

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 9-2, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows.

The title of Part 9 is amended to read as follows:

Part 9 [Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited] Prohibited Substances

A new Subpart 9-1, titled “Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited” is added and section 9.1 through 9.6 are renumbered 9-1.1 through 9-1.6.

A new Subpart 9-2, titled “Required Signage”, is added to read as follows:

Section 9-2.1 Definitions.

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

- (a) The terms “electronic cigarette” and “e-cigarette” mean an electronic device that delivers vapor which is inhaled by an individual user, and shall include any refill, cartridge and any other component of such a device; provided, however, that “electronic cigarette” and “e-cigarette” shall not mean any product approved by the United States food and drug administration as a drug or medical device, or manufactured and dispensed pursuant to title five-A of article thirty-three of the public health law.

(b) The terms “electronic liquid” and “e-liquid” means the solution, substance or material used in an e-cigarette and heated to produce an aerosol or emission to be inhaled by the user, whether the liquid contains nicotine or not.

#### 9-2.2 Required Signage Warning Against the Dangers of Illegal Products.

Any person operating a place of business wherein e-cigarettes or e-liquids are sold or offered for sale shall post in a conspicuous place a sign, to be published by the Department, that warns against the dangers of using illegal e-cigarette and e-liquid products.

#### Section 9-2.3 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 day that a place of business fails to post signage required by this Subpart shall constitute a separate violation under this Subpart.

#### Section 9-2.4 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 regulation furthers the legislative objective by requiring sellers of e-liquids and e-cigarettes to post signage that warns against consumption of illegal products.

### **Needs and Benefits:**

Regulations are necessary to address the alarming number of people that have suffered injury or died from consuming illegal e-liquids and e-cigarette products, which can be adulterated with chemicals that are dangerous or deadly when inhaled. Currently, there is an outbreak of severe lung disease among persons who use illegal e-liquids and e-cigarettes, and the Department is engaged in an educational campaign to warn people against the use of these products. By requiring sellers of legitimate products to warn consumers against the dangers of illegitimate ones, the Department expects that consumers will become more educated and that consumption of illegal products will decrease.

**Costs:****Costs to Private Regulated Parties:**

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

**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 may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

**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:**

This regulation does not require any additional paperwork.

**Duplication:**

These regulations would not duplicate any State or federal regulations regarding e-cigarettes or e-liquids.

**Alternatives:**

The alternative to the regulation is to not exercise the Department's authority to require these notices to the public. That alternative was rejected.

**Federal Standards:**

There are no federal standards regarding signage for dangerous and illegal e-liquid and e-cigarette products.

**Compliance Schedule:**

The regulation will be effective upon publication of a Notice of Adoption in the New York State Register.

**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 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.

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 may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

### **Compliance Requirements:**

Small businesses must comply with the proposed regulation by posting signage published by the Department. 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:**

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

**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 may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding. In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

**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. The Department will assist small businesses by providing the required sign electronically.

**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:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. Given the public health emergency caused by the consumption of illegal e-liquids and e-cigarettes, no cure period was included.



## **Rural Area Flexibility Analysis**

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

## **Job Impact Statement**

No job impact statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

## ASSESSMENT OF PUBLIC COMMENT

The Department of Health (Department) received one comment regarding the proposed addition of Subpart 9-2, Required Signage, to Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

The comment, from the New York City Department of Health and Mental Hygiene, supported the proposed regulations, and suggested modifications to the sign currently published by the Department to include more information and graphic images related to the specific risks of e-cigarettes.

The Department acknowledges the New York City Department of Health and Mental Hygiene's support for this regulation and will take under advisement comments relating to the content of the required signage.