Communicable Diseases Reporting and Control - Adding Severe or Novel Coronavirus

Effective date: 5/6/20

Pursuant to the authority vested in the Commissioner of Health by Executive Order No. 202 and 202.14, and 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

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), including Pediatric Multi-system Inflammatory Syndrome, or any other complication suspected of being associated with SARS-CoV-2 infection

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

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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)]

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Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), including Pediatric Multi-system Inflammatory Syndrome, or any other complication suspected of being associated with SARS-CoV-2 infection

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:

Executive Order No. 202, signed by Governor Cuomo on March 7, 2020, and continued by Executive Order No. 202.14, signed on April 7, 2020, modified Section 225 of the Public Health Law ("PHL") to authorize the Commissioner of Health (Commissioner) to promulgate emergency regulations to establish and amend the State Sanitary Code, including those 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 designating communicable diseases, thereby permitting enhanced disease monitoring and authorizing isolation and quarantine measures, if necessary, to prevent further transmission.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which is the virus that causes the disease COVID-19, have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and can be fatal. According to Johns Hopkins' Coronavirus Resource Center, to date, there have been over 3.6 million cases and

258,085 deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Subsequently, on March 13, 2020, President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

On February 1, 2020, the New York State Commissioner of Health determined that SARS-CoV-2 is communicable, rapidly emergent and a significant threat to the public health and designated it as a communicable disease under 10 NYCRR Section 2.1. On February 6, 2020, the Public Health and Health Planning Council (PHHPC) adopted emergency regulations, which confirmed the Commissioner's designation by adding "severe or novel coronavirus" to the reportable disease list in Part 2. This amendment also permits 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. Additionally, this

regulation makes it possible for the Department to monitor and respond to other severe or novel coronavirus cases that may arise, including Middle East Respiratory Syndrome (MERS).

Since these emergency regulations were first adopted by PHHPC, New York State has rapidly become the national epicenter of the outbreak. Case were first identified in New York State on March 1, 2020. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. With 321,192 confirmed cases and 19,645 deaths, New York State continues to be the most impacted state in the nation.

Based on the foregoing, and pursuant to the Executive Order issued on March 7, 2020, which permits the Commissioner to promulgate emergency regulations and to amend the State Sanitary Code, the Department has made the determination that it is necessary to renew this emergency regulation.

COSTS:

Costs to Regulated Parties:

As COVID-19 is a newly emerging disease, it is not possible to accurately predict the extent of the outbreak or potential costs. It is imperative to public health, however, that COVID-19 cases be reported immediately and investigated thoroughly to curtail additional exposure and potential morbidity and mortality.

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 COVID-19 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 COVID-19, however, could be significant. Control efforts have included and may continue to include isolation and quarantine. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of COVID-19, this regulation may reduce costs associated with public health control activities, morbidity, treatment and premature death.

Costs to the Department of Health:

As COVID-19 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 COVID-19, 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 COVID-19 , 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 COVID-19 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 COVID-19.

Compliance Schedule:

Reporting of COVID-19 is currently mandated, pursuant to the emergency regulation adopted by PHHPC on February 6, 2020.

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

REGULATORY FLEXIBILITY ANALYSIS

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 COVID-19 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 COVID-19, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported. Local health officers 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 COVID-19 and to order laboratory tests.

Compliance Costs:

No initial capital costs of compliance are anticipated. Annual compliance costs will depend upon the number of COVID-19 cases. The reporting of COVID-19 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 COVID-19 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 COVID-19, however, could be significant. Control efforts have included and may continue to include isolation and quarantine. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of COVID-19, 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 (https://www.census.gov/quickfacts/).

Allegany County
Cattaraugus County
Cayuga County
Chautauqua County
Chemung County
Chenango County
Clinton County
Columbia County
Cortland County
Delaware County
Essex County
Franklin County
Fulton County
Genesee County
Greene County
Hamilton County
Herkimer County
Jefferson County
Lewis County
Livingston County
Madison County
Montgomery County
Ontario County
Orleans County
Oswego County
Otsego County
Putnam County
Rensselaer County
Schenectady County
Schoharie County
Schuyler County
Seneca County
St. Lawrence County
Steuben County
Sullivan County
Tioga County
Tompkins County
Ulster County
Warren County
Washington County
Wayne County
Wyoming County
Yates 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
Broome County
Dutchess County
Erie County
Monroe County
Niagara County
Oneida County
Onondaga County
Orange County
Saratoga County
Suffolk 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 COVID-19, will be required to immediately forward such reports to the State Health Commissioner and to investigate and monitor the cases reported. Local health officers 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 COVID-19 cases. The reporting of COVID-19 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 COVID-19 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 COVID-19, however, could be significant. Control efforts have and may continue to include isolation and quarantine. These intensive efforts are critical to minimize the spread of this disease.

However, by potentially decreasing the spread of COVID-19, 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 COVID-19. 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.

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