

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 2.6 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:

2.6 Investigations and Response Activities.

(a) Except where other procedures are specifically provided in law and consistent with any direction that the State Commissioner of Health may issue, every local health authority, either personally or through a qualified representative, shall, with all due speed [immediately] upon receiving a report of a case, suspected case, outbreak, or unusual disease[,], and as the circumstances may require, investigate the circumstances of such report at any and all public and private places in which the local health authority has reason to believe, based on epidemiological or other relevant information available, that such places are associated with such disease. Except as consistent with any direction that the State Commissioner of Health may issue, s[S]uch investigations and response activities shall[, consistent with any direction that the State Commissioner of Health may issue]:

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(6) With the training or assistance of the State Department of Health as necessary, examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

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(c) Investigation Updates and Reports.

- (1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health in consultation with the local health authority.

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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”).

Legislative Objectives:

The legislative objective of section 225 of the PHL is, in part, to protect the public health by authorizing the PHHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

Needs and Benefits:

These regulations update and clarify the Department’s authority as well as that of local health departments (LHDs) to take specific actions to monitor the spread of disease, including actions related to investigation and response for a disease outbreak.

Specifically, the proposed regulatory amendments would add language to clarify and make explicit that the Commissioner may issue guidance that impacts investigation and response activities. For example, guidance may be issued instructing LHDs to prioritize full

investigations of varicella cases to those known to involve congregate residential settings and conduct investigations of other varicella cases only to the extent that resources allow, or guidance may provide details about the extent of investigation for a case of chlamydia in a pregnant individual. Regarding the timing for when investigation must commence, the regulation would change “immediately” to “with all due speed” to account for the fact that there is a range of appropriate response times depending on the condition and situation. In addition, the regulation would add “as necessary” to the provision requiring the local health authority to examine various factors associated with places related to an investigation “with the training or assistance of the State Department of Health”, to acknowledge that local health authorities will not always need training or assistance. Finally, the regulation would add “in consultation with the local health authority” to the provision stating that the Department shall determine the content and other characteristics of investigation updates, to acknowledge that the local health authority can provide valuable input.

COSTS:

Costs to Regulated Parties:

Although there are costs associated with disease investigation and response for any outbreak, these amendments merely clarify the existing authorities and responsibilities of local governments. As such, these amendments do not impose any substantial additional costs beyond what LHDs would incur in the absence of these amendments.

Further, making explicit the Department’s authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments by reducing unnecessary investigatory

activities and allowing resources to be focused on investigations likely to have the greatest public health impact.

Costs to Local and State Governments:

Although there are costs associated with disease investigation and response for any outbreak, these regulations merely clarify the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

Further, making explicit the Department’s authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments.

Paperwork:

These amendments do not require any additional paperwork.

Local Government Mandates:

Under existing regulation, LHDs already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

The alternative would be to leave in place the current regulations on disease investigation. However, these regulatory provisions clarify the regulation and provide additional flexibility to LHDs, while ensuring appropriate responses are taken for communicable disease outbreaks.

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 New York State.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

Under existing regulation, local health departments (LHDs) already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments merely clarify these existing authorities and duties.

Compliance Requirements:

Under existing regulation, LHDs already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments merely clarify these existing authorities and duties.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

Although there are costs associated with disease investigation and response for any outbreak, these regulations merely clarify the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what LHDs would incur in the absence of these regulations being amended.

Further, making explicit the New York State Department of Health's ("the Department") authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As the proposed amendments clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with regulated entities to ensure they are aware of the new regulations and have the information necessary to comply.

Small Business and Local Government Participation:

These proposed amendments to the regulation were previously discussed with the New York State Association of Counties Health Officials (NYSACHO) on three occasions and participants included both NYSACHO and LHD representatives. Discussions involved a detailed review of each of the submitted comments to the prior amendments adopted effective December 20, 2023 and a proposed approach to prioritize the initial scope of the regulatory amendments to incorporate the requested flexibility to prioritize investigation and response efforts at the local level, which is reflective of current practice and supported by both the Department and NYSACHO. These proposed amendments to the regulation are being proposed for permanent adoption, so all parties will have an opportunity to provide comments during the notice and comment period.

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 a population of less than 200,000 based upon 2020

United States Census data:

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	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following 10 counties have populations of 200,000 or greater, and towns with population densities of 150 persons or fewer per square mile, based upon the United States Census estimated county populations for 2020:

Albany County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

Reporting, Recordkeeping, and Other Compliance Requirements; and Professional Services:

As the proposed regulations clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected.

Compliance Costs:

As the proposed regulations clarify existing responsibility and duties among regulated entities and individuals, no initial or annual capital costs of compliance are expected above and beyond the cost of compliance for the requirements currently in 10 NYCRR Part 2.

Minimizing Adverse Impact:

As the proposed amendments to the regulations clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with local health departments (LHDs) to ensure they are aware of the new regulations and have the information necessary to comply.

Rural Area Participation:

These proposed amendments to the regulations are being proposed for permanent adoption, so all parties will have an opportunity to provide comments during the notice and comment period.

