Fiscal Note for addition to rule for North Carolina Division of Public Health
Requires OSBM Review

Agency: Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Communicable Disease Branch
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Rule Citations: 10A NCAC 41A .0205, 10A NCAC 41A .0202

Purpose of Addition : 1) Update rules for discontinuation of respiratory isolation for persons with infectious tuberculosis; 2) Permit use of new blood tests for tuberculosis infection (interferon gamma release assays) in place of tuberculin skin testing for tuberculosis screening.

Relevant Statutes: GS 130A–135; 130A–144

State Impact: Yes
Local Impact: Yes
Substantial Economic Impact: No
Significant Rule Change: No

Reason for Fiscal Note
The modifications in the proposed rule change require a fiscal note because they may affect expenditures related to tuberculosis treatment and screening. The component of the rule change that reduces the number of sputum specimens required to discontinue respiratory isolation from three to two will likely decrease both expenditures for microbiology costs at the North Carolina State Laboratory of Public Health (fewer smears and cultures will be done) and expenditures by local public health staff, who have to collect the specimens from patients.

The component of the rule change permitting use of interferon gamma release assays in place of tuberculin skin testing may increase expenditure on these assays while decreasing expenditure on the labor and materials for tuberculin skin testing. However, the rule only permits the use of these assays without mandating their use in any situation; thus, no new expenditure is required by any provider. The use of interferon gamma release assays may reduce the number of persons testing positive for tuberculosis infection because these assays are more specific than the tuberculin skin test (i.e. fewer false-positive tests). This greater specificity would result in reduced public health expenditures on further evaluation and treatment of persons with false-positive tuberculin skin tests.

The inclusion of the requirement for a two-step testing for certain persons simply codifies what is the current standard of care, so it should not affect costs. Also, requiring persons with a previous positive test to have an interview and/or chest x-ray is part of current practice and would not create new costs.

The proposed modifications should have no measurable fiscal impact on physicians, other healthcare providers, or healthcare facilities, since these modifications are consistent with the current standard of medical care published by the Centers for Disease Control and Prevention (*Treatment of* Tuberculosis; MMWR 52 (RR11), pp. 1-77; *Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection—United States, 2010*; MMWR 59(RR05), pp. 1-25;), which are incorporated by reference in 10A NCAC 41A .0205.

North Carolina Communicable Disease Branch

The Communicable Disease Branch is located within the Epidemiology Section of the Division of Public Health. The goal of the Communicable Disease Branch is to conduct surveillance activities for communicable diseases, including HIV and other STDs, and other diseases reportable under NC law, and to protect the health of the citizens of North Carolina through prevention and control of those diseases. Branch staff review case report data and provide consultation and assistance to local health directors and others to investigate disease cases and outbreaks, determine appropriate controls measures to help prevent disease transmission, and ensure that these control measures are applied. The Branch is also responsible for monitoring health data from hospital emergency departments, poison center calls, ambulance data, and other sources to detect diseases that may result from terrorism and for providing situational awareness during disease outbreaks, natural disasters, or man-made disasters. In addition, the AIDS care component of the Branch ensures that

HIV/AIDS-infected individuals are able to access a continuum of care services, including case management, medical and dental care, complicated and expensive medications regimens, housing, and a full range of ancillary services.

Proposed Rule 10A NCAC 41A .0205 Control Measures-Tuberculosis

Tuberculosis is an infectious disease that predominantly affects the lungs. Persons are infected with tuberculosis when a person with active pulmonary tuberculosis (sick with tuberculosis in the lung) coughs, sneezes, sings, or breathes nearby, releasing infectious germs. These germs are inhaled, taken into the lungs, and multiply, spreading throughout the body. In most cases, the infected person's immune system successfully contains the infection, and that person will not become sick with tuberculosis. However, about 5-10% of infected persons will become sick with tuberculosis over the course of a lifetime, and once sick they may infect others. In the United States, there are two important pillars of tuberculosis control: 1) Detection and treatment of sick (and potentially infectious) persons with tuberculosis, thereby making these persons noninfectious; and 2) Preventive treatment of persons who are infected with tuberculosis but not sick, to reduce the future risk of becoming sick with tuberculosis in these persons.

