



May 28, 2014

Name of Laboratory Director
Or Current Lab Director
Name of Laboratory
Address
City, State Zip Code

RE: Revisions to the Pennsylvania Clinical Laboratory Act - Act 122-2013

Dear

As you are aware, the Pennsylvania Department of Health (Department), Bureau of Laboratories (Bureau) licenses (permits) clinical laboratories under the Pennsylvania Clinical Laboratory Act (Title 35 P.S. Ch. 21) (Lab Act). On December 18, 2013, Governor Corbett signed Act 122-2013 into law, resulting in significant changes to the Lab Act that may impact the operation of your clinical laboratory. These changes, which are summarized below, became effective on December 18, 2013. However, the Department will be phasing-in these changes to ensure an orderly transition to the Act 122 requirements.

Expanded Scope of the Lab Act

The scope of the Lab Act has been expanded to include both those clinical laboratories located in Pennsylvania (in-state clinical laboratories) and those clinical laboratories located outside of Pennsylvania (out-of-state clinical laboratories) that test specimens collected in Pennsylvania. Previously, out-of-state clinical laboratories could perform many tests on specimens collected in Pennsylvania without the need to obtain a permit under the Lab Act provided they were certified under the federal Clinical Laboratory Improvement Amendments (CLIA). Now, both in-state clinical laboratories and out-of-state clinical laboratories that test specimens collected in Pennsylvania are required to hold permits.

Out-of-state clinical laboratories that require licensure under Act 122 but do not currently hold a permit must submit a permit application to the Bureau. Applications are available in the Clinical Lab Licensure section of the Bureau's website (www.health.state.pa.us/labs). The deadline for out-of-state clinical laboratories not currently licensed by the Department to apply for a permit without penalty is August 15, 2014. The initial fee for a permit is \$100. Permits will be valid through August 15, 2015.



Thereafter, annual renewal fees will be imposed as specified in the Department's regulations.

Prohibited Activities

The Lab Act now contains prohibitions against specific activities that might be used to induce a health care provider/practitioner to refer specimens to a particular clinical laboratory.

Under Act 122 it is generally unlawful for clinical laboratories to:

- Pay or receive a commission, bonus, kickback or rebate or engage in a split-fee arrangement in any form with a health care provider/practitioner.
- Lease or rent space, shelves or equipment or other services within a health care provider's/practitioner's office. This includes leasing or renting space for the purpose of establishing a specimen collection station.
- Directly or indirectly provide personnel to perform functions or duties within a health care provider's/practitioner's office for any purpose regardless of whether fair market value is offered or given.
- Permit the placement of paid or unpaid personnel to perform services (e.g., specimen collection, processing, packaging or handling or genetic counseling) in a health care provider's/practitioner's office.

Previously, the Department allowed laboratories licensed under the Lab Act to offer some specimen acceptance services in the offices of health care providers/practitioners. Out-of-state clinical laboratories not required to hold permits were not subject to any prohibitions related to specimen collection and acceptance. This practice is no longer allowed under Act 122. Therefore, laboratories must remove specimen collectors and/or other personnel from health care provider's/practitioner's offices by September 15, 2014 in order to avoid penalties.

Exceptions

Act 122 contains three (3) enumerated exceptions:



- 1) A health care provider/practitioner that owns and operates its own clinical laboratory may place its employees in the clinical laboratory.
- 2) A clinical laboratory licensed by the Department can refer specimens to another clinical laboratory licensed by the Department or to a CLIA-accredited or certified clinical laboratory.
- 3) Clinical laboratories are allowed to own or invest in a building in which space is leased or rented for adequate and fair consideration to health care providers/practitioners.

Fining Authority

The Department now has the authority to impose fines of up to \$500 per day for violations of the Act or Department regulations, including violations relating to specimen collection, handling, and acceptance services.

Please review the enclosed “Frequently Asked Questions” document. Additional questions may be addressed to Mary McCormick, Director, Division of Laboratory Improvement, at mamccormic@pa.gov and will be answered in future FAQ pages on the Bureau’s website. You may also view the entire text of Act 122 at the following link:

<http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=HTM&ses sYr=2013&sessInd=0&billBody=S&billTyp=B&billNbr=1042&pn=1578>

Sincerely,

/signed/

Julia A. Kiehlbauch, Ph.D., D(ABMM)
Director, Bureau of Laboratories