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, Section 2.1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (a) of section 2.1 is amended to read as follows:

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting:

* * *

Rabies

Respiratory syncytial virus (RSV) (laboratory confirmed cases of RSV or deaths caused by laboratory confirmed RSV in persons younger than 18 years)

Rocky Mountain spotted fever

* * *

Typhoid

Varicella (not zoster/shingles)

Vaccinia disease: (as defined in Section 2.2 of this Part)

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is Section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York. Additionally, section 2103 of the PHL requires all local health officers to report cases of communicable disease to the New York State Department of Health (the Department).

Section 2102 of the Public Health Law requires clinical laboratories to report suspected or confirmed positive findings or markers of communicable diseases, and other pertinent facts, to local or state health officials. Additionally, Section 576-c of the Public Health Law requires clinical laboratories to report such test results, and other data elements, electronically on a schedule determined by the commissioner.

Legislative Objectives:

These amendments are consistent with section 225 of the Public Health Law (PHL), which authorizes the PHHPC, subject to the approval of the Commissioner, to establish and amend the SSC related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Needs and Benefits:

The proposed amendments to Section 2.1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR), would add required reporting of laboratory-confirmed cases of respiratory syncytial virus (RSV), pediatric deaths from RSV, and cases of varicella (not zoster/shingles) to the list of reportable communicable disease conditions. The proposed amendment would provide critical surveillance data that could be used to help anticipate hospital bed capacity challenges and could also help quantify the impact of newly approved RSV vaccines. Additionally, pediatric deaths from RSV are expected to become nationally notifiable, likely in the coming year. As of 2020, case-based varicella surveillance is conducted in 39 states and the District of Columbia. Varicella can be severe and is highly contagious, and it has become more important to investigate individual cases as the disease becomes rare. Additionally, making varicella reportable will allow the Department and local health departments to better understand the burden and epidemiology of disease and better anticipate vaccination needs, such as in geographies and in demographics that have lower rates of immunity.

Costs:

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

While it is estimated that there is a sizeable number of cases of RSV and varicella that occur in NYS each year, the Department expects that costs associated with these additional requirements will be minimal. The most serious cases of RSV are hospitalized and diagnosed in the acute care setting, and hospitals already have robust human and electronic resources in place

to comply with their public health reporting and specimen submission requirements. For varicella, the Department does not plan to require laboratory testing; the disease often can be diagnosed clinically, and clinicians can continue to use their best judgement for when testing is indicated.

The Department does not expect that there will be significant cost burdens associated with regulated entities complying with investigations conducted by a local health authority. The proposed regulations related to investigations would only apply where there are cases or suspect cases of reportable diseases or organisms, outbreaks, or unusual diseases. Further, while businesses, organizations, private homes, and those required to report pursuant to proposed section 2.1 would be required to cooperate with such investigations, historically, the types of cooperation sought during disease investigations has primarily consisted of providing information determined to be necessary for the local health authority to control the spread of disease and/or to provide preventive treatment.

Costs to State and Local Governments:

The cost of the proposed disease/organism reporting is expected to be minimal because current systems and procedures already exist for such entities to receive, process, and follow-up on reportable diseases/organisms. Further, by monitoring the spread of reportable diseases/organisms, appropriate precautions can be taken to prevent or contain exposures, thereby reducing costs associated with public health control measures, morbidity, and treatment. Lastly, the Department does not expect that there will be any significant additional cost burden to local or State governments associated with the proposed changes to laboratory submission

requirements; minimal resources may need to be shifted to clean and analyze the incoming data. The infrastructure to electronically receive positive reports from laboratories is already in place.

The Department does not anticipate there will be a significant cost burden for government entities resulting from the proposed investigation of varicella cases and pediatric RSV fatalities. Local health authorities already receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases. As local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here will become part of the requirements that local health authorities already have in place to control disease within their jurisdictions. It is expected the volume of investigations of pediatric RSV fatalities will be minimal in most counties. For investigations of varicella cases, the Department intends to issue guidance for counties as they develop a policy describing which varicella cases require a full investigation.

Costs to the Department of Health:

There are no costs to the Department associated with this regulatory amendment, with the exception of minimal costs associated with analyzing numbers of reported cases of RSV and varicella.

Local Government Mandates:

As is currently the case, local health officers receiving reports of diseases/organisms listed in section 2.1 will be required to forward such reports to the State Department of Health and investigate the sources of infection of reported or suspect cases, based on epidemiological or other relevant information available and consistent with guidance from the Department.

Paperwork:

There will be no new paperwork associated with these proposed amendments; however, revisions will need to be made to the existing general communicable disease reporting form, and an electronic varicella investigation form will be made available. Practically all laboratory reporting is currently done electronically.

Duplication:

No relevant laws of the State and/or federal government exist that duplicate, overlap, or conflict with this proposed rule.

