

**ATTACHMENT C: Agency Justification for Rule
Provided Pursuant to 2-4-403, MCA**



Department of Public Health and Human Services
Office of Legal Affairs ♦ PO Box 4210, 111 N. Sanders ♦ Helena, MT 59604-4210
Telephone: 406-444-6902 Fax: 406-444-9744

Steve Bullock, Governor

Sheila Hogan, Director

August 10, 2020

Members of the Montana Legislature
Montana State Capitol
Helena, MT 59601

Dear Montana Legislator:

I write to provide written justification for the Department's proposed rules restricting the sale of flavored electronic smoking devices (MAR Notice No. 37-923).¹ I will first address the statutory grant of rulemaking authority supporting the proposed rules before turning to the objections by 20 legislators that have resulted in this legislative poll.

1. The epidemic of youth e-cigarette usage is a condition of public health importance for which the legislature has provided the Department with rulemaking authority to remedy.

Under section 50-1-202(1)(p)(i), MCA, the legislature has provided the Department with authority to adopt and enforce rules regarding conditions of public health importance. The term "conditions of public health importance" includes a condition that is identifiable on an individual or community level and that can reasonably be expected to lead to adverse health effects in the community. Mont. Code Ann. § 50-1-101(2).

The use of e-cigarettes by youth constitutes a condition of public health importance due to both the rate of youth usage and the numerous adverse health effects such use poses to youth. 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.²

Montana historically has ranked above the national average in youth e-cigarette use. In 2019, 58.3% of high school-aged youth reported ever trying e-cigarettes, 30.2% reported using them in the past month, and 12.7% reported frequent use (at least 20 days in the prior 30-day period). An estimated 22,500

¹ A copy of the proposed rules is located at: <https://dphhs.mt.gov/Portals/85/rules/37-923pro-arm.pdf>

² 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 accessed Jul. 30, 2020); 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 Jul. 30, 2020).

Montana middle and high schoolers are currently using e-cigarettes.³ Additionally, the rate of high school students reporting frequent vaping has grown 243% since 2017.⁴

E-cigarette use poses significant health risks to Montana's youth. Nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development. 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.⁵ 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.⁶ There are over 15,000 flavors available on the marketplace and none of them have been reviewed by the FDA.⁷

Youth cite flavors as a top reason for vaping.⁸ 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 epidemic of youth e-cigarette usage and the associated harms on Montana's youth clearly present a condition of public health importance. The proposed rules are consistent with the legislature's enactment of section 50-1-202, MCA, authorizing the Department to adopt and enforce rules addressing conditions of public health importance.

2. The department took all required steps to involve the interim committee in the rule-making process.

The objections of 20 legislators to the proposed rules are based primarily upon two contentions: (1) the Department disregarded a formal objection of the Economic Affairs Interim Committee (EAIC) to the proposed rules; and (2) the Department has not presented the rules to the Children, Families, Health, and Human Services (CFHHS) Interim Committee.

³ Montana IBIS Population Estimates, <http://ibis.mt.gov/query/selection/pop/PopSelection.html>, MT Office of Public Instruction, 2019 Youth Risk Behavior Survey (last accessed Jul. 30, 2020)

⁴ Montana Office of Public Instruction, 2017 and 2019 Youth Risk Behavior Survey, <https://opi.mt.gov/Portals/182/Page%20Files/YRBS/2019YRBS/ClassAA-UrbanABC.pdf?ver=2019-09-10-120735-573> (last accessed Jul. 30, 2020).

⁵ HHS, Know the Risks: E-Cigarettes & Young People, <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html> (last accessed Jul. 30, 2020).

⁶ 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 (last accessed Jul. 30, 2020).

⁷ 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.

⁸ FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," March 13, 2019, <https://www.fda.gov/media/121384/download> (last accessed Jul. 30, 2020).

The Department did not disregard the objection made by EAIC. The Department responded immediately to EAIC's objection and explained our appreciation of the interim committee's interest in the rules, and pointed out that by statute the decision of whether to formally object to the proposed rules was within the purview of the CFHHS interim committee.⁹

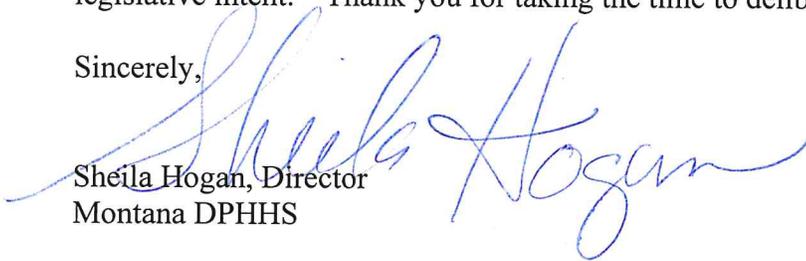
The Department provided timely notice of the proposed rules to the CFHHS interim committee. During its June 29, 2020, meeting the interim committee discussed the proposed rules, but did not make a formal objection.

The Department has been transparent throughout this rulemaking process and has followed all requirements of the Montana Administrative Procedure Act. The proposed rules directly address the epidemic of youth e-cigarette use in Montana, which presents a condition of public health importance. It is critical that this epidemic is addressed immediately. Each year that goes by without action results in more Montana youth becoming addicted to nicotine and exposed to the harms of tobacco.

The Department respectfully requests your affirmance that the proposed rules are "consistent with legislative intent." Thank you for taking the time to deliberate on this important matter.

Sincerely,

Sheila Hogan, Director
Montana DPHHS

A handwritten signature in blue ink that reads "Sheila Hogan". The signature is written in a cursive style and is positioned to the right of the typed name and title.

⁹ A copy of the Department's response to EAIC's objection is located at:
<https://leg.mt.gov/content/Committees/Interim/2019-2020/Children-Family/Rules/july2020-dphhs-response-eaic-objection.pdf>.