

Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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**REGULATORY IMPACT STATEMENT
and COST-BENEFIT ANALYSIS (RIS)**

Agency Information:

Department name:

Health and Human Services

Bureau name:

Population Health and Community Services

Name of person filling out RIS:

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Rule Set Information:

ARD assigned rule set number:

2019-107 HS

Title of proposed rule set:

Protection of Youth from Nicotine Product Addiction

Comparison of Rule(s) to Federal/State/Association Standard:

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

Recent amendments to the Federal Food, Drug, and Cosmetic Act to include a new subsection, 906(d)(5), Minimum Age of Sale, which provides that “It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.” The Act, aka Tobacco 21 or T21, was authorized by Congress and was signed by the President on December 20, 2019. T21 applies to sales of tobacco products – including cigarettes, smokeless tobacco, hookah tobacco, cigars, pipe tobacco, electronic nicotine delivery systems including e-cigarettes and e-liquids – to anyone under 21 years of age.

Recent statistics show the use of electronic nicotine delivery systems (“ENDS”), including vapes, vaporizers, vape pens, hookah pens, and e-cigarettes among youth under the age of 21 has increased exponentially throughout the United States, including Michigan. As a result, in December of 2018, United States Surgeon General Jerome Adams officially declared e-cigarette use among youth in the United States an epidemic, with serious health, both physically and mentally, challenges. Flavored nicotine vaping products were identified in studies as the catalyst for either first time use among high school and middle school students (81%) and continuous use of flavored nicotine vaping products as appealing to youth continues. Therefore, in addition to the federal mandate to raise the age of tobacco products to 21, the proposed rules are designed to prohibit the sale of flavored nicotine vaping products to reduce the use and health consequences to Michigan youth when using these ENDS, as identified by the federal government as a huge health concern by youth and young adults and requiring any ENDS distributor to have a formal FDA authorization to market and sell these products or face enforcement measures effective September 9, 2020. See Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (April 2020).

A. Are these rules required by state law or federal mandate?

The proposed rules are not required by state law or federal mandate. They are being promulgated under the authority of the Public Health Code, MCL 333.1101 - 333.25211. Further, there are currently several bills in progress in the Michigan Legislature that address the prohibition of use of retailing practices for vaping products. See SB 0782, 0783, 0784, 0785, and 0786 (2020).

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

The proposed rules do not exceed a federal standard. There is no federal standard prohibiting the sale of flavored nicotine products.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

As of this writing, Massachusetts, New Jersey, New York, and Rhode Island have permanent bans on the sale of nicotine flavored vaping products. Eight states, including Michigan, issued emergency rules to temporarily ban the sale of nicotine flavored vaping products —Massachusetts, Montana, New York, Oregon, Rhode Island, Utah, and Washington.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

Massachusetts has just implemented a law that took effect June 1, 2020. It limits who can sell them with an emphasis on flavored nicotine products which includes the sale of flavored tobacco, including menthol cigarettes and chew, as well as nicotine vaping products. These will be confined to just any licensed smoking bar where the products may only be smoked and nowhere else. The same restrictions will be applicable to other flavored tobacco products which include flavored chewing tobacco and menthol cigarettes. New Jersey implemented its law in January 2020. New Jersey lawmakers approved a legislative package strengthening regulations on e-cigarettes, including a ban on flavored-vaping products, in a growing campaign to fight tobacco use among young people. One measure stiffens penalties for retailers selling tobacco and vaping products to people under the age of 21, while another forbids the use of coupons or discounts to purchase tobacco and vaping products. The sale of vaping liquid that contains nicotine in a concentration of more than 2% will also be prohibited. New York's law went into effect July 1, 2020 and provides for the prohibition of the sale of flavored nicotine vapor products, and the second bans the sale of all tobacco and nicotine vapor products in pharmacies. Most states have adopted similar standards that prohibit the sale of flavored tobaccos and the sale of vaping products. Additional information on this topic may be updated at the time of the public hearing.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

The Michigan Youth Tobacco Act (YTA), Act 31 of 1915, amended by SB 106 and 155, 2019 PA 18, regulates the sale and possession of "alternative nicotine products," "vapor products," and "liquid nicotine containers" involving minors less than 18 years old. The proposed rules do not conflict with the YTA.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

These rules are different than the prohibitions in the YTA and T21 because they would prohibit the sale, offering for sale, gifting, or distribution of flavored nicotine vaping products to persons in Michigan, regardless of age. Statistics show that in states that enacted youth tobacco bans for 18 and under, youth use of e-cigarettes continued to skyrocket. Thus, action is necessary to further prevent the youth addiction of tobacco and nicotine products in Michigan irrespective of the YTA and T21 laws.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

The proposed rules do not exceed a federal standard. There is no federal standard prohibiting the sale of flavored nicotine vaping products.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, either the statute that specifically authorizes the more stringent rules or a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

These rules do not exceed a federal standard. Additionally, the department is specifically authorized by statute (MCL 333.2226) to promulgate these rules in order to protect the public health.

