Maryland
DEPARTMENT OF HEALTH

Minutes of Meeting – May 21, 2019

The Laboratory Advisory Committee (LAC) meeting took place at the Maryland Public Health Laboratory, Conference Room 128E, located at 1770 Ashland Avenue Baltimore, Maryland 21205. Dr. John G. Newby called the meeting to order at 8:47 AM.

Members Attending: John G. Newby, Chair, American College of Pathology
Barbara S. Caldwell, American Society of Clinical Pathology
Paul Celli, Public Health Administrator, OHCQ
Lindsey Howard, Jr., Industry (via teleconference)
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ
Piyush K. Patel, American College of Physicians
Gattu Rao, Maryland Academy of Family Physicians
Thomas J. Remsberg, Pharmacist (via teleconference)
Malcolm R. Rubinstein, Consumer Member
Robert Yim, American Academy of Pediatricians

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
Martin Tate, OHCQ (Paul Celli guest)

Members Absent: None

I. Welcome and Introduction of New Members

Dr. Newby welcomed everyone to the 2019 annual Laboratory Advisory Committee (LAC) meeting and recognized the presence of a quorum. Dr. Newby introduced himself as the LAC Chair and gave a brief history of the creation of the LAC. He explained the role of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 in requiring higher quality standards for laboratory testing nationwide; and noted that the Maryland State legislature created lab test standards that are more stringent than the requirements of CLIA. In light of the federal and state requirements, the State of Maryland passed legislation to create the Laboratory Advisory Committee. The LAC is therefore responsible for advising and making recommendations to the Secretary on whether certain laboratory tests should be granted excepted status (i.e. authorized by the Secretary to be performed without a permit).

After the LAC overview, the attendees introduced themselves and new appointees were recognized and welcomed. The new appointees are:

- Thomas J. Remsberg, Pharmacist; and
- Gattu Rao, M.D., Maryland Academy of Family Physicians

II. Proposal to Restructure the Laboratory Advisory Committee - Dr. Newby

Dr. Newby initiated a proposal to restructure the LAC. Since the committee only meets periodically and there has not been a need to meet more often, Dr. Newby inquired whether the LAC still has a function and/or relevance. He also inquired about the LAC's current role and whether the LAC should be disbanded or restructured? After a brief discussion, Dr. Newby suggested that the Committee should be restructured.

His proposed plan to restructure the LAC includes the following:

- LAC meetings should only be scheduled only when a problem or issue arises;
- Meetings should be held through new technology (i.e. Skype, Facetime, video/teleconference); and
- A list should be generated of LAC volunteers who are willing to identify problems and issues upon request of the medical community, especially in emergency situations. (An example of a problem and/or issue is a request to implement new testing technology that will help the medical community function better and an inquiring into whether the request for testing meet Maryland standards).

Dr. Newby also noted that test approval requests are required to come from a body of standing (i.e. CLIA certified laboratories); and for each request an assessment should be made based on State guidelines. Thus, in response to the inquiry concerning the LAC's role upon receipt of a request - the Committee should review the proposed test presented, and if agreed, submit a recommendation to the Secretary for approval.

Dr. Myers further stated that the LAC is required by law and cannot simply be disbanded or restructured without changing the law, which is a long and arduous process. In addition, each year during the legislative session, there are always a few bills that require input from the LAC. Although the bills do not always impact the Maryland Public Health Laboratory, there is still a concern on how the bill(s) may impact the public.

Dr. Newby recognizes that the LAC is state law, but holding meetings would be easier to do through new technology versus the current requirement to meet in person. Dr. Newby thereafter proposed the following scenario: Renee and Hope can send the LAC members test request documents via email when there is a need for review. The LAC should then review the documents and comment via email. A conference call will subsequently be scheduled to discuss further in detail. Dr. Rubinstein, however, noted that everyone is not tech savvy and he would prefer to attend the meetings in person.

In an effort to restructure the LAC as per state requirements, Renee Scurry will review State regulations to determine if meeting electronically is acceptable or if there is a specific requirement for the committee members to meet in-person. Electronic meetings are technically open meetings even if the majority of Committee members attend via teleconference. Since the LAC meetings are also open to the public, a meeting space must be available that is accessible to the public (e.g., Maryland Public Health Laboratory, Conference Room 128E).

In summary, Dr. Newby recommends that the LAC should continue as a Departmental Committee with a caveat that electronic meetings be held at least during the late summer/early fall (September/October) and after the legislative session (April/May). He will submit a proposal for review by the Secretary on the details outlining his proposal.

III. Creation of By-laws and New Attendance Requirements for MDH Boards, Commissions and Committees

Renee Scurry informed the Committee of Secretary Neall's memorandum in which the Secretary will be tracking the attendance for all Boards, Commissions and Committees in which he is the appointing authority. Secretary Neall also indicated in his memo that each Board, Commission and Committee is required to implement its own attendance requirements unless a policy is already documented in its by-laws. Therefore, since the LAC does not have documented attendance requirements, by-laws will need to be drafted containing these provisions in an effort to comply with the Secretary's request.

