Maryland
DEPARTMENT OF HEALTH

Minutes of Meeting – May 20, 2022

The Laboratory Advisory Committee (LAC) meeting took place via conference call through the Maryland Public Health Laboratory, located at 1770 Ashland Avenue Baltimore, Maryland 21205. Dr. Piyush K. Patel called the meeting to order at 1:05 PM.

Members Attending: Piyush K. Patel, Vice Chair, American College of Physicians
Barbara S. Caldwell, American Society of Clinical Pathology
Charles K. Cooper, Advanced Medical Technology Association
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ
Gattu P. Rao, Maryland Academy of Family Physicians
Thomas J. Remsberg, Pharmacist
Yahia M. Tagouri, College of American Pathologists

Other Attendees: Dr. Robert Myers, Director, Laboratories Administration
Rodney Hargraves, Deputy Director, Administrative and Support Services
Renee Scurry, Administrator, Regulatory and Administrative Services
Hope Miller, Paralegal II, Regulatory and Administrative Services
Paul Celli, Public Health Administrator for Clinical and Forensic Laboratories, OHCQ

Members Absent: None

Public Attending: None

All attendees went around the table and introduced themselves and their representation.

I. Welcome to New Appointees.

Dr. Patel introduced the two new appointees and asked that they give a brief formal introduction of themselves; Yahia M. Tagouri representing the College of American Pathologists and Charles K. Cooper representing the Advanced Medical Technology Association.

Yahia M. Tagouri representing the College of American Pathologists comes to the LAC with a lot of experience. Presently, Dr. Tagouri is the Medical Director of Laboratories at MedStar St. Mary's Hospital and Southern Maryland Hospital since 1996; Deputy Medical Examiner of Charles, Calvert, St. Mary's and Anne Arundel Counties; and a member of the Inspection Process Committee for College of American Pathologists.

Charles K. Cooper is representing the Advanced Medical Technology Association – Doctor of Infectious Disease. Presently, Dr. Cooper is the Chief Medical Officer, Siemens Healthcare Diagnostics and has been seeing patients at Great Baden Health in PG County for almost 15 years.

Dr. Patel is serving as Acting Chair for this meeting in place of Dr. Newby, who has retired. Dr. Patel is an internist at a private practice in Montgomery County. Dr. Patel thereafter requested that everyone give a short introduction of themselves; their name and what organization they represent.

Dr. Gattu P. Rao – Family Physician representing the Maryland Academy of Family Physicians. She is currently in a healthcare organization, not a private practice.

Gail McGucken – with the Maryland Department of Health, Office of Health Care Quality (OHCQ) – She has been a State laboratory scientist surveyor for 31 years. She brings her laboratory survey skills to the LAC.

Dr. Thomas J. Remsberg – Pharmacist for over 11 years. He is currently with the University of Maryland Outpatient Pharmacy.

Barbara Caldwell – representing the American Society of Clinical Pathology (ASCP). Former Laboratory Administrative Director at Medstar Montgomery Medical Center for 20 years. Has a 42+ year career, but is now retired. Very active with volunteering with ASCP, and is on the Choosing Wisely committee, along with 4 other ASCP committees. She has a lifetime of experience working in laboratories, teaching laboratory science/management at the University of Maryland and being a Laboratory Administrative Director.

Renee Scurry – Administrator for the Office of Regulatory and Administrative Services at the MDH Laboratories Administration. She serves as a legislative liaison and is the regulation and legal response coordinator. (Non-LAC member)

Hope Miller – Paralegal II for the Office Regulatory and Administrative Services at the MDH Laboratories Administration. She assists with legislative review and regulation/legal response coordination. Hope been with the Laboratories Administration for approximately 5 ½ years. (Non-LAC member)

Dr. Robert Myers – Director of the MDH Laboratories Administration. (Non-LAC member)

Rodney Hargraves – Deputy Director for Administrative and Support Services of the MDH Laboratories Administration. (Non-LAC member)

Paul Celli – Public Health Administrator for Clinical and Forensic Laboratories at OHCQ. (Non-LAC member)

II. Brief Overview of the LAC PowerPoint Presentation (for New Appointees)

Dr. Patel briefly went over the LAC PowerPoint that was distributed via email prior to the meeting.

The LAC was created in 1989 to advise and make recommendations to the MDH Secretary on whether certain laboratory tests should be granted excepted status. Excepted status refers to clinical lab tests that are authorized to be performed without a permit. Typically, these tests are the rapid diagnostic tests and non-instrumental tests that are routinely done in a lot of clinical offices (e.g., rapid strep, flu, urine dipsticks). An extensive list is included in the PowerPoint presentation. Accordingly, the LAC was established to protect healthcare consumers who could be adversely effected by the results if the test was not performed correctly or adequately; and to enable healthcare providers to perform these tests for patients in a point of care environment.

The composition of the LAC consists of 1 member of the American Academy of Family Practitioners; 1 member of the American Academy of Pediatricians; 1 member of the American College of Physicians; 1 member of the American Society for Clinical Pathology; 1 member of the American College of Pathology; and 1 representative of the Advanced Medical Technology Association. In addition, the LAC does have representation from outside of the listed societies at the Secretary's discretion.

Expectations of LAC members – stay abreast of any new techniques and developments regarding laboratory tests that may be appropriate for review by the LAC regarding excepted test status. Periodically follow up with representative organizations to see if there are any potential issues or concerns that need to be addressed.

The role of the MDH Laboratory Administration – is to provide administrative support and assistance to the LAC. Review proposed legislation that is introduced during annual legislative sessions that could have a potential impact on clinical laboratory testing, particularly tests that would require excepted test status to be performed in Maryland.

Meeting frequency – before the pandemic, the LAC met in person at least twice a year. Since the pandemic, the LAC has been meeting virtually at least twice a year and "as needed."

Dr. Cooper thereafter inquired whether the approvals of excepted status are blanket approvals for use in all scenarios or are they customized for specific use. For example, a physician's office versus a county fair. Dr. Patel replied that for a physician's office, approvals for excepted status depends on the test to be used at the physician's discretion. However, with regard to county fairs, Dr. Patel asked Renee Scurry if she could expand. Ms. Scurry stated that this would be discussed during the next item on the meeting agenda.

III. Process for Submitting a Request for Excepted Test Status

To help answer Dr. Cooper's questions, Renee Scurry proceeded to discuss the next item on the agenda, i.e. the process for submitting a request for excepted test status.

The process starts at the Secretary's level when acquiring a request for excepted test status. A request must be made in writing by MedChi or a specialty medical society to the Secretary's office, who will then send the request to the LAC for a discussion, review and voting. After review, the LAC sends their written recommendation in response to the request back to the Secretary's office. The Secretary is then responsible to notify MedChi or the specialty medical society that made the original request. After Renee's synopsis of the general process, Dr. Myers provided additional information.

Dr. Myers provided that he would defer to OHCQ for healthcare settings where excepted test status can be used. There are certain tests that can be run at healthcare clinics if they have been granted excepted test status. However, depending on the risk of the test, additional caveats may be added. For example, making sure the physician's office participates in proficiency testing that goes above and beyond the waived status of the FDA.

Gail McGucken further stated that it is expected that laboratory staff follow the manufacturer's instructions. Good laboratory practices include keeping a copy of lot numbers, expiration dates in their record system, and making sure everyone is trained. These protocols are outlined in the Maryland state regulations. Also, laboratory surveyors do not routinely visit physician offices. Therefore, they will not look at waived testing when conducting surveys. However, they will look at waived testing when conducting a survey for moderately complex testing.

IV. Brief Overview of the LAC By-Laws (for New Appointees)

After reviewing the process for submitting a request for excepted test status, Dr. Patel gave a brief overview of the LAC By-Laws. A copy of the LAC By-Laws were distributed via email prior to the meeting.

The main item Dr. Patel highlighted, was the attendance requirement that was added a few years ago. Members are required to attend 50% of meetings in a consecutive 12 month period. Meetings are twice a year and typically last no more than an hour.

V. Review of the 2022 Legislative Session

Renee Scurry gave an overview of the 2022 Legislative Session.

There weren't any bills introduced during the 2022 session that required the LAC to convene for review. There was one bill that came up that was previously introduced in 2019 -- House Bill 969 Medical Laboratories - Advertising or Solicitation of Business - Repeal of Prohibition. The LAC was asked to review House Bill 969 and provide feedback on the bill's repeal of the prohibition on medical laboratories marketing genetic testing products directly or indirectly to the public. It went on for several years because 23andMe and AncestryDNA wanted to be able to market their products in Maryland, but weren't able to because of the prohibition. But this all changed in 2019 when House Bill 969 passed. This year in 2022, they went a little further with House Bill 866 Genetic Information Privacy - Consumer Protection and Forensic Genealogy, which sought to regulate the use of genetic data by direct-to-consumer (DTC) companies and to provide consumers with clear and complete information of the companies' policies on disclosing data and to obtain consumer consent before disclosing data. This has been a big concern for years: What happens with the specimen? Are they selling them? Who has access to this data? The State of Maryland is trying to reign in the concerns that this data was not improperly used with House Bill 866. In the past, Dr. Newby (previous LAC chair) sent a letter of concern which included concerns over the privacy of genetic data. With all that, House Bill 866 Genetic Information Privacy - Consumer Protection and Forensic Genealogy failed. Aside from House Bill 866, the Laboratories Administration reviewed bills concerning COVID-19 response, new born screening, sickle cell disease, lead poisoning prevention, the Open Meetings Act and the Private Well Safety Act of 2022.

VI. Search for an LAC Chair

Dr. Patel reiterated the need for an LAC chair. Dr. Newby has retired leaving the LAC chair position open. Dr. Newby was very knowledgeable and left "big shoes to fill."

In addition, the Office of Appointments and Executive Nominations (OAEN) has requested Renee Scurry to ask the LAC as a whole if anyone would be interested in serving as chair. If there is an interest, the interested person should contact OAEN to further discuss the requirements in detail and all that is involved with serving as LAC chair.

VII. Adjournment

Dr. Patel thanked everyone for attending and again welcomed new members, Dr. Cooper and Dr. Tagouri to the LAC.

Tasks to be accomplished before the next meeting:

- Search for a LAC Chair

The meeting was adjourned at 1:40 PM

Respectfully submitted,

Renee Scurry and Hope Miller
MDH Laboratories Administration
Office of Regulatory and Administrative Services