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Memorandum

To: Gene M. Ransom, III

From: Pamela Metz Kasemeyer

Date: **June 10, 2016**

RE: Senate Bill 926/House Bill 399 – *Lyme Disease – Laboratory Test – Required Notice*

This memorandum is in response to your request for information on the above-referenced legislation, which Governor Hogan signed into law on May 5, 2016. Please feel free to share this information with MedChi members through MedChi News or other appropriate forums. While I believe that the bill's provisions will have minimum impact on the majority of physician offices, for those affected, they will need to meet specific requirements beginning October 1, 2016, which are discussed in detail below.

Affected Providers/Facilities:

1. A health care provider licensed in the State who draws the blood of a patient to perform a laboratory test of Lyme disease.

2. A licensed medical laboratory that performs a laboratory test for the presence of Lyme disease.

Required Action:

1. At the time a patient's blood is drawn for the performance of a laboratory test for the presence of Lyme disease, the patient must be provided a written notice related to the Lyme disease test that is to be performed.

2. The required language of the notice is provided in the law and must read EXACTLY as follows:

   "Your health care provider has ordered a laboratory test for the presence of Lyme disease for you. Current laboratory testing for Lyme disease can be problematic and standard laboratory tests often result in false negative and false positive results and, if done too early, you may not have produced enough antibodies to be considered positive because your immune response requires time to develop antibodies. If you are tested for Lyme disease and the results are negative, this does not necessarily mean you do not

have Lyme disease. If you continue to experience unexplained symptoms, you should contact your health care provider and inquire about the appropriateness of retesting or initial or additional treatment."

Effective Date:

The law is effective October 1, 2016. The written notice provided above must be provided as of that date.

DHMH Authority to Change to the Language of the Notice;

The Department of Health and Mental Hygiene may change the content of the notice through the adoption of regulations if the Department finds significant differences between the content of the required notice and the current medical evidence on Lyme disease testing. Prior to changing the notice, the Department must notify the Senate Finance Committee and the House Health and Government Operations Committee of the proposed changes.

NOTE: Providers who draw blood when ordering a laboratory test for Lyme disease should provide the required written notice utilizing the language reflected above and not presume there have been any regulatory changes to the required notice unless advised by the Department. On a practical note, any changes would not occur until long after the bill is in effect and only if the medical evidence related to Lyme disease testing changes.

Liability Protection:

The provision by a health care provider or medical laboratory of the required notice may not be the sole basis for a cause of action.