Maryland
DEPARTMENT OF HEALTH

# Minutes of Meeting – December 19, 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.

**Members Attending**:
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

**Other Attendees**: Dr. Robert Myers, Director, Laboratories Administration
Rodney Hargraves, Deputy Director, Administrative and Support Services
Renee Scurry, Administration, Regulatory and Administrative Services
Hope Miller, Paralegal II, Regulatory and Administrative Services

**Members Absent**: Piyush K. Patel, Vice Chair, American College of Physicians
Yahia M. Tagouri, College of American Pathologists

**Public Attending:** None

Ms. Renee Scurry called the meeting to order at 2:30 PM.

Ms. Scurry began the meeting with greetings and requested all attendees to introduce themselves and their representation for Ms. Hope Miller to record.

I. May 2022 Meeting Minutes Approved and Posted on LAC Website

Ms. Scurry began with the first agenda item, which was the May 2022 Meeting Minutes that were previously approved by all members earlier in the year. She wanted to include it on the agenda to give meeting attendees the opportunity to provide additional information or to request revisions. All members thereafter accepted the May 2022 Meeting Minutes with no additions and/or revisions.

II. Requests to MDH Secretary to Amend the "Excepted Test Status" under COMAR 10.10.03.02 and 10.10.02.01

Ms. Scurry introduced the second item on the agenda. She discussed a request made by letter to the Secretary by Roche Diagnostics Corporation. On August 22, 2022, via electronic mail, the MDH Secretary, Dennis Schrader, received a letter from Thomas Barnett, Director of State Government Affairs at Roche Diagnostics Corporation. In his letter, Mr. Barnett recommended an amendment to COMAR 10.10.03.02 (Letters of Exception) in which he suggested removing any existing restrictions for CLIA-waived tests that appear on the excepted test list that extend beyond the requirements of FDA reviewed labeling. He also suggested amending COMAR 10.10.02.01, in which he sought to delete the language describing the process for recommending and authorizing “excepted test status”

(which would effectively remove the Laboratory Advisory Committee as an operational MDH Committee and eliminate the processes and procedures for obtaining excepted test status to perform certain laboratory tests under a Letter of Exception instead of a permit).

Mr. Barnett opined that the process to obtain excepted test status/Letter of Exception takes multiple steps and, therefore, is lengthy and requires many years to complete. He additionally claimed that Roche had sought, without success as of the date of his letter, to have CLIA waived testing for influenza A, influenza B and RSV added to the list of "excepted" tests since the Fall of 2018. However, the LAC does not have any record of receiving this request.

In addition, the molecular diagnostics company, Cepheid, received a recommendation from the LAC for their COVID-19, Flu A/Flu B/RSV combination test in December 2020. The mandated process thereafter required Secretary Schrader to notify MedChi (the medical society that requested a letter of exception on Cepheid's behalf) of the authorization, so MedChi could notify Cepheid that approval had been given. However, to date, Secretary Schrader has not notified MedChi of the approval and Cepheid is still waiting for authorization. Several meetings were held with the Secretary's' office to determine the cause of the delay, but ultimately the Secretary's office decided to allow the new incoming MDH Administration to handle this matter. In the meantime, Cepheid sent a letter similar to Roche Diagnostics to the Secretary complaining of the duration of time to obtain approval for excepted test status. They also requested amendments to COMAR 10.10.03.02 and 10.10.02.01 similar to Roche with respect to Maryland's excepted test status requirements.

Ms. Scurry stated that the delay concerning Cepheid receiving authorization and approval was not a reflection of the review performed by the LAC, but a decision by the Secretary's office to delay action until the new MDH Administration is appointed. In addition, based on the Roche letter and the accompanying proposed amended COMAR provisions to remove the Laboratory Advisory Committee (even though this cannot be done by regulation), it is quite possible that legislation could be introduced during the next legislative session to remove the LAC from the State statute due to increasing concerns (among certain companies) that it takes an inordinate amount of time to add new tests to the excepted test list.

Ms. Scurry thereafter asked Dr. Myers if he had anything that he would like to add. Dr. Myers replied that one explanation is that these companies want FDA waived tests recognized without the additional scrutiny of the LAC. They feel that the FDA waived status is sufficient. However, the duties of the LAC also include an assessment of waived tests (upon request) to determine if they can be performed correctly and yield accurate results. This sometimes involves the Committee implementing modules such as proficiency testing, additional staff training, etc. Regardless, Ms. Scurry and Ms. Miller will notify the LAC of any new legislation introduced during future legislative sessions that may impact their tenure and the Department's subsequent position.

Dr. Charles Cooper thereafter inquired whether the primary concern was with the emergency use products. Dr. Myers replied that he did not believe so because emergency use authorizations provide great latitude. This is more about FDA waived tests. These companies want them to have immediate "excepted test status" in Maryland. Confirmed by Ms. McGucken, any health care provider performing clinical laboratory tests on Maryland patients, (e.g. fingerstick glucose, complete blood count, etc.) must hold CLIA certification and either a Maryland Letter of Exception ( if only performing tests found under COMAR 10.10.03.02 B) or a Maryland Laboratory Permit (all other test categories). Since July 1, 2018 all state licensing fees have been removed, however, CMS imposes fees for CLIA certification.

Ms. Barbara Caldwell then asked whether there is a push to eliminate the LAC and the protocols and procedures for "excepted test status" because practitioners/providers want to obtain a faster differential diagnosis and diagnosis a need to have more point-of-care testing. Dr. Myers replied that these requests/complaints are directly from the manufacturers. MedChi is not involved in any of these proposals/complaints/requests.

Finally, Dr. Gattu Rao stated that as a practitioner, we are being asked by our organization to go back to clinical skills because the turnaround for test results is taking forever due to the increased volume of patients and limited availability of supplies.

III. Update on Search for LAC Chair

Ms. Scurry continued with the third item on the agenda. Kim Bennardi, MDH Administrator for Appointments and Executive Nominations, retired in June 2022. Ms. Bennardi was responsible for filling the positions for MDH Boards, Commissions and Committees, including the Laboratory Advisory Committee. Michelle Morningred has assumed Ms. Bennardi's duties. Ms. Scurry and Ms. Miller have reached out to Ms. Morningred on the continuance of the search for the Laboratory Advisory Committee Chair and guidance on how to proceed with handling our roles as administrative support without a Chair. Also, in addition the search for a Chair, Ms. Morningred will also continue the search to fill the appointments for the (1) American Academy of Pediatrics and (2) Public/Consumer Member positions.

IV. Legislative Session 2023

As for the final agenda item, the 2023 Legislative Session will begin on January 11, 2023. Sine Die, or the last day of the session, will be on April 10, 2023. If there are any bills that require attention from the Laboratory Advisory Committee, an emergency Committee meeting will be scheduled.

Ms. Scurry opened the floor for any questions, comments or concerns. With no attendees requesting to be heard, the meeting was adjourned at 2:56 PM.

Tasks to be accomplished before the next meeting:

- 2022 Attendance Reports
- Search for a Laboratory Advisory Committee Chair
- Search for an American Academy of Pediatrics Appointee
- Search for a Public/Consumer Appointee

Respectfully submitted,

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