

Department of Legislative Services  
Maryland General Assembly  
2014 Session

FISCAL AND POLICY NOTE

House Bill 1226 (Delegate A. Kelly, *et al.*)  
Health and Government Operations and  
Judiciary

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Public Health - Forensic Laboratories - Regulation

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This bill defines a “nonprofit accreditation body” and requires that an out-of-state forensic laboratory be accredited by a nonprofit accreditation body to receive licensure in Maryland. The bill also requires the Department of Health and Mental Hygiene (DHMH) to establish, by regulation, requirements for forensic laboratories regarding the calculation and reporting of measurement uncertainty in calibration and testing.

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Fiscal Summary

**State Effect:** Regulations already address calculation and reporting of measurement uncertainty in calibration and testing, and all 10 of the out-of-state forensic laboratories operating and licensed in the State are already accredited. However, the bill may result in minimal savings for DHMH as a result of fewer inspections of out-of-state laboratories. Revenues are not directly affected.

**Local Effect:** None.

**Small Business Effect:** None.

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Analysis

**Bill Summary:** “Nonprofit accreditation body” means an accreditation body that either (1) requires conformance to forensic specific requirements and is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement for testing or (2) a State-approved accreditation body. The bill distinguishes between in-state and out-of-state laboratories and requires that each out-of-state forensic laboratory seeking licensure be accredited by a nonprofit accreditation body before receiving a license.

**Current Law:** Under current law, “forensic laboratory” means a facility, entity, or site that offers or performs forensic analysis (*i.e.*, a medical, chemical, toxicologic, firearms, or other expert examination or test performed on physical evidence for the purpose of determining the connection of the evidence to a criminal act). “Forensic laboratory” includes a laboratory owned or operated by the State, a county, or municipal corporation in the State or another governmental entity. However, “forensic laboratory” does not include a forensic laboratory operated by the federal government or a laboratory licensed or certified by the Maryland Department of Agriculture.

Chapter 147 of 2007 required the Secretary of Health and Mental Hygiene to adopt regulations that set standards and requirements for forensic laboratories. In addition, to assure compliance with these standards and requirements, the Secretary must conduct (1) an inspection of each forensic laboratory for which a license to operate is sought and (2) an inspection of each forensic laboratory for which a license has been issued. Chapter 147 also established the Forensic Laboratory Advisory Committee to advise the Secretary on matters relating to the implementation of specified provisions of law related to forensic laboratories.

Regulations require that, among other things, a forensic laboratory director must ensure that verification procedures are adequate to determine the accuracy, precision, uncertainty, and other pertinent performance characteristics of each forensic analysis method and that a corrective action plan is followed when a proficiency test is found to be unacceptable. Additionally, forensic laboratory technical leaders are responsible for establishing a forensic laboratory’s forensic analysis performance specifications, including precision, accuracy, and uncertainty of measurement. Technical leaders must maintain instrument records for calibration, validation, and maintenance.

**Background:** In order to operate in Maryland, a laboratory must be licensed by DHMH. To receive a license, laboratories must submit to inspections both prior to, and after, licensure. DHMH conducts inspections on all nonaccredited out-of-state laboratories and those accredited out-of-state laboratories that do not received accreditation inspections.

Currently, accreditation is voluntary, but all 10 out-of-state laboratories operating in Maryland are accredited. Accreditation generally means a lab undergoes an inspection, but not always. DHMH accepts accreditation inspection reports in lieu of conducting its own licensure inspections, but the department occasionally conducts follow-up inspections based on the findings in the accreditation report. The bill is not clear regarding DHMH’s continued authority to inspect out-of-state laboratories. Federal law requires all forensic laboratories conducting DNA analysis to be accredited.

Out-of-state forensic laboratories perform forensic testing in many areas including biology, trace analysis of gunshot residue, and latent print examinations. These laboratories help to reduce backlogs in Maryland's forensic laboratories. Additionally, out-of-state laboratories occasionally perform types of forensic testing that Maryland's forensic laboratories do not offer. Since accreditation can be expensive, requiring all out-of-state laboratories to gain accreditation may limit the ability of the smaller laboratories to conduct business in Maryland.

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### **Additional Information**

**Prior Introductions:** Legislation related to accreditation/inspection of forensic laboratories has been considered in the past two sessions. SB 242 of 2013 received a hearing in the Senate Finance Committee, but no further action was taken. Its cross file, HB 1254 received a hearing in the House Health and Government Operations Committee, but no further action was taken. HB 1294 of 2012 received a hearing in the House Health and Government Operations Committee, but no further action was taken.

**Cross File:** SB 746 (Senator Astle, *et al.*) - Finance.

**Information Source(s):** Department of Legislative Services

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