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The proposed rules would prohibit the sale, offer for sale, gifting, and distribution of e-cigarettes and flavored nicotine vaping products. Current statistics prove the use of vaping products by children has increased exponentially. Banning those flavors that appeal to children will significantly reduce youth nicotine use, and ultimately whole population tobacco and nicotine use, and save lives. Further, retailers will be curtailed from advertising to a vulnerable population, which will reduce the use of flavored nicotine vaping products that may lead to regular smoking.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The documented intensification of the youth vaping crisis only confirms what DHHS determined when it originally issued Emergency Rules: the Rules are needed to protect the public health and welfare of Michigan citizens. The proposed rules' prohibition on the sale and distribution of flavored nicotine vaping products will significantly limit the appeal of vaping to youth, curbing the increase in new youth users. Further, the proposed 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.

B. Describe the difference between current behavior/practice and desired behavior/practice.

Michigan's youth flavored nicotine vaping crisis intensified in 2019, with multiple studies showing that regular vaping use among minors increased dramatically. The National Youth Tobacco Survey showed that regular vaping use among middle schoolers increased 114% in 2019 alone. Considering the 48% increase in middle schoolers' vaping in 2018, the rate has tripled in two years. The desired behavior/practice is to reduce the appeal of vaping flavored nicotine products in order to prevent the abuse of tobacco and nicotine products at a young age, to reduce the rate of addiction to tobacco and nicotine as a result of vaping, and to reduce the greater health consequences associated with tobacco and nicotine use, including death. Data from the 2019 Monitoring the Future Survey of 8th, 10th, and 12th graders shows high rates of e-cigarette use, compared to one year ago, with rates doubling over the past two years. Additionally, new data released in 2019 from the University of Michigan to the New England Journal of Medicine also shows significant increases over the past year in the same grades, 8th, 10th, and 12th.

C. What is the desired outcome?

To reduce the appeal of vaping flavored nicotine products in order to prevent the abuse of tobacco and nicotine products at a young age, to reduce the rate of addiction to tobacco and nicotine as a result of vaping, and to reduce the increased negative health consequences associated with tobacco and nicotine use, including death. Further, the restrictions on advertising will limit the flow of misinformation about the safety of vaping to youth, which will also curb the growth in youth use. . A decrease in youth nicotine addiction will eventually produce an overall decline in nicotine addiction, and consequently, combustible cigarette use, leading to improvements in population health (reduction in lung disease and heart disease, specifically).

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The harm identified is the use of flavored nicotine vaping products, e-cigarettes and vaping by minors and those young adults under the age of 21 which attracts young people and glamorizes using tobacco and nicotine at an early age. The ban would result in a decline in the use, the addiction, and the corresponding health issues associated with the use of tobacco and nicotine by youth and young adults at an early age, and ultimately across the whole population. The nicotine in e-cigarettes can rewire the brain to crave more of the substance and create nicotine addiction. Resulting brain changes may have long-lasting effects on attention, learning, and memory. 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.

A. What is the rationale for changing the rules instead of leaving them as currently written?

These proposed rules are a new rule set.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The proposed rules will be consistently applied statewide to curb both the use of and addiction to tobacco and nicotine products by youth, and ultimately across the whole population. This, in turn, will decrease the negative health conditions associated with the practice of vaping and using flavored nicotine products and promote a healthy lifestyle for Michigan youth.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

This is a new rule set. There are no obsolete or unnecessary rules to rescind.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

There are no known costs associated with the rule imposition or savings to the agency. Over time, there will be massive savings to the State of Michigan, insurance companies, and individuals due to decreased nicotine addiction among youth who become adults and continue to be addicted to nicotine. A recent analysis by University of Michigan researchers from the School of Public Health found that in the most likely of several simulations they ran, nearly 3.3 million life-years could be saved by the year 2070. This simulation accounts for e-cigarettes' possible roles in both smoking cessation and initiation. It reflects more than 3.5 million life-years gained by using the electronic nicotine delivery devices to quit conventional cigarettes and 260,000 life-years lost due to additional vaping-induced smoking initiation by young people.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