In addition, Dr. Newby would like the following information included in the by-laws concerning the LAC meetings:

- Meetings shall be conducted electronically (as long as there are no restrictions prohibiting electronic meetings);
- There shall be two (2) fixed meetings per year;
- Each meeting shall be approximately one (1) hour in length;
- The date, time and place shall be posted on the State Lab's website under Laboratory Advisory Committee; and
- The public shall be invited to come.

Dr. Newby further proposed that the two fixed meetings be held on a specific month and on a specific day of the week (e.g., First Tuesday of September). Dr. Myers further suggested that each meeting should be posted on the State Lab's website so the public will have the option to attend either electronically or in person in the Executive Conference Room.

Ms. Caldwell subsequently suggested that Renee and Hope draft the proposed by-laws and upon completion, submit the draft to the Committee members for review and approval. Dr. Newby thereafter asked the Committee email Renee and Hope with suggestions for the by-laws. However, he does not want to reconvene/meet to discuss the proposed by-laws. He would prefer that the Committee engage in an electronic review. Dr. Rao suggested using "Zoom Video Conferencing" for the by-law review and upcoming meetings which is a web-based meeting platform.

IV. Update on Direct-to-Consumer Testing - Senate Bill 495 - Medical Laboratories - Laboratory Tests and Procedures – Advertising

Senate Bill 495 provides authorization for a person to directly or indirectly advertise for or solicit business in the State of Maryland for a laboratory test procedure ordered by a physician and performed by a laboratory certified under 42 U.S.C. §263 (Clinical Laboratory Improvement Amendments or CLIA). The range of laboratory testing permitted under this bill includes (1) diagnostic laboratory tests or procedures for the purpose of screening, diagnosing, managing or treating a physical or mental condition or disease and (2) ancestry testing. However, genetic or genomic testing are excluded if performed in connection with the analysis, diagnosis or prediction of human diseases. The Maryland General Assembly passed Senate Bill 495 and the bill was subsequently approved by the Governor as Chapter 413 of 2019. The bill goes into effect October 1, 2019.

Dr. Newby stated that direct-to-consumer testing creates issues among the public, and particularly among doctors who do not understand or know how to interpret genetic testing. Inaccurate interpretations can lead consumers to make decisions that may be detrimental to their overall health. Nevertheless, since there is so much exposure and advertisement, it

seemed inevitable that direct-to-consumer testing would be permitted in Maryland. With specific reference to the bill, a letter of concern was submitted to provide that clinical laboratories not only require certification under CLIA, but are also required to possess a valid State license for medium and high complexity testing. To this end, an amendment was offered to include COMAR 10.10.13 in the bill since this is the regulatory authority requiring State licensing. However, the proposed amendment was not placed in the bill.

Dr. Patel stated that he has had patients come in with genetic test results – but to his surprise, not as many since last year's meeting. He expected there would have been be more patients. Most clinicians will not know what to do with the information. They barely know what to do with tumor markers. Mr. Celli stated that the problem lies with the companies providing patients with testing and not the patient's physician. Patients are able to have testing performed on their own without the guidance/recommendation of a physician. The company Theranos for instance, now known to be a fraud, is an example of issues associated with direct-to-consumer marketing. It is also important to note that the Maryland Department of Health, Office of Health Care Quality (OHCQ) is not involved with ancestry testing companies (e.g. Ancestry.com) because ancestry testing is not CLIA regulated. However, OHCQ has licensed 23andMe (personal genomics and biotechnology company) who is starting Ancestry Health, a software company that will analyze data.

Dr. Newby additionally noted that genetic data cannot be used by insurance companies to determine a person's health insurance eligibility (i.e. deny coverage or require higher insurance premiums). He requested suggestions on how to make testing as safe as it can be and provide access to health care without obstacles. In terms of issues with over-the-counter (OTC) testing, Dr. Newby stated that self-administered OTC HIV testing is not considered medical, which opens up the flood gates to new types of testing such as the Cologuard test for example. Dr. Rao further stated that the OTC Pap Smear test from Johns Hopkins only tests for HPV. However, this type of testing should not replace having a Pap Smear performed by a physician.

Lastly, Dr. Rubinstein replied that at least medication has a safety net because with advertised pharmaceuticals, patients are required to visit their doctor if they need to be prescribed medication.

V. Maryland Department of Health, Office of Health Care Quality

Dr. Myers asked Mr. Celli whether there was anything new regarding regulations at OHCQ. Mr. Celli replied no, however, he was surprised that Senate Bill 495 became law. In addition, as per an inquiry concerning the Stem Cell Company in Florida seeking Tissue Bank Licensure, Mr. Celli replied that this company is considered a Tissue Bank in the State of Maryland under COMAR 10.50.01, but since an inspection was not conducted of the facility, a license was not issued.

I. AJOURNMENT

Tasks to be accomplished before the next meeting:

- Creation of by-laws;
- Set fixed meeting dates; and
- LAC members to email by-law suggestions by June 30, 2019.

The meeting was adjourned at 9:56 AM.

Respectfully submitted,

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