Alternatives:

The alternative to the proposed amendments would be to maintain the current list of communicable diseases. However, adding required reporting of laboratory-confirmed cases of respiratory syncytial virus (RSV), pediatric deaths from RSV, and cases of varicella (not zoster/shingles) to the list of reportable communicable diseases is necessary to enable local health authorities and the Department to conduct critically important disease surveillance. In turn, this will reduce disease transmission, as well as streamline and provide needed clarification on the control measures local health authorities can implement to control the spread of disease within their jurisdictions.

Federal Standards:

State and local health departments have primary authority for controlling disease within their respective jurisdictions. There are existing national case definitions for varicella and RSV-associated mortality.

Compliance Schedule:

It is anticipated that regulated entities would be able to comply with the rule upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

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

REGULATORY FLEXIBILITY ANALYSIS FOR
SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulation will apply to all local health departments, as well as physicians, hospitals, nursing homes, diagnostic and treatment centers, and laboratories. There are approximately 76,500 licensed and registered physicians in New York State; it is not known how many of them practice in small businesses. It is estimated that approximately five hospitals, 130 nursing homes, 311 diagnostic and treatment centers, and 150 clinical laboratories employ less than 100 persons and qualify as small businesses.

Compliance Requirements:

Hospitals, clinics, physicians, nursing homes, and clinical laboratories that are small businesses and local governments will utilize revised Department of Health reporting forms and existing laboratory referral forms to report the three conditions being added to the list of communicable diseases set forth in 10 NYCRR § 2.1. Local health officers receiving reports of pediatric deaths from RSV and certain cases of varicella (not zoster/shingles), will be required to forward such reports to the State Health Commissioner and to investigate and monitor the cases reported, based on epidemiological or other relevant information available and consistent with guidance from the Department. Laboratory-confirmed cases of respiratory syncytial virus (RSV) will be reported by clinical laboratories and analyzed by the Department of Health.

Professional Services:

These amendments regard the reporting of laboratory test results to the Department and investigation of cases. Entities impacted include public and private laboratories that perform varicella or RSV tests on New York State residents and those that receive and investigate disease reports and test results, including physicians, heads of a private household, or person in charge of any institution, school, hotel, boarding house, camp or vessel or any public health nurse or any other person having knowledge of an individual affected with any disease presumably communicable. Investigation is performed by local health departments.

Compliance Costs:

While it is estimated that there is a large number of cases of RSV and fewer but sizeable cases of varicella in NYS each year, the Department expects that costs associated with these additional requirements will be minimal. Local health authorities already receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases. The most serious cases of RSV are hospitalized and diagnosed in the acute care setting, and hospitals already have robust human and electronic resources in place to comply with their public health reporting and specimen submission requirements. For varicella, the Department does not plan to require laboratory testing; the disease often can be diagnosed clinically, and clinicians can continue to use their best judgement for when testing is indicated.

The Department does not expect that there will be significant cost burdens associated with regulated entities complying with investigations conducted by a local health authority. The proposed regulations related to investigations would only apply where there are cases or suspect cases of reportable diseases or organisms, outbreaks, or unusual diseases. Further, while

businesses, organizations, private homes, and those required to report pursuant to proposed section 2.1 would be required to cooperate with such investigations, historically the type of cooperation sought during disease investigations has primarily consisted of providing information determined to be necessary for the local health authority to control the spread of disease and/or to provide preventive treatment.

The cost of the proposed disease/organism reporting to local governments is expected to be minimal because current systems and procedures already exist for such entities to receive, process, and follow-up on reportable diseases/organisms. Further, by monitoring the spread of reportable diseases/organisms, appropriate precautions can be taken to prevent or contain exposures, thereby reducing costs associated with public health control measures, morbidity, and treatment. Lastly, the Department does not expect that there will be any additional cost burdens to local or State governments associated with the proposed changes to laboratory submission requirements. The infrastructure to electronically receive positive reports from laboratories is already in place.

The Department does not anticipate there will be a substantial cost burden for government entities as a result of the proposed investigation of varicella cases and pediatric RSV fatalities. Local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here will become part of the requirements that local health authorities already have in place to control disease within their jurisdictions, which already include investigations of other reportable diseases. It is expected the volume of investigations of pediatric RSV fatalities will be minimal in most counties. For investigations of varicella cases, the Department intends to issue guidance for counties as they develop a policy describing which varicella cases require a full investigation.

Economic and Technological Feasibility:

The entities impacted will use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated by Public Health Law. As such, there are no economic or technological impediments to the rule change.

Minimizing Adverse Impact:

The entities impacted will use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated by public health law. This minimizes impact, and these amendments are not expected to result in significant additional costs to small business or local governments.

Small Business and Local Government Participation:

The Department has consulted with local governments through ongoing communication on this issue with local health departments and the New York State Association of County Health Officers in the process of making these conditions reportable. They should see very little impact from making RSV reportable but recognize the potential investigative burden from varicella. Local health departments are supportive and view investigating cases of this vaccine-preventable disease as an aid to reducing spread and to encouraging vaccination. Guidance regarding which varicella cases require a full investigation is expected to allay any concerns about the burden of these investigations.

