

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 2803, 3612, 4010, and 4662 of the Public Health Law, Sections 404.12, 405.3, 415.26, 751.6, 763.13, 766.11, 794.3, and 1001.11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subparagraph (iv) of paragraph (2) of subdivision (b) of section 404.12 is amended to read as follows:

Section 404.12 Staffing

(iv) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to employment or affiliation and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay].

The medical staff shall develop and implement policies regarding positive [outcomes] findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated;

Subparagraph (iv) of paragraph (10) of subdivision (b) of section 405.3 is amended to read as follows:

(iv) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to employment or affiliation and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay]. The medical staff shall develop and implement policies regarding positive [outcomes] findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated.

Subclause (1) of clause (a) of subparagraph (v) of paragraph (1) of subdivision (c) of section 415.26 is amended to read as follows:

(1) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to employment or affiliation and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay].

The medical staff shall develop and implement policies regarding positive [outcomes] findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated; and

Paragraph (4) of subdivision (d) of section 751.6 is amended to read as follows:

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to employment or affiliation and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay].

The medical staff shall develop and implement policies regarding positive [outcomes] findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated; and

Paragraph (4) of subdivision (c) of section 763.13 is amended to read as follows:

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the

detection of latent tuberculosis infection), [prior to assuming patient care duties and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay]. The agency shall develop and implement policies regarding follow-up of positive test results, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment and follow-up tests as indicated;

Paragraph (4) of subdivision (d) of section 766.11 is amended to read as follows:

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to assuming patient care duties and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical [follow up but no repeat tuberculin skin test or blood assay] follow-up. The agency shall develop and implement policies regarding follow-up of positive test results, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated; and

Paragraph (4) of subdivision (d) of section 794.3 is amended to read as follows:

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection), [prior to employment or voluntary service, and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical follow-up [but no repeat tuberculin skin test or blood assay]. The hospice shall develop and implement policies regarding follow-up of positive test results, including procedures for facilitating and documenting treatment for latent TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated;

Paragraph (4) of subdivision (q) of section 1001.11 is amended to read as follows:

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or [whole] Food and Drug Administration (FDA) approved blood assay for [tuberculosis screening] the detection of latent tuberculosis infection), [prior to assuming patient care duties and no less than every year thereafter for negative findings] and annual assessments thereafter. Positive findings shall require appropriate clinical [follow up but no repeat skin test] follow-up. The residence shall develop and implement policies regarding [follow up] follow-up of positive test results, including procedures for facilitating and documenting treatment for latent

TB infection where indicated. Annual TB assessment shall include education, individual risk assessment, and follow-up tests as indicated.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) §§ 2803, 3612(5), and 4010 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Articles 28, 36 and 40, respectively, including the establishment of uniform standards governing the operation of health care facilities, certified home health agencies (CHHAs) and hospices.

PHL §§ 3612(7) and 4662 authorize the Commissioner to adopt and amend regulations to implement the purposes and provisions of PHL Articles 36 and 46-B, respectively, including the establishment of uniform standards governing the operation of licensed home care services agencies (LHSCAs) and assisted living residences (ALRs).

Legislative Objectives:

The legislative objectives of PHL Articles 28, 36, 40, and 46-B includes the protection of the health of the residents of the State by assuring the efficient provision of health services of the highest quality by a range of providers, including hospitals, hospices, CHHAs, LHCSAs and ALRs.

Needs and Benefits:

Current requirements for annual tuberculosis screening in health care settings were established in the 1990s at the time of large outbreaks and sustained transmission of tuberculosis in New York State (NYS). The requirements were subsequently updated to allow use of U.S.

Food and Drug Administration-approved blood tests as an alternative option to tuberculin skin tests, and to exempt certain personnel in non-clinical settings, but the serial testing requirement was not changed. Over the past two decades, with improved infection control, diagnostic testing and treatment of persons with tuberculosis (TB) disease, incidence has decreased. Evaluation of persons at risk for TB to detect and treat latent infection, including contacts with infectious TB, is also ongoing in all settings including health care facilities.

Recent systematic reviews have documented that U.S. health care personnel have a low rate of TB infection on baseline testing and very low rate of tuberculin skin test conversions. Persons retested after apparent conversion in the absence of documented close contact to infectious tuberculosis were often negative on subsequent tests. The Centers for Disease Control and Prevention (CDC), with the National Tuberculosis Controllers Association and in coordination with occupational health and infection control associations, updated recommendations in 2019 which discourage routine serial testing, and instead focused on evaluating individual risk and encouraging treatment for persons with untreated latent tuberculosis infection.

In NYS, providing universal annual tuberculosis education and individual risk assessment, followed up as needed with appropriate testing, clinical evaluation, and encouragement of optimal treatment, is expected to benefit health care personnel, minimize risk of transmission from health care personnel to others, and refocus occupational health and infection control efforts. Thus, the requirement to be tested “no less than every year” for negative findings is no longer necessary and is being eliminated from these regulations.

Furthermore, in June 2019, CDC issued a Health Advisory providing notification of a nationwide shortage of one of the two purified protein derivative solution products for tuberculin

skin testing. The CDC advisory also stated that annual TB testing of health care personnel was not recommended unless there is a known exposure or ongoing transmission. To align regulations with current best medical practices and CDC guidelines, and to prevent unnecessary disruption of health care providers, it is necessary to adopt these proposed regulations.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The proposed amendments will reduce requirements for testing of employees, and as such will result in a reduction in costs for regulated entities.

