

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 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.

NOTICE OF ADOPTION

School Immunization Requirements

I.D. No. HLT-36-19-00005-A

Filing No. 1152

Filing Date: 2019-12-17

Effective Date: 2019-12-31

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Subpart 66-1 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 2164(10) and 2168(13)

Subject: School Immunization Requirements.

Purpose: To be consistent with national immunization regulations and guidelines and to define "may be detrimental to the child's health".

Substance of final rule: This regulation will amend Subpart 66-1 (School Immunization Requirements) to conform to recent amendments to Sections 2164 and 2168 of the Public Health Law (PHL). In addition, these amendments make the regulations consistent with national immunization recommendations and guidelines. The regulations also define the phrase "may be detrimental to the child's health" for purposes of medical exemptions to vaccination requirements. The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

Technical amendments throughout Section 66-1.1 update references to the "Advisory Committee on Immunization Practices" (ACIP) schedule to its current title, the "Advisory Committee on Immunization Practices Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger." Technical amendments also clarify the grades covered by the varicella, poliomyelitis and vaccine interval requirements.

Amendments to subdivision (g) of section 66-1.1 clarify that positive serologic tests for all three serotypes of poliomyelitis performed prior to September 1, 2019 may be accepted as evidence of poliomyelitis immunity. However, serologic tests against poliomyelitis performed on or after September 1, 2019 may not be accepted in place of poliomyelitis vaccination, in accordance with current ACIP guidance. Similar amendments are made to section 66-1.6 to incorporate these changes into the certificate of immunization.

A new subdivision (k) of section 66-1.1 adds a definition of laboratory confirmation of measles, mumps, rubella and varicella infections, and amendments to subdivision (g) of that section expand the definition of immunity to include laboratory confirmation against these diseases. Laboratory confirmation of immunity means a positive culture or polymerase chain reaction test against measles, mumps, rubella or varicella, or a positive blood test for Immunoglobulin M against measles or rubella, where such positive laboratory test is not otherwise explained by recent vaccination. Amendments to section 66-1.6 add laboratory confirmation of measles, mumps, rubella and varicella to the certificate of immunization.

A new subdivision (l) of section 66-1.1 defines "may be detrimental to the child's health" to mean that a physician has determined that a child has a medical contraindication or precaution to a specific immunization consistent with ACIP guidance. Amendments to subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2 require that the reason why an immunization is detrimental to a child's health be documented in the New York State Immunization Information System. Additionally, amendments to subdivision (c) of section 66-1.3 require the use of medical exemption forms approved by the New York State Department of Health or New York City Department of Education; a written statement from a physician is no longer allowed.

Finally, subdivision (d) of section 66-1.3 is repealed, and amendments to section 66-1.10 remove references to subdivision (d) of section 66-1.3.

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 66-1.1(g)(4), (h), (j)(2), (4) and 66-1.2(c)(4)(ii).

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.ny.gov

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

Changes made to the last published rule does not necessitate revision to the previously published Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement.

Initial Review of Rule

As a rule that requires a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2022, which is no later than the 3rd year after the year in which this rule is being adopted.

Assessment of Public Comment

The New York State Department of Health (Department) received comments from healthcare professional organizations, healthcare providers, schools and the general public regarding the proposed amendments to Subpart 66-1 of Title 10 of the New York Codes, Rules and Regulations, relating to school immunization requirements.

The NYS American Academy of Pediatrics, the NYS Academy of Family Physicians, the NYS Association of County Health Officials, the American Nurses' Association, the Medical Society of the State of New York, the NYS Society of Dermatology and Dermatologic Surgery, and private individuals all expressed support of the regulations.

Additional comments and the Department's responses are summarized below.

Comment: Under section 66 1.1(j)(2) in the proposed regulation, a child is in process when "a child is obtaining serologic tests within 14 days of notification of the parent/guardian that such testing is requested." Some commenters suggested that this language is unclear.

Response: The Department made a technical amendment to the final rule, in section 66-1.1(j)(2), to clarify that a child is “in process” if the “child has had blood drawn for a serologic test and is awaiting test results within 14 days after the blood draw.”

Comment: Under section 66 1.1(j)(4) in the proposed regulation, a child is no longer “in process” and must be excluded from school “within 14 days of the missed dose” unless otherwise exempt. Some commenters stated that this language is unclear.

Response: The Department made a technical amendment to the final rule, in section 66-1.1(j)(4), to clarify that a child is no longer in process and must be excluded from school “within 14 days after the minimum interval identified by the ACIP catch-up schedule.”

