

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

CERTIFICATE OF NEED FOR EXTENSION OF EMERGENCY

The Department of Health and Human Services has advised me that data released since the promulgation of the Emergency Rules for the Protection of Youth from Nicotine Product Addiction demonstrates that Michigan's youth vaping crisis intensified again in 2019, with multiple studies showing that regular vaping use among minors increased dramatically.

As cited in the Department of Health and Human Services' Emergency Rules, The National Youth Tobacco Survey (NYTS) showed that from 2017-2018, e-cigarette use by youth increased by 78% among high school students and 48% among middle school students. We now know that trend only increased over the past year.¹ The results of the 2019 NYTS revealed that 27.5% of high school students used e-cigarettes regularly,² an increase of 32%. And, alarmingly, 10.5% of middle schoolers used e-cigarettes regularly, an increase of 114%.³ Considering the 48% increase in middle schoolers' use of e-cigarettes in 2018, the rate has tripled in two years.

Among current users of tobacco products, e-cigarettes are the most commonly used flavored tobacco product at an alarmingly increasing rate (68.8% of current e-cigarette users).⁴ Data from the 2019 Monitoring the Future Survey of eighth, 10th, and 12th graders also shows high rates of youth e-cigarette use compared to just one year ago, with rates doubling over the past two years.⁵

¹ <https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use>

² "Regularly" means within the past 30 days.

³ Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States," Nov. 5, 2019 JAMA available at <https://jamanetwork.com/journals/jama/article-abstract/2755265>

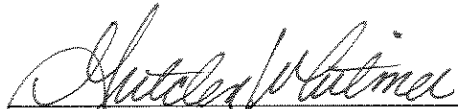
⁴ Teresa W. Wang, PhD¹; Andrea S. Gentzke, PhD¹; MeLisa R. Creamer, PhD¹; Karen A. Cullen, PhD²; Enver Holder-Hayes, MPH²; Michael D. Sawdey, PhD²; Gabriella M. Anic, PhD²; David B. Portnoy, PhD²; Sean Hu, DrPH¹; David M. Homa, PhD¹; Ahmed Jamal, MBBS¹; Linda J. Neff, PhD, "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019." December 6, 2019 CDC Morbidity and Mortality Weekly Report (MMWR), available at <https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm>

⁵ <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/monitoring-future-2019-survey-results-vaping>

New data released from the University of Michigan to the New England Journal of Medicine also shows significant increases over the past few months in each of the three grade levels surveyed (eighth, 10th, and 12th grade).⁶

The documented intensification of the vaping crisis only confirms what DHHS determined when it, with my concurrence, originally issued the Emergency Rules: to protect the public health and welfare from the emergent and worsening crisis of youth vaping, the Emergency Rules must go into effect immediately. The Emergency Rules' prohibition on flavored vapor products will significantly limit the appeal of vaping to youth, curbing the increase in new youth users. Meanwhile, the Emergency Rules' restrictions on marketing will limit the flow of misinformation about the safety of vaping to youth, which will also curb the growth in youth use. The urgent need for these protections has not flagged since the original issuance of the Emergency Rules; if anything, it, like the crisis itself, has only intensified.

Therefore, pursuant to Section 48(1) of 1969 PA 306, as amended, MCL 24.248(1), I hereby certify that it is necessary to extend the Bureau of Health and Wellness, Public Health Administration Emergency Rules, Protection of Youth from Nicotine Product Addiction. The emergency rules were filed with the Secretary of State on March 18, 2020. By requesting the six months extension, the current rules will remain effective until September 18, 2020.


Gretchen Whitmer, Governor

3/11/20
Date

⁶ Richard Miech, Ph.D., Lloyd Johnston, Ph.D., Patrick M. O'Malley, Ph.D., Jerald G. Bachman, Ph.D. "Trends in Adolescent Vaping," 2017-2019, N Engl J Med 2019; 381:1490-1491, available at <https://www.nejm.org/doi/full/10.1056/NEJMc1910739>

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Filed with the Secretary of State on September 18, 2019

These rules take effect upon filing with the Secretary of State and shall remain in effect for 6 months.