Cost to State and Local Government:

State agencies and local government units that operate health care facilities will see a reduction in costs associated with serial testing of employees.

Cost to the Department of Health:

The Department of Health will see a reduction in costs associated with serial testing of employees at health care facilities operated by the Department.

Local Government Mandates:

This amendment does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

These amendments will decrease the record keeping currently required of covered entities since annual testing will no longer be required, only assessments.

Duplication:

These amendments will not conflict with any state or federal rules.

Alternative Approaches:

An alternative would be to maintain current requirements for regular serial testing for TB. This is not advisable or practicable given the current shortage of tuberculin skin testing solutions.

Federal Requirements:

These amendments reflect current guidelines issued by the Centers for Disease Control and Prevention.

Compliance Schedule:

This proposal will go into effect upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations would require small businesses and local governments that operate hospitals, hospices, CHHAs, LHCSAs or ALRs, to revise policies for tuberculosis testing that ensure adequate baseline assessments, and that replace serial testing with annual individual risk assessment and education, with further testing as indicated. Impacted health care providers can consider using serial TB screening of certain groups who might be at increased occupational risk for TB exposure (e.g. pulmonologists or respiratory therapists) or in certain settings if transmission has occurred in the past (e.g. emergency departments). Policies would also require clear procedures for offering and documenting treatment of TB infection. As this proposed rule will reduce the need for TB testing, the overall effect of the rule will be to reduce costs for regulated entities.

Compliance Requirements:

All hospitals, hospices, CHHAs, LHCSAs and ALRs must revise policies for tuberculosis testing to ensure adequate baseline assessments, and replace serial testing with annual individual risk assessment and education, with further testing as indicated and provide documentation to demonstrate compliance as part of ongoing occupational health records.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

The State will develop overall guidance. Health care providers may have initial implementation costs related to changes in diagnostic test products, assessment procedures, risk assessment forms, and education and databases, but this rule change will result in a permanent reduction of costs once implemented.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not require any special technology and does not impose an unreasonable financial burden on health care institutions or local health departments.

Minimizing Adverse Impact:

This amendment does not create any adverse effect on regulated parties.

Small Business and Local Government Participation:

Health care provider organizations, individual institutions, local health departments and the public are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council.

Cure Period:

This regulation allows a cure period of 90 days, to allow health care entities and local health departments to modify procedures in order to comply. Full implementation is expected to

occur over a one year period as successive groups of persons are screened according to the revised protocols.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

These regulations would require hospitals, hospices, CHHAs, LHCSAs and ALRs in rural areas, to revise policies for tuberculosis testing that ensure adequate baseline assessments, and that replace serial testing with annual individual risk assessment and education, with further testing as indicated. Impacted health care providers in rural areas can consider using serial TB screening of certain groups who might be at increased occupational risk for TB exposure (e.g. pulmonologists or respiratory therapists) or in certain settings if transmission has occurred in the past (e.g. emergency departments). Policies would also require clear procedures for offering and documenting treatment of TB infection. As this proposed rule will reduce the need for TB testing, the overall effect of the rule will be to reduce costs for regulated entities in rural areas.

Compliance Requirements:

All hospitals, hospices, CHHAs, LHCSAs and ALRs must revise policies for tuberculosis testing to ensure adequate baseline assessments, and replace serial testing with annual individual risk assessment and education, with further testing as indicated and provide documentation to demonstrate compliance as part of ongoing occupational health records.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

The State will develop overall guidance. Health care providers may have initial implementation costs related to changes in diagnostic test products, assessment procedures, risk assessment forms, and education and databases, but this rule change will result in a permanent reduction of costs once implemented.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not require any special technology and does not impose an unreasonable financial burden.

Minimizing Adverse Impact:

The Department will work with institutions, occupational health groups and local health departments to provide guidance, respond to questions and share best practices.

Public and Local Government Participation:

Health care organizations and facilities, health care personnel, local health departments and the public are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received public comments in response to the proposed rulemaking amending sections 404.12, 405.3, 415.26, 751.6, 763.13, 766.11, 794.3, and 1001.11 of Title 10 of the Codes, Rules and Regulations of the State of New York relating to the requirements for annual tuberculosis testing of health care workers. The comments and the Department’s response are summarized below.

Comment: University of Rochester Medical Center submitted a letter supporting the rule change and suggesting an alternative wording to clarify the meaning of “annual assessments thereafter.”

Response: These comments in support are noted by the Department. As proposed, the regulation already states that annual TB assessments shall include education, individual risk assessment, and follow-up tests as indicated. During annual assessments, health care workers should be tested only if there are any symptoms suggestive of TB disease, or new risk for infection. The Department will provide further guidance as needed.

Comment: The New York State Office of Mental Health submitted a letter supporting the proposed rule change, noting the change will conform with new CDC recommendations.

Response: These comments in support are noted by the Department.

Comment: The Home Care Association of New York State submitted a letter of support, stating that the proposed rule also addresses the problem of testing product shortages and increased costs.

Response: These comments in support are noted by the Department.

Comment: The Olean General Hospital, Upper Allegheny Health System, submitted a letter of support for the rule change, asking it be expedited.

Response: These comments in support are noted by the Department.