

Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements

*Thursday, December 12, 2019
9:30 AM*

Location: 90 Church Street 4th Floor, Room 4A & 4B, New York City (Main Meeting Site)

Empire State Plaza, Concourse Level, Meeting Room 5, Albany

A. Agenda

For Adoption	Program Area	Unit Representative
Addition of Subpart 9-2 to Title 10 NYCRR – Required Signage Warning Against the Dangers of Illegal Products	Office of Public Health	Brad Hutton
For Emergency Adoption	Program Area	Unit Representative
Addition of Subpart 9-3 to Title 10 NYCRR – Prohibition on the Sale of Electronic Liquids with Characterizing Flavors	Office of Public Health	Brad Hutton
For Information	Program Area	Unit Representative
Addition of Subpart 9-3 to Title 10 NYCRR – Prohibition on the Sale of Electronic Liquids with Characterizing Flavors	Office of Public Health	Brad Hutton
Amendments to 405.4 – Physician Limited Permit Holder Requirements	Office of Primary Care and Health Systems Management	Deirdre Astin
Amendments to Subpart 765-1 – Licensed Home Care Services Agencies	Office of Primary Care and Health Systems Management	Mark Kissinger and Kelly Scholl

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Wednesday, December 11, at (212) 417-6218 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.
2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

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:

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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.

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. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. 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 e-cigarette 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. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

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), and menthol flavor, including mint and wintergreen. 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 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 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 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 sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

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 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) 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, which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

In a study performed at the Stanford University School of Medicine, scientists found that menthol and cinnamon flavored e-liquids, specifically, caused the most damage to endothelial cells (the cells that line the interior of blood vessels). Some of the effects of the e-liquid flavors were independent of the nicotine concentration. Researchers concluded that flavoring liquid used in e-cigarettes may increase the risk of heart disease. In a study at the Duke University School of Medicine, high levels of a carcinogenic oil banned in the U.S. as a food additive were found in samples of menthol-flavored e-cigarette liquids and smokeless tobacco products. Concentrations of the additive pulegone were 100 to more than 1,000 times higher than the concentrations considered safe for ingested food products by the FDA.

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 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:

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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. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. 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 e-cigarette 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. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

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), and menthol flavor, including mint and wintergreen. 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 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 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 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 sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

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 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) 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 took 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, 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.

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 publication of a Notice of Adoption in the New York State Register, to read as follows:

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, obtaining or possessing flavored e-liquids or products containing the same, by reason of his or her official duties;

(e) common carriers or warehouse worker, while engaged in lawfully transporting or storing of flavored e-liquids or products containing the same, or to any employee of the same within the scope of his or her employment; and

(f) an accredited college or university, laboratory, hospital, medical center or other institution that is possessing flavored e-liquids or products containing the same for health, scientific or other research or experimental purposes.

Section 9-3.4 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 9-3.5 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:

These 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. A review of youth risk behavior data since 1997 revealed that there has never before been such a dramatic increase, in such a short amount of time, of any substance use among youth. 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 e-cigarette 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. A biennial survey of high school youth has shown that since 2014, openness to vaping has increased from 24% to 31%. After years of decline in openness to smoking, students in NY showed an uptick in openness to combustible smoking (decreased from 22% in 2010 to 17% in 2016, increased to 19% in 2018). Openness to smoking is a predictor of smoking experimentation among youth.

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), and menthol flavor, including mint and wintergreen. 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 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 2019 survey of adolescent e-cigarette users in NYS, 51.8 percent preferred fruit flavors, followed by mint/menthol (34.1%) and chocolate, candy or other sweets (8.8%). In that same survey, 19.8 percent of adolescent e-cigarette users say that flavors are the reason they currently use e-cigarettes, and for 11.5 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 sweet flavors like fruit, chocolate and candy and menthol/mint flavors are less harmful than traditional flavors like tobacco.

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 4.2 percent in 2018. The rate of e-cigarette use among young adults 18 to 24 years of age is about 14 percent. A lower proportion of young adults (9%) 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, which is a serious concern that has symptoms that are similar to chronic obstructive pulmonary disease.