By authority conferred on the Department of Health and Human Services by the sections 2221, 2226, and 2233 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, and 333.2233, Executive Reorganization Order No. 2015-1, MCL 400.227, and section 48 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.248.

FINDING OF EMERGENCY

For the reasons below, the Michigan Department of Health and Human Services finds that the State of Michigan faces a vaping crisis among youth and recommends the promulgation of emergency rules to address this crisis.

Since 2014, e-cigarettes (also known as vapor products) 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) witnessed 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-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-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-e-cigarette-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.

E-cigarettes use an e-liquid that may contain nicotine, in addition to a combination of flavoring, propylene glycol, vegetable glycerin, and other ingredients.⁶ They 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 e-cigarettes 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 e-cigarettes are significantly 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 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.”¹²

According to a recent study, 81% of youth e-cigarette users reported using a flavored e-cigarette at first use.¹³ This study concluded that flavored tobacco products may attract young users and serve as “starter products to regular tobacco use.” Another study

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 Id.

¹² <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-for-e-cigarette-press-conference.html>

¹³ 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>.

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.¹⁴

This epidemic can therefore be attributed in large part to the appeal of flavored vapor products to youth as well as the advertising and promotional activities by companies that glamorize use of nicotine products nationwide.

Rule 1. (1) As used in these rules:

(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, vapor product, or alternative nicotine product, or any byproduct produced thereof. 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 nicotine vapor product” means any vapor product that contains nicotine and imparts a characterizing flavor.

(d) “Retailer” means any person or entity that operates a business engaging in the sale of tobacco products or vapor products.

(e) “Reseller” means any person who purchases tobacco products or vapor products and intends to distribute such product(s) for resale in the State of Michigan.

(2) The terms defined in the youth tobacco act, 1915 PA 31, MCL 722.641 to 722.645, have the same meaning when used in these rules.

Rule 2. (1) Beginning 14 days after these rules are filed with the secretary of state, a retailer or reseller shall not:

(a) Sell, offer for sale, give, transport, or otherwise distribute, nor possess with intent to sell, give, or otherwise distribute a flavored nicotine vapor product.

(b) Use imagery explicitly or implicitly representing a characterizing flavor to sell, offer for sale, give, or otherwise distribute a vapor product.

(2) Beginning 14 days after these rules are filed with the secretary of state, a person shall not transport flavored nicotine vapor products intended for delivery to any retailer or reseller in violation of these rules.

¹⁴ 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, 2019;173(3):282–284. doi:10.1001/jamapediatrics.2018.4595.

Rule 3. (1) Beginning 14 days after these rules are filed with the secretary of state, a retailer or reseller shall not use, either directly or indirectly, fraudulent or misleading terms or statements to sell, offer for sale, give, or otherwise distribute vapor products.

(2) As used in this rule, "fraudulent or misleading terms or statements" include those that are likely to induce false or unevicenced beliefs regarding the properties of the vapor products in a substantial portion of the audience. Fraudulent or misleading terms include, but are not limited to, "clean;" "safe;" "harmless;" and "healthy."

(3) This rule does not apply to products for which advertising is exclusively regulated by the Food and Drug Administration.

Rule 4. Beginning 14 days after these rules are filed with the secretary of state, the restrictions on advertising set forth at 21 CFR 1140.32 apply with equal force to vapor products. Violations of 21 CFR 1140.32 are violations of this rule.

Rule 5. These rules apply with equal force to retailers and resellers utilizing online and other remote sales methods that are intended to deliver flavored nicotine vapor products to this state.

Rule 6. (1) Beginning 14 days after these rules are filed with the secretary of state, advertisements for vapor 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 7. (1) A person who violates any provision of these rules is guilty of a misdemeanor, punishable by imprisonment for not more than 6 months, or a fine of not more than \$200, or both, as set forth by section 2261 of the public health code, 1978 PA 368, 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 6 are calculated daily, with each 24-hour period during which the violation occurs constituting a separate violation.

Rule 8. If any rule or subrule 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.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES



Robert Gordon
Director

Date:

Pursuant to Section 48(1) of the administrative procedures act of 1969, 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: 9/18/19