Businesses that are impacted, including private and commercial laboratories, already perform the tests that detect these pathogens, use existing reporting mechanisms, and many report already, even though not currently required to do so.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

N/A.

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.

ASSESSMENT OF PUBLIC COMMENTS

The New York State Department of Health (NYSDOH or "the Department") published a Notice of Proposed Rulemaking in the State Register on September 13, 2023, regarding a change to Section 2.1 of 10 New York Codes, Rules and Regulations (NYCRR) pertaining to communicable disease that would add laboratory-confirmed respiratory syncytial virus (RSV) cases, pediatric deaths from RSV, and varicella to the reportable disease list. The Department received three (3) public comments from: New York City Health and Hospitals, the New York State Association of County Health Officials (NYSACHO), and the New York City Department of Health and Mental Hygiene (NYCDOHMH). These comments and the Department's responses are summarized below.

COMMENT: New York City Health and Hospitals asked whether the phrase, "in persons younger than 18 years" applies only to deaths or reporting of laboratory-confirmed cases of RSV. Additionally, New York City Health and Hospitals pointed out that laboratories cannot know whether a positive varicella zoster virus (VZV) polymerase chain reaction (PCR) test result is from varicella or from zoster and therefore, it is unclear how to implement "not shingles/zoster."

RESPONSE: The phrase "in persons younger than 18 years" applies only to deaths from RSV. For laboratories, positive VZV PCR, culture, or Immunoglobulin M (IgM) results should be considered indicative of suspected varicella cases and therefore reported, regardless of age. Of note, VZV is already reportable by laboratories pursuant to New York City Health Code § 11.03(a). The "not shingles/zoster" designation on the reportable disease list is intended to clarify for clinicians that they need not report cases of zoster, because that condition is not the

result of a new infection. No changes to the regulation are necessary as a result of these comments.

COMMENT: NYCDOHMH shared concerns about the burden and necessity of varicella investigations and the need for additional flexibility in Section 2.6 of Title 10 of the NYCRR. NYCDOHMH pointed out that Section 2.6 requires local health authorities to *immediately* investigate *all* suspected and confirmed cases of *all* reportable communicable diseases and stated that it's not feasible to conduct a full case and contact investigation for each disease report received. Furthermore, they pointed out that varicella is already laboratory-reportable in New York City and that they receive approximately 2,000 reports (including varicella and zoster) per year. NYCDOHMH urged the Department to allow local health authorities flexibility to determine when investigations are warranted, and recommended that varicella be only laboratory-reportable to avoid the burden of reporting on both providers and NYCDOHMH.

RESPONSE: Section 2.6 contains qualifying language such as "based on epidemiological or other relevant information available" and "consistent with any direction that the State Commissioner of Health may issue," that provides local health authorities with flexibility to prioritize which cases of varicella are fully investigated. For example, laboratory-confirmed influenza and COVID-19 are both listed in Section 2.1 and guidance has been provided that local health authorities need not investigate individual influenza or COVID-19 cases. Another example is Lyme disease which, until a national case definition change in 2022, the Department had provided guidance to high-prevalence counties about investigation of a 20% sample of cases. Currently, Lyme disease investigations in those counties involve only analysis of the numbers of laboratory-confirmed cases with no expectation of individual case interviews. Guidance has also been provided to local health authorities about prioritizing certain elements of chlamydia

investigations to pregnant persons based on burden and capacity, and prioritizing gonorrhea investigations based on drug resistance, co-infections, or infection in high-risk groups. The Department intends to issue guidance to local health authorities that will allow them to tailor their investigations of varicella to those cases with the highest associated risks in their county, such as cases in congregate settings. The guidance will also include recommendations for if and how to respond to various types of laboratory reports. It is not appropriate to include investigation criteria in the regulation itself because priorities might differ between local health authorities and over time. NYCDOHMH also suggested that varicella be laboratory-reportable only; however, varicella can be clinically diagnosed without laboratory testing, and because the identification of cases in need of investigation often depends on information reported from other sources, the Department has opted to make it reportable by both laboratories and other mandated reporters. No changes are being made to the regulation at this time; however, the Department plans to work with key stakeholders to update Section 2.6 as soon as possible, consistent with NYCDOHMH's recommendations regarding additional explicit flexibility and clarity.

COMMENT: NYSACHO expressed concerns regarding the need for flexibility and decision-making autonomy for local health authorities to determine which individual varicella cases warrant investigation and the importance of expediting updates to Section 2.6 to explicitly provide "additional flexibility in investigation and response activities at the local level."
RESPONSE: The same response to the NYCDOHMH comment above applies to this NYSACHO comment. The Department intends to offer the desired flexibility in guidance and, as soon as possible, more explicitly in regulation.