In a study performed at the Stanford University School of Medicine, scientists found that menthol and cinnamon flavored e-liquids, specifically, caused the most damage to endothelial cells (the cells that line the interior of blood vessels). Some of the effects of the e-liquid flavors were independent of the nicotine concentration. Researchers concluded that flavoring liquid used in e-cigarettes may increase the risk of heart disease. In a study at the Duke University School of Medicine, high levels of a carcinogenic oil banned in the U.S. as a food additive were found in samples of menthol-flavored e-cigarette liquids and smokeless tobacco products. Concentrations of the additive pulegone were 100 to more than 1,000 times higher than the concentrations considered safe for ingested food products by the FDA.

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 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 publication of a Notice of Adoption in the New York State Register.

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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 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.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, section 405.4 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (2) of subdivision (g) of Section 405.4 is amended to read as follows:

(2) physicians who possess limited permits to practice medicine issued by the New York State Education Department pursuant to section 6525 of the State Education Law if such physicians are under the supervision of a physician licensed and currently registered to practice medicine in the State of New York, [and if the physicians possessing limited permits are:

(i) graduates of medical school offering a medical program accredited by the Liaison Committee on Medical Education or the American Osteopathic Association, or registered with the State Education Department or accredited by an accrediting organization acceptable to the State Education Department, and have satisfactorily completed one year of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department;

(ii) graduates of a foreign medical school and have satisfactorily completed three years of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department; or

(iii) graduates of a foreign medical school who have satisfactorily completed three years in a postgraduate training program and who are receiving advanced training as part of an official exchange visitor program approved by the United States Information Agency and the Educational Commission for Foreign Medical Graduates (ECFMG);]

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) §2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to implement the purposes and provisions of PHL Article 28 and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high quality health services at a reasonable cost.

Needs and Benefits:

10 NYCRR §405.4(g)(2) allows an unlicensed physician to provide medical services in a hospital under a limited permit to practice medicine under Education Law §6525 when the State Education Department (SED) determines that the applicant meets SED criteria for issuance of a limited permit and appropriate levels of supervision and oversight are in place. Section 405.4(g)(2) requires additional years of training, beyond what is required for a limited permit under Education Law §6525. This proposed regulation would eliminate the extra years of training required for limited permittees to work in hospitals.

New York State is experiencing a shortage of licensed physicians in all areas of the state. Limited permit holders are fully trained physicians, often graduates of international medical

schools, that are working in various health care settings until full licensure requirements can be met. It is typically the U.S. citizenship requirement that prevents many limited permit holders from initially obtaining full licensure.

Currently, section 405.4(g)(2) imposes additional years of training for limited permit holders, specifically one year for domestic medical graduates and three years for international (foreign) medical graduates, as a condition of working in a New York State hospital. This requirement was originally intended to ensure that international students' educations were equivalent to those of physicians educated in the United States. SED has confirmed the understanding of the New York State Department of Health that any educational disparities are minimal today due to medical school accreditation standards. Nevertheless, under the current regulations, hospitals must require the limited permit holders to have the additional years of training. As a result, hospitals hiring doctors to meet patient needs often must turn away otherwise qualified applicants to maintain compliance with the regulation. These candidates, if unable to work in New York State hospitals, may seek employment in other states or in other types of health care settings where the extra years of experience are not required.

SED already considers training and experience before approving and issuing limited permits; however, SED does not screen candidates for their eligibility to work in hospitals. In addition, limited permit holders working in other settings in New York State, such as nursing homes and psychiatric hospitals, are not required to have these additional years of training. As such, there is inconsistency in the standards required of limited permit holders with equivalent background and training, making limited permit holders less likely to be to be utilized in hospitals. Given the shortage of licensed physicians to cover vital hospital services, this proposed amendment will eliminate a barrier to limited permit holders practicing in hospitals.

Finally, since all limited permit holders are subject to supervision and oversight by a licensed physician, their practice within the hospital will be monitored and safe.

COSTS:

Costs to Private Regulated Parties:

This proposal will not result in increased costs to regulated parties.

Costs to Local Government:

This regulation amendment will not impact local governments unless they operate a general hospital. In any event, this proposal will not increase costs for local governments.

Costs to the Department of Health:

The proposed regulatory changes will not result in any additional operational costs to the Department of Health.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other state agencies.

Local Government Mandate:

The proposed regulatory changes will not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposed regulatory changes will not create any additional paperwork.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulatory changes.

Alternatives:

The alternative would be to take no action and have hospitals continue to screen limited permit holders for additional years of training as a condition of employment.

