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, Sections 2.1 and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is hereby amended, to be effective upon filing with the Secretary of State, 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:

**Amebiasis** 

Anthrax

Arboviral infection

**Babesiosis** 

Botulism

Brucellosis

Campylobacteriosis

Chancroid

Chlamydia trachomatis infection

Cholera
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli 0157:H7 infections
Ehrlichiosis
Encephalitis
Giardiasis
Glanders
Gonococcal infection
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus disease
Hemolytic uremic syndrome
Hemophilus influenzae (invasive disease)
Hepatitis (A; B; C)
Herpes infection in infants aged 60 days or younger (neonatal)
Hospital-associated infections (as defined in section 2.2 of this Part)
Influenza (laboratory-confirmed)
Legionellosis
Listeriosis
Lyme disease
Lymphogranuloma venereum

Malaria
Measles
Melioidosis
Meningitis
Aseptic
Hemophilus
Meningococcal
Other (specify type)
Meningococcemia
Monkeypox
Mumps
Pertussis (whooping cough)
Plague
Poliomyelitis
Psittacosis
Q Fever
Rabies
Rocky Mountain spotted fever
Rubella
Congenital rubella syndrome
Salmonellosis
[Severe Acute Respiratory Syndrome (SARS)]
Severe or novel coronavirus

2019-Novel Coronavirus (2019-nCoV)

Severe Acute Respiratory Syndrome (SARS)

Middle East Respiratory Syndrome (MERS)

Other (specify type)

Shigellosis

Smallpox

Staphylococcal enterotoxin B poisoning

Streptococcus pneumoniae invasive disease

Syphilis, specify stage

**Tetanus** 

Toxic Shock Syndrome

**Trichinosis** 

Tuberculosis, current disease (specify site)

Tularemia

**Typhoid** 

Vaccinia disease (as defined in section 2.2 of this Part)

Viral hemorrhagic fever

Yersiniosis

\* \* \*

Section 2.5 is amended to read as follows:

2.5. Physician to submit specimens for laboratory examination in cases or suspected cases of certain communicable diseases. A physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such

specimens as may be designated by the State Commissioner of Health, together with data
concerning the history and clinical manifestations pertinent to the examination:
Anthrax
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chlamydia trachomatis infection
Cholera
Congenital rubella syndrome
Conjunctivitis, purulent, of the newborn (28 days of age or less)
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli 0157:H7 infections
Ehrlichiosis
Giardiasis
Glanders
Gonococcal infection
Group A Streptococcal invasive disease
Group B Streptococcal invasive disease
Hantavirus disease
Hemophilus influenzae (invasive disease)

Hemolytic uremic syndrome
Herpes infection in infants aged 60 days or younger (neonatal)
Legionellosis
Listeriosis
Malaria
Melioidosis
Meningitis
Hemophilus
Meningococcal
Meningococcemia
Monkeypox
Plague
Poliomyelitis
Q Fever
Rabies
Rocky Mountain spotted fever
Salmonellosis
[Severe Acute Respiratory Syndrome (SARS)]
Severe or novel coronavirus
2019-Novel Coronavirus (2019-nCoV)
Severe Acute Respiratory Syndrome (SARS)
Middle East Respiratory Syndrome (MERS)
Other (specify type)

Shigellosis
Smallpox
Staphylococcal enterotoxin B poisoning
Streptococcus pneumoniae invasive
Syphilis
Tuberculosis
Tularemia
Typhoid
Viral hemorrhagic fever
Yellow Fever
Yersiniosis

#### REGULATORY IMPACT STATEMENT

### **Statutory Authority:**

Section 225 of the Public Health Law ("PHL") authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner) to establish and amend State Sanitary Code provisions relating to the designation of communicable diseases which are dangerous to public health, designation of diseases for which specimens shall be submitted for laboratory examination, and the nature of information required to be furnished by physicians in each case of communicable disease.

### **Legislative Objectives:**

The legislative objective of PHL § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to designate communicable diseases, thereby permitting enhanced disease monitoring and authorizing isolation and quarantine measures, if necessary, to prevent further transmission.

#### **Needs and Benefits:**

The 2019 Novel Coronavirus (2019-nCoV) is a virus that was found to be the cause of an outbreak of respiratory illness in Wuhan, Hubei Province, China in December 2019. It is associated with mild to severe respiratory illness including symptoms of fever, cough, and difficulty breathing. People infected with the virus have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and may be fatal.

As of February 3, 2020, 17,391 confirmed cases of 2019-nCoV were reported to the World Health Organization from 23 countries, including Canada and the United States, with 362 deaths reported.

