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

In the matter of the adoption of Temporary Emergency Rules I through III pertaining to prohibiting sale of flavored vapor products to reduce youth risk of vaping-associated lung injury or death	))))))	NOTICE OF ADOPTION OF TEMPORARY EMERGENCY RULES

TO: All Concerned Persons

1. The Montana Department of Public Health and Human Services (department) is adopting the following emergency rules in response to the concurrent epidemic of youth e-cigarette or vapor products use ("vaping") and the emerging outbreak of lung injury and death associated with vaping. The rules prohibit the sale of flavored vaping products, regardless of whether they contain nicotine or tetrahydrocannabinol (THC).

According to the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the National Youth Tobacco Survey, national youth vaping rates increased 78 percent from 2017 to 2018. 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 May 29, 2018). In late 2018, then FDA Commissioner Scott Gottlieb, M.D., issued a statement that was unequivocal: "I now have good reason to believe that it's reached nothing short of an epidemic proportion of growth." 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). The United States Surgeon General, Jerome Adams, M.D., repeated this alarm in December officially declaring youth vaping an epidemic and warning that action must be promptly taken to protect the health of young people. 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 Oct. 2, 2019).

Montana historically has ranked above the national average in youth vaping rates. In 2019, 58 percent of high school-aged youth reported ever trying vaping, 30 percent reported vaping in the past month, and 13 percent report 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. For example, the rate of high school students reporting frequent vaping has grown 243 percent since 2017. MT Office of Public Instruction, *2019 Youth Risk Behavior*

Survey, https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/2019_MT_YRBS_FullReport.pdf?ver=2019-08-23-083248-820 (last accessed Oct. 2, 2019).

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. Menglu Yuan, Sarah J Cross, Sandra E Loughlin, Frances M Leslie, *Nicotine and the Adolescent Brain*, 593.16 J Physiology, 3397–3412 (2015). This concern is compounded by the popularity with youth of product called JUUL. Teens between 15 and 17 years old have 16 times greater odds of using JUUL than 25- to 34-year-olds. Truth Initiative, *Behind the explosive growth of JUUL*, https://truthinitiative.org/research-resources/emerging-tobacco-products/behind-explosive-growth-juul (posted Jan. 3, 2019). JUUL is unique in that it has one of the highest levels of nicotine of any vapor product on the market and uses nicotine salts—a chemical formulation that greatly increases the rate and amount of nicotine delivered into the blood. *Id.*

A metanalysis of 21 prior studies also recently revealed that young people who vaped were also 3.5 times more likely to use marijuana. Reuters, *Teen vaping tied to marijuana use*, https://www.reuters.com/article/us-health-kids-smoking/teen-vaping-tied-to-marijuana-use-idUSKCN1V324S (posted Aug. 19, 2019). Likewise, studies of the impact of THC—the psychoactive component in marijuana—on the young brain consistently show evidence of both structural brain abnormalities and altered neural activity. American Psychological Association, *Marijuana and the developing brain*, https://www.apa.org/monitor/2015/11/marijuana-brain (posted Nov. 2015).

Vaping products contain a liquid that may contain nicotine, THC and other cannabinoid oils, flavoring, propylene glycol, vegetable glycerin, and other ingredients. Vaping liquids may also contain chemicals such as diacetyl, formaldehyde, acrolein, acrylonitrile, propylene oxide, crotonaldehyde and acetaldehyde; as well as metals such as nickel, lead, and chromium.

The federal Centers for Disease Control and Prevention, the federal Food and Drug Administration, and state and local health departments nationally are investigating a multistate outbreak of lung injury and death associated with vaping. As of October 3, 2019, the CDC had confirmed 1080 cases across 48 states and U.S. territories, including 21 fatalities in 15 different states. The department has confirmed two cases in Montana and is tracking several potential cases.

The only commonality in all cases is a history of vaping, but victims otherwise report mixed histories of using vapor products containing THC, nicotine, or a combination of both. Cases show diverse symptoms and signs of injury, including cough, chest pain, shortness of breath, low levels of blood oxygen, abnormal chest X-rays or CT scans, and pathologic evidence of severe damage to the lungs. People suffering from the condition have experienced grievous harms to their health

with some requiring admission to intensive care units and mechanical ventilation. Several other states have already taken steps to protect the public from this harm.

Promulgation of these emergency rules is necessary because no other administrative act can be taken to avert this imminent peril to public health, safety, and welfare of Montana youth who vape or may be considering trying vapor products. The explosive growth of youth use of vapor products in the state has been concerning, but the present outbreak of lung injury and death associated with vaping gives rise to an immediate and alarming condition of public health importance. For the foregoing reasons, the department enacts these emergency rules. These rules will remain in effect no longer than 120 days after the date of enactment.

