

COVID-19 Reporting and Testing

Effective date: 12/1/21

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is adding new sections 2.9 and 2.62, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.9 is added to read as follows:

2.9. COVID-19 Reporting in Schools. In addition to all other reporting requirements in this Part, every kindergarten, elementary, intermediate, or secondary school as well as any pre-kindergarten programs and school districts, as identified by the Department, shall report to the Department of Health, on a daily basis, in a form and manner to be determined by the Commissioner, all COVID-19 testing, positive test results reported in any manner to the school, and related information among students, teaching staff, and any other employees or volunteers. Such daily report shall include any other data elements as the Commissioner determines to be appropriate to track outbreaks of COVID-19 within such schools and school districts.

Section 2.62 is added to read as follows:

2.62. COVID-19 Testing Requirements.

(a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, the Commissioner may require routine COVID-19 testing in certain settings, which may include schools, homeless shelters, correctional facilities, nursing homes, and health care settings, and which may distinguish between individuals who have received full vaccination against COVID-19 and those who have not. Such testing determination may also include alternatives to testing as well as prevention protocols pending test results based on symptoms and/or exposure in certain settings.

(1) Entities subject to routine COVID-19 testing pursuant to a Commissioner's determination may accept documentation demonstrating full vaccination in lieu of imposing such testing requirements, if permitted in a Commissioner's determination. "Full vaccination", for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of full vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system;

(iii) Excelsior Pass; or

(iv) any other documentation determined acceptable by the Department.

(2) Entities subject to a Commissioner's determination pursuant to this section shall document testing or vaccination in appropriate records in accordance with applicable privacy laws and submit data and information related thereto to the Department in a manner and format set forth in such determination.

(3) The Commissioner shall issue findings regarding the necessity of testing requirements at the time such requirements are announced.

(b) Enforcement and Penalties

(1) All local health officers shall take such steps as may be necessary to assist with the enforcement of the provisions of this section in accordance with the Public Health Law and this Title.

(2) A violation of any provision of this section is subject to all civil and criminal penalties as provided for by law. Entities that violate this section are subject to a maximum fine of \$1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the section shall constitute a separate violation under this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new section 2.9 and 2.60 is sections 201, 206, and 225 of the Public Health Law (PHL). Subdivision (c) of section 201 of the PHL requires the Department to supervise the reporting and control of disease. Subdivision (d) of section 206 of the PHL requires the Commissioner to investigate the causes of diseases and epidemics. 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 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.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health (“Department”) to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

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 COVID-19 have had symptoms ranging from those that are substantially similar to a common cold to severe pneumonia requiring medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical conditions.

The Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

In response to this significant public health threat, the Department of Health seeks to empower the Commissioner through this emergency regulation to issue determinations requiring the immediate implementation of heightened COVID-19 testing protocols for population segments that may be at increased risk of transmission due, in part, to their employment or residential circumstances. Regular COVID-19 testing enables the immediate identification of COVID-19-positive individuals, even if they are not symptomatic, so that they can isolate and prevent further transmission. Additionally, the reporting of positive COVID-19 test results to public health authorities facilitates the rapid initiation of contact tracing to ensure close contacts are quarantined, tested, and isolated as needed.

These regulations also permit the Department to require reporting of testing and positive reports among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and positive reports in schools, given

the number of students that are currently unvaccinated. Children ages 5 through 11 years old were only recently authorized by the U.S. Food and Drug Administration (FDA) to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

COSTS:

Costs to Regulated Parties:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation

Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and positive reports for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Costs to Local and State Governments:

Costs to local health departments and the Department are expected to be minimal and related to monitoring compliance with these regulations, which can be incorporated into existing reporting and oversight activities and resources.

Paperwork:

This measure will require documentation related to the testing requirement, as well as documentation to opt-out of testing by providing documentation of full vaccination against COVID-19 in appropriate records. No additional paperwork requirements are anticipated for the school reporting requirement, which is expected to take the form of electronic submission to the Department.

Local Government Mandates:

These regulations impose an obligation on schools and school districts to report COVID-19 testing and positive report data for students, teaching staff, and any other employees or

volunteers. Local government may also be impacted if subject to a Commissioner's testing determination.

Duplication:

There is no duplication of federal law.

Alternatives:

The alternative to the school reporting requirement would be to not require COVID-19 related reporting for schools and school districts. A lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing. In addition, the Department would lose the ability to communicate with the community about COVID transmission patterns at the individual school level.

