

State of Louisiana

Louisiana Department of Health
Office of the Secretary

March 10, 2021

Via Statutorily Required Email

To:

The Honorable Patrick Page Cortez, President, Louisiana Senate

The Honorable Clay Schexnayder, Speaker, Louisiana House of Representatives The Honorable Chairman Fred H. Mills Jr., Senate Health & Welfare Committee The Honorable Chairman Larry Bagley, House Health & Welfare Committee

From:

Dr. Courtney N. Phillips

Secretary

Re:

First Report: Proposed Amendments to IAC 51:II.503 and 505 - Mandatory

Tuberculosis (TB) Testing

Under the authority of the laws of the State of Louisiana and in accordance with the provisions of Chapter 6 of Title 36 of the Louisiana Revised Statutes of 1950, and with the Administrative Procedure Act, La. R.S. 49:950 et seq., the secretary hereby gives notice that rulemaking procedures have been initiated to promulgate amendments to the rules governing the administration of Mandatory Tuberculosis (TB) Testing, LAC 51:II.503 and 505.

I. Copy of the rule as it is proposed after amendment, with new proposed language indicated by the underscored text and deleted language indicated by the strike-through type.

See attachment.

II. A statement of the proposed action.

The proposed rule revisions are to update the Louisiana Administrative Code (LAC) by following guidance from the Centers for Disease Control and Prevention (CDC), as well as data monitored by LDH-OPH's Tuberculosis (TB) Control Program.

III. Specific citation of law authorizing promulgation of the rule.

R.S. 40:4(A)(2) and R.S. 40:5, and R.S. 49:954, et. seq.

IV. Circumstances which require the amendment of the rule.

Following guidance from the Centers for Disease Control and Prevention (CDC), as well as data monitored by LDH-OPH's Tuberculosis (TB) Control Program, the proposed rule eliminates the current requirement for annual TB testing for most employees, students or volunteers at any medical or 24-hour residential facility requiring licensing by the LDH, or at any LDH-OPH parish health unit or an LDH-OPH out-patient health care facility. In lieu of annual TB testing for these persons, the rule proposes to require that certain educational materials be provided to those persons annually.

V. Statement of Fiscal and Economic Impact.

See attachment.

Please contact Katheryn Yoo, <u>Katheryn Yoo@la.gov</u>, if you have any questions or require additional information about this matter.

Attachments (2)

Cc: Melissa Mendoza, JD, MPH, Legislative and Regulatory Affairs Director, OPH LDH

Aliya Rubenstein, JD, MPH, Rulemaking Liaison, OPH LDH Bethany Blackson, Legislative Liaison, LDH Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

Notice of Intent

Department of Health Office of Public Health

Mandatory Tuberculosis (TB) Testing LAC 51:II.503 and 505

Under the authority of R.S. 40:4(A)(2) and R.S. 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), intends to enact and amend Sections 503 and 505 of Chapter 5 (Health Examinations for Employees, Volunteers and Patients at Certain Medical Facilities) of Part II (The Control of Diseases) of Title 51 (Public Health-Sanitary Code) of the Louisiana Administrative Code (LAC). Following guidance from the Centers for Disease Control and Prevention (CDC), as well as data monitored by LDH-OPH's Tuberculosis (TB) Control Program, this proposed rule eliminates the current requirement for annual TB testing for most employees, students or volunteers at any medical or 24-hour residential facility requiring licensing by the Louisiana Department of Health (LDH), or at any LDH-OPH parish health unit or an LDH-OPH out-patient health care facility. In lieu of annual TB testing for these persons, the rule proposes to require that certain educational materials be provided to these persons annually.

For the reasons set forth above, the following amendments to LAC 51 are proposed to be adopted.

Title 51 PUBLIC HEALTH—SANITARY CODE Part II. The Control of Diseases

Chapter 5. Health Examinations for Employees, <u>Students</u>, Volunteers and Patients at Certain Medical Facilities §503. Mandatory Tuberculosis Testing

A. [formerly paragraph 2:022] All persons, including employees, students or volunteers, having no history of latent tuberculosis infection or tuberculosis disease, prior to or at the time of employment, beginning clinical rotations in the healthcare profession, or volunteering at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the Louisiana Department of Health and Hospitals or at any Louisiana Department of Health and Hospitals, Office of Public Health (LDH-OPH) parish health unit or an LDH-OPH out-patient health care facility, or any person prior to or at the time of commencing volunteer work involvingwhose duties include direct patient care, at any hospital or nursing home (as defined in Parts XIX and XX, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the Department of Health and Hospitals or at any Department of Health and Hospitals, Office of Public Health out patient health care facility shall be free of tuberculosis in a communicable state as evidenced by either:

- 1. a negative purified protein derivative skin test for tuberculosis, five tuberculin unit strength, given by the Mantoux method or a blood assay for *Mycobacterium tuberculosis* approved by the United States Food and Drug Administration;
- 2. a normal chest X-ray, if the skin test or a blood assay for *Mycobacterium* tuberculosis approved by the United States Food and Drug Administration; is positive; or
- B. [formerly paragraph 2:023] Any employee, student or volunteer at any medical or 24-hour residential facility requiring licensing by the Louisiana Department of Health and Hospitals or at any Department of Health and Hospitals, Office of Public HealthLDH-OPH parish health unit or Department of Health and Hospitals, Office of Public Health and LDH-OPH out-patient health care facility who has a positive purified protein derivative skin test for tuberculosis, five5 tuberculin unit strength, given by the Mantoux method, or a positive blood assay for Mycobacterium tuberculosis approved by the United States Food and Drug Administration; or a chest *X-ray other than normal, in order to remain employed, remain in clinical rotations, or continue work as a volunteer, shall complete an adequate course of ehemotherapymedical treatment for tuberculosis as prescribed by a Louisiana licensed physician, or shall present a signed statement from a Louisiana licensed physician stating that ehemotherapymedical treatment for tuberculosis is not indicated.
- C. [formerly paragraph 2:024] Any employee or volunteer at any medical or 24 hour residential facility requiring licensing by the Department of Health and Hospitals or at any Department of Health and Hospitals, Office of Public Health parish health unit or Department of Public Health and Hospitals, Office of Public Health out patient health care facility who has a negative purified protein derivative skin test for tuberculosis, five tuberculin unit strength, given by the Mantoux method, or a negative result of a blood assay for Myeohaeterium tuberculosis approved by the United States Food and Drug Administration in order to remain employed or continue work as a volunteer, shall be rescreened annually by one of the following methods: purified protein derivative skin test for tuberculosis, five tuberculin unit strength, given by the Mantoux method, or a blood assay for Mycobacterium tuberculosis approved by the United States Food and Drug Administration remains negative, or a completed questionnaire asking of the person pertinent questions related to active tuberculosis symptoms, including, but not limited to: do you have a productive cough that has lasted at least 3 weeks? (Yes or No), are you eoughing up blood (hemoptysis)? (Yes or No), have you had an unexplained weight loss recently? (Yes or No), have you had fever, chills, or night sweats for 3 or more days? (Yes or No). Any employee converting from a negative to a positive purified protein derivative skin test for tuberculosis, five tuberculin unit strength, given by the Mantoux method or a blood assay for Mycobacterium tuberculosis approved by the United States Food and Drug Administration or having indicated symptoms of active tuberculosis revealed by the completed questionnaire, which indicates the person may have tuberculosis in a communicable state shall be referred to a physician and followed as indicated in §503.B. All persons with a history of latent tuberculosis infection or tuberculosis disease prior to or at the time of employment, including employment as a student in clinical rotations, or volunteering at any medical or 24-hour residential facility requiring licensing by the LDH, at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the LDH, at any LDH-OPH parish health unit. or at any LDH-OPH out-patient health care facility, whose duties include direct patient care,

must present a statement from a Louisiana licensed physician that he or she has been satisfactorily treated for tuberculosis and is non-infectious or, for persons with a history of untreated latent tuberculosis infection, a statement that he or she is non-infectious.

