

September 9, 2008

MDCH to Recommence the Enforcement of Michigan Clinical Laboratory Licensure Laws

On August 25, 2008, the Michigan Department of Community Health ("MDCH"), Bureau of Health Systems, sent thousands of letters to Michigan clinical laboratories mandating each laboratory to provide it with information sufficient to enable MDCH to determine if the laboratories are required to be licensed under the Michigan Public Health Code ("Code"). By requesting the information, MDCH deviated from its historical practice of not enforcing those laws requiring certain clinical laboratories to be licensed in the State of Michigan.

Although Michigan law technically has required the licensure of clinical laboratories for many years, MDCH discontinued enforcing the state licensure laws following the release of the federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). We understand that this practice was based on the belief that the Michigan Legislature would repeal state licensure laws in light of CLIA's comprehensive regulation of laboratory testing. Michigan's Legislature, however, has yet to repeal the state laws regarding licensure of clinical laboratories. Therefore, after years of non-enforcement, MDCH has indicated that it is obligated to enforce all relevant state laboratory licensure laws. Thus, it is requiring **all** clinical laboratories performing testing in the State of Michigan to submit an Application for Laboratory Licensure ("Application").

While not every one of the clinical laboratories operating in Michigan will be obligated to be licensed under the Code, **all** clinical laboratories performing testing in the State of Michigan must complete and submit an Application to MDCH by **September 12, 2008**. Failure to complete the Application by the deadline could jeopardize a laboratory's ability to perform testing in Michigan.

The Application can be accessed at the [MDCH Laboratory Improvement Section website](#). If you need assistance completing the Application, or have questions regarding the State of Michigan's licensure of clinical laboratories, please contact Matthew R. Keuten or any member of the Honigman Health Care Department listed below.

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