Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
286 Water Street
Augusta, Maine 04333-0011
Tel; (207) 287-8016; Fax (207) 287-9058
TTY: Dial 711 (Maine Relay)

March 22, 2023

Senator Joseph Baldacci, Chair
Representative Michele Meyer, Chair
Members, Joint Standing Committee on Health and Human Services
100 State House Station
Augusta, ME 04333-0100

Re: LD 906 - An Act to Ensure Physicians Receive Full Diagnostic Test Data Concerning Tick-borne Diseases

Dear Senator Baldacci, Representative Meyer, and Members of the Committee on Health and Human Services:

This letter is to provide information about LD 906, *An Act to Ensure Physicians Receive Full Diagnostic Test Data Concerning Tick-borne Diseases*, and the potential impact of the proposed legislation, if enacted.

The Maine Center of Disease Control and Prevention (Maine CDC) has concerns with this bill and offers the following information for your consideration.

LD 906 requires a medical laboratory that reports the results of a diagnostic test for a tick-borne disease, including Lyme disease, babesiosis, anaplasmosis and ehrlichiosis, to report all information gathered in the process of producing the test result, including the specific data used to determine the result.

Commercially available human clinical diagnostic laboratory tests, also known as in vitro diagnostic tests, are regulated by the U.S. Food and Drug Administration (FDA). Laboratory developed tests (LDTs) are a type of in vitro diagnostic test that is designed, manufactured, and used within a single laboratory. Both commercially available tests and LDTs are regulated by the Centers for Medicare and Medicaid Services (CMS) in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Both the FDA and CLIA regulate the description and narrative of the laboratory result. Laboratories using a commercial test may not modify the description or narrative of the laboratory result without first contacting and submitting a request to the FDA. Laboratories utilizing LDTs are not required to submit requests to FDA to modify the description and/or narrative of their results, but still must follow FDA and CLIA regulations.

Laboratory test reports are designed to provide the most medically important information in an easily understandable format so that medical providers can understand the results and discuss the results with their patients. Additional information may cause confusion as to the true result, potentially impacting clinical management of the patient.

Test methods, including sample management, reference ranges, personnel, and equipment, are not consistent across all laboratories. Therefore, patient results may not be directly comparable between laboratories whether using different test methods or even the same test methods. Instead, all laboratory results must be individually evaluated by a medical provider in combination with other medically relevant information specific to the patient.

Extraneous information, other than the actual laboratory test result, is not relevant to medical decisions and patient management. This 'other information' is used by laboratories to monitor test quality and may be used for academic research purposes.

The bill language is broad; as written, reporting facilities could have an infinite number of requirements. This additional burden is an undue cost to the laboratories responsible for reporting these additional data. Meeting these requirements would likely require personnel and informatics costs that would need to be passed on to consumers and patients.

In summary, the Maine CDC respectfully recommends this bill ought not to pass. Providing all laboratory data related to reporting tick-borne disease results would cause a significant workload increase resulting in increased costs to the laboratory and patients. All medically important information is already required to be reported and the inclusion of all non-medically pertinent data may cause confusion related to the results.

Thank you for your consideration of this matter. The Maine CDC is available to provide additional details for the Committee's consideration.

Respectfully,

Nancy Beardsley, Acting Director
Maine Center for Disease Control and Prevention