There has not been an agency appropriation or a funding source identified for any expenditure under these proposed rules.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

Any burden placed on adults who may legally purchase tobacco is far outweighed by the positive effect on the health and welfare of Michigan youth in removing the incentive to begin vaping and/or continue vaping flavored nicotine products. Although businesses will have to eliminate the in-state sale of flavored nicotine vaping products, those businesses may continue to sell tobacco and menthol flavored vaping products and flavored products with 0% nicotine in Michigan and flavored nicotine vapor product outside of Michigan. Any burden placed on businesses selling the flavored nicotine vaping products is far outweighed by the health and welfare of Michigan youth. The burden placed on local health officials in ensuring the ban is being followed is outweighed by further health issues of Michigan youth being able to obtain the flavored nicotine vaping products for use.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

Removal of the products that are enticing youth to either begin or continue to use flavored nicotine vapor products reduces the number of youth who will begin vaping and using the flavored products and, for those currently using the product in violation of the law, removes the availability of the product and will result in the eventual cessation of the use of tobacco and nicotine products. The 2020 US Surgeon General report on tobacco concluded that there is inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

As opposed to non-ENDS tobacco products, there are currently no taxes assessed on vaping cartridges or other ENDS products in Michigan. The increase or decrease of revenue to cities, counties, and school districts does not appear to be affected by a flavored nicotine vaping product ban.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

As with urban areas, health officials and local law enforcement entities will be expected to ensure that local businesses do not have flavored nicotine vaping products as identified in the rules and that businesses and individuals comply with the rules.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

The governmental units must have enforcement actions in place and designate how the violation of the rules are going to be enforced for the prohibition of the sale of vape and tobacco-less products. Local health departments and law enforcement, and licensing authorities may need to coordinate on this enforcement aspect. Currently, the only restriction for shops is the prohibition of selling of tobacco products to those under the age of 21.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

There have been no appropriations made or a funding source identified associated with these proposed rules.

16. In general, what impact will the rules have on rural areas?

The rules will have equal impact on both rural and urban areas. The prohibition of the sale of flavored nicotine vapor products is applied consistently statewide.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

The public interests include more robust compliance inspections by the local health officials in ensuring the rules are being complied with. Use of vaping and flavored tobacco on school grounds should diminish. There is an impact on small businesses related to the prohibition of the sale of flavored tobaccos. However, the shops can still sell tobacco flavored products and 0% nicotine flavored products to adults who wish to continue vaping or step down from smoking combustible cigarettes.

17. Do the proposed rules have any impact on the environment? If yes, please explain.

With a prohibition on sale of vape canisters and other vaping products, primarily composed of plastic, metal, glass, and ceramic, there will be fewer materials to dispose of which will benefit the environment.

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

Because exempting small businesses from the rules would undermine their intended effect (limiting access to flavored vaping products), the agency did not consider exempting small businesses from the proposed rules. The impact of the rules impacts small and large businesses alike.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

Reduction of impact on small businesses via any kind of exemption would be unfeasible because the rules are designed to limit access to flavored vaping products. Allowing small businesses to continue to sell flavored vaping products would undermine that rule. When the agency filed emergency rules to prevent the sale of flavored nicotine vaping products, in addition to marketing prohibitions, further discussions were had internally and with stakeholders regarding the proposed permanent rules moving forward. These proposed permanent rules permit the following in order to ease the burden on small businesses and individuals who may lawfully possess these products: allowing the transport of these products from Michigan to outside states; allowing the mere possession of flavored nicotine vaping products by someone who is lawfully permitted to do so; and permitting the transportation of flavored nicotine vaping products within the state of Michigan and to persons outside the state of Michigan.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

There are 8,590 tobacco retailers in Michigan. These retailers are a mix of tobacco, vape retailers, and retailers who sell both tobacco and vape products which are most common. According to LARA, business entities using the word “vape” or “vapor” results in 472 records. The probable effect on the small businesses vs the larger entities that sell additional products outside the prohibited items may lead to the small businesses losing profits, reducing staff, and/or choosing to stock alternative products to remain viable.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

There is no differing compliance or reporting requirements for small businesses. The proposed rules will apply uniformly and consistently statewide for both small and large businesses associated with flavored nicotine vaping products.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

All businesses, large or small, will follow the same rules. There are no reporting requirements at this time and the rules appear to be easily adaptable to businesses regarding compliance.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

