DEPARTMENT OF HEALTH AND HUMAN SERVICES BUREAU OF HEALTH AND WELLNESS, PUBLIC HEALTH ADMINISTRATION PROTECTION OF YOUTH FROM NICOTINE PRODUCT ADDICTION EMERGENCY RULES

Filed with the Secretary of State on

These rules take effect upon filing with the Secretary of State and shall remain in effect for 180 days.

By authority conferred on the Department of Health and Human Services by the Public Health Code, PA 368 of 1978; sections 2221, 2226, 2233, Executive Reorganization Order No. 2015-4; MCL 333.2221, MCL 333.2226, MCL 2233, MCL 400.227, and the Administrative Procedures Act, PA 306 of 1969; sections 41, 42, and 48; MCL 24.241, MCL 24.242, and MCL 24.248.

FINDING OF EMERGENCY

The following emergency rules are promulgated by the Department of Health and Human Services to address a recent and staggering increase in youth usage of electronic nicotine delivery systems ("ENDS"), including vapes, vaporizers, vape pens, hookah pens, and e-cigarettes. E-cigarettes entered the U.S. marketplace around 2007, and since 2014, have been the most commonly used tobacco product among youth in the U.S.¹ Nationwide, e-cigarette use among middle and high school students increased 900% from 2011-2015.² From 2017 to 2018, e-cigarette use among youth increased 78% among high school students and 48% among middle school students.³ The total number of children who are currently using e-cigarettes rose to an astonishing 3.6 million in 2018, 1.5 million more than the previous year alone.⁴ From the years 2015-2016 and 2017-2018, counties across Michigan (cross section of 39 reporting) saw between a 30% and 118% increase in use among high school students who used an e-cigarette during the past month.⁵

¹ U.S. Surgeon General's Advisory on E-Cigarette Use among Youth, available at https://e-cigarette-use-among-youth-2018.pdf

² Surgeon General's Advisory, see footnote 1; citing Wang TW, Gentzke A, Sharapova S, et al. Tobacco Use Among Middle and High School Students – United States, 2011-2017. MMWR Morbidity and Mortality Weekly Report. 2018;67(22):629-633.

³ See https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-ecigarette-use citing the most recent National Youth Tobacco Survey (NYTS) data.

⁴ See Footnote 3.

⁵ Michigan Profile for Healthy Youth Survey by MDE & MDHHS, 39 County Data from 2015-2016 and 2017-2018 for e-cigarette usage among high schoolers.

ENDS products use an e-liquid that may contain nicotine, in addition to a combination of flavoring, propylene glycol, vegetable glycerin, and other ingredients.⁶ ENDS aerosols may also contain toxic chemicals such as formaldehyde, acrolein, acrylonitrile, propylene oxide, crotonaldehyde and acetaldehyde (also found in cigarette smoke), as well as metal particles such as nickel, lead, and chromium, which can be inhaled into the lungs.⁷

The nicotine in these products can rewire the brain to crave more of the substance and create a nicotine addiction. Resulting brain changes may have long-lasting effects on attention, learning, and memory.⁸ Research has also shown that youth who use ecigarettes are more likely to start smoking combustible cigarettes despite the well-known, documented, and often deadly health consequences such as lung cancer and heart disease.⁹

In December of 2018, the United States Surgeon General Jerome Adams officially declared e-cigarette use among youth in the United States an epidemic. ¹⁰ Dr. Adams issued an advisory on e-cigarette use among youth, noting that action must be promptly taken to protect the health of young people. ¹¹ Steps identified by the Surgeon General include implementation of evidence-based population-level strategies such as including e-cigarettes in smoke-free indoor air policies, restricting young peoples' access to e-cigarettes in retail settings, licensing retailers, implementing price policies, developing educational initiatives targeting young people, curbing e-cigarette advertising and marketing that are appealing to young people, and reducing access to flavored tobacco products by young people. ¹² Dr. Adams was joined by the Secretary of the U.S. Department of Health & Human Services, Alex Azar, who called the historic increase in e-cigarette use by youth, which has outpaced any other substance, an "unprecedented challenge." ¹³

⁶ https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends#references

⁷ https://www.fda.gov/tobacco-products/ctp-newsroom/think-e-cigs-cant-harm-teens-health

⁸ See footnote 6, referencing Abreu-Villaca. Y., Seidler, F. J., Tate, C. A., & Slotkin, T.A. (2003). Nicotine is a neurotoxin in the adolescent brain: critical periods, patterns of exposure, regional selectivity, and dose thresholds for macromolecular alterations. Brain Res, 979 (1-2), 114-128.

⁹ https://www.fda.gov/tobacco-products/ctp-newsroom/think-e-cigs-cant-harm-teens-health; referencing Berry KM, Fetterman JL, Benjamin EJ, Bhatnager A, Barrington-Trimis JL, Leventhal AM, Stokes A. Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in U.S. Youths. JAMA Netw Open. 2019;2(2)e187794. Doi: 10.1001/jamanetworkopen.2018.8894.

¹⁰ https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf

¹¹ ld.

¹² ld.

