettes to persons located in Montana. The department does not collect or have information that would enable it to determine the number of licensees that meet the definition of a small business under 2-4-102(13), MCA. For the purpose of this analysis, the department presumes a significant portion of the licensed entities meet the definition of a small business.

The probable and significant direct effects of the proposed rules on small businesses that sell or distribute flavored e-cigarettes will be from lost sales of flavored e-cigarettes. The department does not collect or have information that would enable it to determine what percentage of e-cigarette sales consist of flavored products. Additionally, the degree of impact on any particular small business selling flavored e-cigarettes is dependent on the type of small business. For example, the proposed rules logically will have a greater impact on small business vape shops that exclusively sell e-cigarettes than small business convenience stores and gas stations that sell a much wider variety of products. Another variable impacting the degree of lost flavored e-cigarette sales is the number of persons who formerly used flavored e-cigarettes that will transition to non-flavored e-cigarettes, which will at least partially offset the lost revenue stream. Given the number of variables and lack of available data, the department cannot provide a dollar estimate as to the impact of the proposed rules on small businesses. This measure is not a total ban on e-cigarettes; it only prohibits the sale of the flavors that are most attractive to children. Vape shops will continue to sell tobacco-flavored e-cigarettes, e-cigarette devices, and components. Adult e-cigarette users are likely to switch to tobacco-flavored e-

cigarettes if they are the only product on the market. Until e-cigarette manufacturer Juul entered the market and pushed the market to its flavored products, tobacco-flavored e-cigarettes were the single most widely used flavor.²³

The department considered several alternatives to a rule restricting the sale of flavored e-cigarettes. First, the department considered taking no action. This option was rejected as it would allow the rise in youth usage to continue unabated and would do nothing to achieve the goal of reducing youth usage of e-cigarettes. Second, the department considered a rule restricting the sale of all e-cigarettes. This option would achieve the purpose of the proposed rules but was rejected for several reasons. The approach would be costlier for small businesses. Additionally, the approach would prohibit adults from using any e-cigarettes and could lead to an increased use of combustible tobacco by existing e-cigarette users. Third, the department considered regulating only closed systems. Youth are already using a variety of e-cigarettes, not just closed systems, so it is not effective to regulate only closed systems. Data from the 2019 National Youth Tobacco Survey, published in *Journal of the American Medical Association*, found that after Juul, Suorin and Smok are the most popular e-cigarette devices among high school students. Among high school e-cigarette users, 7.8% reported using Smok and 3.1% reported using Suorin.²⁴ These prevalence estimates are solely from write-in responses, since Suorin and Smok were not listed as options in the questionnaire, so actual use rates are likely higher. Both Suorin and Smok are open pod systems. Unlike Juul, which sells pre-filled, closed cartridges, Suorin and Smok devices come with empty, refillable pods which can be filled with e-liquids of varying nicotine strengths and flavors. Youth who are already addicted to these products will simply switch to whichever product is left on the market.

Further, while youth e-cigarette use skyrocketed after pod devices like Juul came on the market, we also saw youth use rates as high as 16% before the emergence of pod devices. Some of the most appealing flavors to children, like gummy bear and cotton candy, are used in open systems. With the epidemic on our hands and newer, easier-to-use open system devices, it's likely that youth will easily switch to open system devices, especially since open systems are becoming increasingly kid-friendly. There are open systems that look just like Juul, are easy to refill, and are becoming more popular among children. The Trump Administration's policy that only regulated closed systems exempted kid-friendly disposable products. These products are cheap, easy to use, have high levels of nicotine, come in a wide range of flavors, and are easy to conceal. Anecdotal evidence has shown these products have become increasingly popular with youth. We must take all of these products off the market now to avoid worsening the epidemic as youth switch to whatever product is left available for them.

Fourth, the department considered exempting small businesses (vape shops) from the proposed rules. Nationally, about two-thirds of tenth-graders say that it's easy to get vaping devices and e-liquids.²⁵ In Montana, 18.9% of high school e-cigarette users got their e-cigarette product from a store such as a convenience store, supermarket, discount store, gas station, or vape shop.²⁶ If flavored products are

allowed for sale anywhere, children will be able to purchase them. Children will still obtain these products from older social sources, and by asking others to buy for them. Vape shops sell thousands of kid-friendly flavors. In fact, many of the most egregious versions of kid-friendly flavors, like cotton candy and gummy bear, are only available in vape shops and online. Exempting vape shops will keep the most youth-appealing flavors readily available.

There is also no evidence that adults need flavored e-cigarettes. No flavored e-cigarette has been approved or even reviewed for smoking cessation purposes by the Food and Drug Administration. Public health authorities in the U.S., including the Centers for Disease Control and Prevention and the Surgeon General, have found that there is not enough evidence to recommend e-cigarettes for tobacco cessation. E-cigarette companies may claim that adult smokers are their target audience, but that is not who is using the product. E-cigarettes have become increasingly popular among youth and young adults, while there has been no significant uptake among older adults.