The proposed rule changes would affect both of these pillars of in tuberculosis control as follows:

1. Permitting blood tests for tuberculosis infection (interferon gamma release assays) to be used to screen for tuberculosis infection in specified populations (in place of the tuberculin skin test)
2. Reducing the number of negative sputum specimens required to discontinue respiratory isolation from three to two for infectious (i.e. smear-positive) tuberculosis cases

The fiscal impact of these changes will be considered separately. Overall, the state government stands to incur annual cost savings of about $23,000, and the local health departments would incur almost $160,000 cost savings per year.

1) Fiscal impact of permitting blood tests for tuberculosis infection (interferon gamma release assays) to be used to screen for tuberculosis infection in specified populations (in place of the tuberculin skin test)

Background: Interferon gamma release assays are relatively new blood tests to detect tuberculosis infection. These blood tests are recommended for use by the Centers for Disease Control and Prevention in most situations in which a tuberculin skin test could be used. Advantages of these tests over the tuberculin skin test are the need for only a single patient visit to perform the test (single blood draw), as opposed to two visits for the tuberculin skin test, and greater test specificity, which theoretically will result in fewer persons testing positive when they do not truly have tuberculosis infection.

Costs: Interferon gamma release assays have a list price of approximately $90-$180 per test (state cost for the least expensive test, the T-SPOT.TB, currently is $48.50). If the T-SPOT test is drawn at a local health department, approximately 10 minutes of phlebotomist time (at $12.84/hour=$2.14) plus the cost of a tube and phlebotomy supplies (estimated at $2: $0.34 for a 9 ml lithium heparin tube plus another $1.66 for butterfly needle, gauze, and other supplies) would be needed, and those costs would pass to the local health department. When these assays are drawn at private laboratories, these costs are usually folded into the list price. The reagent for the tuberculin skin test costs about $2 per test, plus nursing costs to place and read the test (estimated ½ hour total for placement and reading x $19.59/hr=$9.80), for total test cost of about $12 per test. Persons with a positive test (either tuberculin skin test or interferon gamma release assay) require an interview (approximately 20 minutes nursing time x $19.59/hr=$6.53), a chest radiograph (approximately $150 cost), and are offered treatment for latent tuberculosis if they are not sick (approximate monthly cost of treatment is $26.52 for clinic visits and laboratory monitoring, $1.20 for medication, and treatment lasts for 9 months).

Payment sources: Interferon gamma release assays will not generally be paid for by state or local health departments, with the exception of selected tuberculosis contact investigations. Costs will be borne by private insurance, Medicaid, or self-payment by patients. The rule change does not require these tests in place of the tuberculin skin test, only makes them acceptable, so no patient will be required to pay for the more expensive test. Currently, tuberculin for the tuberculin skin test is provided by the state to local health departments at no charge, as are tuberculosis medications. Persons who are contacts to an infectious tuberculosis case or otherwise high-risk are provided a chest radiograph at no cost to the patient (paid for by the local health department). Medications for treatment and prevention of tuberculosis are, in turn, provided to patients at no charge. The provision of tuberculin skin testing, chest radiographs, and medications are current policy and will not be affected by the proposed rule change. Furthermore, the proposed rule change does not add any new categories of persons to be tested, so the overall number of persons to be tested should remain approximately the same.

Total estimated fiscal impact: The total estimated fiscal impact of the proposed rule changes is shown below. Note that these estimates are based on specific assumptions (see below), and the actual impact will likely differ from these estimates.