There are no known established performance standards that will replace design or operation standards for small businesses. The rules will require action only for the removal of flavored nicotine vaping products from small business inventories. The rules ban advertising of characterizing flavors such that businesses cannot depict a characterizing flavor in order to entice individuals who may otherwise avoid the store to enter, despite the fact that the business cannot sell characterizing flavors.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

Although small businesses will have to eliminate or sell out-of-state its flavored nicotine vaping products, those businesses may continue to sell tobacco and menthol flavored nicotine vaping products and flavored products with 0% nicotine in state. Because the rules apply to all businesses that sell vaping products and flavored nicotine, any disproportionate impact identified would affect all businesses in the State. It is possible that businesses that only sell e-cigarettes and vapor products will be significantly affected and some may close. Those businesses will need to focus sales on tobacco and menthol flavored vaping products or 0% nicotine flavored products and adjust operations accordingly.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

There is no known report or estimated costs for small businesses to comply with the rules.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

Small businesses that are affected by these rules will need to decide what to do with current inventory for return if for in-state use or for sale out-of-state, if desired. Loss of revenues regarding the prohibition on vaping products and flavored nicotine products may impact a small business' labor costs, i.e. reduction in staff. Small businesses may continue to sell tobacco and menthol flavored nicotine vaping products and other flavored products with 0% nicotine.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

There are no known costs associated with legal or consulting services. There may be associated accounting services that may be impacted due to inventory controls, returns, and replacement of other products in lieu of the vaping and nicotine products prohibitions.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

Small businesses may continue to sell regular tobacco products, tobacco and menthol flavored nicotine vaping products, and flavored vaping products that contain 0% nicotine. Small businesses are not prohibited from selling their product out-of-state and may ship to out-of-state purchasers.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

Exemption or lesser standards for small businesses defeats the purpose of prohibiting the sale of flavored nicotine vaping products and the corresponding health risks to Michigan youth. The majority of the businesses involved with the sale of these products are small businesses.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

Exempting or setting lesser standards will defeat the purpose of protecting the health and safety of youth. The intent of the rules is to end the attractiveness of flavored nicotine vaping products and misleading advertising. All rules must be applied to all business involved with these products.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The emergency rules protecting youth from nicotine addiction did not have input from small businesses in light of the circumstances surrounding their promulgation. However, these proposed rules will undoubtedly offer and receive input from small businesses and the individuals who are affiliated with them as a properly noticed comment period and public hearing will be set for discussion on the rules.

A. If small businesses were involved in the development of the rules, please identify the business(es).

Small businesses were not involved in the development of the rules.

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

There are no rule amendments, this is a new rule set. There do not appear to be any compliance costs borne by businesses or groups. The compliance factor involves the removal of vaping products and flavored nicotine from a business. The estimated cost of compliance is minimal for businesses that will need to remove and transport product. Additionally, there may be minimal costs associated with signage changes.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

All businesses involved with the sale of vaping products and flavored nicotine vaping products will be directly affected by these proposed rules. All adults who use flavored nicotine vaping products (other than tobacco or menthol flavored) will be affected by these proposed rules. Physicians and other health staff, officials, and medical facilities should be affected by seeing a decrease in the use or adverse effect on the health of youth and young adults using these products, in addition to older adults who may stop using the banned products for their own health decisions. Insurance companies and health insurance consumers will benefit as a result of lower rates of heart and lung disease among Michiganders. There are no known businesses costs that should be borne by these businesses. There will be revenue issues with the absence of sales of these products. The public, youth, young adults, and older adults will benefit from these rules by promoting the health of Michigan citizens by reduction in the use of vaping products and flavored tobaccos. Some adults may revert to combustible cigarettes; however, these rules will provide significant long-term health benefits to the general population. There is a risk that adults may revert to combustible cigarettes but statistical support for that proposition is limited. On the other hand, the long-term health benefits of a decline in nicotine usage among youth is well-documented.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

There are no known additional costs that businesses or groups will incur as a result of these proposed rules.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

There are no known compliance costs associated with the proposed rules other than possible minimal costs associated with relabeling products for transport or out-of-state resale. Otherwise, the products are removed from sale or distribution in Michigan.