2. EMERGENCY RULE 1 provides definitions that apply to this rulemaking. These definitions are necessary to clarify that a flavor includes any substance, including mint or menthol, that imparts a taste or smell to a vapor product other than the natural taste or smell that comes from the psychoactive plant component of a nicotine or THC-containing product. These definitions clarify that the emergency rules apply to all individual and corporate entities that sell vapor products in the normal course of business. The definitions further clarify that the rules are intended to apply to all electronic smoking products that produce a vapor or aerosol, regardless of whether they do or do not contain nicotine or THC.

3. EMERGENCY RULE 2 is necessary to curtail the sale or distribution of flavored vapor products within the state of Montana by any means, including by remote or online methods. Emergency Rule 2 protects Montana youth who vape or may be considering trying vapor products by temporarily removing from intrastate commerce the flavored, youth-targeted products that have been identified as a primary draw to vaping—a practice that is presently inflicting grievous injury and illness on people throughout the country, including Montana.

4. EMERGENCY RULE 3 is part of a comprehensive, national effort to expand outbreak reporting to capture information related to lung injury and death associated with vaping. The inclusion of this rule allows public health officials and medical practitioners to better respond to individual cases, but also allows for the gathering of critical information to identify a root cause of the present outbreak and recommend appropriate control measures to stop its spread. Under the rule, cases of unexplained vaping-associated lung injury will be immediately reportable to the department in order to conduct surveillance activities necessary for the investigation, monitoring, control and prevention of this condition.

5. EMERGENCY RULE 4 is necessary to prevent the impairment of functioning of the remaining emergency rules package should a single provision or portion of any provision be invalidated by a court of competent jurisdiction.

6. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice. If you require an accommodation, contact Gwen

Knight at the 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.

7. The emergency rules are effective October 22, 2019. This fourteen-day delay in effectiveness will allow for all impacted parties sufficient opportunity to receive notice and come into compliance.

8. The text of the emergency rules provide as follows:

EMERGENCY RULE I DEFINITIONS As used in these emergency rules, the following definitions apply:

(1) "Flavored vapor product" means a vapor product that imparts a taste or smell other than the taste or smell of tobacco or marijuana. This includes but is not limited to menthol, mint, wintergreen, fruit, chocolate, cocoa, vanilla, honey, or the taste or smell of any candy, dessert, alcoholic beverage, herb, or spice. A vapor product shall be presumed to be a flavored vapor product if a retailer, manufacturer, or a manufacturer's agent or employee has made a statement or claim directed to consumers or the public, whether expressed or implied, that the product or device has a distinguishable taste or aroma other than the taste or aroma of tobacco or marijuana.

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

(3) "Vapor product" means a noncombustible product, regardless of nicotine or Tetrahydrocannabinol (THC) content, that uses a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from a solution or other substance. The term includes an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device and 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. The term does not include a product regulated as a drug or device by the United States food and drug administration under Chapter V of the Federal Food, Drug, and Cosmetic Act.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, MCA

EMERGENCY RULE II DISTRIBUTION OF FLAVORED VAPOR PRODUCTS PROHIBITED (1) A person shall not sell, offer for sale, give, or otherwise distribute flavored vapor products to persons within this state.

(2) A person shall not transport within this state flavored vapor products 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 vapor products to this state.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, MCA

EMERGENCY RULE III REPORTING REQUIREMENTS (1) Cases of pulmonary illness associated with the use of vaping products are a reportable disease and condition under ARM 37.114.203 and are subject to the reporting requirements set forth under ARM Title 37, Chapter 114, Subchapter 2.

AUTH: 50-1-202, 2-4-303, MCA
IMP: 50-1-202, 50-2-118, MCA

EMERGENCY RULE IV SEVERABILITY (1) If any rule or subsection of these emergency 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, 2-4-303, MCA
IMP: 50-1-202, MCA

9. The rationale for the temporary emergency rule is as set forth in paragraphs 1 through 4.

10. It is presently unknown whether a standard rulemaking procedure will be undertaken prior to the expiration of this temporary emergency rule. The necessity and efficacy of these emergency rules will be continuously evaluated as the investigation into the outbreak of vaping-associated pulmonary injury develops.

11. 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 paragraph 6 above or may be made by completing a request form at any rules hearing held by the department.

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

Nicholas Domitrovich
Rule Reviewer

Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State October 8, 2019.