NC DPH TB Control Measures Rule Change- Impact Analysis Base Case Local Health Department Costs			
		Unit Cost	**Total Cost**
Total number of persons tested for TB infection with a tuberculin skin test in 2009	92,974	$9.80	$911,145
Total number testing positive for TB infection in 2009	4,045		
Total number of persons testing positive for TB infection who were candidates for preventive treatment in 2009	3,613		
Estimated number of chest radiographs paid for by local health departments to screen persons with TB infection in 2009 (includes cost of radiograph and nursing time)	2,278	$156.53	$356,575
Estimated number of persons testing positive for TB infection who started preventive treatment in 2009	2,006		
Estimated number of persons starting preventive treatment who did not complete preventive treatment	540	$79.56	$42,962
Estimated number of persons starting preventive treatment who completed preventive treatment	1,466	$238.68	$349,905
Estimated total costs			$1,660,587

Assumptions: Cost of radiography, laboratory monitoring, and labor are borne by the local health department. Cost of TB medication and tuberculin is borne by the state TB program. Persons who don't complete preventive treatment complete an average of 3 months (of 9 months total) of treatment, with the same monthly labor cost as those who do complete preventive treatment. The number of persons would hold for the next few years if there were no rule change (while TB cases are decreasing, there is year-to-year variability in the amount of persons undergoing treatment and testing due to immigration, migration, and other factors; the agency feels that the 2009 numbers are a close estimate of future levels).

NC DPH TB Control Measures Rule Change- Impact Analysis Post-rule change projected Local Health Department Costs			
		Unit Cost	**Total Cost**
Total number of persons tested for TB infection with a tuberculin skin test	83,677	$9.80	$820,035
Total number of persons tested for TB infection **at a local health department using local health department funds** with an interferon gamma release assay	100	$48.50	$4,850
Total number of persons tested for TB infection at a local health department using either local health department or state funds with an interferon gamma release assay (phlebotomy/local health department laboratory costs)	400	$4.14	$1,656
Total number testing positive for TB infection	3,641		
Total number of persons testing positive for TB infection who were candidates for preventive treatment in 2009	3,252		
Estimated number of chest radiographs paid for by local health departments to screen persons with TB infection in 2009	2,050	156.53	$320,887
Estimated number of persons testing positive for TB infection who started preventive treatment in 2009	1,805		
Estimated number of persons starting preventive treatment who did not complete preventive treatment	486	$79.56	$38,666
Estimated number of persons starting preventive treatment who completed preventive treatment	1,319	$238.68	$314,819
Estimated total costs			$1,500,913

Assumptions: Permitting interferon gamma release assays will reduce tuberculin skin testing performed at local health departments by 10%, and will reduce the proportion of positive results by 10% due to greater specificity. The 10% reduction in tuberculin skin testing by local health departments is a conservative estimate based on the increased convenience of the interferon gamma release assay for non-health department providers and patients. The assumption of a reduction in the proportion of positive results is a conservative estimate based on a recently published study of military recruits at Fort Jackson, SC, in which 38/2017 recruits tested positive using tuberculin skin testing, and 34 tested positive using the T-SPOT (38-34/38=0.10, reference Mancuso JD et al., *Clinical Infectious Diseases* 2011; Volume 53, pp. 234-244). Of the 400 people getting tested using the interferon gamma release assay, 100 will be testing using local health department funds and the other 300 using state funds. This assumption is an estimate based on discussion with local health departments (willingness to pay for such testing) and the amount of unobligated funds that have been available to the state tuberculosis program for this use, and is clearly subject to change. The proportion of persons accepting and completing preventive treatment will remain the same.

Net estimated cost to local health departments=$1,500,913-$1,660,587=-$159,674. So, local health departments would be incurring a cost savings of $159,674 per year from the proposed rule.