Comment: Some commenters argued that the repeal of non-medical exemptions to school immunization requirements infringes students’ and their parents’ rights to religious liberty.

Response: Non-medical exemptions to the requirements of Public Health Law (PHL) § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019. The Department respectfully disagrees that Chapter 35 of the Laws of 2019 unconstitutionally infringes religious freedom under either the United States or the New York State Constitution.

Comment: Commenters stated that the repeal of non-medical exemptions is causing financial and emotional distress.

Response: Families experiencing distress related to homeschooling may enroll their children in school provided that their children comply with PHL § 2164 and other requirements established by the New York State Education Department and any relevant school board or individual school policies.

Comment: Some commenters argue that the Department is incorrectly interpreting the ACIP schedule.

Response: The federal Centers for Disease Control and Prevention (CDC) has issued guidance stating that “[a]s a general rule, infants or children who are more than 1 month or 1 dose behind schedule should be on an accelerated schedule, which means the intervals between doses should be reduced to the minimum allowable.”

Comment: Some commenters stated that the amended requirements for medical exemptions are too strict.

Response: The definition of “[m]ay be detrimental to the child’s health” includes medical contraindications or precautions to a specific immunization consistent with ACIP guidance or other nationally recognized evidence-based standard of care. The regulations do not remove a physician’s ability to issue a medical exemption.

Comment: Some commenters asked that the Department provide additional time for children to be vaccinated before enforcing school immunization requirements.

Response: Non-medical exemptions to the requirements of PHL § 2164 were repealed by the enactment of Chapter 35 of the Laws of 2019, which went into effect immediately upon enactment of the law.

Comment: Some commenters argued that only religious exemptions to measles-containing vaccines should be repealed.

Response: The repeal of non-medical exemptions to the requirements of PHL § 2164, enacted in Chapter 35 of the Laws of 2019 applies to all school immunization requirements, not only measles immunizations.

Comment: Some commenters stated that unvaccinated children do not pose a risk to the public health and that the Department has not sufficiently documented vaccine preventable disease transmission from unvaccinated individuals to other people.

Response: An analysis of confirmed cases of measles in New York State outside of New York City found that 80% of confirmed cases occurred in children less than 18 years of age, and that 92% of the children with confirmed measles had no or unknown MMR vaccine status.

Comment: Several commenters questioned the safety of vaccines.

Response: The United States’ long-standing vaccine safety system ensures vaccines are as safe as possible and that national vaccine recommendations are modified as appropriate when new vaccine effectiveness or safety data becomes available. The CDC, American Academy of Pediatrics, American Association of Family Physicians, American College of Physicians and other reliable healthcare and public health associations all agree that vaccines are a safe, effective and important preventive measure.

Comment: Some commenters questioned why children are required to be immune to types 2 or 3 poliovirus.

Response: The CDC and ACIP continue to recommend that children be immune to all three types of poliomyelitis.

Comment: One commenter noted that PHL § 2168 does not require reporting of the reasons for medical exemptions in the New York State Immunization Information System (NYSIIS).

Response: Regulations in place prior to the emergency adoption of these regulations in August 2019, already required that “[f]or individuals exempt from administration of vaccines, providers must submit patient information, including the reason for the exemption,” to NYSIIS.

Comment: Some commenters noted that the regulations only require immunizations for students but not for teachers, staff and visitors to schools nor for students aged eighteen years or older.

Response: PHL § 2164 only requires immunizations for children between the ages of two months and eighteen years entering or attending public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten, elementary, intermediate or secondary school.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Prohibition on the Sale of Electronic Liquids with Characterizing Flavors

I.D. No. HLT-53-19-00001-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Addition of Subpart 9-3 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 225

Subject: Prohibition on the Sale of Electronic Liquids with Characterizing Flavors.

Purpose: To prohibit the sale of electronic liquids with characterizing flavors.

Text of proposed rule: 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, 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, menthol, 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.

(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, for purposes of retail sale in New York State; 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, for purposes of retail sale in New York State.

Section 9-3.3 Exemptions. The provisions of this Subpart prohibiting the possession of any flavored e-liquid or product containing the same shall not apply to:

(a) individuals who are in possession of flavored e-liquids or products containing the same for personal use;

(b) public officers or their employees in the lawful performance of their official duties requiring possession of flavored e-liquids or products containing the same;

(c) temporary or incidental possession of flavored e-liquids or products containing the same by employees or agents of persons lawfully entitled to possession, or persons whose possession is for the purpose of aiding public officers in performing their official duties;

(d) a person in the employ of the United States government or of any state, territory, district, county, municipal or insular government, obtain-