- 1. Further, for persons with a history of untreated latent tuberculosis infection an annual symptom screen shall be done, including, but not limited to, the following questions.
 - a. Do you have a productive cough that has lasted at least 3 weeks? (Yes or No)
 - b. Are you coughing up blood (hemoptysis)? (Yes or No)
 - c. Have you had unexplained weight loss recently? (Yes or No)
 - d. Have you had fever, chills, or night sweats for 3 or more days? (Yes or No)
- 2. Any employee, student, or volunteer with a history of untreated latent tuberculosis infection giving a positive response to any one of the questions under Paragraph 1 of this Subsection shall be referred to a physician for medical evaluation as soon as possible.
- 3. All initial screening test results and all follow-up screening test results shall be kept in each employee's, student's, or volunteer's health record or facility's personnel record.
- D. [formerly paragraph 2:033] All persons with acquired immunodeficiency syndrome (AIDS) or known to be infected with the human immunodeficiency virus (HIV), in the process of receiving medical treatment related to such condition, shall be screened for tuberculosis in a communicable state, with screening to include a chest X-ray. Sputum smear and culture shall be done if the chest X-ray is abnormal or if the patient exhibits symptoms of tuberculosis. Screening for tuberculosis shall be repeated as medically indicated. Annually, but no sooner than 6 months since last receiving tuberculosis educational information (more fully described at the end of this sentence) or symptom screening, all employees, students in the healthcare professions, or volunteers at any medical or 24-hour residential facility requiring licensing by LDH or at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the LDH or at any LDH-OPH parish health unit or an LDH-OPH and LDH-OPH out-patient health care facility shall receive, at a minimum, educational information explaining the health concerns, signs, symptoms, and risks of tuberculosis.
- E. [formerly paragraph 2:033] All persons with acquired immunodeficiency syndrome (AIDS) or known to be infected with the human immunodeficiency virus (HIV), in the process of receiving medical treatment related to such condition, shall be screened for tuberculosis, with screening to include a chest X-ray. Sputum smear and culture shall be done if the chest X-ray is abnormal or if the patient exhibits symptoms of tuberculosis disease. Screening for tuberculosis shall be repeated as medically indicated.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1220 (June 2002), amended LR 32:98 (January 2006), LR 33:93 (January 2007), LR 37:598 (February 2011), LR 40:1942 (October 2014), amended by the Department of Health, Office of Public Health, LR 47:

§505. Required Medical Examinations of All Persons Admitted to Nursing Homes and Residential Facilities [formerly paragraph 2:026]

A. Any person (adult or child) admitted to any nursing home or other residential facility shall have a complete history and physical examination, including symptoms and signs of pulmonary tuberculosis, by a licensed physician within 30 days prior to or up to 72 hours after

admission, except that any resident/patient who has complied with this provision shall be exempt from re-examination if transferred to another residential facility provided the record of examination is transferred to the new facility. This examination shall include laboratory tests as indicated by the history and physical examination. A federal United States Food and Drug Administration approved screening test for tuberculosis, i.e., a purified protein derivative skin test for tuberculosis, five tuberculin unit strength, given by the mMantoux method or a blood assay for Mycobacterium tuberculosis shall be given to all residents/patients. A chest X-ray shall be given to all residents/patients whose screening test for tuberculosis is positive, or who have signs and/or symptoms of tuberculosis no more than 30 days prior to admission to any nursing home or other residential facility. If the skin test or a blood assay for Mycobacterium tuberculosis is not done prior to admission, it may be done within 72 hours after admission and interpreted at the appropriate time. A repeat skin test or a blood assay for Mycobacterium tuberculosis is not required if the resident/patient has a chest *X-ray with no abnormalities indicative of tuberculosis and has had a negative skin test or a blood assay for Mycobacterium tuberculosis approved by the United States Food and Drug Administration, documented within one year of admission or if the resident/patient has a previously documented positive skin test or a positive result of a blood assay for Mycobacterium tuberculosis and had a chest *X-ray with no abnormalities indicative of tuberculosis. A record of the admission history, physical examination, purified protein derivative skin test for tuberculosis, five5 tuberculin unit strength, given by the Mantoux method, or a blood assay for Mycobacterium tuberculosis approved by the United States Food and Drug Administration, chest *X-ray, and any other laboratory tests shall be a part of the permanent record of each resident/patient. No resident/patient with evidence of active tuberculosis shall be admitted unless the examining physician states that the resident/patient is on an effective drug regimen, is responding to treatment, and presents no imminent danger to other residents/patients or employees, or unless the facility has been specifically approved by the Office of Public Health and the Department of Health and Hospitals LDH-OPH to house residents/patients with active tuberculosis. The approval by the Office of Public Health and the Department of Health and HospitalsLDH-OPH will include the provision that the nursing home or residential facility has a designated isolation (negative pressure) room.

B. — D. ..

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1220 (June 2002), amended LR 33:94 (January 2007), LR 38:2928 (November 2012): amended by the Department of Health, Office of Public Health, LR 47:

Family Impact Statement

In accordance with Sections 953 and 972 of Title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a family impact statement on the rule proposed for adoption, amendment or repeal.

- 1. Will the proposed rule affect the stability of the family? No; however, the identification of a family member found to be positive for TB will assist in maintaining the stability of the family because that particular family member could then seek treatment and/or isolation from other family members.
- 2. Will the proposed rule affect the authority and rights of parents regarding the education and supervision of their children? No.

- 3. Will the proposed rule affect the functioning of the family? No; however, the proposed rule will help to maintain the health of all family members and this will allow for the family to continue to function as normal.
- 4. Will the proposed rule affect family earnings and family budget? No; however, keeping family members healthy will ensure their ability to continue working and maintaining the family budget.
 - 5. Will the proposed rule affect the behavior and personal responsibility of children? No.
- 6. Is the family or a local government able to perform the function as contained the proposed rule? A family is not able to perform the function contained in the proposed rule; however, a local governmental unit which owns or operates a medical or 24-hour residential facility meeting the criteria specified in the proposed rule would be able to perform the function as contained in the rule.