NC DPH TB Control Measures Rule Change- Impact Analysis
Base Case State TB Program Costs

		Unit Cost	Total Cost
Total number of persons tested for TB infection with a tuberculin skin test in 2009	92,974	$2.00	$185,948
Total number testing positive for TB infection in 2009	4,045		
Total number of persons testing positive for TB infection who were candidates for preventive treatment in 2009	3,613		
Estimated number of persons testing positive for TB infection who started preventive treatment in 2009	2,006		
Estimated number of persons starting preventive treatment who did not complete preventive treatment	540	$3.60	$1,944
Estimated number of persons starting preventive treatment who completed preventive treatment	1,466	$10.80	$15,833
Estimated total costs			$203,725

NC DPH TB Control Measures Rule Change- Impact Analysis
Post-rule change projected State TB Program Costs

		Unit Cost	Total Cost
Total number of persons tested for TB infection with a tuberculin skin test	83677	$2.00	$167,354
Total number of persons tested for TB infection **at a local health department using NC TB control funds** with an interferon gamma release assay	300	$48.50	$14,550
Total number testing positive for TB infection	3641		
Total number of persons testing positive for TB infection who were candidates for preventive treatment in 2009	3252		
Estimated number of persons testing positive for TB infection who started preventive treatment in 2009	1805		
Estimated number of persons starting preventive treatment who did not complete preventive treatment (medication costs)	486	$3.60	$1,750
Estimated number of persons starting preventive treatment who completed preventive treatment	1319	$10.80	$14,245
Estimated total costs			$197,899

Net estimated cost to state TB control program=$197,899-$203,725=-$5,826. The state government would be incurring a cost savings of $5,826 annually from the proposed rule.

We have not explicitly quantitated the time and cost savings for patients, in part because of the wide range of incomes and situations faced by our patients. However, the interferon gamma release assays will clearly save patients time, as they obviate the need for the second provider visit currently required for tuberculin skin test reading. Each interferon gamma release assay saves the patient the time to travel to and attend this second provider visit, and for those patients who are working, reduces time off from work and potentially saves money. The net cost of the interferon gamma assay to patients is difficult to quantitate, as insurance policies vary in coverage of the test and co-payment policies, but test costs would be at least partially offset by savings in time/travel costs, as well as (on a population basis) a reduction in the number of persons who would require medications for latent tuberculosis infection.

These estimated costs are obviously sensitive to the assumptions used, but given that use of interferon gamma release assays is entirely optional under the rule change, the conclusion that permitting use of these tests will be cost-saving is robust under a wide range of assumptions, with a minimum cost savings of $0 if no providers use interferon gamma release assays (i.e. status quo).

2) Fiscal impact of reducing the number of negative sputum specimens required to discontinue respiratory isolation from three to two for infectious (i.e. smear-positive) tuberculosis cases

Background: Sputum smears for acid-fast bacilli (AFB) are used, along with clinical response to treatment, to determine whether a person with tuberculosis disease in the lungs is contagious. The prior rule 10A NCAC 41A .0205 required three consecutive sputum smears to be negative for AFB to deem a patient no longer contagious and permit discontinuation of respiratory isolation. The proposed rule change reduces this requirement to two consecutive sputum smears, which is consistent with scientific data (i.e. the additional yield of the third specimen in detecting infectious tuberculosis is very low) and Centers for Disease Control and Prevention guidelines.

Costs: A sputum specimen for AFB smear and culture (done on all specimens) costs $37.69 at the North Carolina State Laboratory of Public Health (which is where almost all specimens used for follow-up testing are sent). Also, this reduction will reduce the loss of income and inconvenience to 86 patients due to excessive time on respiratory isolation as well as health department and laboratory workload.

Payment sources: The sputum specimens are performed at the North Carolina State Laboratory of Public Health at state expense (no charge to the patient or local health department). If a specimen cannot be obtained spontaneously, a nurse from the local health department will attempt induction with hypertonic saline, which requires approximately ½ hour of nursing time. As an estimate, approximately 25% of specimens will be obtained by sputum induction.