Federal Standards:

The proposed regulatory changes do not duplicate or conflict with any federal regulations.

Compliance Schedule:

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

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because the proposed amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

Summary of Express Terms

The proposal would amend various provisions of Part 765 of Title 10 NYCRR to implement recently enacted legislation.

Section 765-1.2. Applications for licensure. This section will be amended to require applications for licensure as a Licensed Home Care Service Agency (LHCSA) to include information on the public need for additional LHCSAs and the financial resources of the proposed agency as required by law, in addition to the existing requirement of a character and competence review. Amendments would specify that applications for licensure based on change of ownership for LHCSAs actively serving at least 25 patients shall only be evaluated based on financial feasibility and the character and competence of the proposed operator.

Section 765-1.3. Requirements for approval. This section will be amended to require applicants for licensure as a LHCSA to satisfactorily demonstrate to the Public Health and Health Planning Council (PHHPC) the public need for the agency and the financial resources of the agency in order to be approved for licensure, in addition to the existing requirement of a character and competence review.

Section 765-1.4. Amendments to applications. This section will be amended to add to the list of actions that constitute an amendment to a pending application for licensure for a home care services agency, requiring review and approval by PHHPC. The proposal will require that any significant change to the proposed patient capacity, any change in the agency's proposed service area, and any significant change to the agency's proposed annual operating budget will constitute an amendment and require approval by PHHPC, in addition to the existing language stating that changes to services and changes in the principles of the applicant as considered by PHHPC are

amendments. A new section will be added specifying that failure to disclose this information prior to the issuance of a license shall be grounds for revocation, limitation, or annulment of the approval for licensure. This is consistent with the approval processes for other types of home care agencies including certified home health agencies and hospices.

This proposal would also add a new section 765-1.16, Determinations of public need, to detail the public need methodology to be used to implement recent statutory changes. Subdivisions of this new section will include planning area designations, determination of public need, public need exemption criteria and additional requirements for applications seeking PHHPC approval, and priority considerations for the Department.

The regulations will affect all agencies applying for licensure as a home care services agency or for changes of ownership on or after April 1, 2020.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 3612 of the Public Health Law, Subpart 765-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective on April 1, 2020.

Section 765-1.2 is amended to read as follows:

765-1.2 Applications for licensure. (a) An application to the Public Health and Health Planning Council for its approval, as required by law, shall be in writing on application forms provided by the department and subscribed by the chief executive officer duly authorized by the board of a corporate applicant, a general partner or proprietor of the proposed licensed home care service agency, or, where an application is to be submitted by a governmental subdivision as the applicant, the president or chairman of the board of the proposed agency or the chief executive officer if there is no board; and accompanied by a certified copy of a resolution of the board of a corporate applicant authorizing the undertaking which is the subject of the application, and the subscribing and submission thereof by an appropriate designated individual. In the event that an application is to be submitted by an entity which necessarily remains to be legally incorporated, it shall be subscribed and submitted by one of the proposed principal stockholders or directors. If a local government applicant submitting an application has not designated a president, chairman or chief executive officer for the proposed agency, the application shall be subscribed by the chairman or president of the local legislature or board of supervisors having jurisdiction, or another appropriate executive officer. If available, the application must be electronically submitted to the Department of Health in a form designated by the commissioner. In the absence of an electronic system, an original application and five copies thereof shall be prepared and filed

with the Public Health and Health Planning Council through the project management unit in the department's central office in Albany [, which shall transmit one copy to the health systems agency having jurisdiction].

(b) Applications to the council shall contain information and data as applicable with reference to:

(1) the public need for the existence of the licensed home care service agency or proposed agency at the time and place and under the circumstances proposed as outlined in Section 765-1.16 of this Title;

(2) the character, experience, competence and standing in the community of the proposed persons, incorporators, directors, controlling persons, officers, principal stockholders, sponsors, governmental subdivisions, individual operators or partners of the applicant or of any parent or health-related subsidiary corporation as applicable. The application shall include copies of personal qualifying and disclosure information, as appropriate, as may be required by the council with regard to any such individual or organization[.];

[(1)] (i) Disclosure information shall include, but not be limited to, a list of health care, adult care or mental health facilities, programs or agencies controlled or operated in the United States by an individual or organization specified in this subdivision; the name and address of each such facility, program or agency; and the dates of control or operation of each such facility, program or agency.