¹³ https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-for-e-cigarette-press-conference.html

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According to a recent study, 81% of youth e-cigarette users reported using a flavored e-cigarette at first use. 14 This study concluded that flavored tobacco products may attract young users and serve as "starter products to regular tobacco use." Another study revealed that nearly two thirds (63.6%) of current middle and high school tobacco users have used a flavored tobacco product in the past month. 15 Because this epidemic can be attributed to the appeal of flavored vapor and alternative nicotine products to youth as well as the advertising and promotional activities by companies that glamorize use of tobacco nationwide, prohibiting the retail sale of flavored vapor and alternative nicotine products will result in less product available on the market, and the products that are available will be substantially less appealing to youth, which should ultimately result in decreased youth tobacco use. Reducing exposure to such advertising may help reduce youth initiation and continued use of tobacco products. Michigan will thus curb youth exposure to tobacco advertisements specifically designed to pull youth into tobacco usage at an early age.

The Department of Health and Human Services is empowered to exercise authority and promulgate rules to safeguard the public health. MCL 333.2226(d). The Department may also promulgate rules without following the notice and participation procedures required by sections 41, 42, and 48 of 1969 PA 306, MCL 24.241, MCL 24.242, and MCL 24.248 of the Michigan Compiled Laws in circumstances where a finding of emergency is made. Based upon the above information and pursuant to its authority under the Public Health Code and the Administrative Procedures Act, the Department of Health and Human Services concludes that an emergency exists with regard to the youth use of e-cigarettes and alternative nicotine products and that the following emergency rules are necessary to preserve the public health, safety, and welfare.

Rule 1. (1)(a) "Characterizing flavor" means a taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product or any byproduct produced from the tobacco product. This includes, but is not limited to, tastes or aromas relating to food or drink of any sort; menthol; mint; wintergreen; fruit; chocolate; vanilla; honey; candy; cocoa; dessert; alcoholic beverages; herbs; or spices.

- (b) "Flavored vapor product" means any vapor product that imparts a characterizing flavor.
- (c) "Flavored alternative nicotine product" means any alternative nicotine product that imparts a characterizing flavor.

¹⁴ Villanti AC, Johnson AL, Ambrose BK, et al. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). Am J Prev Med. 2017;53(2):139–151. doi:10.1016/j.amepre.2017.01.026. https://www.ncbi.nlm.nih.gov/pubmed/28318902.

¹⁵ Dai H. Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017. JAMA Pediatr. Published online January 07, 2019173(3):282–284. doi:10.1001/jamapediatrics.2018.4595.

- (d) "Retailer" means any person or body that operates a business engaging in the sale of vapor products or alternative nicotine products.
- (2) The terms defined in the Youth Tobacco Act, MCL 722.641-722.645, have the same meaning when used in these rules.
- Rule 2. (1) A retailer shall not sell, offer for sale, give, transport, or otherwise distribute, nor possess with intent to sell, give, or otherwise distribute, a flavored vapor product, or flavored alternative nicotine product.
- (2) A retailer shall not sell, offer for sale, give, transport, or otherwise distribute a flavored vapor product or flavored alternative nicotine product via the use of imagery explicitly or implicitly representing a characterizing flavor.
- (3) A person who possesses four or more flavored vapor products, or flavored alternative nicotine products is rebuttably presumed to possess said items with the intent to sell.
- (4) A person shall not transport a flavored vapor product or flavored alternative nicotine product intended for delivery to a retailer in violation of these rules.
- Rule 3. (1) A retailer shall not sell, offer for sale, give, or otherwise distribute vapor products or alternative nicotine products via the use of fraudulent or misleading terms or statements.
- (2) Fraudulent or misleading terms or statements are those which are likely to induce false or unevidenced beliefs regarding the properties of the vapor products or alternative nicotine products in a portion of the viewing audience. Fraudulent or misleading terms include but are not limited to: "clean;" "safe;" "harmless;" "healthy."
- (3) This section does not apply to products for which advertising is exclusively regulated by the Food and Drug Administration.
- Rule 4. The restrictions on advertising set forth at 21 CFR 1140.32 apply with equal force to vapor products, and alternative nicotine products. Violations of 21 CFR 1140.32 are violations of this subsection.
- Rule 5. (1) Advertisements for Vapor Products or Alternative Nicotine products shall not be placed:
- (a) Within 25 feet of the point of sale. Where this cannot be achieved, advertisements must be placed at the greatest possible distance from the point of sale.
- (b) Within 25 feet of candy, foodstuff, or soft drinks. Where this cannot be achieved, advertisements must be placed at the greatest possible distance from candy, foodstuff, and soft drinks.
- (c) In such a manner that the advertisement can be readily seen by a person standing outside of the building at a distance of 25 feet.

Rule 6. (1) A person who violates any provision of these rules is guilty of a misdemeanor, punishable by imprisonment for not more than six months, or a fine of not more than \$200, or both, as set forth by MCL 333.2261.

- (2) Violations of rule 2 are calculated on a per-item and per-transaction basis and may be punished cumulatively.
- (3) Violations of rules 3, 4, and 5 are calculated daily, with each 24-hour period during which the violation occurs constituting a separate violation.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

Joneigh Khaldun, MD MPH FACEP
Chief Medical Executive
Chief Deputy Director for Health

Date:

Pursuant to Section 48(1) of 1969 PA 306, MCL 24.248(1), I hereby concur in the finding of the Department of Health and Human Services that circumstances creating an emergency have occurred and the public interest requires the promulgation of the above rules.

Honorable Gretchen Whitmer

Governor

Date: