



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH**

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Audrey Tayse Haynes
Secretary

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Dear Health Care Facility Operator or Long Term Care Administrator:

Health care facility and long term care facility employee health programs may be impacted by two nationwide shortages of medications used in your Tuberculosis (TB) Infection Control Program. First, the Centers for Disease Control (CDC) announced a nationwide shortage of 300 mg isoniazid (INH) tablets in the MMWR issue of December 21, 2012, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6150a4.htm?s_cid=mm6150a4_w. Since that time, shortages of 100 mg INH tablets have also been reported. These INH shortages may not be resolved before late March 2013. Second, in late January 2013, the Association of Health System Pharmacists announced shortages of some formulations of Tubersol[®] brand of Tuberculin Purified Protein Derivative (tuberculin) produced by Sanofi Pasteur that is used for tuberculin skin tests (TSTs). The Tubersol shortage may also not be resolved before late March 2013, <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=973>.

The Kentucky Tuberculosis Program does not recommend that health care facilities or long term care facilities experiencing shortages of Tubersol switch to Aplisol[®], the other brand of tuberculin marketed in the United States. CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005," <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>, recommended that "TB screening programs should use one antigen consistently and should realize that changes in products might make serial changes in TST results difficult to interpret. In one report, systematic changes in product use resulted in a cluster of pseudoconversions that were believed to have erroneously indicated a health-care-associated outbreak." The shortage of INH that can be used to treat either active TB disease or latent TB infection diagnosed during TB screening would further magnify the impact of any false-positive test results or pseudoconversions on your employee health programs.

A Blood Assay for *Mycobacterium tuberculosis* (BAMT) would be another option for TB screening in health care facilities and long term care facilities and would remove some of the administrative and logistic problems associated with using tuberculin. The QuantiFERON[®]-TB Gold In-Tube test and the T-SPOT[®].TB test are the two BAMTs marketed in the United States, and both those tests are interferon-gamma release assays (IGRAs). In 2010, CDC recommended in "Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection – United States, 2010," <http://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf>, that "An IGRA may be used in place of (but not in addition to) a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing *M. tuberculosis* infection, with preferences and special considerations noted [in those guidelines]. . . Despite the indication of a preference in these instances, use of the alternative test (FDA-approved IGRA or TST) is acceptable medical and public health practice."



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A CDC Fact Sheet titled "TB Elimination: Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection," lists advantages and disadvantages of these tests and is available online, <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf>.

Presently, BAMTs (IGRAs) are not listed as TB screening options in Kentucky regulations for health care facilities and long term care facilities. Regulation changes have been drafted to permit health care facilities and long term care facilities to use either TSTs or BAMTs (IGRAs) for TB screening, and the Cabinet anticipates that those changes should be submitted to the Legislature in April, 2013.

Additionally, the Office of Inspector General will not cite any health care facility or long-term care facility in violation of regulatory requirements for skin testing if the facility elects to use BAMTs in lieu of TSTs for TB screening. This policy is consistent with forthcoming regulatory changes and is effective as of the date of this letter.

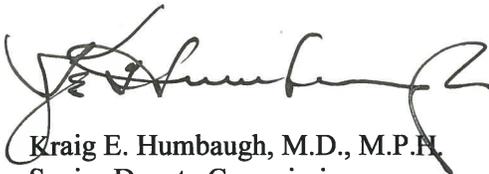
The Kentucky Department for Public Health and the Office of Inspector General hope that the information provided in this letter will aid your employee health programs.



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