A. How many and what category of individuals will be affected by the rules?

Flavored vaping product users will be affected by these rules, as will individuals not addicted to nicotine who would become addicted to nicotine but for these rules.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

Quality of life impact on youth and young adults should improve with the proposed rule changes in prohibiting the sale of flavored nicotine vaping products, as will population health over the long-term. While older adults may revert back to combustible cigarette use, these rules are intended to curb use of ENDS by youth in Michigan, and reduce overall nicotine addiction population-wide over the long-term. There is no known quantitative impact on these individuals.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

Health insurance companies and health insurance consumers will reap the benefit of reduced insurance cost, as population health improves due to lower nicotine usage.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The primary and direct benefits are improved health and safety for Michigan youth, young adults, and older adults through reduced usage of nicotine. Reducing vaping product usage among youth will reduce nicotine addiction among youth, and across the entire population, leading to lower rates of combustible tobacco use. The CDC has found that, for every dollar spent on tobacco prevention, states can reduce tobacco-related health care expenditures and hospitalizations by up to \$55.

In 2019, smoking caused health care costs of \$4.59 billion, according to Campaign for Tobacco-Free Kids. Reduced nicotine usage among youth, and population-wide, will reduce these costs substantially.

A recent analysis by University of Michigan researchers from the School of Public Health found that in the most likely of several simulations they ran, nearly 3.3 million life-years could be saved by the year 2070. This simulation accounts for e-cigarettes' possible roles in both smoking cessation and initiation. It reflects more than 3.5 million life-years gained by using the electronic nicotine delivery devices to quit conventional cigarettes and 260,000 life-years lost due to additional vaping-induced smoking initiation by young people.

32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

Business growth on businesses that solely rely on the sale of flavored nicotine vaping products will be impacted by these rules. In 2019, smoking caused productivity losses of \$4.78 billion, according to Campaign for Tobacco-Free Kids. Reduce nicotine usage among youth, and population-wide, will reduce these productivity losses substantially.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

The rules are a general prohibition on sale, not directed at any particular industrial sector. Nevertheless, all businesses that sell flavored nicotine vaping products will be affected by the proposed rules. Over the long-term, all business that rely on nicotine addiction as a customer growth strategy will be negatively affected. This economic cost will be outweighed by productivity gains in other sectors.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

Input and evaluation of the MDHHS Tobacco Section, utilization of the Department of Licensing & Regulatory Affairs lists of tobacco retailers and vape shops. Legal and public policy review by MDHHS staff, members of the executive branch, and Department of Attorney General.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rules.

Published reports by the Food and Drug Administration; US Surgeon General Advisory on E-Cigarette Use Among Youth; Michigan Profile for Healthy Youth Survey by MDE & MDHHS; Dai H. Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014-2017. JAMA Pediatr. (2019); the National Youth Tobacco Survey; CDC, States Update Number of Hospitalized EVALI Cases and EVALI Deaths (Feb 2020); New England Journal of Medicine, Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Final Report (March 2020); and MDHHS Tobacco Section of the Population and Health Division.

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

There are several bills pending in the Michigan Legislature regarding vaping and use of tobacco products. See SB 0782, 0783, 0784, 0785, and 0786 (2020). The proposed legislation has not moved out of committee, nor does the proposed language in the legislation adequately address the means of eliminating the harm affecting Michigan youth and young adults. The proposed rules should be promulgated to address the harm of the ongoing epidemic of youth vaping use and youth nicotine addiction.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

As reflected in Answer 35, the proposed legislation would need to be expanded to similar language found in the proposed rules to ensure the removal of both the vaping product and the flavored nicotine from sellers' stores. Anything less than what is reflected in the proposed rules would not adequately address the problems associated with vaping use.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

The enforcement of the ban on flavored nicotine vaping products cannot be delegated to a private, market-based mechanism. It is currently being handled by the local law enforcement with the support of the MDHHS Tobacco Section and Attorney General's Office as part of the agency-wide obligation by statute to protect the health and welfare of Michigan citizens.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Several alternative rules were considered by the MDHHS staff and the Governor's Office. The proposed rules contain the most health-protective yet least restrictive rules to protect the health of Michigan youth and prevent a lifetime of nicotine addiction. A prohibition on all flavored vaping products was considered, but rejected, because of the risk that eliminating tobacco and menthol flavored vaping products cause more adults to revert to combustible cigarettes.

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

This is a new rule set. DHHS will coordinate with its divisions in providing instructions to small businesses and other affected parties on their compliance with the rules. When the emergency rules were signed, a retailer mailing went out to all businesses that sell e-cigarettes. That mailing included a link to a website with up-to-date information. Additionally, between the emergency rules and the present, engagement with stakeholders has taken place. That engagement has been immensely helpful to the agency.