A comprehensive rule that restricts the sale of all flavored e-cigarettes in all retailers is the best way to reduce youth access and protect Montana's youth. The state is facing a public health crisis. With the skyrocketing rate of youth e-cigarette use, protecting our children's health should be the top priority.

6. Fiscal Impact

The anticipated financial impact to retailers and distributors of flavored e-cigarettes is described in the above Small Business Impact Statement. The proposed rules are not anticipated to have a significant fiscal impact on the department.

7. Planned Next Steps and Contact Information

a. The department intends for these proposed rules to be effective upon date of adoption.

b. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Heidi Clark, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., July 24, 2020.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which

program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 7 above or may be made by completing a request form at any rules hearing held by the department.

10. The bill sponsor contact requirements of section 2-4-302, MCA, do not apply.

/s/ Peter Bovingdon
Peter Bovingdon
Rule Reviewer

/s/ Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State June 16, 2020.

¹ FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use> (last updated Sept. 12, 2018); Office of the Surgeon General, *Surgeon General's Advisory on E-cigarette Use Among Youth*, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf> (last accessed Jun. 12, 2020).

² FDA, *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey> (last updated Nov. 18, 2019).

³ Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online Nov. 5, 2019, <https://jamanetwork.com/journals/jama/fullarticle/2755265>.

⁴ Centers for Disease Control, *Youth and Tobacco Use*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last accessed Jun. 12, 2020).

⁵ Truth Initiative, *E-cigarettes: Facts, Stats, and Regulations*, <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations> (last accessed Jun. 12, 2020).

⁶ Montana IBIS Population Estimates <http://ibis.mt.gov/query/selection/pop/PopSelection.html>, MT Office of Public Instruction, 2019 Youth Risk Behavior Survey

⁷ Montana Office of Public Instruction, 2019 Youth Risk Behavior Survey, https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/2019_MT_YRBS_FuIIReport.pdf?ver=2019-08-23-083248-820 (last accessed Jun. 12, 2020).

⁸ HHS, *Know the Risks: E-Cigarettes & Young People*, <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html> (last accessed Jun. 12, 2020).

⁹ HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm#report. See also: CDC Office on Smoking and Health, "Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults," March 2019.

¹⁰ U.S. Department of Health and Human Services (HHS), *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016, https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.

¹¹ See endnote 10.

¹² Menglu Yuan, Sarah J Cross, Sandra E Loughlin, Frances M Leslie, Nicotine and the Adolescent Brain, 593.16 *J Physiology*, 3397–3412 (2015).

¹³ Chadi, N., et al., "Association Between Electronic Cigarette Use and Marijuana Use Among Adolescents and Young Adults," *JAMA Pediatrics*, 173(10), 2019.

¹⁴ Willett JG, et al., "Recognition, use and perceptions of JUUL among youth and young adults," *Tobacco Control*, 28:115-116, published online April 18, 2018.

¹⁵ Cheng, T, "Chemical Evaluation of Electronic Cigarettes," *Tobacco Control* 23:ii11-ii17, May 2014, http://tobaccocontrol.bmj.com/content/23/suppl_2/ii11.full. Goniewicz, ML, et al., "Levels of selected carcinogens and toxicants in vapour from electronic cigarettes," *Tobacco Control* 23(2):133-9, March 6, 2013. Williams, M, et al., "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol," *PlosOne*, 8(3), March 2013. See also Williams, M, "Electronic Cigarette Liquids and Vapors: Is It Harmless Water Vapor," presented October 3, 2013 at TRDRP Electronic Cigarette Webinar, <https://www.trdrp.org/files/e-cigarettes/williams-slides.pdf>. NASEM, *Public Health Consequences of E-Cigarettes*, 2018.

¹⁶ See endnote 10.

¹⁷ Gottlieb, S and Abernethy, A. *Understanding the Health Impact and Dangers of Smoke and 'Vapor'*. FDA Voices: Perspectives from FDA Leadership and Experts.

<https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/understanding-health-impact-and-dangers-smoke-and-vapor>.

¹⁸ Zhu, S-H, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," *Journal of Medical Internet Research*, 20(3), published online March 12, 2018.

¹⁹ See endnote 10.

²⁰ National Academies of Sciences, Engineering, and Medicine. 2018. *Public health consequences of e-cigarettes*. Washington, DC: The National Academies Press. <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

²¹ FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," March 13, 2019, <https://www.fda.gov/media/121384/download>.

²² See endnote 21.

²³ Romberg, et al., "Patterns of nicotine concentrations in electronic cigarettes sold in the United States, 2013-2018," *Drug and Alcohol Dependence*, 203:1-7, Oct. 2019. And NHIS 2014-2018.

²⁴ Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.

²⁵ Monitoring the Future, *Trends in Availability of Drugs as Perceived by 10th Graders*, 2019, <http://monitoringthefuture.org/data/19data/19drtbl16.pdf>.

²⁶ See endnote 7.