[(2)] (ii) In the event that any such health care, adult care or mental health facility, program or agency, while under the control or operation of an individual or organization specified in this subdivision, has been subjected to financial penalties, or suspension or revocation of its operating certificate, license or certification because of a failure to comply with provisions governing the conduct and operation of the facility, program or agency, then information must be

provided which describes the nature of the violation, the agency or body enforcing the violation (including its name and mailing address), the steps taken by the facility, program or agency to remedy the violation or violations, and an indication of whether the suspension, revocation or accreditation has since been restored.

(3) the financial resources of the proposed licensed home care service agency and its projections of revenues and expenses. The standards of this review will require, at a minimum:

(i) an examination of the sources of available working capital that the proposed licensed home care services agency operators have, with a minimum requirement equal to at least two months of estimated operating expenses of the agency;

(ii) that the application passes a reasonableness test with respect to the financial capability of the agency or sources for start-up funding; and

(iii) an examination of the financial feasibility of the agency or projections indicating that the agency's operating revenues will be equal to or greater than projected expenditures over time.

(4) any other information that the commissioner shall deem pertinent for inclusion in the application.

(c) The following documents shall be filed as attachments to the application: (1) where the applicant will be operating the licensed home care service agency under an assumed name, a photocopy of the applicant's existing or executed proposed certificate of doing business;

(2) where the applicant is a partnership, full and true copies of all partnership agreements, which shall include the following language:

"By signing this agreement, each member of the partnership created by the terms of this agreement acknowledges that the partnership and each member thereof has a duty to report to the New York State Department of Health any proposed changes in the membership of the

partnership. The partners also acknowledge that the prior written approval of the Public Health and Health Planning Council is necessary for such change before such change is made, except that a change resulting from an emergency caused by the severe illness, incompetency or death of a member of the partnership shall require immediate notification to the New York State Department of Health of such fact, and application shall be made for the approval by the Public Health and Health Planning Council of such change within 30 days of the commencement of such emergency. The partners also acknowledge that they shall be individually and severally liable for failure to make the aforementioned reports and/or applications."

(3) where the applicant or licensed operator has or proposes to have a controlling person or a parent corporation, or is affiliated with a health-related subsidiary corporation, full and true copies of any such corporation's bylaws, certificate of incorporation and any existing or proposed amendments thereto, all agreements between the applicant and any such controlling person or parent corporation relating to the manner and mechanisms by which any such controlling person or parent corporation controls or will control the applicant and/or all agreements by which the applicant is affiliated with any health-related subsidiary corporation, and a detailed description of such control or affiliation relationship;

(4) where an applicant corporation is formed pursuant to the requirements of section 3611 of the Public Health Law, documentation demonstrating the designation of an agent for service of process pursuant to section 305 of the Business Corporation Law or section 305 of the Not-for-Profit Corporation Law, as applicable; and

(5) such additional pertinent information or documents necessary for the council's consideration, as requested.

Section 765-1.3 is amended to read as follows:

765-1.3 Requirements for approval. (a) The application must be complete and in proper form. It shall provide all the information essential for the Public Health and Health Planning Council's consideration.

(b) The applicant must satisfactorily demonstrate to the council:

(1) that there is a public need for the licensed home health care service agency pursuant to the methodology outlined in Section 765-1.16 of this Title;

(2) that there are adequate finances and sources of future revenue to properly establish and operate the licensed home care service agency pursuant to the minimum requirements outlined in Section 765-1.2 of this Title;

[(1)] (3)(i) if a not-for-profit corporation, that the controlling persons and sponsors, if any, the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(2)] (ii) if a proprietary business, that the owner, or all the partners of a partnership, are persons of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the business in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(3)] (iii) if a business corporation, that the controlling persons and sponsors, if any, the members of the board of directors, the officers and the principal stockholders of the corporation or, in the case of an application solely for a change in the principal stockholder(s), that the proposed new

principal stockholder(s) of the corporation, are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency;

[(4)] (iv) with respect to any parent corporation or health-related subsidiary corporation, that the directors, sponsors, controlling persons and principal stockholders of any such corporation, insofar as applicable, are of such character, competence and standing in the community as to give reasonable assurance that, to the extent they have or will have the ability, through control or influence, to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care service agency;

[(5)] (v) with respect to any application solely for the acquisition of control of an operator of a licensed home care service agency by a controlling person or a change of a controlling person, that such new controlling person, insofar as applicable, is of such character, competence and standing in the community as to give reasonable assurance that, to the extent it has or will have the ability to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care service agency; or

[(6)] (vi) if a public or government agency, that the governing authority of the governmental subdivision applying to operate the agency has provided reasonable assurance of its ability to

conduct the affairs of the agency in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care service agency.