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.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH or “the Department”) published a Notice of Proposed Rulemaking in the State Register on June 05, 2024, regarding a change to Section 2.6 of 10 New York Codes, Rules, and Regulations (NYCRR) pertaining to communicable disease that authorizes the Department to provide flexibilities to local health departments (LHDs) to prioritize reportable diseases that need to be fully investigated. The Department received two (2) public comments from: the New York State Association of County Health Officials (NYSACHO) and the New York City Department of Health and Mental Hygiene (NYCDOHMH) that were overall supportive of the proposed amendments, along with recommendations from both for additional amendments and continued discussions to further clarify state and local authority for leading local communicable disease investigations. These comments and the Department’s responses are summarized below.

Comment: Both NYSACHO and NYCDOHMH acknowledged the productive discussions had with the Department in developing regulatory amendments that incorporate necessary flexibility to prioritize investigation and response efforts at the local level. NYSACHO expressed that they are “fully supportive” of these amendments and noted that the approach “reflects current practices” and “provides a more adaptable framework that allows LHDs to allocate resources efficiently and respond effectively to public health threats.” NYCDOHMH expressed explicit support of the flexibility provided by the proposed addition of “as the circumstances may require” to Section 2.6(a); the addition of “in consultation with the local health authority” to Section 2.6(c)(1), and the addition of “as necessary” to Section 2.6(a)(6).

Response: The Department appreciates the support of the proposed amendments by both NYSACHO and NYCDOHMH and the collaborative discussions to develop a regulatory framework that protects public health and is reflective of current practices for prioritizing investigation and response efforts at the local level. No changes were made to the proposed regulation in response to these comments.

Comment: NYSACHO reiterated prior concerns and opposition to the provisions of Section 2.6(d), which pertain to the Commissioner of Health’s authority to lead investigation and response activities in certain circumstances. Both NYSACHO and NYCDOHMH expressed interest in continuing discussions with the Department and recommended amendments to other provisions in regulation outside of the scope of the proposed rulemaking. Suggested future amendments included: adding language to Section 2.6 that provides local health authorities the opportunity to request that the Department assume lead role for disease investigation at facilities not regulated by the local health department; modifying language in Section 2.6(c)(2) to allow for flexibility in the content and timeframe of disease investigation reports in consultation with local health authorities; adding language to Section 2.6(d)(1) that provides the Commissioner of Health as the designated lead for disease investigation involving state-regulated facilities over which the Department has regulatory oversight; and modifying language in Section 2.6(d)(2) to clarify decision-making and response activities conducted by local health authorities in consultation and coordination with the State Health Commissioner, rather than at the direction of the Health Commissioner.

Response: The Department appreciates the clarification from NYSACHO that the additional recommendations are for future discussion and not part of the comment on the current proposed

amendments to Section 2.6. The current proposed regulatory amendments are responsive to prior feedback and comments received from both NYSACHO and the NYCDOHMH submitted in response to amendments to Sections 2.1 and 2.6, adopted in 2023. The current amendments to Section 2.6 were discussed at length with NYSACHO and the NYCDOHMH and specifically address concerns about flexibility and clarity pertaining to investigation and response of communicable disease at the local level. The Department discussed with NYSACHO the fact that these amendments would not address all the organization’s concerns about Section 2.6, that the currently proposed amendments were generally agreed upon and therefore could likely be implemented relatively quickly, and that many of the additional proposed changes would require more extensive discussion. With the concurrence of NYSACHO, the Department therefore prioritized development of the current proposed regulatory amendments to provide expeditious relief to local health departments. No changes were made to the proposed regulation in response to these comments.

Comment: The NYCDOHMH expressed concern about the inclusion of the language “consistent with any direction that the State Commissioner of Health may issue” in Section 2.6(a), which explicitly allows the Commissioner to issue guidance impacting investigation and response activities. NYCDOHMH asserts that the language undermines local health departments and suggests this language be omitted.

Response: This language was specifically included to provide flexibility in the regulation, allowing local health authorities to prioritize their investigation activities and make the best use of their resources for the good of public health. Without this language, the wording and intention of the regulation might be unclear: on one hand it could be read as not offering any flexibility to

local health authorities; on the other hand, it could be read as allowing each local health authority to create their own disparate investigation protocols, possibly unbeknownst to the Department, resulting in confusion and disorder in investigation and surveillance. No changes were made to the proposed regulation in response to this comment.

Comment: The NYCDOHMH commented that Section 2103 of the Public Health Law (PHL) is cited as the specific statutory authority for the current proposed regulatory amendments; however, this provision is not applicable to New York City.

Response: While the Department recognizes that Article 21 of the Public Health Law is not applicable to the city of New York, pursuant to the authority vested in the Public Health and Health Planning Council (PHHPC) and the Commissioner of Health by Public Health Law § 225, any amendments made to the State Sanitary Code, including to Section 2.6, are applicable to New York City. Hence New York City is subject to the requirements set forth in the regulation. No changes were made to the proposed regulation in response to this comment.