COVID-19 and Influenza Confirmatory Testing

Effective: September 1, 2020

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2800 and 2803 of the Public Health Law, and in the Commissioner of Health by Section 3401 of the Public Health Law and Executive Order No. 202.59, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon filing with the Secretary of State, to read as follows:

Section 405.11 of 10 NYCRR is amended by adding a new subdivision (h) to read as follows:

(h) *COVID-19 and Influenza Confirmatory Testing.*

(1) Any patient who is known to have been exposed to COVID-19 or influenza or has symptoms consistent with COVID-19 or influenza shall be tested for both such diseases.

(2) Whenever a person expires while in the hospital, or while en route to the hospital, and in the professional judgment of the attending clinician there is a clinical suspicion that COVID-19 or influenza was a cause of death, but no such tests were performed in the 14 days before death, the hospital shall administer both a COVID-19 and influenza test within 48 hours after death, in accordance with guidance published by the Department. Such tests shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of both such test results through the Health Emergency Response Data System (HERDS). Notwithstanding the foregoing, no test shall be

administered if the next of kin objects to such testing. Should the hospital lack the ability to perform such testing expeditiously, the hospital should request assistance from the State Department of Health.

A new section 415.33 of 10 NYCRR is added to read as follows:

415.33 COVID-19 and Influenza Confirmatory Testing

(1) Any resident who is known to have been exposed to COVID-19 or influenza or has symptoms consistent with COVID-19 or influenza shall be tested for both such diseases.

(2) Whenever a person expires while in a nursing home, where in the professional judgment of the nursing home clinician there is a clinical suspicion that COVID-19 or influenza was a cause of death, but no such tests were performed in the 14 days before death, the nursing home shall administer both a COVID-19 and influenza test within 48 hours after death, in accordance with guidance published by the Department. Such tests shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of both such test results through the Health Emergency Response Data System (HERDS). Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the nursing home lack the ability to perform such testing expeditiously, the nursing home should request assistance from the State Department of Health.

A new section 77.13 of 10 NYCRR is added to read as follows:

77.13 COVID-19 and Influenza Confirmatory Testing – Funeral Directors.

Whenever the funeral director has been advised by an attending health care practitioner (whether the death was in hospice, an adult care facility, or any another setting where a positive diagnosis was not made) and there is a clinical suspicion that COVID-19 or influenza was a cause of death, but no such tests were performed within 14 days prior to death in a nursing home or hospital, or by the hospice agency, coroner, or medical examiner, the funeral director shall administer both a COVID-19 and influenza test within 48 hours after death, whenever the body is received within 48 hours after death, in accordance with guidance published by the Department. Such tests shall be performed using rapid testing methodologies to the extent available. The funeral director shall report the death to the Department immediately after and only upon receipt of both such test results, through a means determined by the Department. Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the funeral director lack the ability to perform such testing expeditiously, the funeral director should request assistance from the State Department of Health.

A new section 77.14 of 10 NYCRR is added to read as follows:

77.14 COVID-19 and Influenza Confirmatory Testing – Coroners and Medical Examiners.

Whenever a coroner or medical examiner has a reasonable suspicion that COVID-19 or influenza was a cause of death, but no such tests were performed within 14 days prior to death in a nursing home or hospital, or by the hospice agency, the coroner or medical examiner shall administer both a COVID-19 and influenza test within 48 hours after death, whenever the body is received within 48 hours after death, in accordance with guidance published by the Department. Such

tests shall be performed using rapid testing methodologies to the extent available. The coroner or medical examiner shall report the death to the Department immediately after and only upon receipt of both such test results, through a means determined by the Department. Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the coroner or medical examiner lack the ability to perform such testing expeditiously, the coroner or medical examiner may request assistance from the State Department of Health.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article." PHL section 2801 defines the term "hospital" as also including residential health care facilities, which are commonly referred to as nursing homes. PHL section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of such health care facilities. PHL 3401 authorizes the Commissioner to issue regulations pertaining to the business of funeral directing.

Executive Order No. 202, as extended, authorizes the Commissioner to directly issue emergency regulations pursuant to PHL section 2803, Article 2-B of the Executive Law authorizes the Governor in the course of any emergency to direct any person to take any action

necessary to cope with the declared disaster emergency. Pursuant to Article 2-B, Executive Order 202.59 issued on August 28, 2020, as may be extended from time to time, directed the Commissioner to act to ensure accuracy in contacts tracing and testing of persons under investigation (PUI) who may have COVID-19. Executive Order 202.59 directs the Commissioner to develop, by emergency regulations, comprehensive statewide protocols for the timely testing and reporting of all COVID-19 and Influenza cases to continue to ensure, as flu season approaches, that the State has the most accurate data to evaluate the number of positive cases and to best ensure timely contact tracing efforts are implemented in all regions. Upon the future declaration of any disaster emergency, any further authorization by the Governor pursuant to Article 2-B of the Executive Law, if it should suspend any statutes which otherwise conflict with these regulations, will establish the immediate effectiveness of these provisions, and the current actions taken establish their immediate effectiveness.