The alternative to permitting the Commissioner to issue determinations to require testing in certain settings would limit the ability for the Department to monitor trends related to COVID-19 transmission in more vulnerable populations, making it more difficult to work with partners to implement prevention strategies. Regular testing also helps to isolate infected individuals more quickly, as well as identify any contacts that need to be quarantined to prevent additional spread of COVID-19.

Federal Standards:

States and local governments have primary authority for controlling disease within their respective jurisdictions. Accordingly, there are no federal statutes or regulations that apply to disease control within NYS.

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address the COVID-19 pandemic, small businesses and local governments have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Given the testing and reporting mechanisms that have already been established in many settings, it is not anticipated that this regulation will have a significant impact on or cost to these entities. With regard to the school COVID-19 reporting requirement, this regulation will apply to private schools, including parochial schools, some of which may be small businesses, as well as public schools operated by local governments.

Compliance Requirements:

These regulations provide that testing may be required under certain circumstances, and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner's testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. These regulations also set forth specific COVID-19 testing and positive report reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

Professional Services:

As testing is a requirement of this regulation, the types of professional services that will be needed to comply with this rule include diagnostic and screening testing services offered by clinical laboratories that hold the appropriate New York State approval to carry out testing. Because there will be flexibility in the types of tests that can be used to operationalize testing, the types of clinical laboratories that can be used for testing will depend on the type of testing being performed. If a laboratory-based nucleic acid amplification tests (e.g., PCR) will be used to meet the testing requirement, testing will need to be performed off-site by a fully permitted clinical laboratory. In this scenario, individuals are sent to a partner for testing, or an arrangement can be made to conduct sample collection on-site for testing off-site at the clinical laboratory. If rapid waived tests will be used to meet the testing requirement, testing can be performed by a Limited Service Laboratory (LSL). Due to the lower requirements that need to be met for waived testing, an LSL can be established for on-site testing of individuals (e.g., performing testing on-site at a school).

Compliance Costs:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of

approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and diagnoses for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Any adverse impacts related to school reporting requirements are expected to be minimal, as it carries forward reporting requirements that schools were required to implement last year. The Department, however, will work with schools to ensure they are aware of the new regulations and have the information necessary to comply.

With regard to minimizing adverse impacts related to the Commissioner's authority to issue test-related determinations, many settings have been increasingly implementing COVID-19 prevention strategies, with testing being one such example. Specifically, schools became

familiar with COVID-19 testing last year when the Department provided no cost antigen test cards as part of the microcluster testing initiative. Some schools have already implemented regular pooled surveillance testing to give communities confidence in the safety of their schools. Where the Commissioner issues a testing-related determination, the Department will work with the entities subject to such determination to provide the guidance necessary to comply.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small business and local governments were not consulted.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

While 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 44 counties have an estimated population of less than 200,000 based upon the 2019 United States Census county populations projections:

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| Allegany County | Greene County | Schoharie County |
| Broome County | Hamilton County | Schuyler County |
| Cattaraugus County | Herkimer County | Seneca County |
| Cayuga County | Jefferson County | St. Lawrence County |
| Chautauqua County | Lewis County | Steuben County |
| Chemung County | Livingston County | Sullivan County |
| Chenango County | Madison County | Tioga County |
| Clinton County | Montgomery County | Tompkins County |
| Columbia County | Ontario County | Ulster County |
| Cortland County | Orleans County | Warren County |
| Delaware County | | |

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| 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 of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon the 2019 United States Census population projections:

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|-----------------|-----------------|-----------------|
| Albany County | Niagara County | Saratoga County |
| Dutchess County | Oneida County | Suffolk County |
| Erie County | Onondaga County | |
| Monroe County | Orange County | |

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

These regulations provide that testing may be required under certain circumstances and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner’s testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. Lastly, these regulations also set forth specific COVID-19 testing and positive test reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

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Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted.

JOB IMPACT STATEMENT

A Job Impact Statement is not being submitted with this rule because it is evident from the subject matter of the rule that it will have no impact on jobs and employment opportunities. The primary purposes of this rule is to carry forward COVID-19 related reporting and to permit the Commissioner to impose COVID-19 testing requirements in certain settings based on specified criteria.

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are substantially similar to a common cold to severe pneumonia requiring medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

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number of students that are currently unvaccinated. Children ages 5 through 11 years old only recently were authorized by the FDA to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.