Total estimated fiscal impact: Of the 192 reported tuberculosis cases in 2009 with pulmonary (and potentially infectious) disease, 86 had positive AFB sputum smears. The rule change would apply to these persons. Per the North Carolina TB Manual, a set of sputums (3 previously, will be 2 under the rule change) are collected at least every 2 weeks for these patients until culture conversion is documented. The mean time to culture conversion for smear-positive patients is approximately 5 weeks, and cultures require 6 weeks from collection to receive a final “negative” report, so on average specimens would be collected for 11 weeks (5 additional sets of specimens after the first). The rule change will reduce the number of specimens collected for each of the five additional sets from three to two (as per standard practice, 3 specimens will continue to be collected at the initial set of sputums), resulting in the following yearly decrease in costs:

5 fewer specimens/patient x 86 patients x ($37.69 laboratory cost + .25 x $19.59/hr x 0.5 nursing hours in case of sputum induction) = $17,260 in savings to the state, assuming number of patients sputum is collected from stays constant.

The reduction in number of sputum specimens required could potentially reduce the average time spent in respiratory isolation for each patient by one day, depending on how frequently sputums were being obtained before (Centers for Disease Control permit collection as frequently as every 8 hours, which in practical terms means that 2 sputums can be collected in a day), but given the time required for a specimen to get to the laboratory, be processed and a result reported, the reduction in respiratory isolation is likely to average less than one day per patient under the new rule.

Note: Mean hourly wage for a Public Health Nurse II, obtained from the Public Health Nursing Program in the NC Division of Public Health=$19.59.

APPENDIX

10A NCAC 41A.0205 is proposed for amendment as follows:

10A NCAC 41A .0205 CONTROL MEASURES – TUBERCULOSIS

(a) The local health director shall investigate all cases of tuberculosis disease and their contacts in accordance with the provisions of the Control of Communicable Diseases Manual which is hereby incorporated by reference including subsequent amendments and editions. Copies of this publication may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldorf, MD 20604 for a cost of twenty-two dollars ($22.00) each plus five dollars ($5.00) shipping and handling. A copy is available for inspection in the Division of Public Health, 1931 Mail Service Center, Raleigh, North Carolina 27699-1931.

(b) The following persons shall ~~be skin tested for tuberculosis~~ have a tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) and given appropriate clinical, microbiologic and x-ray examination in accordance with the ~~"Diagnostic Standards and Classification of Tuberculosis in Adults and Children," published by the American Thoracic Society.~~ "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis," "Guidance for Preventing the Transmission of Tuberculosis in Health Care Facilities," "Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from the CDC," and the "Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection---United States, 2010" published by the Centers for Disease Control and Prevention. The recommendations contained in ~~this~~ these references shall be the required control measures for evaluation, testing, and diagnosis for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions:

(1) Household and other high priority contacts of active cases of pulmonary and laryngeal tuberculosis. For purposes of this Rule, a high priority contact is defined in accordance with Centers for Disease Control and Prevention guidelines which are incorporated by reference in Rule .0201 of this Section. If the contact's initial IGRA or skin test is negative ~~(0-4mm)~~, and the case is confirmed by culture, a repeat IGRA or skin test shall be performed 8 to 10 weeks after the exposure has ended;

(2) Persons reasonably suspected of having tuberculosis disease;

(3) Inmates in the custody of~~, and staff with direct inmate contact in,~~ the Department of Corrections upon incarceration ~~or employment~~, and annually thereafter;

(4) Staff with direct inmate contact in the Department of Corrections upon employment, and annually thereafter. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months. A single skin test shall be given if the individual has had a single, documented, negative tuberculin skin test within the preceding 12 months. A single IGRA may be used in place of the tuberculin skin test; only one IGRA need be performed upon employment regardless of whether the individual has had a documented skin test within the preceding 12 months;

~~(4)~~(5) ~~Patients and s~~Staff in long term care facilities upon ~~admission or~~ employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months. A single skin test shall be given if the individual has had a single, documented, negative tuberculin skin test within the preceding 12 months. A single IGRA may be used in place of the tuberculin skin test; only one IGRA need be performed upon employment regardless of whether the individual has had a documented skin test within the preceding 12 months;