[(c)] (4) that the proposed operator has demonstrated satisfactory character and competence. In conducting a character and competence review, the Public Health and Health Planning Council shall, as applicable, evaluate any parent or health-related subsidiary corporation, the controlling persons, sponsors, members of the board of directors, the officers and principal stockholders, if any, of a corporate applicant, any sole proprietor, all partners in a partnership or, in the case of a governmental subdivision as the applicant, the governmental subdivision and the governing body thereof as a whole rather than the individual elected or appointed members thereof, by:

[(1)] (i) reviewing the findings of inspection reports, patient care reviews, complaint investigations and any other pertinent information relating to the operation of any health care, adult care or mental health facility, program or agency located in New York approved to operate by the Department of Health, [Department of Social Services] or the Department of Mental Hygiene or, if located outside New York, would require the approval to operate by any one of such agencies if located in New York, with which an individual, corporation, other organization or governmental subdivision has been affiliated as a director, sponsor, controlling person, principal stockholder, sole proprietor, partner or governmental operator;

[(2)] (ii) reviewing whether such individual, corporation, other organization or governmental subdivision exercised supervisory responsibility of the facility/agency operation to assure a consistent pattern of compliance with applicable standards and to prevent conditions which could result in harm to the health, safety or welfare of patients/residents; and

[(3)] (iii) determining that, if a violation of applicable standards did occur, the applicant investigated the circumstances surrounding the violation and took steps appropriate to the gravity

of the violation which a reasonably prudent operator would take to promptly correct and to prevent the reoccurrence of the violation. [; and]

[(4) considering such other pertinent matters relating to the character, competence and standing in the community of the applicant(s).]

(5) any other pertinent matters that the commissioner shall deem appropriate for inclusion in the application.

(d) The applicant must supply:

(1) any additional information requested by the department within 30 days of such request, or must obtain from the department an extension of the time in which to provide such information.

Any request for such extension of time shall set forth the reasons why such information could not be obtained within the prescribed time. The granting of such extension of time shall be at the discretion of the commissioner, provided such extensions are not for more than 30 days and the commissioner is satisfied as to the reasons why such information could not be obtained within the prescribed time. The commissioner is authorized to deny a request for an extension of time. Failure to provide such information within the time prescribed shall constitute an abandonment and withdrawal of the application by the applicant.

(2) any authorization the department requests in order to verify any information contained in the application or to obtain additional information which the department finds is pertinent to the application. Failure to provide such authorization shall constitute an abandonment and withdrawal of the application.

Section 765-1.4 is amended to read as follows:

765-1.4 Amendments to applications. (a) An application made to the Public Health and Health Planning Council pursuant to this Subpart may be amended while the matter is pending before the council. Such amendments shall be made on appropriate forms supplied by the department.

(b) Any amendment to an application which constitutes a substantial change in the information contained in the original application, or any prior amendments thereto, must be accompanied by a satisfactory written explanation as to the reason such information was not contained in the original application.

(c) Prior to the issuance of a license, any change as set forth in this subdivision shall constitute an amendment to the application and the applicant shall submit appropriate documentation as may be required in support of such amendment. The amended application shall be referred to the [health systems agency having geographic jurisdiction and the State Hospital Review and] Public Health and Health Planning Council for [their] its comments. The approval of the Public Health and Health Planning Council must be obtained for any amended application. Each of the following shall constitute an amendment:

(1) any change in the types of licensed services to be provided; [and/or]

(2) any significant change in the principals of the applicant as considered by the council[.];

(3) any significant change in the proposed patient capacity;

(4) any change in the agency's proposed service area; and/or

(5) any significant change to the agency's proposed annual operating budget.

(d) Failure to disclose an amendment prior to the issuance of a license shall constitute sufficient grounds for the revocation, limitation or annulment of the approval.

