

Pursuant to the authority vested in the Commissioner of Health by sections 461 and 461-l of the Social Services Law, Sections 487.9, 488.9, and 490.9 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are hereby amended, to be effective 90 days from publication of a Notice of Adoption in the New York State Register, to read as follows:

Clause (a) of subparagraph (ii) of paragraph (8) of subdivision (a) of section 487.9 is amended to read as follows:

(a) [a ppd (Mantoux) skin test for tuberculosis] an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or blood assay approved by the Food and Drug Administration for the detection of latent tuberculosis infection) [within 30 days] prior to employment and subsequent annual assessments [no less frequently than every two years] after employment begins; positive findings shall require appropriate clinical follow-up [but no repeat skin test]. The operator shall develop and implement policies regarding positive findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. The annual TB assessments shall include education, individual risk assessment, and follow-up tests as indicated; and

Clause (a) of subparagraph (ii) of paragraph (5) of subdivision (a) of section 488.9 is amended to read as follows:

(a) [a ppd (Mantoux) skin test for tuberculosis] an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or blood assay approved by the Food and Drug Administration for the detection of latent tuberculosis infection) [within 30 days] prior to employment and subsequent annual assessments [no less frequently than every two years] after employment begins; positive findings shall require appropriate clinical follow-up [but no repeat skin test]. The operator shall develop and implement policies regarding positive findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. The annual TB assessments shall include education, individual risk assessment, and follow-up tests as indicated; and

Clause (a) of subparagraph (ii) of paragraph (6) of subdivision (a) of section 490.9 is amended to read as follows:

(a) [a ppd (Mantoux) skin test for tuberculosis] an initial individual tuberculosis (TB) risk assessment, symptom evaluation, and TB test (either tuberculin skin test or blood assay approved by the Food and Drug Administration for the detection of latent tuberculosis infection) [within 30 days] prior to employment and subsequent annual assessments [no less frequently than every two years] after employment begins; positive findings shall require appropriate clinical follow-up [but no repeat skin tests]. The operator shall develop and implement policies regarding positive findings, including procedures for facilitating and documenting treatment for latent TB infection where indicated. The annual TB assessments shall include education, individual risk assessment, and follow-up tests as indicated; and

REGULATORY IMPACT STATEMENT

Statutory Authority:

Sections 461(1) and 461-l(5) of the Social Services Law (SSL) provide authority to promulgate these regulations. Section 461(1) provides the authority for the Department to promulgate regulations for adult care facilities, specifically adult homes, enriched housing, and residences for adults. Section 461-l(5) provides the authority for the Commissioner of Health to promulgate regulations for assisted living programs.

Legislative Objectives:

The legislative objective of SSL sections 461 and 461-l is to promote the life, health, safety and comfort of adults residing in adult care facilities (see SSL section 460).

Needs and Benefits:

The proposed regulatory changes will advance the Legislature's objectives to protect the health and well-being of adult care facility residents, insofar as the proposed rule change will update the requirements for personnel regarding testing and assessment for tuberculosis to ensure that those who care for adult care facility residents are evaluated and, where necessary, tested for tuberculosis based on current clinical standards. For the reasons explained below, providing 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 working in ACF settings, minimize risk of transmission from health care personnel to others, and refocus occupational health and infection control efforts.

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. 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 to 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 a 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 U.S. 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 TB testing, and instead focus on evaluating individual risk and encouraging treatment for persons with untreated latent TB infection.

Thus, the requirement to be tested for negative findings is no longer necessary and is being eliminated from these regulations.

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

Current regulations requiring serial testing of employees imposes a cost on covered entities. The proposed amendments will reduce this testing and result in a reduction in costs for regulated entities.

Cost to State and Local Government:

State agencies and local government units 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.

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 given that annual testing will no longer be required for all employees, only annual assessments.

Duplication:

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

Alternative Approaches:

The alternative would be to leave the requirements for regular serial testing in place. However, that alternative is not viable because it is contrary to recommended guidelines for TB testing.

Federal Requirements:

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

Compliance Schedule:

This proposal will go into effect 90 days following publication of a Notice of Adoption in the New York State Register.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations would require all adult care facilities to revise policies for tuberculosis (TB) testing to ensure adequate baseline assessments and to replace serial testing with regular individual risk assessment and education, with further testing as indicated. Adult care facilities can consider using serial TB screening of certain groups who might be at increased occupational risk for TB exposure or in certain settings if transmission has occurred in the past. Policies would also require clear procedures for offering and documenting treatment of TB infection.

