

Prohibition on the Sale of Electronic Liquids with Characterizing Flavors

Effective date: 9/17/19

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Subpart 9-3, to be effective upon filing with the Department of State.

A new Subpart 9-3, titled “Prohibition on the Sale of Electronic Liquids with Characterizing Flavors”, is added to read as follows:

Section 9-3.1 Definitions.

As used in this Subpart, the following terms shall have the following meanings:

- (a) The terms “electronic cigarette,” “e-cigarette”, “electronic liquid,” and “e-liquid” shall have the same meanings as established in Subpart 9-2.
- (b) The term “flavored e-liquid” means any e-liquid with a distinguishable taste or aroma, other than the taste or aroma of tobacco or menthol, imparted either prior to or during consumption of an e-cigarette or a component part thereof, including but not limited to tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, mint, wintergreen, herb or spice, or any “concept flavor” that imparts a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor. An e-liquid shall be presumed to be a flavored e-liquid if a tobacco 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 menthol.

(c) The term “possession” means having physical possession or otherwise exercising dominion or control over flavored e-liquids or a product containing the same. For purposes of this definition, among other circumstances not limited to these examples, the following individuals and/or entities shall be deemed to possess flavored e-liquids, or a product containing the same: (1) any individual or entity that has an ownership interest in a retail, distribution or manufacturing establishment that possesses, distributes, sells or offers for sale flavored e-liquids, or a product containing the same; and (2) any clerk, cashier or other employee or staff of a retail establishment, where the establishment possesses, distributes, sells or offers for sale a flavored e-liquids or a product containing the same, and who interacts with customers or other members of the public.

Section 9-3.2 Possession, Manufacture, Distribution, Sale or Offer of Sale of Flavored E-Liquid Prohibited.

It shall be unlawful for any individual or entity to possess, manufacture, distribute, sell or offer for sale any flavored e-liquid or product containing the same.

Section 9-3.3 Penalties.

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each individual container or other separate unit of flavored e-liquid, product containing the same, or any component part that imparts flavor

to an e-cigarette, that is possessed, manufactured, distributed, sold, or offered for sale, shall constitute a separate violation under this Subpart.

Section 9-3.4 Severability.

If any provisions of this Subpart or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Subpart or the application thereof to other persons, entities, and circumstances.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC) subject to the approval of the Commissioner of Health. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

Legislative Objectives:

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. This proposed regulation furthers this legislative objective by prohibiting the possession, manufacture, distribution, sale or offer for sale of flavored electronic liquids (e-liquids) to discourage youth electronic cigarette (e-cigarette) use.

Needs and Benefits:

Emergency regulations are necessary to address the alarming increase of e-cigarette use among New York's youth. New York State-specific surveillance data shows that youth e-cigarette use has risen at a dramatic rate over just the last four years, driven primarily by the abundance of e-liquid flavors. Swift interventions are needed to protect our youth from a lifetime addiction to nicotine. Therefore, restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use.

According to the U.S. Food and Drug Administration (FDA), the use of e-cigarettes by youth has reached epidemic proportions nationally. Since the New York State Department of Health (Department) began tracking e-cigarette use in New York State (NYS) in 2014, use by youth in high school has increased 160 percent, from 10.5 percent in 2014, to 20.6 percent in 2016, to an astounding 27.4 percent in 2018. The rate for 2018 is equivalent to youth use of combustible cigarettes in 2000 prior to the dramatic decline in the use of combustible cigarettes among NYS youth. Currently, just 4.8 percent of NYS youth smoke a combustible cigarette, one of the lowest rates in the nation. However, the rate of smoking by youth is increasing, as the rate in 2016 was 4.3 percent. Schools across New York State are finding it especially challenging to address the alarming increase in use by adolescents. Enforcement of minimum age statute and prohibitions on school grounds are especially difficult given that most products are sleek and easy to conceal by youth users.

The recently published National Academy of Science, Engineering, and Medicine (NASEM) report on the *Public Health Consequences of E-Cigarettes* concluded that there is:

- 1) “...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,” and
- 2) “...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking” among youth and young adults.

Given the recent rise in combustible cigarette use by youth and the fact that e-cigarettes are now the most commonly used tobacco product by youth in NYS, evidence exists that use of e-cigarettes could reverse the long-standing decline in combustible cigarette use and reverse the public health benefits that NYS has achieved.

The flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion only; however, these chemicals have not been approved for inhalation. Because inhalation and ingestion are very different processes, nothing about the approval for ingestion should be interpreted to suggest that these products are safe for inhalation. Food products, chemicals and flavorings that are ingested are detoxified through the liver before entering the circulatory system. Aerosols that are inhaled have a direct impact on lung tissue and directly enter the circulatory system, and are not detoxified through the liver.

Some of the over 15,000 flavors now available include fruit flavors (apple, cherry, peach, melon, strawberry), dessert flavors (vanilla custard, peanut butter cup, cream cookie, milk 'n honey), candy flavors (cinnablaze, bubblerazz, mango burst, caramel). More recently, manufacturers have developed “concept flavors” that may be difficult to perceive as a single distinctive flavor and the product names reflect that (e.g., Jazz, First Flight, and Unicorn Milk) and simple color names (such as Blue and Yellow) that substitute for the names of flavors (Vanilla and Banana respectively). The list of flavors continues to grow. The commonality of all these flavors is that they are distinct from plain tobacco flavor, menthol or unflavored tobacco.

The dramatic increase in use of e-cigarettes by youth is driven in large part by flavored e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. In a recent survey of adolescent e-cigarette users in NYS, 46.3 percent preferred fruit flavors, followed by mint/menthol (19.9%) and chocolate, candy or other sweets (18.2%). In that same survey, 27.3 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 19.3 percent of adolescent e-cigarette users, flavors were the primary reason for first use. Some flavors also confer misperceptions about the relative safety of e-cigarettes. The survey also found that adolescents are more likely to believe that fruit and

chocolate or other sweet flavors are less harmful than flavors like alcohol, tobacco, and spice flavors.

There is also concern regarding human exposure to nicotine. Users are often unaware of how much nicotine they are consuming. The newest and most popular e-cigarettes deliver high levels of nicotine, the addictive component in all tobacco products.

Nicotine is not a benign chemical. Nicotine has deleterious effects on the developing human brain – a process that continues through the mid-twenties. According to the US Surgeon General, these deleterious effects from nicotine can lead to lower impulse control and mood disorders; disrupt attention and learning among youth and young adults; and prime the developing brain for addiction to alcohol and other drugs.

Adult use of e-cigarettes differs by age category. Adults over age 24 use e-cigarettes at very low rates; just 4.4 percent in 2017. The rate of e-cigarette use among young adults 18 to 24 years of age is about 13 percent. The same proportion of young adults (13%) use combustible cigarettes. Almost 40 percent of the young adult smokers are concurrently using e-cigarettes, known as dual use. The same health concerns described above apply to the use of e-cigarettes by adults aged 18 to 24.

The Department will continue to monitor the impact of new legislation that takes effect on November 13, 2019 that raises the legal age for purchase of e-cigarettes and related products to 21 years to determine the impact that has on youth use rates. In addition, the Department routinely conducts surveys that ask youth, among other things, their preference and current use of flavored products and will monitor the trends with respect to use of menthol, mint and other broad flavoring categories.

In addition, although it is too soon to understand the long-term health effects of a lifetime of e-cigarette use, research is beginning to accumulate about certain health effects related to cardiovascular conditions and respiratory conditions. Some e-cigarette flavors contain diacetyl, the buttery-flavored chemical that is used in foods like popcorn and caramel. When inhaled, diacetyl can cause bronchiolitis obliterans, a scarring of the tiny air sacs in the lungs that is commonly referred to as “popcorn lung,” which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

The Department will continue to closely monitor the research literature for health impact related to e-cigarettes. Adult smokers who want to continue to use e-cigarettes will have the option of unflavored, menthol or tobacco flavored e-cigarettes.

Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available.

Paperwork:

The regulation imposes an increase of administrative paperwork for program implementation in regard to developing adequate enforcement mechanisms, record-keeping of enforcement activities and compliance history, and complaint-driven enforcement actions.

Duplication:

There are currently no State or federal regulations regarding the possession, manufacture, distribution, sale or offer for sale of e-cigarettes with characterizing flavors.

Alternatives:

The alternative to the proposed regulation is to wait for the FDA to regulate in this area; however, due to the health concerns associated with increase e-cigarette use among youths, this alternative was rejected.

Federal Standards:

The FDA has not proposed any standards for e-cigarette devices or for the constituents used in the devices to create the aerosol, including characterizing flavors. FDA only requires that

those purchasing e-cigarette products be at least 18 years old, that e-liquids carry a warning statement about the addictiveness of nicotine, and that e-liquids be in child-proof containers.

Compliance Schedule:

The regulation will be effective upon filing with the Department of State.

Contact Person:

Katherine E. Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect the small businesses that are engaged in selling flavored e-liquids or e-cigarettes. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists.

Compliance Requirements:

Small businesses must comply with the proposed regulation by not engaging in any possession, manufacturing, distribution, sale, or offer of sale of flavored e-liquids. Local governments must comply by enforcing the proposed regulations as they are part of the State Sanitary Code.

Professional Services:

Small businesses will need no additional professional services to comply.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation will impose costs, in terms of lost sales, for private regulated parties whose primary product line focuses on the sale of e-cigarettes, flavored e-liquids, and related products.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

Economic and Technological Feasibility:

The rule does not impose any economic or technological compliance burdens.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website.

Small Business and Local Government Participation:

Small business and local governments were not consulted during the creation of this proposed rule; however, small businesses and local governments will be able to submit public comments during the public comment period.

Cure Period:

Violations of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by flavored e-liquids, the risk that some small businesses will not comply with the regulations and continue to possess, manufacture, distribute,

sell or offer for sale any flavored e-liquid or product containing the same justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas. The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

E-cigarettes and e-liquids are sold in many types of retail outlets. The impact on businesses where e-cigarette sales is not the focus of the business (e.g., convenience store) will have no job impact from this regulation as e-cigarettes make up only a small percentage of their sales. Some e-cigarette retailers focus the bulk of their business on e-cigarettes and e-liquids and these outlets will be affected by this regulation. Although they will still be able to sell e-cigarette devices and unflavored, menthol or tobacco flavored e-liquid, the prohibition on flavored e-liquids is likely to affect these businesses. The Department does not have an accurate estimate of the number of stores affected since the registration requirement for e-cigarette retailers will not be effective until December 1, 2019.

Categories and Numbers Affected:

The main category affected by this regulation is the store that focuses its primary business on the sale of e-cigarette devices and e-liquids. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 of such “vape shops” employing 2700 persons across the state, although the Department cannot confirm this information as no official registration mechanism for “vape shops” currently exists. Because of the lack of data about the number of these stores, it is not possible to accurately estimate the number of jobs affected.

Regions of Adverse Impact:

The Department anticipates any jobs or employment impacts will occur equally throughout the regions of the state.

Minimizing Adverse Impact:

The Department will consider different types/levels of enforcement while retailers adapt to the new regulation.

Emergency Justification

Emergency regulations are necessary to address the alarming increase of e-cigarette use among New York's youth. New York State-specific surveillance data shows that youth e-cigarette use has risen at a dramatic rate over just the last four years, driven primarily by the abundance of e-liquid flavors. Swift interventions are needed to protect our youth from a lifetime addiction to nicotine. Therefore, restricting the availability of flavored e-liquids will deter youth from initiating e-cigarette use and reduce ongoing e-cigarette use.

According to the U.S. Food and Drug Administration (FDA), the use of e-cigarettes by youth has reached epidemic proportions nationally. Since the New York State Department of Health (Department) began tracking e-cigarette use in New York State (NYS) in 2014, use by youth in high school has increased 160 percent, from 10.5 percent in 2014, to 20.6 percent in 2016, to an astounding 27.4 percent in 2018. The rate for 2018 is equivalent to youth use of combustible cigarettes in 2000 prior to the dramatic decline in the use of combustible cigarettes among NYS youth. Currently, just 4.8 percent of NYS youth smoke a combustible cigarette, one of the lowest rates in the nation. However, the rate of smoking by youth is increasing, as the rate in 2016 was 4.3 percent. Schools across New York State are finding it especially challenging to address the alarming increase in use by adolescents. Enforcement of minimum age statute and prohibitions on school grounds are especially difficult given that most products are sleek and easy to conceal by youth users.

The recently published National Academy of Science, Engineering, and Medicine (NASEM) report on the *Public Health Consequences of E-Cigarettes* concluded that there is:

- 3) "...**substantial evidence** that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults," and
- 4) "...**moderate evidence** that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking" among youth and young adults.

Given the recent rise in combustible cigarette use by youth and the fact that e-cigarettes are now the most commonly used tobacco product by youth in NYS, evidence exists that use of e-cigarettes could reverse the long-standing decline in combustible cigarette use and reverse the public health benefits that NYS has achieved.

The flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion only; however, these chemicals have not been approved for inhalation. Because inhalation and ingestion are very different processes, nothing about the approval for ingestion should be interpreted to suggest that these products are safe for inhalation. Food products, chemicals and flavorings that are ingested are detoxified through the liver before entering the circulatory system. Aerosols that are inhaled have a direct impact on lung tissue and directly enter the circulatory system, and are not detoxified through the liver.

Some of the over 15,000 flavors now available include fruit flavors (apple, cherry, peach, melon, strawberry), dessert flavors (vanilla custard, peanut butter cup, cream cookie, milk 'n honey), candy flavors (cinnablaze, bubblerazz, mango burst, caramel). More recently, manufacturers have developed "concept flavors" that may be difficult to perceive as a single distinctive flavor and the product names reflect that (e.g., Jazz, First Flight, and Unicorn Milk) and simple color names (such as Blue and Yellow) that substitute for the names of flavors (Vanilla and Banana respectively). The list of flavors continues to grow. The commonality of all these flavors is that they are distinct from plain tobacco flavor, menthol or unflavored tobacco.

The dramatic increase in use of e-cigarettes by youth is driven in large part by flavored e-liquids, and flavors are a principal reason that youth initiate and maintain e-cigarette use. In a recent survey of adolescent e-cigarette users in NYS, 46.3 percent preferred fruit flavors, followed by mint/menthol (19.9%) and chocolate, candy or other sweets (18.2%). In that same survey, 27.3 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 19.3 percent of adolescent e-cigarette users, flavors were the primary reason for first use. Some flavors also confer misperceptions about the relative safety of e-cigarettes. The survey also found that adolescents are more likely to believe that fruit and chocolate or other sweet flavors are less harmful than flavors like alcohol, tobacco, and spice flavors.

There is also concern regarding human exposure to nicotine. Users are often unaware of how much nicotine they are consuming. The newest and most popular e-cigarettes deliver high levels of nicotine, the addictive component in all tobacco products.

Nicotine is not a benign chemical. Nicotine has deleterious effects on the developing human brain – a process that continues through the mid-twenties. According to the US Surgeon General, these deleterious effects from nicotine can lead to lower impulse control and mood disorders; disrupt attention and learning among youth and young adults; and prime the developing brain for addiction to alcohol and other drugs.

Adult use of e-cigarettes differs by age category. Adults over age 24 use e-cigarettes at very low rates; just 4.4 percent in 2017. The rate of e-cigarette use among young adults 18 to 24 years of age is about 13 percent. The same proportion of young adults (13%) use combustible cigarettes. Almost 40 percent of the young adult smokers are concurrently using e-cigarettes,

known as dual use. The same health concerns described above apply to the use of e-cigarettes by adults aged 18 to 24.

The Department will continue to monitor the impact of new legislation that takes effect on November 13, 2019 that raises the legal age for purchase of e-cigarettes and related products to 21 years to determine the impact that has on youth use rates. In addition, the Department routinely conducts surveys that ask youth, among other things, their preference and current use of flavored products and will monitor the trends with respect to use of menthol, mint and other broad flavoring categories.

In addition, although it is too soon to understand the long-term health effects of a lifetime of e-cigarette use, research is beginning to accumulate about certain health effects related to cardiovascular conditions and respiratory conditions. Some e-cigarette flavors contain diacetyl, the buttery-flavored chemical that is used in foods like popcorn and caramel. When inhaled, diacetyl can cause bronchiolitis obliterans, a scarring of the tiny air sacs in the lungs that is commonly referred to as “popcorn lung,” which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

The Department will continue to closely monitor the research literature for health impact related to e-cigarettes. Adult smokers who want to continue to use e-cigarettes will have the option of unflavored, menthol or tobacco flavored e-cigarettes.