On January 30, 2020 the World Health Organization designated the 2019-nCoV outbreak as a Public Health Emergency of International Concern, advising that further cases may appear in any country. On January 31, 2020, the Secretary of Health and Human Services determined that as a result of confirmed cases of 2019-nCoV in the United States, a public health emergency exists and has existed since January 27, 2020, nationwide.

If 2019-nCoV spreads in the general population, there could be severe public health consequences. On February 1, 2020, the New York State Commissioner of Health determined that 2019-nCoV is communicable, rapidly emergent and a significant threat to the public health, and designated 2019-nCoV as a communicable disease under 10 NYCRR Section 2.1. This designation will expire at the next scheduled meeting of the Public Health and Health Planning Council on February 6, 2020. Adding "severe or novel coronavirus" to the reportable disease list will confirm the Commissioner's designation and permit the Department of Health (Department) to systematically monitor for the disease and permit decisions about isolation or quarantine of suspect or confirmed cases to be made on a timely basis.

The regulation will also permit the Department to monitor and respond to other severe or novel coronavirus cases that may arise, including Middle East Respiratory Syndrome (MERS).

#### **COSTS:**

### **Costs to Regulated Parties:**

As 2019-nCoV is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs. In the event of the occurrence of 2019-nCoV cases, however, it is imperative to the public health that they be reported immediately and investigated thoroughly to curtail additional exposure and potential morbidity and mortality and to protect the public health.

The costs associated with implementing the reporting of this disease are lessened as reporting processes and forms already exist. Hospitals, practitioners and clinical laboratories are accustomed to reporting communicable disease to public health authorities.

#### **Costs to Local and State Governments:**

As 2019-nCoV is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs.

Costs to local or state governments associated with investigating and implementing control strategies to curtail the spread of 2019-nCoV, however, could be significant. Control efforts may include isolation or quarantine. Close contacts of individuals diagnosed with 2019-nCoV may need to be closely monitored with daily follow-up by local health departments for up to two weeks post-exposure. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of 2019-nCoV, this regulation may reduce costs associated with public health control activities, morbidity, treatment and premature death.

### **Costs to the Department of Health:**

As 2019-nCoV is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs. Costs to the Department associated with assisting local health departments investigating and implementing control strategies to curtail the spread of 2019-nCoV, however, could be significant.

### Paperwork:

The existing general communicable disease reporting form (DOH-389) will be revised.

This form is familiar to and is already used by regulated parties.

#### **Local Government Mandates:**

Under Part 2 of the State Sanitary Code (10 NYCRR Part 2), the city, county or district health officer receiving reports from physicians in attendance on persons with or suspected of being affected with 2019-nCoV, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported.

### **Duplication:**

There is no duplication of this initiative in existing State or federal law.

#### **Alternatives:**

No other alternatives are available, because reporting of cases of 2019-nCoV is of critical importance to public health. There is an urgent need to conduct surveillance, identify human cases in a timely manner, and reduce the potential for further exposure to contacts.

**Federal Standards:** 

Currently there are no federal standards requiring the reporting of 2019-nCoV.

**Compliance Schedule:** 

Reporting of 2019-nCoV is currently mandated, pursuant to the authority vested in the

Commissioner of Health by 10 NYCRR Section 2.1(a). This mandate will be extended upon

filing of a Notice of Emergency Adoption of this regulation with the Secretary of State and made

permanent by publication of a Notice of Adoption of this regulation in the New York State

Register.

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#### REGULATORY FLEXIBILITY ANALYSIS

### **Effect on Small Business and Local Government:**

This rule will apply to physicians, hospitals, nursing homes, diagnostic and treatment centers and clinical 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. Five hospitals, 130 nursing homes, 311 diagnostic and treatment centers, and 150 clinical laboratories employ less than 100 persons and qualify as small businesses.

Implementation will require reporting of 2019-nCoV in all 57 counties of the State outside of New York City. New York City has already adopted regulations identifying severe or novel coronavirus as a reportable, communicable disease.

#### **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.

Local health officers receiving reports from physicians in attendance on persons with or suspected of being affected with 2019-nCoV, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported.

Local health officers may also need to isolate or quarantine individuals to stop the spread of disease.

#### **Professional Services:**

No additional professional services will be required since providers are expected to be able to utilize existing staff to report occurrences of 2019-nCoV and to order laboratory tests.

#### **Compliance Costs:**

No initial capital costs of compliance are anticipated. Annual compliance costs will depend upon the number of 2019-nCoV cases. The reporting of 2019-nCoV should have a negligible to modest effect on the estimated cost of disease reporting by hospitals, but the exact cost cannot be estimated. The cost would be less for physicians and other small businesses.