(6) Residents upon admission to licensed nursing homes or adult care homes. The two-step skin test method shall be used if the individual is being admitted from any setting other than a hospital, licensed nursing home or adult care home in North Carolina without a documented tuberculin skin test within the preceding 12 months. A single skin test shall be given if the individual is being admitted directly from any setting with only a single documented negative tuberculin skin test within the preceding 12 months. If the individual is being admitted directly from another hospital, licensed nursing home or adult care home in North Carolina and there is documentation of a two-step skin test, the individual would not need to be retested. A single IGRA may be used in place of the tuberculin skin test; only one IGRA need be performed upon admission regardless of whether the individual has had a documented tuberculin skin test within the preceding 12 months;

(5) Staff in adult day care centers providing care for persons with HIV infection or AIDS upon employment. The two-step skin test method shall be used if the individual has not had a documented tuberculin skin test within the preceding 12 months. A single IGRA may be used in place of the tuberculin skin test; only one IGRA need be performed upon admission regardless of whether the individual has had a documented tuberculin skin test within the preceding 12 months; and

(6) Persons with HIV infection or AIDS.

Persons with a prior positive tuberculin skin test or IGRA should be evaluated by an interview to screen for symptoms and a chest x-ray if they do not have a documented chest x-ray that was performed on the date of the positive test or later.

A copy of "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" is available by contacting the Division of Public Health, 1931 Mail Service Center, Raleigh, North Carolina 27699-1931 or by accessing the Centers for Disease Control and Prevention website at http://www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/cdc_ats_guidelines.htm.

(c) Treatment and follow-up for tuberculosis infection or disease shall be in accordance with "Treatment of Tuberculosis," published by the American Thoracic Society. The recommendations contained in this reference shall be the required control measures for testing, treatment, and follow-up for tuberculosis patients, contacts and suspects, except as otherwise provided in this Rule and are incorporated by reference including subsequent amendments and editions. Copies of this publication are available by contacting the Division of Public Health, 1931 Mail Service Center, Raleigh, North Carolina 27699-1931 or by accessing the Centers for Disease Control and Prevention website at http://www.cdc.gov/nchstp/tb/pubs/mmwrhtml/Maj_guide/cdc_ats_guidelines.htm.

(d) The attending physician or designee shall instruct all patients treated for tuberculosis regarding the potential side effects of the medications prescribed and prescribed medications, including instructions to promptly notify the physician or designee if side effects occur.

(e) Persons with active tuberculosis disease shall complete a standard multi-drug regimen, unless otherwise approved by the State Tuberculosis Medical Director or designee, and shall be managed using Directly Observed Therapy (DOT), which is the actual observation of medication ingestion by a health care worker (HCW).

(f) Persons with suspected or known active pulmonary or laryngeal tuberculosis who have sputum smears positive for acid fast bacilli are considered infectious and shall be managed using airborne precautions, including respiratory isolation,

or isolation in their home, with no new persons exposed. These individuals are considered noninfectious and use of airborne precautions, including respiratory isolation or isolation in their home, may be discontinued when:

(1) Appropriately obtained sputum specimens meet Centers for Disease Control and Prevention and North Carolina Tuberculosis Control guidelines for discontinuation of respiratory isolation;

(~~1~~2) They have ~~three~~ two consecutive sputum smears collected at least eight hours apart which are negative; ~~and~~

(3) It has been at least seven days since the last positive sputum smear; and

(~~1~~)(4) They have been compliant on tuberculosis medications to which the organism is judged to be susceptible and there is evidence of clinical response to tuberculosis treatment.

(g) Persons with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative do not require respiratory isolation once they have been started on tuberculosis treatment to which the organism is judged to be susceptible and there is evidence of clinical response to treatment.

History Note: Authority G.S. 130A-135; 130A-144;