A new Section 765-1.16 is added to Subpart 765-1 of Part 765 of 10 NYCRR to read as follows:

765-1.16. Determinations of public need. (a) The process of determining need in this section will be used in the evaluation of certificate of need applications requiring a review of the public need by the Public Health and Health Planning Council.

(b) Planning areas. (1) The commissioner shall designate each county as a separate planning area.

(c) Determination of need.

(1) There shall be a presumption of no need for additional licensed home care service agencies in a planning area if there are 5 or more Licensed Home Care Service Agencies (LHCSA) actively serving patients within the planning area as of April 1, 2020. Beginning in 2021, the commissioner shall have the authority to adjust the target date for determining need for additional LHCSAs in a planning area, in subsequent years.

(2) Applications for licensure based on change of ownership for Licensed Home Care Service Agencies actively serving at least 25 patients will not be subject to public need review and shall be evaluated only on financial feasibility and the character and competence of the proposed operator unless the proposed operator seeks to serve patients outside of the approved planning area.

(3) The determination of need for licensed home care service agencies in accordance with this subdivision does not include Assisted Living Program (ALP) or Program of All-Inclusive Care for the Elderly (PACE) affiliated licensed home care services agencies. ALP or PACE -affiliated agencies are not subject to the public need review unless the agency seeks to serve patients outside the ALP program or who are not PACE members. For the purpose of this regulation affiliated shall mean common ownership.

(4) The department shall review the adequacy of the need methodology set forth under paragraph (1) of this subdivision and issue a report to the commissioner and the Public Health and Planning Council no later than 6 years from adoption.

(d) Notwithstanding any other provision of this section, factors to be considered when determining need for licensed home care service agencies shall include, but are not limited to:

(1) the demographics and/or health status of the residents in the planning area or the state, as applicable;

(2) documented evidence of the unduplicated number of patients on waiting lists who are appropriate for and desire admission to a licensed home care service agency but who experience a long waiting time for placement and who cannot be served adequately in other settings;

(3) the number and capacity of currently operating licensed home care services agencies;

(4) the quality of services provided by existing agencies;

(5) the availability and accessibility of the workforce;

(6) personnel and resources dedicated to adding and training additional members of the workforce including committed resources in an organized training program;

(7) cultural competency of existing agencies; and

(8) subpopulations requiring specialty services.

When making recommendations to the Public Health and Health Planning Council concerning the impact of the factors set forth above, the department shall, to the extent practicable, indicate the relative priority of such factors.

(e) In addition to meeting the other applicable provisions of this section, an applicant for initial certification shall be approved as meeting public need only if the applicant agrees to serve population groups in the planning area that have difficulty gaining access to appropriate licensed

home care service agency care due to minority status, age, medical history, case complexity, or payment source.

(f) Any application wherein a determination of public need is made pursuant to this section shall be subject to the following: (1) The Public Health and Health Planning Council and/or the commissioner, as appropriate, may, during the processing of an application, propose to disapprove the application solely on the basis of a determination of public need in advance of the consideration of the other review criteria required by article 36 of the Public Health Law without, however, waiving the right to consider such other criteria at a later date.

(2) In the event the Public Health and Health Planning Council and/or the commissioner proposes to disapprove an application on the basis of a lack of public need and the applicant requests a hearing according to the provisions provided in Section 765-1.9 of this Title, the Public Health and Health Planning Council and/or the commissioner, as appropriate, may direct the completion of the other reviews required by Article 36 of the Public Health Law. The application shall then be returned to the Public Health and Health Planning Council and/or the commissioner as appropriate, to consider such reviews, the results of which may then be included as grounds for the proposed disapproval to be considered at the hearing. If the Public Health and Health Planning Council and/or the commissioner, as appropriate, directs the completion of such reviews, a copy of the report containing the results of the reviews shall be mailed to the applicant at least 60 days prior to the date set for hearing.

(3) In the processing of an establishment application, the commissioner may recommend disapproval based on a review limited to a determination of public need. In the event the Public Health and Health Planning Council does not concur with the commissioner's recommendation of disapproval, it shall return the application to the department at which time all other required

reviews shall be completed. When all other reviews are completed, the application shall be returned to the Public Health and Health Planning Council for action.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 3612 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations to effectuate the provisions and purposes of PHL Article 36 with respect to licensed home care service agencies (LHCSAs). Additionally, Section 9-b, Part B of Chapter 57 of the Laws of 2018 (codified at Public Health Law § 3605[4]) requires PHHPC to consider the public need for new LHCSAs as well as the financial resources and revenues of the proposed LHCSA when PHHPC reviews initial licensure and change of ownership applications.