As 2019-nCoV is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs for local governments. Costs to local governments associated with investigating and implementing control strategies to curtail the spread of 2019-nCoV, however, could be significant. Control efforts may include isolation or quarantine. Close contacts of individuals diagnosed with 2019-nCoV may need to be closely monitored with daily follow-up by local health departments for up to two weeks post-exposure. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of 2019-nCoV, this regulation may reduce costs associated with public health control activities, morbidity, treatment and premature death.

### **Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

## **Minimizing Adverse Impact**:

There are no alternatives to the reporting requirement. Adverse impacts have been minimized since revised forms and reporting staff will be utilized by regulated parties. Electronic reporting will save time and expense.

## **Small Business and Local Government Participation:**

Local governments have been consulted in the process through ongoing communication on this issue with local health departments and the New York State Association of County Health Officers (NYSACHO).

#### RURAL AREA FLEXIBILITY ANALYSIS

### **Types and Estimated Numbers of Rural Areas:**

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<a href="https://www.census.gov/quickfacts/">https://www.census.gov/quickfacts/</a>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	<b>Tompkins County</b>
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
<b>Dutchess County</b>	Oneida County	Suffolk County
Erie County	Onondaga County	

### **Compliance Requirements:**

Hospitals, clinics, physicians, nursing homes, and clinical laboratories that are located in rural areas will utilize revised Department of Health reporting forms and existing laboratory referral forms.

Local health officers in rural areas receiving reports from physicians in attendance on persons with or suspected of being affected with 2019-nCoV, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported. Local health officers may also need to isolate or quarantine individuals to stop the spread of disease.

#### **Professional Services:**

No additional professional services will be required. Rural providers are expected to use existing staff to comply with the requirements of this regulation.

### **Compliance Costs:**

No initial capital costs of compliance are anticipated. Annual compliance costs will depend upon the number of 2019-nCoV cases. The reporting of 2019-nCoV should have a negligible to modest effect on the estimated cost of disease reporting by hospitals in rural areas, but the exact cost cannot be estimated. The cost would be less for physicians and other small businesses.

As 2019-nCoV is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs for local governments in rural areas. Costs to local governments associated with investigating and implementing control strategies to curtail the

spread of 2019-nCoV, however, could be significant. Control efforts may include isolation or quarantine. Close contacts of individuals diagnosed with 2019-nCoV may need to be closely monitored with daily follow-up by local health departments for up to two weeks post-exposure. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of 2019-nCoV, this regulation may reduce costs associated with public health control activities, morbidity, treatment and premature death.

### **Minimizing Adverse Impact:**

No alternative to the reporting requirements were considered due to the obvious need to prevent the spread of nCoV. Adverse impacts have been minimized since familiar forms and reporting staff will be utilized by regulated parties.

### **Rural Area Input:**

The New York State Association of County Health Officers, including representatives of rural counties, has been informed about of this rule change and supports the need for it.

# JOB IMPACT STATEMENT

The Department of Health has determined that this regulatory change will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

#### **EMERGENCY JUSTIFICATION**

Compliance with the requirements of the State Administrative Procedure Act for filing of a regulation on a non-emergency basis including the requirement for a period of time for public comment cannot be met because to do so would be detrimental to the health and safety of the general public.

The 2019 Novel Coronavirus (2019-nCoV) is a virus that was found to be the cause of an outbreak of respiratory illness in Wuhan, Hubei Province, China in December 2019. It is associated with mild to severe respiratory illness including symptoms of fever, cough, and difficulty breathing. People infected with the virus have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and may be fatal.

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On January 30, 2020 the World Health Organization designated the 2019-nCoV outbreak as a Public Health Emergency of International Concern, advising that further cases may appear in any country. On January 31, 2020, the Secretary of Health and Human Services determined that as a result of confirmed cases of 2019-nCoV in the United States, a public health emergency exists and has existed since January 27, 2020, nationwide.

If 2019-nCoV spreads in the general population, there could be severe public health consequences. On February 1, 2020, the New York State Commissioner of Health determined that 2019-nCoV is communicable, rapidly emergent and a significant threat to the public health, and designated 2019-nCoV as a communicable disease under 10 NYCRR Section 2.1. This

designation will expire at the next scheduled meeting of the Public Health and Health Planning Council on February 6, 2020.

This emergency regulation is necessary to confirm the Commissioner's designation and permit the Department of Health (Department) to systematically monitor for this disease and permit decisions about isolation or quarantine of suspect or confirmed cases to be made on a timely basis.