Regulating Crime Labs: The Maryland Experience

Introduction

Unlike crime laboratories, in healthcare, clinical laboratories have been strictly regulated by federal legislation, since Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to the Public Health Services Act. Enacted in 1988, these Amendments strengthened pre-existing regulations for federal oversight and certification of clinical laboratory testing on specimens from humans for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. The CLIA also provided transparency by publishing an annual registry of any clinical laboratory or person that has committed a violation of CLIA, has been convicted of fraud, have had their accreditations or certifications removed. These standards help ensure that the assessments are performed by qualified individuals, that the results are accurate, and any lapses of certification or instances of fraud are public knowledge.

There are many similarities between clinical laboratories and forensic laboratories; they even conduct some quite similar types of analysis on bodily fluids, DNA, and tissue. While the CLIA, as well as other federal and state regulations govern clinical labs, but in most of the country, forensic labs are not subjected to the same rigor of regulations.

One exception is Maryland, the first state that began licensing crime labs in 2007 after a discredited state police ballistics and fire armor expert named was found to have falsified his academic credentials. Joseph Kopera had worked for 37 years with the Baltimore Police Department and the state police. In 2007, defense attorneys and state prosecutors uncovered that Kopera had repeatedly misstated his education credentials, falsely claiming degrees from Rochester Institute of Technology and the University of Maryland. As a result of Kopera's falsifications, over 4,041 cases were reviewed for discrepancies. In response to this misconduct, Maryland enacted legislation and regulations for forensic laboratories. Here, we describe the Maryland model, but also how when other states consider adopting similar regulations, they should consider stronger enforcement mechanisms.

The Maryland Legislation

The new law that was passed, Maryland General Code § 17-2A, focuses on regulations for standards and requirements for forensic laboratories. The laws cover crime laboratories in Maryland, but also people unaffiliated with licensed laboratories performing forensic analysis, and also out-of-state labs performing analysis in Maryland cases. The law includes a section with definitions (§ 17-2A-01), standards for proficiency testing and compliance for labs (§ 17-2A-02; § 17-2A-03), licensing processes and standards (§ 17-2A-04 through § 17-2A-09), rules prohibiting discrimination or retaliation against employees and the penalties for violations (§ 17-2A-10; § 17-2A-11), and finally an outline of a Maryland laboratory advisory committee.

This statute applies to crime laboratories the types of rules that had applied to medical laboratories in the State. Maryland is the only jurisdiction in the United States that adopts many of the same rules for clinical and medical laboratories. Maryland General Code § 17-2 outlines the requirements for operating a medical laboratory in the state. While statutes § 17-2 and §

17-2A are similar, the standards for medical laboratories are more detailed, including proficiency testing programs for physicians. Such provisions could be added to § 17-2A to create regulations for forensic and medical laboratories that are on par with each other.

The accompanying regulations, in Title 10.51 of the Code of Maryland Regulations, provides more specific and detailed information for forensic laboratories, including guidance necessary to employ qualified employees, operate and perform forensic analyses under reliable procedures, effective quality control and quality assurance programs, and qualified supervision.

The statute also calls for a Maryland Forensic Laboratory Advisory Board to provide oversight over compliance with the law and regulations. That board consists mostly of crime lab professionals and forensic practitioners.

Enforcement

Since the introduction of forensic laboratory regulations in 2007, there have been a number of cases where auditors and whistleblowers uncovered or identified procedural issues within Maryland Forensic Laboratories. A few noteworthy instances of process or quality issues are outlined below.[1]

2008 – Baltimore DNA kits

Baltimore Police Department revealed that their lab analysts had been contaminating evidence with their own DNA. The Department had also broken standard protocol by not collecting and storing samples of all employee-DNA as a protective measure against contamination (The Innocence Project, 2008). The crime lab director was dismissed as a result of these findings (Bykowicz, 2008). In response to the information, the Innocent project filed a request for investigation, re-examination of cases and a public report on findings with Maryland State Police (The Innocence Project, 2008).

2018 – Maryland Rape Kits

During regular audits in 2018, it was revealed that over 6,500 rape kits were untested and stored with police and laboratories in Maryland. Additional investigations into the high number revealed that a previous lab manager in Prince George County has incorrectly reported only 99 cases in the previous audit (compared to the accurate 2,747 in 2018). The lab manager had been terminated prior to the secondary audit (Rentz, 2018).

2021 – Unlicensed Pennsylvania Chemists

The Harford County State's Attorney's Office discovered that a Pennsylvania Chemist was not certified, despite testing over 4,400 drug cases for Maryland prosecutors. The lack of certification breached the contracts between Maryland State Police and Pennsylvania-based National Service which stipulated that all chemists were required to be state-certified to avoid being called for testimony in court. According to the CEO of

[1] Maryland's chief medical examiner, Dr. David Fowler, testified in Derek Chauvin's case that the cause of death of Mr. Floyd was "inconclusive". The testimony causes 432 doctors from across the country (including D.C. former chief medical examiner) to write to the Attorney General and Governor and question all previous work done by Dr. Fowler. The Attorney General initiated an investigation into all previous work done by Dr. Fowler (Associated Press, 2021).

the Pennsylvania lab in question, the Maryland regulation created an impossible situation where the chemists were required to be certified for the contract with MSPD to be signed, yet the certification was not permitted by Maryland Department of Health until the chemists were actively doing business in Maryland. (Whitlow, 2021)

2021 – Baltimore Fingerprint Kits

Whistleblower forensic scientists alerted Baltimore City Council that fingerprint kits from Baltimore property crimes were not analyzed. The information was provided by Ken Phillips and Roy Michael Jones who each spent over 30 years in forensic analysis, some of which with the Baltimore Police Department crime lab. (Fenton, 2021). In response to the whistleblowers, the Department confirmed that they had a backlog of 11,000 fingerprints from crime scenes to be analyzed due to a staffing shortage[2]. A following audit identified that test kits from property crimes were retained and tested "if/when requested" but were by default placed into a "decline" category. Maryland Department of Health and the American National Standards Institutes accreditation board reviewed the case and did not find any conflicts with their policies or procedures (Fenton, 'Serious questions' raised by reports on problemsinside Baltimore Police crime lab, 2021). Additionally, the audit uncovered that over a 10-month period, one of the firearms examiners had misplaced, mislabeled, or switched swats from at least 3 evidence packages. The examiner had previously been retrained in June of 2020 because of correct action, and once his mistakes were uncovered again in 2021, all firearms swabbing was paused for four weeks to understand the scope of damage (Fenton, 2021). To help resolve the backlog, the Department of Justice granted over $1.8 million to Six Maryland Law Enforcement Agencies (The United States Attorney's Office District of Maryland, 2021).

The response to whistleblower complaints is a positive example of the quality assurance and audit process at work. In 2008, the Innocence Project was able to request a public report on the findings due to the provisions in Md. General Code Ann. § 17-2A-03 which state: "A forensic laboratory shall make discrepancy logs, contamination records, and test results available to the public within 30 days of a written request." In 2018, a regular audit identified a discrepancy in the number of kits within the backlog and the country was able to self-resolve the reporting issues.

However, there is still room for concern about the transparency and efficacy of the Maryland forensic laboratories. In the 2021 Baltimore case, the whistleblowers reportedly had unsuccessfully attempted to address the concerns internally for months – including writing to Mayor Brandon Scott, filing complaints with the Office of the Inspector General and his own department - before going public (Fenton, 'Serious questions' raised by reports on problemsinside Baltimore Police crime lab, 2021). The necessity for the whistleblowers to go public indicates an opportunity to improve the process of responding to employee complaints of irregularities.

[2] It is worth noting that the lab's staffing has more than doubled from 72 people in 2014 to 167 in 2019 (Fenton, 2021).

Additionally, the 2021 example of unlicensed Pennsylvania chemists performing test for Maryland PD indicate opportunities to improve the certification process. As identified by the CEO of the impacted Pennsylvania lab, the current requirements for chemists to be certified in Maryland prior to beginning work for the state conflicts with the guidance from the Maryland Department of Health, which expects a chemist to be actively doing business with the state before receiving a certification. Resolving the procedural conflict would streamline and strengthen the licensure and certification process.

The audit expectations for different certifications can be improved. The regulation currently requires permitted forensic laboratories to submit to a routine audit within 6 months of starting operation. However, forensic laboratories are not subject to the same rigorous requirements if they are undergoing routine on-site assessment conducted by an accreditation organization. Further, the 3-year "letter of permit "exception allows individuals and entities to provide forensic services within specific disciplines for extended periods of time, without the requirements for additional audits.

Finally, the Maryland Forensic Laboratory Advisory could benefit from transparency standards provided on a federal level to clinical laboratories through the CLIA. Making information about the licensure and certification statuses as well as suspensions or revocation would allow independent auditors or researchers access to the information and create consistency across the different types of laboratories – forensic and clinical.

Conclusion

The Maryland Forensic Laboratory statutes provide an example of well-written and considered regulations for forensic laboratories that, nonetheless, has real space for improvement. Recent cases of procedural breaches in Maryland State Police and Baltimore Police, indicate that the auditing process may need to be reexamined to identify the gaps that allowed kits to do untested, whistleblower complaints unaddressed, and licensure requirements for chemists omitted. Nevertheless, the Maryland experience shows that medical laboratory regulations can be extended to crime labs. However, it is also important for those regulations to be robustly enforced.

Appendix:

Detailed summary of Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland § 17-2A-01. Definitions.

This section provides definitions for terms in the subtitle and outlines examples of entities that are not included within the scope of the regulation. The words defined include:

- Forensic analysis
- Forensic information technology
- Forensic laboratory
- License
- Limited forensic analysis
- Physical evidence

§ 17-2A-02. Regulations for standards and requirements and for forensic proficiency testing program; inspections; compliance.

Aims to ensure forensic laboratories provide safe, reliable, and accurate services (17-2A-a2) by establishing frameworks for compliance (17-2A-d), forensic proficiency testing (17-2A-b), and regular inspections (17-2A-c). The regulation expects forensic labs to establish and verify qualifications (17-2A-a3iii), background, and education of personnel (17-2A-a3iv), to assure they provide accurate and reliable services (17-2A-a3v). The regulation also requires each laboratory to retain all cases filed for at least 10 years (17-2A-a3ii). Forensic laboratories are also required to pass proficiency testing related to the forensic analysis performed (17-2A-b1), and submit to the results of the performance, licenses, educational and background check to the review of the Secretary (17-2A-b3; 17-2Ac, 17-2A-d).

§ 17-2A-03. Availability of deficiency statements and plans of correction, confidentiality of compliance proceedings and records.

Outlines that all deficiency statements and plans of correction are to be made available within 30 days of written request and are to include discrepancy logs, contamination records, and test results. Other proceeding, records and files are confidential and not admissible in evidence in civil or criminal actions.

§ 17-2A-04. License requirements; exceptions.

Requires forensic laboratories to hold a license issued by the state-Secretary unless the laboratory performs only limited forensic analysis; and meets the exception requirements. The Secretary may also waive requirements for out-of-state forensic laboratories (as of December 31, 2011)

§ 17-2A-05. License qualifications.

Requires the applicant to satisfy the requirement of the subtitle.

§ 17-2A-06. Application for license.

Requires the license application to follow the form provided by the Secretary and include submit an application to the Secretary on the required form. The form includes the name of the operator or owner; the tests or examinations that the forensic laboratory would provide; and other required information.

§ 17-2A-07. Issuance, scope, and status of license.

An applicant that meets the standards and requirements of this subtitle will be issues a license with the names of the forensic laboratory; laboratory director and operator/owner of the laboratory. The license will outline permitted tests, examinations, or analyses and forbid other tests not designated by the license to be completed.

§ 17-2A-09. Denial, suspension, revocation, or limitation of license.

If the forensic laboratory no longer meets the required standards, the Secretary may suspend, revoke, deny or limit their license after a guaranteed notice and hearing. The Secretary may also choose to impose a plan of correction, limit the authorization of the license, and require regular inspections. If the laboratory is found to provide erroneous or questionable results, it may be required to notify the agency that ordered the tests, the Office of the Public Defender or counsel, and the State's Attorney who will then notify the victim. Noncompliance with the order is subject a penalty of up to $1,000 daily (max of $50,000).

§ 17-2A-10. Discrimination or retaliation against employees reporting irregularities prohibited.

Employees are entitled to report noncompliance with the standards and requirements to the Secretary without fear or discrimination or retaliation. The employees of forensic laboratories will be informed of their right through a document developed by the Secretary of State and posted in a conspicuous place. Any employee who has been discriminated against shall be entitled to initiate an action, and potentially be reinstated, reimbursed lost wages, work benefit, and attorney's fees. These rights are limited to 2 years after the discrimination or retaliation.

§ 17-2A-11. Violations; penalties.

Violating the subtitle is a misdemeanor and the violator may be subject to fines. First offense fine will not exceed $100, and subsequent violations will not exceed $500. Each day on which a violation occurs is a separate violation under this section.

§ 17-2A-12. Forensic Laboratory Advisory Committee.

The state Governor establishes a Forensic Laboratory Advisory Committee which consists of 10 members who hold staggered appointment of 3 years. The members are not compensated but can be reimbursed for expenses. The Governor designates one member as the chair and provides supporting staff.

1. The Director of the Laboratories Administration in the Department, or designee.
2. The Director of the Office of Health Care Quality in the Department, or designee.
3. Governor appointee from the American Society for Clinical Laboratory Science;
4. Governor appointee from the University of Maryland School of Medicine, Department of Medical Research and Technology;
5. Governor appointee from the American Association for Laboratory Accreditation;
6. Governor appointee from the American Academy of Forensic Sciences;

7. Governor appointee from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board; and
8. Director from a forensic laboratory operated by the State;
9. Director from a forensic laboratory operated by a county; and
10. Director from a forensic laboratory operated by a municipal corporation.

Summary of regulation: Code of Maryland Regulations Title 10. Maryland Department of Health Part 5 Subtitle 51

Chapter 10.51.00 Notations

Authority is granted through Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland

Chapter 10.51.01 Purpose

Chapter 10.51.02. Responsibilities, Accreditations, and Audits

Audits include but are not limited to the observation and examination of (a) Laboratory facilities; (b) Equipment; (c) Quality assurance and quality control program records; (d) Operating procedures; (e) Employees; (f) Employee records; (g) Proficiency testing; (h) Forensic analysis reports; and (i) Other records and files pertinent to this subtitle.

Distinction between a permitted (subject to routine audits) and an accredited (not subject to routine audits) forensic laboratory.

Chapter 10.51.03. Licenses

Licensure is required to perform or offer to perform a forensic analysis in Maryland, **unless** the Secretary grants a Letter of Permit Exception.

Letters of Permit Exception can be given if the application is limited to an individual performing limited forensic analysis in a discipline or subdiscipline without affiliation with a public or commercial laboratory that performs forensic analyses and if the individual can present documentation that demonstrates the individual's competency and experience in the specific forensic discipline or subdiscipline in which the forensic analysis will be performed. Permits of exception are valid for 3 years from data of issuance.

Waivers can be granted to forensic laboratories not located in the State, if the examination or forensic analysis is not performed by a licensee; is limited to a single case or related cases; and the person requesting the waiver has documentation that demonstrates the forensic laboratory's competency and quality.

Out-of-state laboratories may be required to apply for licensure depending on the number of waivers requested.

Permits are valid for 3 years from the date of issuance. Licenses are specific to each location of a forensic laboratory.

Chapter 10.51.04. Proficiency Testing

A. Proficiency Testing. Each year a licensee shall participate in an external proficiency testing program for each forensic science discipline in which the laboratory performs forensic tests and examinations, including but not limited to: (1) Firearms and toolmarks; (2) Questioned documents; (3) Latent prints; (4) Trace evidence; (5) Biology; (6) Controlled dangerous substances; and (7) Toxicology.

Forensic analysts are required to participate in proficiency testing annually for each discipline and in the same methods and procedures in which the forensic analyst is qualified to perform tests or examinations for casework. Each subdisciplines of forensic analysist requires proficiency testing least once in the 3-year license period or if applicable within the required time period outlined by the accreditation organization.

The testing standards, protocols, and results of the proficiency tests will be designed, documented and maintained by the quality assurance manager or technical leader, as designated by the director.

DNA Testing requirements are set forth in 42 U.S.C. §14131

Chapter 10.51.05. Quality Assurance

Laboratories are required to establish and follow policies and procedures for a comprehensive quality assurance program that includes documentation of all activities, employee records, documenting and investigating complaints. Administrative review of all cases and reports including a technical review, of no less than 5 percent of cases as determined by the laboratory director or designee.

Section. 10.51.05.02 and 03 provides specific details on Policies and Procedures, Identifying and Handling Evidence, Deficiencies, Errors, and Corrective Actions, and requirements for public records for all laboratories as well as laboratories Postmortem Forensic Toxicology.

Calibration, Validation and performance checks, examination and analysis, employee training and competency (including subcontractors), equipment maintenance and facilities. Noteworthy is separate section on Ethics and Data Integrity Policy which requires forensic laboratory employees to participate in mandatory ethics and data integrity trainings.

Chapter 10.51.06. Employees

The section outlines specific duties and responsibilities, character and education verification for the positions in a forensic laboratory: individual employees, directors, quality assurance managers, technical leaders, and forensic analysis employees.

Chapter 10.51.07. Sanctions

If the laboratory fails to meet the rules of both (1) Code of Maryland Regulations Title 10. Maryland Department of Health Part 5 Subtitle 51 and (2) Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland, the Secretary may impose some principal and alternative sanctions. The principal sanctions are denial, suspension, and revocation of licenses. Alternative sanctions include directed plans of correction, limitation on forensic analyses, training, and technical assistance. Individuals who owned, operated, or directed a forensic laboratory that has had the laboratory's license revoked may not, within 1 year of the revocation, apply for a license for or own, operate, or direct a forensic laboratory.

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