Poverty Impact Statement

In accordance with Sections 953 and 973 of Title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a poverty impact statement on the rule proposed for adoption, amendment or repeal.

- 1. The effect on Household Income, Assets, and Financial Security. It is not expected that the proposed rule will have any effect on household income, assets, and financial security.
- 2. The effect on Early Childhood Development and Preschool through Postsecondary Education Development. It is not expected that the proposed rule will have any effect on early childhood development and preschool through postsecondary education development.
- 3. The effect on Employment and Workforce Development. It is anticipated that the amended rule will have a positive effect on employment and workforce development, as the amended rule eliminates the requirement for annual TB testing for most employees, students, and volunteers.
- 4. The effect on Taxes and Tax Credits. It is not expected that the proposed rule will have any effect on taxes and tax credits.
- 5. The effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. It is not expected that the proposed rule will have any effects on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

In accordance with Sections 978.1 through 978.8 of the Small Business Protection Act of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis/small business analysis on the rule proposed for adoption, amendment or repeal.

The impact of the proposed rule on small businesses as defined in the Small Business Protection Act has been considered. The Office of Public Health's TB Control Program does not expect that adoption of the proposed amendments will have an adverse economic impact on small businesses.

Provider Impact Statement

The proposed Rule should have a positive impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. Per HCR 170, "provider" means an organization that provides services for individuals with developmental disabilities. In particular, there should be a positive effect associated with no longer having the responsibility to enforce annual TB testing for all employees, students, and volunteers, as attested to by:

1. staffing level requirements or qualifications required to provide the same level of service;

- 2. total direct and indirect effect on the cost to the providers will decrease, since the cost allocated for testing will be eliminated or reduced, as testing will no longer be required for all employees, students, or volunteers; and
 - 3. overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Thursday, April 8, 2021 at COB, 4:30 p.m., and should be addressed to Allen Enger, LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Thursday, April 8, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10:00 a.m. on Tuesday, April 27, 2021, in Room 173 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after April 8, 2021. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to the Bienville Building's front security desk.

Joseph Kanter, MD, MPH State Health Officer

and

Dr. Courtney N. Phillips LDH Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

Person Preparing Michael Lacassagne Statement: LDH OPH Dept.: Phone: (504) 568-5010 Office: Tuberculosis Control Program Return Rule Address: 1450 Poydras St. Title: Mandatory Tuberculosis (TB) Testing Suite 1239 Date Rule New Orleans, LA 70112 Takes Effect: <u>Upon Promulgation</u>

SUMMARY (Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

In FY 21, this rule change is anticipated to increase the expenses of the Office of Public Health (OPH) by \$1,118 SGF for publication costs. There are no other anticipated impacts on state or local government expenditures.

The proposed rule amends Title 51, Chapter 5, Health Examinations for Employees, Students, Volunteers and Patients at Certain Medical Facilities, Sections 503 and 505. Specifically, the proposed rule clarifies which persons are required to take a tuberculosis (TB) test, adds that certain persons testing positive for TB must provide a statement to the medical facility from a doctor indicating that they are non-infectious, and adds that employees, students, and volunteers at certain health care facilities must receive annually educational information explaining the signs, symptoms, and risks of TB. The proposed rule change also removes the annual retesting requirement for certain persons that test negative for TB.

State or local governmental units that own or operate a medical or 24-hour residential facility licensed by LDH will experience a net decrease in operating costs. TB testing costs will be reduced due to the removal of the annual testing requirement. However, these savings may be partially offset by costs associated with providing annual educational materials.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no anticipated impact on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

Affected persons, small businesses, and non-governmental groups that own or operate medical facilities, nursing homes, or long-term acute care facilities will no longer have to pay for annual TB testing for employees, students, and volunteers. However, there will be a cost to produce and provide educational materials to these groups on an annual basis to employees.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There are no anticipated effects on competition or employment. However, the proposed rule may present an opportunity for interested parties to create and provide educational materials on behalf of those facilities that are required to provide annual TB education training. The proposed rule may also reduce TB testing activity for laboratories.

	Allan M. Rotan
Signature of Agency Head or Designee	Legislative Fiscal Officer or Designee
Kimberly L. Hood, JD, MPH Assistant Secretary, Office of Public Health Typed Name & Title of Agency Head or Designee	
3-8-2021	3/9/21
Date of Signature	Date of Signature