Legislative Objectives:

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. The objective of PHL Section 3401 is to authorize the Commissioner to regulate the business of funeral directing.

Needs and Benefits:

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, "temporarily suspend any statute, local law, ordinance, orders, rules, or regulations, or parts thereof, of any agency . . . if compliance with such provisions

would prevent, hinder, or delay action necessary to cope with the state disaster emergency." To that end, on March 7, 2020 and in response to the COVID-19 pandemic, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency, thereby enabling additional State action that aided in addressing the threat that COVID-19 presents to the health and welfare of New York State residents and visitors.

Additionally, New York State is entering flu season, and the similar symptoms of COVID-19 and influenza make correct diagnoses difficult without appropriate testing. Contact tracing is particularly important for cases of COVID-19 as the State continues its highly effective containment and mitigation strategies to ensure that the spread of COVID-19 remains at a level that the hospital system can accommodate. In order for New York State to more fully assess and differentiate the number of COVID-19 and influenza related cases and conduct contact tracing, testing of hospital patients and nursing home residents must be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19 and/or influenza. Significantly, this includes testing whenever a resident or patient is suspected of having either illness. Further, in the event of an unattended death, in those instances where such testing was not already performed, the coroner, medical examiner, or funeral director must perform the test, depending on who first receives the deceased.

Costs:

Costs to Regulated Parties:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCT) test ranges from

$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as $5 per test. Rapid influenza tests are advertised at $10-15 per panel.

Costs to Local Governments:

For those local governments that operate a general hospital or nursing home, the costs will be the same as those described above.

Cost to State Government:

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

Paperwork:

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although this regulation will require hospitals and nursing homes to test persons for COVID-19 and influenza, the Department does not anticipate that such additional tests will be burdensome given that these facilities are already testing patients and residents for these diseases in many instances.

Local Government Mandates:

Facilities operated by local governments will be subject to the same requirements as any other regulated facility, as described above.

Duplication:

These proposed regulatory amendments do not duplicate state or federal rules.

Alternatives:

The alternative would be to not promulgate the regulation, and to allow deaths to be reported as "presumed" deaths of COVID-19. However, this alternative was rejected on two grounds. First, a lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing, which would allow COVID-19 to spread indefinitely. Second, the regulations would encourage hospitals, nursing homes and hospices to test patients early for both COVID-19 and influenza, which will increase safety of patients and residents.

Federal Standards:

No federal standards apply.

Compliance Schedule:

These regulatory amendments will become effective upon filing with the Department of State.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

For those local governments or small businesses that operate a general hospital or nursing home, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19 and/or influenza. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

Compliance Requirements:

As discussed above, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19 and/or influenza. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

Professional Services:

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used when available.

Compliance Costs:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCT) test ranges from $100-150 per sample. However, where testing is conducted on a deceased person, rapid testing methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as $5 per test. Rapid influenza tests are advertised at $10-15 per panel.

Economic and Technological Feasibility:

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

Minimizing Adverse Impact:

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19 and influenza. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.40. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these emergency regulatory requirements, thus helping to minimize any adverse impacts.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small business and local governments were not consulted. However, parties representing local governments and small businesses may submit comments during the notice and commenter period in the event the Department promulgates proposed regulations.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Number of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein." The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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	Tompkins County
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
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Reporting, recordkeeping, and other compliance requirements; and professional services:

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used.

Compliance Costs:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected, but not known, to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCT) test ranges from $100-150 per sample. However, where testing is conducted on a deceased person, rapid testing

methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as $5 per test. Rapid influenza tests are advertised at $10-15 per panel.

Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas

Economic and Technological Feasibility:

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

Minimizing Adverse Impact:

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19 and influenza. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.40. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these emergency regulatory requirements, thus helping to minimize any adverse impacts.

Rural Area Participation

Due to the emergency nature of COVID-19, parties representing rural areas were not

consulted in the initial draft. However, parties representing rural may submit comments during the notice and commenter period in the event the Department promulgates proposed regulations.

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, "temporarily suspend any statute, local law, ordinance, orders, rules, or regulations, or parts thereof, of any agency . . . if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the state disaster emergency." To that end, on March 7, 2020 and in response to the COVID-19 pandemic, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency, thereby enabling additional State action that aided in addressing the threat that COVID-19 presents to the health and welfare of New York State residents and visitors.

Additionally, New York State is entering flu season, and the similar symptoms of COVID-19 and influenza make correct diagnoses difficult without appropriate testing. Contact tracing is particularly important for cases of COVID-19 as the State continues its highly effective containment and mitigation strategies to ensure that the spread of COVID-19 remains at a level that the hospital system can accommodate. In order for New York State to more fully assess and differentiate the number of COVID-19 and influenza related cases and conduct contact tracing, testing of hospital patients and nursing home residents must be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19 and/or influenza. Significantly, this includes testing whenever a resident or patient is suspected of having either illness. Further, in the event of an unattended death, in those instances where such testing was not already performed, the coroner, medical examiner, or funeral director must perform the test, depending on who first receives the deceased.

Given the foregoing, the Department has determined that these regulations should be issued on an emergency basis.