TO: Local and District Health Directors

FROM: Jason Stout, M.D., MHS
Medical Director, North Carolina Tuberculosis Control Program

DATE: July 20, 2012

RE: Permanent Rule Change 10A NCAC 41A .0205

1) Effective August 1, 2012, a permanent rule change has been implemented that impacts two areas of tuberculosis control: respiratory isolation as an outpatient and screening for tuberculosis infection.

2) The permanent rule implements the changes from the temporary rule that took effect August 1, 2011. As a reminder, these changes modified the requirements for discontinuation of respiratory isolation for persons with smear-positive pulmonary or laryngeal tuberculosis. The requirement for three negative sputum smears for acid-fast bacilli has been reduced to two negative sputum smears.

3) In light of the rule change, the procedure for sputum collection from persons with suspected or confirmed pulmonary or laryngeal tuberculosis is modified as follows:
   a. For initial evaluation, three (3) sputum specimens (induced or natural) should be collected, with a minimum interval of 8 hours between specimens. At least one specimen should be an early morning specimen if possible.
   b. For subsequent evaluation of all patients (initially acid-fast smear-negative or smear-positive), two (2) sputum specimens (induced or natural) should be collected, with a minimum interval of 8 hours between specimens. At least one specimen should be an early morning specimen if possible.
   c. Subsequent sets of sputum specimens should be collected no more frequently than 1 week apart. If a patient has a positive sputum smear in a given week, that patient should remain on isolation for the week, and another set of sputum specimens should be collected the following week.
   d. Respiratory isolation may be discontinued for patients who are clinically responding to antituberculous medications if two consecutive sputum specimens (collected at least a week after the most recent smear-positive sputum specimen) are smear-negative with no subsequent smear-positive specimens.

4) The second major area impacted by the rule change involves screening for latent tuberculosis infection. The permanent rule change permits the use of interferon gamma release assays (Quantiferon Gold in-tube® or T-SPOT.TB®) for latent tuberculosis screening in many populations. The rule change also clarifies when two-step tuberculin skin testing should be used. These changes are summarized as follows:
a. Interferon gamma release assays may be used in essentially all circumstances where a tuberculin skin test would be used. A single interferon gamma release assay replaces either one-step or two-step tuberculin skin testing.

b. Specifically, the rule change permits use of interferon gamma release assays for the following populations (for whom tuberculosis screening is required): tuberculosis contacts, persons suspected of having active tuberculosis, inmates, Department of Corrections staff, persons with HIV/AIDS, residents and employees of licensed nursing homes and adult care homes

c. Two-step testing (if a single interferon gamma release assay is not used) is required for the following populations: staff of adult care homes/nursing homes upon employment, residents upon initial admission to a licensed nursing home or adult day care, Department of Corrections staff upon employment, and staff in adult day care centers providing care for persons with HIV/AIDS upon employment

d. Two-step testing is not necessary (only a single skin test need be used) if the individual has had a documented skin test within the preceding 12 months or has ever had documented two-step skin testing in the past

e. Individuals who are being admitted directly from a hospital, licensed nursing home or adult care home and who have documentation of either a two-step tuberculin skin test or a single interferon gamma release assay do not need to be retested

This rule change and change in policy are consistent with best practices and Centers for Disease Control and Prevention guidelines. Note that hospital policies for discontinuation of respiratory isolation, which are determined by individual hospitals’ infection control departments and based on CDC guidelines, would take precedence if they require more specimens (usually 3) for discontinuation of respiratory isolation. Furthermore, the rule does not proscribe yearly testing of correctional employees or initial/yearly testing of healthcare workers. Such persons should be tested in accordance with current CDC guidelines, depending on the risk assessment profile of the facility (see relevant guidelines at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm and www.cdc.gov/mmwr/pdf/rr/rr5417.pdf, respectively). Please contact me or your regional nurse consultant if you have any questions or concerns.

Cc: Megan Davies, MD, MPH
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    Jean-Marie Maillard, MD
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    TB Medical Advisory Committee