Legislative Objectives:

PHL Article 36 was intended to promote the quality of home care services provided to residents of New York State and to assure adequate availability as a viable alternative to institutional care.

Needs and Benefits:

The proposed regulation is necessary to implement statutory changes required under Section 9-b, Part B of Chapter 57 of the Laws of 2018. The proposal will revise Part 765 of Title 10 NYCRR to include the relevant statutory requirements related to the new public need determination for licensed home care services agencies, the review of the proposed agency's financial feasibility, and the process for reviewing applications for licensure.

Part 765 of Title 10 of the NYCRR regulates the approval and licensure of home care services agencies. Sections 765-1.2 and 765-1.3 outline what is required to be included in applications for licensure as a home care services agency and the information that an applicant for licensure must supply to PHHPC for approval. Section 765-1.4 includes what types of changes to a pending application for licensure constitute an amendment and what an applicant must submit to PHHPC for the amendment to be considered.

These current regulations were developed to govern the approval of licensure applications for home care services agencies when PHHPC was only required to conduct a character and competence review of applicants and was prohibited from considering the public need for these agencies under Public Health Law. To comply with changes made to the Public Health Law under Section 9-b, Part B of Chapter 57 of the Laws of 2018, the regulations must be updated to include the new requirement of public need review and financial feasibility review.

With the existing regulatory prohibition on public need consideration for new agencies, the Department of Health (Department) and PHHPC have been unable to limit the growth of unnecessary agencies. Currently, there are approximately 1,100 approved licensed home care operators with over 1,300 licensed, registered sites statewide. An average of 40 new LHCSA sites have been approved on an annual basis over the past ten years. There is no consideration of the need for additional services based on the public demand. Applications for licensure are submitted to the Department and are subject to approval by PHHPC. As part of the application process, applications are reviewed to ensure the character, competence, and standing in the community of the applicant's incorporators, directors, sponsors, stockholders, or operators.

Applications must be submitted for initial licensure, purchase or mergers, change of stock ownership, or other acquisition or control change.

Given the new statutory mandate, new regulations are required to define the public need methodology and the process that will be used to apply the methodology to new licensure applications. The public need methodology will also assist the Department in planning for the appropriate number of licensed agencies and may also inform policy and practice around the types of services needed, underserved populations that require additional focus, and other factors that contribute to the long term care landscape, such as workforce issues or transportation infrastructure.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The rule does not impose any new implementation or compliance costs on regulated parties.

Costs to the State and Local Governments:

The proposed changes are not expected to impose any costs upon New York State or local governments.

Costs to the Department of Health:

Additional work by Department staff to determine public need and to process applications with the new requirements will be managed with existing resources.

Local Government Mandates:

The proposed regulations do not impose any new mandates on local governments.

Paperwork:

Consistent with the statutory provisions, the proposed regulations will require a new application form to be completed by home care services agencies seeking initial licensure or change of ownership on or after April 1, 2020. New documentation will be required as part of the application process that was not included in the application for licensure prior to April 1, 2020.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There are no viable alternatives to this proposal. The regulatory changes are necessary to implement a statutory mandate, which directs PHHPC to include public need and financial feasibility in the review process for initial applications for licensure of home care services agencies.

One alternative considered including the development of a county normative use rate using the number of cases and visits/hours for LHCSA services for each agency in a planning area as reported on the LHCSA Statistical Report. This alternative may account for variation in the amount of services used per patient, however, and it is a more complex methodology that may

lead to greater error in ongoing need methodology calculations. As such, this option was rejected as unviable.

A second alternative considered establishing estimates of need based on demographics. Under this proposal, the Department would undertake a review of the total number of residents in each planning area with a reported disability resulting in a limitation in completing activities of daily living. The information could be broken down by age group and projected to accommodate the expected growth in the older adult population. This method to determine use rates may better reflect the number of residents in need of care, rather than using the patient count. However, reporting on disease and disability status and limitations in functional abilities has proven difficult, as various definitions of disability exist with multiple reporting methods. Therefore, this alternative was also rejected.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The amendments will take effect on April 1, 2020.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.