Compliance Requirements:

All DOH-regulated adult care entities must comply with the revised requirements, which includes developing policies for TB testing to ensure adequate baseline assessments, documenting treatment of TB infection, and replacing serial testing with annual individual risk assessment and education, with further testing as indicated. Facilities must also 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 general guidance documents related to health care personnel screening and education, and facilities are expected to develop specific policies and procedures in accordance with the overall guidance. Facilities may have initial implementation costs related to development of 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 that would require a minimization analysis.

Small Business and Local Government Participation:

The Department will send a Dear Administrator Letter (DAL) to all adult care facility administrators, including those of adult care facilities owned and operated by small businesses and local governments, which notifies these entities of the proposed regulatory amendments and the availability of submitting comments during the public comment period. The DAL specifically indicates that ACFs owned and operated by small businesses and local governments must comply with the regulatory changes.

Cure Period:

This regulation allows a cure period of 90 days, to allow facilities time 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 apply to DOH-regulated adult care facilities equally in all areas of the state, including rural areas. Adult care facilities can consider using serial tuberculosis (TB) screening of certain groups who might be at increased occupational risk for TB exposure or in certain settings if transmission has occurred in the past, and facilities must develop policies that set forth clear procedures for offering and documenting treatment of TB infection. Nevertheless, most rural areas in New York State have low rates of TB, and 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 DOH-regulated adult care facilities must comply with the revised requirements, which includes developing policies for TB testing to ensure adequate baseline assessments, documenting treatment of TB infection, and replacing serial testing with annual individual risk assessment and education, with further testing as indicated. Facilities must also 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 general guidance documents related to health care personnel TB screening and education, and facilities are expected to develop specific policies and procedures in accordance with such guidance. Facilities may have initial implementation costs related to development of 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 facilities, occupational health groups and local health departments to provide documentation, respond to questions, and share best practices.

Public and Local Government Participation:

All stakeholders, including health care provider organizations, individual facilities, local health departments and the public are invited to submit public comments in response to the filing of the proposed regulation.

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 (the Department) received comments regarding the proposed amendments to Sections 487.9, 488.9, and 490.9 of Title 18 of the New York Codes, Rules and Regulations. The comments and the Department's responses are summarized below.

Comment: A public health agency stated that the regulations do not adequately stress the importance of assessment after known exposure.

Response: Post exposure assessment should be covered by infection control guidance and facility policies.

Comment: A commenter asked the Department to clarify the meaning of the phrase "positive findings" in the regulation.

Response: A positive finding can be a positive TB test result or information obtained in the annual TB risk assessment that requires further action/investigation.

Comment: A commenter asked if the intention of the regulation is to eliminate a re-test requirement after a negative baseline.

Response: The proposed changes ensure that after a TB baseline is established (either positive or negative), there is enhanced awareness of TB risk factors, facilitation of latent TB treatment, and promotion and dissemination of TB information/education. The annual TB assessments must include education, individual risk assessment, and follow-up tests as indicated.

Comment: A public health agency recommended that the regulation reflect the State’s authorized use of Interferon-Gamma Release Assays (IGRAs) and therefore leave in place the requirement for a repeat tuberculosis infection test.

Response: Forthcoming guidance documents will address two-step tuberculin skin testing where indicated, as well as more detail on IGRA tests.

Comment: A commenter pointed out that not all adult care facilities have medical staff and suggested that the regulation clarify that the operator of the adult care facility is responsible for developing and implementing policies.

Response: The Department agrees with this commenter, and the final regulation clarifies that the “operator” is required to develop and implement policies, not the “medical staff.”

Comment: One commenter stated that after the baseline tuberculosis test, annual assessments should be conducted during the employee’s annual health assessment.

Response: The Department agrees that after the initial baseline TB testing, the annual TB risk assessment can be conducted at the time of the employee annual health screening, in accordance with any further guidance.

Comment: One commenter stated that the Department should authorize the clinicians who may conduct the tuberculosis assessment, including the education, individual risk assessment, and follow-up tests as indicated.

Response: The annual TB risk assessment can be conducted by any licensed medical professional acting within the scope of their practice, including physicians, physicians’

assistants, nurse practitioners, or registered professional nurses working under physician supervision.